GROWING PAINS FOR NEW ACADEMIC/INDUSTRY RELATIONSHIPS

by David Blumenthal

Prologue: If fiction gives voice to certain anxieties that confront a society, then concerns about recent changes in academic/industry relationships extend far beyond the halls of congress and academe. David Blumenthal points out that the issue of foreign industrial control over major American universities forms the backdrop for Michael Crichton’s 1992 bestseller, Rising Sun: “The concern about these new technology transfer arrangements is that they encourage closer ties between universities and industry, thus potentially threatening academia’s traditional role as a bulwark of open and disinterested inquiry. In raising the specter of foreign control over university research in the United States, Crichton merely adds a nationalistic twist to a discussion that has provoked soul-searching and anxiety in American government and academia for a number of years.”

Blumenthal, who holds advanced degrees in medicine and public policy from Harvard University, is a widely recognized expert on academic/industry relationships who has shown an enduring commitment to shaping and informing national health policy. He monitored federal biomedical research policy for Sen. Edward Kennedy (D-MA) in the late 1970s and later worked as the chief health policy adviser in the 1988 presidential campaign of Democratic nominee Michael Dukakis. In a 1989 paper for The New England Journal of Medicine he drew from his campaign experiences to highlight why health policy issues are created superficially in presidential campaigns and to suggest solutions for future elections. Here Blumenthal examines the tenuous relationship between the nature of academic research and the public support required to ensure further gains in medical innovation. He now is chief of the Health Policy Research and Development Unit, Massachusetts General Hospital, and associate professor of medicine and health care policy at Harvard Medical School in Boston.
Abstract: Five decades of almost unwavering federal support of university research in biomedicine have spawned a biotechnology revolution that holds dramatic promise for the public health and the U.S. economy. To make that promise a reality, the federal government now strongly encourages universities to facilitate the practical application of research results by participating in academic/industry relationships. These relationships are yielding important health and economic benefits, but the new economic entanglements of U.S. universities also could undermine the public trust that has sustained federal support of biomedical research. Thus, efforts to speed the transfer of technologies through academic/industry relationships may have enormous effects on the government/university partnership that gave birth to those technologies.

The recent growth of academic/industry relationships in biotechnology and other life sciences raises basic questions about the appropriate relationship between our nation’s research-intensive universities and society. Since World War II Congress has supported an implicit social contract between universities and society, under which the former have received relatively unconditional federal support for biomedical research in return for the hope and promise that such support would pay off in the form of medical breakthroughs. In the 1980s the terms of that social contract began to change. For a variety of reasons, government began to demand more accountability from universities by encouraging them to work with industry to speed their research results to market. Current controversy over the resulting academic/industry relationships in biotechnology seems to reflect a deep-seated public ambivalence over whether the benefits of such relationships for technology transfer justify their possible risks to the culture, norms, and values that have prevailed in universities during a time of unparalleled scientific progress.

This paper explores the history of academic/industry relationships in the biomedical sciences generally, and biotechnology in particular. It discusses their known and suspected consequences and the policy issues they have raised. As this history reveals, the current debate is ironic in one respect. Academic/industry relationships in biotechnology and other areas of the life sciences are very much the product of explicit federal policies. In public policy, as elsewhere, success is often the prelude to new problems.

Definition Of Academic/Industry Relationships

Academic/industry relationships consist of arrangements between for-profit corporations and academic institutions (or their faculty or trainees) in which something of value is exchanged. Most commonly, universities provide a service (such as research or training) or intellectual property (a patent, a license, or commercially useful know-how) in return for financial reward (research support, honoraria, consulting fees, royalties, or equity).

The most common and important academic/industry relationships are
(1) research relationships, in which industries support university-based research through grants or contracts; (2) consulting relationships, in which industries compensate universities or members of their community in exchange for advice or information; (3) patenting or licensing relationships, in which industries obtain the rights to commercialize intellectual property owned by universities, by either purchasing or licensing university patents; (4) equity relationships, in which members of the university community or academic institutions themselves own substantial equity positions in new companies (sometimes such companies are formed to commercialize the intellectual property resulting from university research); and (5) training relationships, in which industries support the research or educational expenses of doctoral or postdoctoral trainees, or contract with universities to provide training to industry employees.

