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A Discourse on the Public Nature of Research in Contemporary Life Science: A Law-Policy Proposal to Promote the Public Nature of Science in an Era of Academia-Industry Integration

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A Discourse on the Public Nature of Research in Contemporary Life Science:*

A Law-Policy Proposal to Promote the Public Nature of Science in an Era of Academia-Industry Integration

Keynote Address

(Delivered on December 21, 2008)

Michael J. Malinowski**

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* My appreciation to Owen Hughes and Alan Jakimo, with whom I had the pleasure of co-authoring *U.S. Regulation of Stem Cell Research: Recasting Government's Role and Questions to be Resolved*, 37 HOFSTRA L. REV. 101 (2009). Part II of this paper was derived from the background section of our Hofstra article, and the deliberations surrounding that project and a related panel presentation benefited this effort significantly. I also am deeply thankful to the faculty and administration of Academia Sinica for the opportunity to return to Taiwan and to participate in "Science Regulation, Freedom of Research, and Pluralist Democracy."

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"*We shall not cease from exploration and the end of all our exploring will be to arrive where we started... and know the place for the first time.*"

T.S. Eliot[1]

Ⅰ. Introduction

Academia and industry have integrated extensively in science, and within just a few decades—a fundamental transformation of the field of science that fits readily within the ongoing careers of today's senior scientists.[2] The resulting research establishment has enabled an enormous, global life science enterprise focused on application, which in turn has created unprecedented potential to improve human health.[3] The academia-industry integration in science also has profoundly impacted the interactions, culture, and norms of the research community, and, arguably, the very nature of science itself. "Science Regulation, Freedom of Research, and Pluralist Democracy" is a welcomed opportunity to reflect upon the public nature of science and to ponder measures to increase democratization in today's aggressively commercial science climate.

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1 T.S. Eliot, *Little Gidding*, *in* FOUR QUARTETS (1943) (quartet No. 4).

2 *See generally* Michael J. Malinowski & Radhika Rao, *U.S. National Report: Legal Limitations on Genetic Research and the Commercialization of Its Results*, 54 AM. J. COMP. L. 45, 45-65 (2006) (prepared for the "17th International Congress on Comparative Law," Utrecht, Netherlands, July 16-22, 2006).

3 For an industry-based overview of the accomplishments of the sector and its potential, *see generally* BIOTECHNOLOGY INDUSTRY ORGANIZATION, GUIDE TO BIOTECHNOLOGY (2008), *available at* http://bio.org/speeches/pubs/er/ (last visited on June 13, 2009).

This paper begins in Part II with an overview of the forces, events, and law-policy over the last half of the Twentieth Century that have shaped today's research establishment. This discussion pays particular attention to the roles of and relationships among government, academia, and industry.[4]

Part III profiles science in the present and probes the extent to which the existing research establishment has intruded upon the public nature of science. The section identifies democratic principles that, through the transformation of academic science, have diminished—principles such as intellectual freedom; the pursuit of intellectual curiosity; the sharing of materials and information; overall collegiality; and access to knowledge, information, and research resources. Loss of these principles has clouded the transparency of research and science findings during most of the last century—even turned it opaque in some instances.

Part IV proposes that discourse on the democratization of science and responsive law and policy are essential in an age of such intense commercialization. This section identifies regulatory shortcomings and offers some specific suggestions for law-policy interventions.

The paper concludes that law-policy interventions are necessary to protect, preserve, and promote the public nature of science. Doing so is essential to shore up the contemporary science enterprise, above which towers vast potential to improve human health.

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4 This discussion is derived from Owen C.B. Hughes, Alan L. Jakimo & Michael J. Malinowski, *U.S. Regulation of Stem Cell Research: Recasting Government's Role and Questions to Be Resolved*, 37 HOFSTRA L. REV. 101, 386-401 (2009).

Ⅱ. Government and Science from Atomic Bombs to Biotechnology

The commercialization of and, consequentially, need to democratize science are rooted in a government mission to protect democratic society from and with technology. The threat of annihilation of democratic society during World War II ("WWII") by advances in technology inspired tremendous U.S. investment to raise the base of science.[5] The U.S. continued and increased its investment, other governments did the same and, as explained below, government involvement evolved into our present, shared research establishment—with its fulcrum resting on commercialization.[6] This evolution unfolded in three distinguishable eras: the military-industrial complex establishment era ("MIC") (1939 into the 1940s); the academia-industry separation era (mid-1940s into

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5 The uranium atom was split successfully in early 1939. Fearing that the Nazis could and would develop an atomic bomb, the United States undertook the Manhattan Project to pre-empt them. *See* National Atomic Museum, Manhattan Project, *available at* http://www.atomicmuseum.com/Tour/manhattanproject.cfm (last visited on July 25, 2008).

6 *See* Titus Galama & James Hosek, *U.S. Science is Holding Its Own: Despite Cries of Alarm, We Remain the Global Leader in Innovation*, PITTSBURGH POST-GAZETTE , July 9, 2008, at B7. According to one recent report on the state of U.S. investment in science relative to other nations, although China, India, and South Korea are starting to account for a significant portion of the world's science and technology activities, and are showing rapid growth, they still account for a very small share of patents, science publications and citations. The United States, meanwhile, continues to invest in science and technology infrastructure, is creating significant employment in science and engineering, and benefits from the immigration of foreign-born science and engineering students and workers. *Id.* For detailed, timely data on research and development ("R&D") expenditures, visit the site of the National Science Foundation, *available at* http://www.nsf.gov/statistics/ (last visited Aug. 4, 2008). The two largest R&D efforts of the war were the Manhattan Project and the Radiation Laboratory at the Massachusetts Institute of Technology ("MIT"). ROGER G GEIGER, RESEARCH AND RELEVANT KNOWLEDGE, AMERICAN RESEARCH UNIVERSITIES SINCE WORLD WAR II 7 (2004).

the 1980s); and the government-academia-industry integration era (1980s to the present).

A. MIC (1939-1940s)

The U.S. entered WWII without a standing army and with little meaningful infrastructure to manufacture military weapons.[7] The war effort imposed a focus on application in science and technology, and the U.S. government became a contract purchaser and financier of invention from both academia and industry.[8] The U.S. left WWII with established, expansive, and ongoing relationships with industry and academia.[9] Financial support of the same became a permanent, major expenditure and budget priority.[10] President Eisenhower recognized this right of passage and its implications in his "Farewell Address to the Nation" radio broadcast on January 17, 1961:[11]

> Akin to, and largely responsible for the sweeping changes in our industrial-military posture, has been the technological revolution during recent decades. In this revolution, research

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7 *See* Jesse Smith, *Introduction*, *in* THE MILITARY-INDUSTRIAL COMPLEX, THE FAREWELL ADDRESS OF PRESIDENT EISENHOWER 3-4 (2006). *See generally* DWIGHT D. EISENHOWER, FAREWELL ADDRESS TO THE NATION, PUBLIC PAPERS OF THE PRESIDENTS 1035-1040 (1960), *available at* http://coursesa.matrix.msu.edu/~hst306/documents/indust.html (last visited July 26, 2008).

8 GEIGER, *supra* note 6, at 7 ("Given the absolute priority of the war effort, the usual academic tasks of universities were largely displaced for the duration."). "The basic relationship between the federal government and universities for conducting wartime research was government by contracts negotiated according to the principle of no-loss and no gain. Universities were reimbursed for the direct costs they incurred and also given some allowance for overhead." *Id*. at 6. Thus the precedent for "administerative overhead" that later became commonplace with federal grant funding for research.

9 *See generally* GEIGER, *supra* note 6.

10 *Id.*

11 EISENHOWER, *supra* note 7, at 1035-1040.

> has become central; it also becomes more formalized, complex, and costly. A steadily increasing share is conducted for, by, or at the direction of, the Federal government.
>
> Today, the solitary inventor, tinkering in his shop, has been overshadowed by task forces of scientists in laboratories and testing fields. In the same fashion, the free university, historically the fountainhead of free ideas and scientific discovery, has experienced a revolution in the conduct of research. Partly because of the huge costs involved, a government contract becomes virtually a substitute for intellectual curiosity. For every old blackboard there are now hundreds of new electronic computers.
>
> The prospect of domination of the nation's scholars by Federal employment, project allocations, and the power of money is ever present and is gravely to be regarded.
>
> Yet, in holding scientific research and discovery in respect, as we should, we must also be alert to the equal and opposite danger that public policy could itself become the captive of a scientific-technological elite.
>
> It is the task of statesmanship to mold, to balance, and to integrate these and other forces, new and old, within the principles of our democratic system—ever aiming toward the supreme goals of our free society.

As President Eisenhower predicted, the MIC continued and raged in the decades following his Farewell Address—culminating in today's

"War on Terror."[12] However, until the 1980s, the U.S. government maintained a duality in federal funding that kept academia and industry largely separate in science research.[13]

B. The Era of Separation

With the end of WWII, academia and industry largely separated and returned to their traditional priorities, cultures, and norms.[14] The GI Bill expanded enrollment and increased tuition revenue, which benefited higher education in general.[15] The U.S. Government shifted its war effort funding into dual, separate tracks with industry and academia, and this separation was reinforced by U.S. intellectual property law and policy.[16] Industry was cautious about commingling its investments with government funding through mutual relationships with researchers and institutions, thereby creating a risk of government claims to their inventions.[17] Academia was eager to return to pre-war norms, and a reliable financial base enabled them to do so: significant state government funding and tuition revenues for land grant and other public universities, and higher tuition revenues and major philanthropic funding for private schools.[18] Nevertheless, the WWII experience created a