History Of Academic/Industry Relationships

Academic/industry relationships in the life sciences first appeared in the early twentieth century, when pharmaceutical companies developed their own intramural research and development capabilities. Drug companies found that university scientists could be helpful in providing technical assistance and support to industry research. In this early stage, these arrangements generally took the form of focused research and consulting relationships between individual faculty members and industrial concerns.

Consulting and research relationships expanded after World War I. Universities also began experimenting with academic/industry relationships by patenting and licensing the discoveries of their scientists. Ironically, the groundwork for the current explosion of academic/industry relationships in the life sciences was laid in the period immediately following World War II by a development that initially inhibited academic/industry cooperation. This development was the swelling federal commitment to university research in the biomedical sciences. In 1948 Congress began pouring money into the then tiny National Institutes of Health (NIH) for the purpose of improving the health of the American people.

Federal support of biomedical research. One of the most remarkable things about the federal government’s support of biomedical research is the consistency with which it has been sustained over time. Through recession and war, through changing party control over the legislative and executive branches, federal funding of biomedical research has followed a steady upward course in nominal dollars, and with few exceptions, in constant dollars as well. Interestingly, in recent years growth in government spending on biomedical research and development (R&D) has lagged somewhat compared with other sources. The NIH share of biomedical R&D funds has
dropped nationally from 40 percent to 32 percent since 1980, while industry’s share has increased from 31 percent to 46 percent. Nevertheless, the record of federal support for biomedical R&D contrasts sharply with the government’s commitment to other fields of domestic R&D, both in absolute terms and in rates of growth over time (Exhibits 1 and 2).

To be sure, the motives and methods underlying this commitment have not always been noble and certainly did not anticipate current interest in biotechnology as a contributor to U.S. economic competitiveness. Academic investigators and their lobbyists have at times behaved in a manner indistinguishable from traditional special interests, as they have used almost every technique in the legislative book to achieve increases in appropriations and the establishment of new NIH institutes and programs.

One result of the generous treatment of biomedical research by the federal government was that universities and their scientists, who received the lion’s share of federal largesse in this field, had enough financial independence to follow the logic of their scientific fields for several decades. The implicit social contract underlying federal support was that NIH would support “disease-oriented” research, so that elected representatives and their constituents could understand the relevance of the work. However,
under the aegis of the National Cancer Institute; the National Heart, Lung, and Blood Institute; the National Eye Institute; and the other disease-specific NIH institutes, the scientific community remained largely free to pursue fundamental investigation into the basic biological mechanisms underlying health and disease. Investigators did not have to prove the short-term applicability of their work, because they did not have to rely on sponsors, such as industry, with such short-term orientations. During the 1950s and 1960s less than 4 percent of university research support was from private industry. An increasing cultural and institutional distance developed between biomedical researchers and the industrial organizations that, in free market economies, have to use the results of research to translate them into practical application. This distance certainly did not prevent the transfer of useful technologies from universities to biomedical industries. But it did result in less direct interaction between academic scientists and industrial organizations.

Several factors combined in the late 1970s and early 1980s to force industry and university-based scientists to bridge this divide. The first grew out of the success of the social compact between government and universities. In 1973 Herbert Boyer and Stanley Cohen, NIH-supported professors at the University of California, San Francisco, and Stanford University, discovered recombinant deoxyribonucleic acid (DNA) technology. This basic research finding provided Stanford with a very profitable patent and resulted in the establishment of Genentech, the first of thousands of new
biotechnology companies spawned by the Cohen-Boyer research and other contemporary biological advances. Policymakers, industries, and universities suddenly were presented with the opportunity to craft a new generation of therapeutic modalities, and pressure to apply the new technology became irresistible.

A second factor that brought university scientists and industry together was the changing U.S. economy. During the Carter administration, and increasingly during the Reagan administration, the nation’s unquestioned postwar global economic supremacy was challenged by Japan and western Europe. The United States developed deficits in its balance of trade with foreign competitors, and chronic budget deficits strained the resources of federal sponsors of research. Resourceful policymakers began looking for novel ways to bolster regional and national industrial capacity and to support university-based biomedical research. They naturally turned toward biotechnology and industry support of academic research as part of a new partnership to support local and national development.

A third factor forcing academic/industry cooperation as important as but more elusive than the others was the pendular swing of American public policy. A law of federal policy dynamics is that every major thrust eventually prompts an equal and opposite counterthrust. A counterthrust to two decades of nearly unconditional support of university-based biomedical research began to emerge as early as 1966, when President Lyndon Johnson landed by helicopter on the NIH campus and unexpectedly chided the federal agency and its academic clients with the comment: “We must make sure that no life-giving discovery is locked up in the laboratory.”

The university community was outraged at the suggestion that it was not living up to its responsibility to move new research findings into practice, and said so. Nevertheless, the view took hold that universities should be held accountable for the public research monies they receive. While continuing their generous support of university-based research, federal and state policymakers began rewriting the conditions of that support in effect, drafting a new social compact between the taxpayer and the university biomedical research community. Under the terms of this new agreement, universities had a responsibility to be actively engaged in promoting the practical application of their work. In American society this inevitably meant cooperation with industry.

**Federal policy vis-a-vis academic/industry relationships.** In the late 1970s the federal government became an aggressive promoter of academic/industry relationships. Once again, it showed rare persistence in this policy commitment. Its first and perhaps most important initiative was the Bayh-Dole Act of 1980 (P.L. 96-517) also known as the 1980 Patents
This law enabled university and small-business contractors and grantees of the federal government to receive title to patentable inventions made with federal support. It also allowed those contractors and grantees to license those patents exclusively to small businesses (and later, to businesses of all sizes) and provided march-in rights by the federal government if those licensees failed to commercialize the resulting products. This law made it possible for universities to own the intellectual property resulting from their federally sponsored research and to provide industrial partners with effective monopolies over the exploitation of that intellectual property—necessary incentives for future investment in the development of new drugs and devices.

In 1980 the Supreme Court made a major contribution to promoting academic/industry relationships in the life sciences when it ruled that new life forms created by biotechnological techniques could be patented. Then, at the urging of the Reagan administration, Congress passed a second initiative that indirectly encouraged academic/industry relationships: the Economic Recovery Tax Act of 1981, which included several provisions favorable to companies supporting university research. The law provided a tax credit to industries that increased their investment in basic research, including investment in universities. These provisions were regularly renewed by Congress until 1992.

In 1986 the federal government sent another potent signal to universities and industries of the importance it attached to academic/industry relationships. It enacted the Federal Technology Transfer Act of 1986 (FTTA), which made it federal policy for the first time to encourage commercialization of results of intramural federal research: that is, research conducted in federal laboratories. Though not universities per se, some federal laboratories, including those at NIH, had cultivated and preserved the traditional values of academia. University scientists frequently spent time at NIH, and NIH scientists often finished their careers as senior faculty in academic institutions. Because of its dependence on NIH funding, the academic biomedical research community watches internal NIH policy attentively, and this new initiative could not have gone unnoticed. The FITA was amended in 1989. One of the new provisions allowed government scientists to protect the confidentiality of proprietary information shared with their new industrial partners.

**Growth Of Academic/Industry Relationships**

These policy thrusts by all three branches of government, together with the other trends noted above, contributed to increased interaction between academia and the biotechnology industry. This growth is best documented
for research and patenting and licensing relationships, but it is almost
certainly true of other types of academic/industry relationships as well.

One indicator of this increase is the number of so-called strategic alli-
ances between these two sectors. Strategic alliances consist of large, long-
term agreements to conduct cooperative research, in which industries con-
tribute at least $500,000 annually for a minimum of three years. As Ashley
Stevens has shown, the rate of formation of strategic alliances increased
rapidly during the 1980s and early 1990s (Exhibit 3).

A second indicator of the increase in academic/industry research rela-
tionships is the rate of formation of patenting and licensing arrangements.
The Association of University Technology Managers has documented dra-
matic growth in the number of patents from all scientific fields issued to
universities during the 1980s and early 1990s (Exhibit 4). According to
Bernadine Healy, former NIH director, the number of patent applications
based on NIH support grew from 890 in the decade before the Bayh-Dole
Act to 2,617 in the decade after its passage.18 In 1991 the U.S. General
Accounting Office (GAO) surveyed the thirty-five American universities
that received the most funding from NIH and the National Science Foun-
dation. During 1989-1990 these universities filed 2,043 patent applica-
tions, received 1,036 patents, licensed 731 patents to industries, and real-
ized income of more than $113 million. Seventy-five percent of exclusively
licensed patents, which tend to be the most lucrative, resulted from NIH-
funded research.19 Data from a 1992 survey of academic institutions belong-

![Exhibit 3](https://example.com/exhibit3.png)

**Exhibit 3**
**History Of Strategic Alliances Between Academe And Industry, 1974-1992**

<table>
<thead>
<tr>
<th>Number of alliances</th>
<th>Millions of dollars</th>
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**Source:** Ashley Stevens, Dana Farber Cancer Institute, personal communication.