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12 *See generally* Smith, *supra* note 7.
13 *See generally* GEIGER, *supra* note 6.
14 *See* James Stuart, *The Academic-Industrial Complex: A Warning to Universities*, 75 U. COLO. L. REV. 1011, 1032-1035 (2004).
15 GEIGER, *supra* note 6, at 41.
16 *See* Stuart, *supra* note 14, at 1032-1035.
17 The U.S. government has made claims to marketed pharmaceuticals, including the breast cancer drug Taxol. *See generally* Ron Bouchard, *Balancing Public and Private Interests in the Commercialization of Publicly Funded Medical Research: Is there a Role for Compulsory Government Royalty Fees?*, 13 B.U. J. SCI. & TECH. L. 120 (2007).
18 Jed Scully, *The Virtual Professorship: Intellectual Property Ownership of Academic Work in a Digital Era*, 35 MCGEORGE L. REV. 227, 241-242 (2004).

lingering appetite among academics and academic administrators for federal government research funding.[19] Institutions comfortable with an emphasis on application in science—most notably the Massa-chusetts Institute of Technology ("MIT")—embraced opportunities to work directly with industry.[20]

The 1950s and early 1960s were dominated by the Cold War and a series of confrontations centered on science—Sputnik 1, launched on Oct. 4, 1957, followed by the Bay of Pigs Invasion, the Cuban missile crisis, and placement of man on the moon, all of which increased demand that federally-funded science produce tangible applications.[21] The U.S. federal government grew impatient with academic research and diminished its funding. "The *annus horribilis*, 1968, brought an end to the expansion of academic research and anguish over the role that the university had assumed."[22] The 1970s proved a challenging decade for academia:

For the next ten years universities endured stagnation in

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19 GEIGER, *supra* note 6, at 41.

20 *See generally* UNITED STATES GENERAL ACCOUNTING OFFICE REPORT TO CONGRESSIONAL COMMITTEES, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES (1998) ["GAO REPORT"].

21 *See* Barton Beebe, *Law's Empire and the Final Frontier: Legalizing the Future in the Earlyorpus Juris Sparialis*, 108 YALE L.J. 1737, 1745, 1769-70 (1999). To summarize, the immediate effect of the Sputnik Crisis in America was a call for total mobilization, for 'blood, sweat and tears,' in pursuit of scientific and technological superiority. This call extended to the nation's educational system, to its industrial base, to its commodity culture, and, of course, to its methods of governance. Ever prudent, Eisenhower refused to be carried away by the panic. In his 1958 State of the Union Address, he declared that the Soviet Union had begun to wage "total cold war," but proposed only modest reforms. It was left to the Kennedy and Johnson Administrations, to the New Frontier and the Great Society, to wage total cold war in return. *See* GEIGER, *supra* note 6, at xv.

22 GEIGER, *supra* note 6, at xv.

> research support, the end of enrollment growth in higher education, a crash in the job market for new Ph.D.'s, intrusive government regulation, and fiscal distress. Universities largely reacted to student rebellion and public chastisement by withdrawing to the ivory tower. Higher education rhetoric and university actions disdained entanglements with the defense establishment or the corporate world, extolling instead the role of unsullied social critic. Egalitarianism and social justice informed the new zeitgeist as a powerful campus polity sought to enlist the university in such virtuous causes as racial and social gender equity, third world liberation, urban revitalization, and environmental preservation. ... [B]y the late 1970s it was becoming increasingly apparent that there was too little research, academic or otherwise, reaching the productive economy.[23]

C. The Era of Integration

Frustration with the economy provoked a government response: "By the end of the 1970s, the decade-long bout with 'stagflation' (coined at the time to capture the combination of a stagnant economy, a floundering stock market, and inflation) led to demand for more R&D and translation of the fruits of that R&D into economy-stimulating technology."[24] The sentiment in Congress was that big business was not investing enough in research, and that the federal government, mired in bureaucracy, was allowing invention resulting from taxpayer investment in research to remain in file cabinets.[25]

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23 *Id.*

24 Hughes et al., *supra* note 4, at 110.

25 *Id. See also* GEIGER, *supra* note 6, at xv-xvi; GAO REPORT, *supra* note 20, at 2-3;

In fact, taxpayer investment *was* wasting away in file cabinets due to the absence of a clean, consistent, and predictable federal policy. Rather, there was a policy abyss filled with a case-by-case, agency-specific approach that was unpredictable and invited tremendous transaction costs.[26] "At the time, fewer than 5 percent of the 28,000 patents being held by federal agencies had been licensed, compared with 25 percent to 30 percent of the small number of federal patents for which the government had allowed companies to retain title to the invention."[27]

The U.S. Congress responded and put into motion an intense academia-industry science policy that, through globalization, has impacted the world's science norms. The U.S. enacted the Bayh-Dole Act[28] and the Stevenson-Wydler Act:[29]

> The legislative intent of Bayh-Dole was, through reform of patent policy related to government-sponsored research: (1) to enable and encourage universities, not-for-profit corporations, and small businesses to patent and commercialize their federally-funded inventions; and (2) to enable and encourage federal agencies to grant exclusive licenses for their

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Chester Morore, *Killing the Bayh-Dole Act's Golden Goose*, 8 TUL. J. TECH. & INTELL. PROP. 151, 151 (2006).

26 GAO REPORT, *supra* note 20, at 3.

27 *Id. See also* Stuart, *supra* note 14, at 133-134 ("Whereas the major principle in the decades after World War II was that technology owned by the government was for 'everyone's benefit,' supporters of the Act claimed that this policy effectively rendered government-owned technology for 'nobody's benefit.' It simply gathered dust in government repositories.").

28 Bayh-Dole University and Small Business Patent Procedures Act of 1980, Pub. L. No. 96-517, §6(a), 94 Stat. 3019 (1980) (codified as amended at 35 U.S.C.A. §§200-212 (West 2005)).

29 Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. §§ 3701-3715 (2000); Federal Technology Transfer Act of 1986, 15 U.S.C. §§ 3710a-3710d (2000).

technology to provide more incentive to businesses.[30]

The net result is a "give away" of invention created with federal taxpayer dollars for commercial application, which has integrated government, academia, and industry in science research.[31] This law-policy effectively "unlocked all the inventions and discoveries that had been made in laboratories throughout the U.S. with the help of taxpayers' money."[32] The impact on research institutions, researchers, and science itself has been profound: "A fruitful collaboration between academic researchers and industry promised to fuel not only economic develop-

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30 Hughes et al., *supra* note 4, at 111 (*citing* GAO REPORT, *supra* note 20, at 3); NATIONAL INSTITUTES OF HEALTH (NIH) RESPONSE TO THE CONFERENCE REPORT REQUEST FOR A PLAN TO ENSURE TAXPAYERS' INTERESTS ARE PROTECTED 4-5 (2001) ["NIH REPORT"]. *See generally* Morore, *supra* note 25; Matthew Herder, *Asking for Money Back—Chilling Commercialization or Recouping Public Trust in the Context of Stem Cell Research?*, 9 COLUM. SCI. & TECH. L. REV. 203 (2008) (detailed discussion of proposed recoupment provisions and associated testimony). As explained by the NIH, the collective goal of these acts "is to promote economic development, enhance U.S. competitiveness, and benefit the public by encouraging the commercialization of technologies that would otherwise not be developed into products due to lack of incentives." NIH REPORT at 4. Later, Congress added to these Acts with enactment of the Federal Technology Transfer Act of 1986 (FTTA), which authorizes federal agencies to enter into cooperative research and development agreements (CRADA) with non-federal partners to conduct research. In 1987, the Department of Commerce issued regulations, codified in 37 C.F.R. 401, to fully implement Bayh-Dole. For a clear summary of the requirements set forth in these regulations, see GAO REPORT, *supra* note 20, at 5.

31 The GAO evaluated the impact of technology transfer in a report issued in 1998 and NIH did the same in 2001. *See generally* GAO REPORT, *supra* note 20; NIH REPORT, *supra* note 30. Reports also have been done by consulting groups such as the Boston Consulting Group, and on the national and state levels. *See generally* BOSTON CONSULTING GROUP, THE PHARMACEUTICAL INDUSTRY INTO ITS SECOND CENTURY: FROM SERENDIPITY TO STRATEGY (1999). State reports can be accessed through the state affiliates' links on the Biotechnology Industry Organization (BIO) internet site at www.bio.org. *See generally* Michael Malinowski & Radhika Rao, *Legal Limitations on Genetic Research and the Commercialization of Its Results*, 54 AM. J. COMP. L. 45, 45-65 (2006).

32 *Innovation's Golden Goose*, 365 ECONOMIST 3, 3 (2002) (no author identified).

ment but also new sources of revenue for universities. A vast movement of privatization was underway by the mid-1980s, and it reinvigorated research universities."[33]

From the 1990s onward, government, academia, and industry have integrated with explosive intensity, "giving rise to all the benefits, concerns, and controversies that accompany such dramatic and rapid change."[34] As stated by one observer, "It has turned universities into commercial entities, created a multibillion-dollar industry of technology transfer, and subsidized virtually every biotechnology company and discovery of the past twenty-five years."[35]

Science transcends borders, especially in an age of information technology, and the opportunities associated with biotechnology in the life sciences, both economic and to improve human health, have attracted the attention of many governments.[36] Globalization has infused the academia-industry science norms, expectations, and practices worldwide—hence our forum today, and the questions we raise about the fundamental impact of commercialization on science.

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33 GEIGER, *supra* note 6, at 115.