**Notes:** Number of alliances (solid bars) corresponds with left axis; funding (shaded bars) corresponds with tight axis. Data are not available for 1975, 1976,1977, and 1979.
ing to the Association of University Technology Managers (approximately 150) indicated that their total receipts from royalties that year alone exceeded $250 million, and were growing at the rate of 20 to 30 percent a year. On rare occasions university-held biotechnology patents have realized dramatic one-time financial gains for their owners. In 1991 the Memorial Sloan-Kettering Cancer Center of New York City, which is affiliated with Cornell University, sold part of its patent on erythropoietin to Amgen for $50 million.

A third area of growth in academic/industry relationships in biotechnology has been participation of faculty members in founding new biotech companies. Faculty participation in start-up companies appeals to venture capitalists because of the "stickiness" of new knowledge necessary to commercialize research findings. Even after publication and patenting, much of the know-how critical to making a patent or trade secret into a viable product remains in the lab, or even in the head, of the inventor. Thus, one of the most efficient mechanisms for technology transfer is the complete or partial transfer of the inventor's time and interest from the university to the industrial setting. The movement of inventors out of universities into industries has occurred in sectors other than biomedicine and explains in large measure the concentration of the computer industry close to university communities, such as in Silicon Valley. What has distinguished this phenomenon in biotechnology is that university faculty have acquired equity and leadership roles in start-up companies while retaining their faculty positions in universities. This has drawn the university community

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Exhibit 4

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<th>Number of U.S. patents issued</th>
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Source: AUTM (Association of the University Technology Managers).
into the industrial setting in new, controversial ways.

The actual frequency with which university biomedical faculty help start new companies is poorly understood. The only systematic data derive from a survey of approximately 1,000 life science faculty in the nation’s fifty most research intensive universities during the mid-1980s. At that time, about 8 percent of respondents reported that they held equity in a company whose work was related to their own university-based research.\textsuperscript{23}

Still another growing form of academic/industry relationships about which even less is known is the involvement of parent universities and academic medical centers in the founding of new companies. It has become relatively common for universities as institutions to take equity in new companies that are founded by their faculty, usually with initial funding from venture capitalists. From the university’s standpoint, the rationale for this participation is that academic institutions are usually the legal owners of the intellectual property on which new companies are based, a direct result of the entitlement created by the Bayh-Dole Act. Thus, academic institutions feel entitled to a share in prospective economic gains. Also, university officials argue, those economic gains can assist in endowing and maintaining the research enterprises on which the biotechnology revolution has been based. Some institutions, such as Harvard University, have used complicated legal structures to keep their involvement at arm’s length. Others, such as The Johns Hopkins University, have made an explicit commitment to fostering start-up companies in which the university participates directly.\textsuperscript{24}

**Benefits Of Academic/Industry Relationships**

It is far too early, and the data are far too sketchy, to reach any definitive conclusions concerning the consequences of academic/industry relationships in biotechnology for universities, industries, government, or society at large. Nevertheless, tantalizing hints suggest where evaluators should look in the future.

**Public health benefits.** The rationale for promoting and participating in academic/industry relationships in biotechnology and other fields has hinged importantly on their promise for realizing practical health care benefits for U.S. society. So far, comprehensive evidence of such benefits has never been accumulated, but early indications are that certain discoveries originating in or based upon university research and commercialized by industry have yielded important benefits to specific groups of patients.\textsuperscript{25} Among those already being marketed are the following: human insulin, a nonallergenic alternative for diabetic patients sensitized to traditional pork or beef insulin; human growth hormone, used to treat certain rare condi-
tions in which children fail to grow normally; erythropoietin, a naturally occurring hormone that stimulates the human bone marrow to produce red blood cells and is used to treat anemia in patients with kidney failure and other conditions; granulocyte and macrophage stimulating factors, naturally occurring substances that stimulate the production of white blood cells and are used in patients with natural or treatment-induced shortages of these essential cells; interferons, naturally occurring substances produced by human white blood cells that have proved useful in treating certain chronic, autoimmune conditions, such as chronic active hepatitis and multiple sclerosis, chronic infections in immunocompromised patients, and certain cancers; recombinant tissue plasminogen activator (r-TPA), used to dissolve clots in the arteries of heart attack patients; recombinant factor VIII, the protein that is missing in hemophiliacs and was previously replaced with factor VIII from human donors, thereby exposing hemophiliacs to AIDS and other bloodborne diseases; recombinant vaccine against hepatitis B, used to immunize high-risk adults against this bloodborne illness and now recommended for routine use in children and adolescents; recombinant vaccine against Hemophilus influenza B, used to immunize children against this rare, commonly fatal source of meningitis in infants and young children; diagnostic tests for the genes that cause cystic fibrosis and Huntington’s disease and certain other genes associated with cancer; and a diagnostic assay for hepatitis C, now the form of hepatitis most commonly transmitted by blood transfusion and associated with both chronic liver infections and cancer of the liver.