34 Hughes et al., *supra* note 4, at 115-116 (page numbers not available; forthcoming).

35 Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 42 HOUS. L. REV. 1373, 1375 (2007) . For another evaluation of Bayh-Dole, *see generally* DAVID C. MOWERY, RICHARD R. NELSON, BHAVEN SAMPAT & ARVIDS ZIEDONIS, IVORY TOWER AND INDUSTRIAL INNOVATION: U.S. UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT (2004).

36 For examples, visit the internet site of EuropaBio, *available at* http://www.europabio.org (last visited Dec. 11, 2008), a Europe-based international trade organization that blankets over numerous individual country affiliates.

Ⅲ. Science Today

We are fortunate to live in an age when our species is bettering its health so significantly through its ingenuity in and commitment to science and technology.[37] The academic science shift towards intense commercialization was inevitable. Contemporary life science is extraordinarily complicated and costly, and biopharmaceutical R&D demands collaboration among government, academia, and industry. Decades ago, major research institutions could provide faculty with the means to compete at the forefront of science comfortably from within the oasis of academia. Today, doing so requires accessing a universe of enabling technologies—for example, voluminous databases, biobanks of DNA samples and medical information, bioinformatics capabilities that are constantly expanding and improving, and cell lines and other research materials—largely created and controlled by the commercial sector and made proprietary through intellectual property protection. In summary:

> Arguably, this integration [between academia and industry] was a categorical imperative: in some fields, particularly life science, neither universities nor industry could reach and remain at the leading edge of scientific research and product development, respectively, without engaging with each other. The rapid pace of the science, and its complexity, meant that any given research project depended on many different tools

37 As observed by one expert on the evolution of university research, "Biotechnology manifested its commercial potential in unmistakable fashion. Pure biological research had yielded roots to transform life itself, with enormous implications for medicine and agriculture." GEIGER, *supra* note 6, at xvi.

> and skill sets, on many scales and schedules; and many of these were constantly being superseded or expanded. No single participant or R&D sector could afford to develop and maintain all of these complementary technologies without help from other participants both within and outside its particular sector. In some cases, this was personified by individuals moving between academia and industry and acting as agents for both simultaneously.[38]

Although academia had to integrate with industry to maintain its position at the forefront of knowledge in the life sciences and to continue satisfying its tri-fold mission of teaching, scholarship and service,[39] the timing and intensity of the integration were crafted by government policy that does not go far enough.[40] The manner in which the integration has taken place should have been more regulated—more mechanisms introduced—to better preserve the public nature of science. Disclosure of invention is a quid pro quo for intellectual property ("IP") protection, and commercialization has dramatically increased IP activity,[41] but the disclosure associated with IP protection is no substitute for the loss of information sharing in academic research that was so prevalent just a few decades ago. Most major research institutions take administration of technology transfer very seriously. Colleagues among different institutions, sometimes even within a single

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38 Hughes et al., *supra* note 4, at 116.

39 GEIGER, *supra* note 6, at xvii ("By no means is all new knowledge discovered in universities, but most of it soon finds it's way there. Universities serve as the warehouse and distribution center for the most advanced and theoretical forms of knowledge.").

40 U.S. federal technology transfer law and policy is addressed *supra* in notes 24-36 and the accompanying text.

41 *See generally* NIH REPORT, *supra* note 30.

institution, are forbidden from sharing materials and information without executing material transfer agreements ("MTAs") and confidentiality and disclosure agreements ("CDAs"). Professional organizations such as the Association of University Technology Managers ("AUTM")[42] and the Licensing Executives Society ("LES")[43] have attempted to lighten this administrative burden by introducing standard form documents,[44] but these efforts have largely failed.[45] Resources provided by organizations such as AUTM and LES and experience negotiating and otherwise interfacing with—even hiring managers from—the commercial sector have enabled academic institutions to become commercially savvy in technology transfer. A broader, related assertion is that:

> [F]ederal technology transfer law and policy has resulted in frantic patenting in biotechnology, creating a thicket of patents and administrative burden in licensing that threatens to shut the field down .... Certainly, the rocketed acceleration of the state of the art in biotech fueled by the unprecedented progression of the underlying science leaves us with many patents issued early in the genomics revolution that would not sustain reexamination, and this has driven those in the field to

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42 For information about AUTM', visit the organization's internet site, *available at* http://www.autm.net/aboutTT/aboutTT_umbta.cfm (last visited Dec. 11, 2008).

43 For information about the LES chapter covering the U.S. and Canada,, visit the organization's internet site, *available at* http://www.usa-canada.les.org/chapters/oregon/ (last visited on Dec. 11, 2008).

44 One example is the Uniform Biological Material Transfer Agreement ("UBMTA"), *available at* http://www.bioinfo.com/ubmta.html (last visited Dec. 11, 2008). The UBMTA is a model agreement for general use in the exchange of biological materials between organizations.

45 This is the author's observation based upon work in the field and, in particular, the efforts to accomplish the same among Louisiana research institutions from 2007 to the present.

> an obsessive-compulsive drive to patent. Perhaps the US Patent and Trademark Office should exercise the mechanism of reexamination and clear much of this perceived thicket.[46]

Globally, a patent regime "common denominator" has been introduced through the Trade Related Intellectual Property Provisions ("TRIPS") of the General Agreement on Tariffs and Trade ("GATT"), which was put into force fully in 2006.[47] The combination of TRIPS, research globalization, and intense commercialization suggests that, over time, these U.S.-centered IP norms, practices and controversies will infiltrate the world's science community on an even more expansive scale.

Commercialization also has impacted science publication norms and practices. The vast capacity to publish research and to share knowledge is tainted by conflicts of interest which threaten the reliability and integrity of the peer review process and, consequently, the underlying research. Governments, professional societies, and most science journals have failed to introduce and enforce the mechanisms necessary to manage conflicts of interest in an era of aggressive commercialization with meaningful confidence.[48] Several of the most renowned science publications, including the *New England Journal of Medicine* and *Journal of the American Medical Association ("JAMA"),* have been involved in embarrassing conflicts of interest controversies.[49]

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46 Hughes et al., *supra* note 4, at n.65 (forthcoming).

47 19 U.S.C.A. S 3501. Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (codifiedd in scattered sections of Chapters 7, 17, 18, 19 and 29 of the U.S. Code).

48 *See generally* Symposium, *Conflicts of Interest in Clinical Research: Legal and Ethical Issues*, VIII WIDENER L. SYMP. J. 1-162 (2001).

49 *See* Linda A. Johnson, *New England Journal of Medicine Admits Lapses in Ethics*

The deaths of human subjects and discovery of systemic violations at several renowned institutions inspired a movement in the U.S. at the end of the Clinton Administration to raise standards and to increase enforcement with the mission of policing conflicts more meaningfully.[50] The movement dissipated during the Bush administration, though the integration of government, academia, and industry and commercialization of research certainly did not. Rather, these trends intensified and spread globally.

Commercialization of science also has inspired journals to act more commercially themselves by imposing high cost barriers to access their publications. This trend has given rise to a countermovement, the open access movement. Open access is a call to publish in journals such as the

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Policy, CHICAGO SUN-TIMES, Feb. 24, 2000, at 21 (reporting that the New England Journal of Medicine admitted violating its financial conflict-of-interest policy nineteen times over the past three years in its selection of doctors to review new drug treatments). The primary guidance for conflict of interest management by medical journals is the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, a consensus document issued and subsequently revised by the International Committee of Medical Journal Editors ("ICMJE"), *See* International Committee of Medical Journal Editors, *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, 277 J. AM. MED. ASS'N 927, 927 (1997). However, Despite widespread utilization of the ICMJE requirements, according to a report published in the April 2001 issue of Science and Engineering Ethics by Sheldon Krimsky and co-authors from the University of California at Los Angeles, "[i]n reviewing 61,134 scholarly articles published in 181 academic journals in 1997, researchers…found that just one-half of 1 percent detailed personal financial interests, including consulting arrangements, honorariums, expert witness fees, company equity and stock, and patents." Sheryl Gay Stolberg, *Scientists Often Mum About Ties To Industry*, N.Y. TIMES, Apr. 25, 2001, at A17. Moreover, those disclosures all appeared in just one-third of the 181 journals. *Id.* See also Michael J. Malinowski, *Conflicts of Interest in Clinical Research: Legal and Ethical Issues*, 8 WIDENER L. SYMP. J. 47, n. 57 (2001).

50 The most noted controversy was the death of Jesse Gelsinger, an 18-year-old gene-therapy subject in a protocol approved by the University of Pennsylvania. *See* Gelsinger v. Trustees of the Univ. of Pa., Case No. 000901885 (Pa. Ct. Com. Pl., filed Sept. 18, 2000), *available at* http://www.sskrplaw.com/links/healthcare2.html (last visited Aug. 23, 2001).

Public Library of Science ("PLoS"), which makes all of its publications immediately available online to everyone free of charge and without restrictions, with the mission of disseminating research results quickly and broadly.[51] As explained by PLoS,

> PLoS is one of several initiatives that promote open access to scientific and medical literature. Although they still represent only a tiny fraction of the published research literature, many open access journals have already been launched. A related project is the Open Archives Initiative, which encourages researchers and their institutions to establish free electronic repositories of research literature throughout the world. BioMed Central is a commercial publisher that is publishing original research papers using an open access model. There are also groups, such as the Open Society Institute and the Scholarly Publishers and Academic Resource Coalition, that are providing support and advocacy for open access publishing.[52]

Perhaps the most troubling concern about the state of the public nature of science today is cumulative of the preceding and parallels the drive and support for integration and commercialization: concern about product development and its impact on human health. The number of innovative new drugs entering the market has declined in recent years, and many pharmaceuticals have been recalled.[53] As illustrated too