The precise role of the new academic/industry relationships in realizing these benefits of biomedical and biotechnology research has yet to be defined. Some industrial sponsors feel that universities have overstated their contribution to technology transfer through academic/industry relationships. It is also well documented that universities make major contributions to new technology through the more traditional route of open publication and dissemination of their research results. Nevertheless, when asked if industrial support of university research increases the rate of applications from basic research, 67 percent of life science faculty with such support and 52 percent of those without it agreed that research relationships have this effect.

Economic benefits. The federal investment in biomedical research at American universities was not originally intended to bolster local or national economies or to provide universities with economic security. However, in recent years the potential economic benefits of academic/industry relationships seem to have played an increasing role in motivating federal research support for biological sciences and university research generally. Here again, there is early evidence of some returns.
Evidence of benefits to industrial organizations can be gleaned indirectly from data on the income of patenting and licensing academic/industry relationships to universities. The royalties paid to universities by companies licensing their patents typically are less than 10 percent of sales, and often less than 5 percent. Thus, the GAO’s finding that thirty-five universities received more than $113 million from such research relationships in 1989 and 1990 suggests that revenues to companies from those licenses exceeded $1 billion for 1989 and 1990, or more than $500 million annually. This is undoubtedly a fraction of the total revenues accruing to the pharmaceutical and device industries as a result of products commercialized with the assistance of academic/industry relationships. Assuming a royalty rate of 3 percent of sales, and using 1992 data on total royalties to universities, Ashley Stevens has estimated that industry realized more than $9 billion in revenues from sales of products developed wholly or partly in universities (including nonbiomedical products). As a quick perusal of advertisements in the major biomedical research journals makes clear, there is also a new industry supporting the biotechnology research enterprise itself, supplying substances and equipment that were entirely unknown ten years ago.

Other indirect evidence of the economic benefits of academic/industry relationships to industrial sponsors derives from data on the comparative productivity of research dollars that companies spent in their own labs versus the productivity of such funds spent in university labs. A survey of biotechnology companies in the mid-1980s indicated that they were realizing up to four times as many patent applications per dollar invested in university research as from investigation in their own labs. Whether patent applications generated by academia turn out to be as useful or profitable as those developed from industry research remains to be seen. 29

The economic benefits of academic/industry relationships to universities include the royalties noted above, although these should be kept in perspective. The average annual income from patents and licenses of all kinds reported by university respondents to the GAO survey was $1.6 million. However, only nine of the thirty-five institutions surveyed realized annual incomes of more than $1 million, and only six realized more than $2 million. This suggests that many institutions may be spending more on obtaining and licensing patents than they are realizing in revenues. These findings are consistent with experience with patenting and licensing arrangements prior to the biotechnology revolution. 30

Another economic benefit to universities is the flow of research dollars from relationships that support university-based investigation. It has been estimated that in the mid-1980s industry supported between 7 percent and 16 percent of university-based investigation in biotechnology. 31 A few universities, such as the Massachusetts Institute of Technology (MIT), also
have begun to realize capital gains from the sale of equity positions in start-up biotech companies, although data on such sales are scarce. Given the huge budgets of modern American research universities, such income would have to be very large to have any significant effect on university finances.

**Scientific and educational benefits.** Some evidence suggests that academic/industry relationships may have scientific and educational benefits in addition to their health and economic payoffs. Life science faculty with industrial research support publish more peer-reviewed articles (controlling for level of support from all sources) than faculty without industry funding. The positive association between industrial support and publication rates is most notable for faculty with one-third or less of their research funding from industry, and disappears as dependence on industrial support increases. In the mid-1980s more than 87 percent of trainees with industry support believed that the benefits of such funding outweigh the risks, and the reported quality of graduate training was the same for persons with and without such funding.