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51 PLoS, *available at* http://www.plos.org/journals/pubfees.html (last visited Dec. 10, 2008). PLoS covers expenses by charging a publication fee to the authors or research sponsors of the articles they publish. Authors who are affiliated with one of the PLoS' Institutional Members are eligible for a discount on this fee. *See id.*

52 *Id.*

53 "2007 was the single worst year for new drug approvals in a quarter century and 2008

vividly through the Vioxx controversy, it may take years of market use, tremendous financial costs to consumers and taxpayers, and the loss of opportunity to improve human health, even the loss of many human lives, to fully appreciate shortcomings in the present research establishment.[54] Similarly, agbiotech seeds have failed to perform in parts of the economically developing world not a focus during their creation. Consequently, they have destroyed farming sectors—such as cotton farmers in India who relied on Monsanto's BT Cotton.[55] We must consider the extent to which failure to sufficiently preserve the public nature of science and democratic principles in science is responsible for the poor integrity of these resulting products, and ponder the implications for the life science product pipelines.

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proved to be only slightly better." Steven Burrill, *Steven Burrill Predicts Biotechnology's Fortunes for First-Half 2009*, PHARMA MARKETLETTER, Jan. 19, 2009 (pg. nos. unavailable online), 2009 WLNR 7402398 (Westlaw). The FDA approved twenty-four innovative new drugs in 2008 and eighteen in 2007. *See* Jared A. Favole, *FDA Approved More Drugs in 2008*, WALL. ST. J., Jan. 2, 2009, at A9.

54 In recent years, both the Institutes of Medicine ("IOM") and the Government Accountability Office ("GAO") have criticized the FDA's performance regulating new drugs in the marketplace and the lack of transparency of clinical research data that gets them there. *See generally* UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL REQUESTERS, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS (2006); INSTITUTE OF MEDICINE, THE FUTURE OF DRUG SAFETY: ACTION STEPS FOR CONGRESS (2006). In the wake of these controversies over recalls, poor performance, and enforcement, newly-appointed FDA Commissioner Margaret Hamburg has established a task force to develop recommendations to increase transparency of the agency's activities and decision-making. *See generally* Donna Young, *FDA Seeks Greater Openness with Transparency Task Force*, 20 BIOWORLD TODAY (June 8, 2009) (pg. nos. unavailable online), 2009 WLNR 10825524.

55 *See* Bertram Verhaag & Gabriele Krober, *Life Running Out of Control* (Bullfrog Films, 2004) (multi-award winning documentary on the genetic manipulation of plants, animals, and human beings); Press Release, Institute of Science in Society, *Organic Cotton Beats Bt Cotton in India* (May 5, 2005), *available at* http://www.i-sis.org.uk/OCBBCI.php (last visited Dec. 11, 2008).

Ⅳ. A Responsive Law-Policy Proposal

The state of today's financial markets illustrates all too vividly that aggressive commercialization necessitates regulation to ensure integrity and stability.[56] It was shortsighted at best to enact law-policy to integrate academia and industry without introducing accompanying regulatory modifications to promote core elements of the public nature of science. Today's academia pursues the mission of commercial application in science with continued, heavy reliance on the "old world" regulatory mechanisms of self-policing and peer review.

The very intent of U.S. federal technology transfer law and policy has been to create conflicts of interest in science—a necessary counterpart to intensely integrating academia and industry with a sweeping application-commercialization model.[57] Yet, no appropriately meaningful law-policy complement was introduced to police conflicts of interest and, more generally, to preserve core features of academic science, such as broad dissemination of information so crucial for advancing research and ensuring its integrity.

Now that the transformation of academic science has taken place and is proving productive on an unprecedented scale, the law-policy mission should be to strengthen the public nature, integrity, and reliability of our science enterprise. Strengthening regulations to identify, police, and manage conflicts of interest and to protect human subjects is

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56 There is considerable consensus attributing the failure of the markets to the absence of meaningful, effective regulation which invited irresponsible corporate behavior. *See, e.g.*, Michael Struchbury, *Still Flesh on the Bones of Raw Capitalism*, AUSTRALIAN, Sept. 23, 2008, at 12.

57 *See supra* notes 34-36 and accompanying text.

long overdue.[58] So are regulations to make clinical research associated with new biopharmaceuticals transparent for public scrutiny.[59]

The Human Genome Project ("HGP") should serve as a model for additional government-sponsored projects with the objective of facilitating collaboration in the science community for endeavors set in the public domain. Yes, in the end, a commercial competitor pushed HGP to completion, but government support, collaboration among a worldwide network of science talent and resources, and public dissemination of the data generated along the way enabled the commercial competitor and made HGP possible and successful on many levels.[60]

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58 *See generally* Symposium, *Conflicts of Interest in Clinical Research*, *supra* note 48.

59 In response to Vioxx and related product controversies, the U.S. Congress proposed such measures, but then backed away when some of the major pharmaceutical companies announced doing so voluntarily. The voluntary efforts dissipated almost entirely soon after. Michael J. Malinowski, *A Law-Policy Proposal to Know Where Babies Come From During the Reproductive Revolution*, 9 J. GENDER, RACE & JUSTICE 549, n.44 (2006), *citing* Ted Agres, *Congress Wants Data to Be Free*, DRUG DISCOVERY & DEV., 14, (Nov. 1, 2004) (facing a Congressional mandate, "Eli Lilly and a handful of major drug companies have agreed to voluntarily make public their clinical trials results either on their own Internet sites or through an industry database maintained by the Pharmaceutical Research and Manufacturers of America..."); Tamsin Waghorn, *Rattled Drug Giants Act Over Safety Concerns*, EXPRESS DAILY, Jan. 7, 2005 ("Leading pharma players, including the UK's GlaxoSmithKline and AstraZeneca, have backed plans for companies to [voluntarily] publish on the Internet details and results of all clinical trials on new prescription-only drugs."); Editorial, *Hiding the Data on Drug Trials*, N.Y. TIMES, June 1, 2005, at A22 (commenting on a government survey that "determined three of the largest drug companies [Merck, GlaxoSmithKline, and Pfizer] have effectively reneged on their pledges to list trials in a federal database"). *See also* Congressional Testimony, Improving Drug Safety, Nov. 17, 2006, *available at* 2006 WLNR 19959330 (Westlaw).

60 HGP was driven to completion years ahead of schedule through competition between industry and government-led teams that ultimately joined forces to declare a joint victory. *See generally* 291 SCIENCE 1145 (Feb. 16, 2001) (issue entitled "The Human Genome"); 409 NATURE 745 (Feb. 15, 2001) (issue Information about HGP dedicated to the release of a draft map of the human genome). Information about HGP may be obtained from the National Human Genome Research Institute (NHGRI) *available at* http://www.nhgri.nih.gov. (also http://www.genome.gov).

Similar government-sponsored projects to advance science capabilities fundamentally—namely, the creation of enabling technologies and resources—and that provide reliable access to substantial grant funding over a period of time would help to bolster academic science community independence in an era of industry integration and commercialization. In addition, just as HGP had an Ethical, Legal, and Social Implications Project ("ELSI") complement,[61] ongoing government funding for science application should be balanced with grant projects to promote the public nature of science.[62]

The overarching law-policy objective should be intervention to protect and enhance the dual existence of those in the academic science community as members of a public enterprise and collaborators in commercial application. With this dual role more crisply defined, protected, and promoted through government incentives and other law-policy interventions, members of the academic science community would be better positioned to contribute to and more effectively police the integrity of our ongoing science enterprise.

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61 For full information about the ELSI Project, visit the site of the National Human Genome Resource Institute (NHGRI), *available at* http://www.genome.gov/ (last visited Dec. 11, 2008).

62 For an illustrative example, consider a project orchestrated among major academic science institutions, perhaps in several countries, to identify considerations for entering into specific kinds of collaborations and alliances with industry with a focus on protecting and promoting the public nature of science. This idea was inspired by a thoughtful discussion of considerations for major medical centers entering into alliances with industry. *See* Hamilton Moses, Eugene Braunwald, & Joseph Martin, *Industrial Collaboration*, 348 N. ENG. J. MED. 863-864 (Feb. 27, 2004).

Ⅴ. Conclusion

The U.S. has been engaged in aggressive commercialization of science for decades, and that trend is global.[63] Applying science to improve human health and integrating the vast resources of government, academia, and industry to accomplish the same has proven productive. A sizeable, global biotechnology industry was created within the timeframe—approximately fifteen years—associated with the development of a single innovative biopharmaceutical.[64]

This paper has proposed that the integration of academia and industry in science was inevitable given the university mission to remain at the forefront of knowledge and the nature of contemporary life science. Meaningful engagement in today's science necessitates access to proprietary enabling technologies and materials, and often commercial collaborators.[65] The paper also has suggested that the U.S. law-policy intervention to overhaul academic science through integr-ation with industry and to shift the focus of academia to center more on application is making invaluable contributions to science and human health, but was executed in a shortsighted manner in many ways.[66] The paper concludes that government interventions are necessary to protect and preserve the public nature of science, which is essential to shore up the contemporary science enterprise. The dual existence of academic science as a public enterprise and a commercial collaborator is

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63 *See supra* notes 24-36 and accompanying text.

64 For full appreciation of the success and scope of the industry, visit the site of BIO, *available at* http://www.bio.org, and the organization's latest industry report (available therein).

65 *See supra* note 38 and accompanying text.

66 *See supra* notes 56-57 and accompanying text.

crucial to promote the integrity and reliability of science all along the lengthy, often winding, continuum from the laboratory bench to pharmacy shelves. The implications for human health are profound.