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**Potential Hazards Of Academic/Industry Relationships**

Indications of the hazards of academic/industry relationships in the life sciences (and other fields) also are emerging. The least concrete but most troubling of these concerns is that these relationships may be undermining academia’s claim to special status and autonomy.

**Changing role and norms of universities.** Academic/industry relationships in the life sciences reflect in part a conscious public effort to enlist the support of previously protected academic institutions in the international competition for economic supremacy. Henry Etzkowitz and Lois Peters have argued that to some extent the decision to involve academia in this struggle was an attempt to compensate for the lack of a more explicit and functional industrial policy during the 1980s. However, it seems likely that any comprehensive industrial policy would have sought to take full advantage of the United States's strong academic research advantage in the field of biotechnology, and such an effort would have led almost automatically to the promotion of academic/industry relationships.

The question now confronting universities, policymakers, and thoughtful industrial leaders is whether the new terms of the relationship between universities and society will be as beneficial over the long term as they seem to be now. The reason for anxiety has to do with the effect of academic/industry relationships in encouraging a not-so-subtle shift in the norms that dominated academic life during the biotechnology revolution and are thus associated, if only temporally, with the conditions that made that revolu-
tion possible.\textsuperscript{38} Those norms, as characterized by Robert Merton, include “disinterestedness” and “communalism.”\textsuperscript{39} The former denotes a willingness to share the results of research without promise of economic reward; the latter consists of a commitment to the scientific community as manifested by open communication and an aversion to secrecy.

Of course, academic behavior has never conformed perfectly with these lofty ideals. Self-interest, both economic and professional, has always strongly influenced faculty behavior, and secrecy in the service of academic priority has been widespread. Nevertheless, the promotion and growth of academic/industry relationships has made it not only acceptable but almost expected for universities and their faculties and staff—and, more recently, researchers in federal labs—to depart to some degree from the Mertonian norms.\textsuperscript{40} In a recent review of 375 research agreements between academic institutions and industry, NIH officials found that 22 percent contained provisions allowing an industry partner to delay publication of research findings by more than sixty days to allow time for industry review.

Two major anxieties surround the departure of modern academic institutions from Mertonian norms. One is that the progress of science will be retarded because of the erosion of traditional conditions. A second, related concern is that observers will cease to see universities as sources of impartial, disinterested knowledge that deserve public support and the freedom to use that support as they see fit. Academic/industry relationships, it is feared, may result in reduced trust of universities, reduced federal support, the imposition of more conditions on that support, and greater dependence on industry funding to sustain the academic research effort. Ultimately, the biomedical research enterprise, industry, and the public may suffer from the resulting loss of confidence in academic life sciences.

**Changing research environment.** Limited evidence suggests that involvement in academic/industry relationships is, in fact, associated with faculty behavior that departs from traditional academic norms. In a 1985 survey of 1,000 life scientists, 13 percent of biotechnology faculty with industrial research support, but only 3 percent without it, said that trade secrets (information kept secret to protect its proprietary value) had resulted from their university research.\textsuperscript{42} When asked whether they had taken commercial considerations into account in choosing research projects, 30 percent of life science faculty with industry research funding, but only 7 percent without it, replied that they had. Faculty participating in academic/industry relationships were also significantly more likely to report that they had conducted research whose results were the property of their sponsors and could not be published without those sponsors’ permission.

More compelling—at least to the media and to government officials—than these statistics has been a series of highly publicized examples of real
or apparent conflict of interest on the part of academicians and universities involved in academic/industry relationships. The most celebrated case involved a research fellow at Harvard University’s Massachusetts Eye and Ear Infirmary who benefited substantially from selling his holdings in a private company established to market a new drug he was testing in clinical trials. His unpublished work later showed the drug to be ineffective. Questions naturally arose about whether the investigator’s patients suffered any ill effects from his conflict of interest. No evidence of such damage was ever found, but the research was found to have violated university procedures, including those governing the protection of human subjects.43

Questions were raised in 1989 during congressional subcommittee hearings about whether an investigator from the University of Pittsburgh had been influenced by the receipt of large fees from industrial sponsors in his interpretation of the results of industry-sponsored clinical trials. The charges were never proved.44 Questions also have been raised about the appropriateness of a relationship between Boston University and a spin-off company, the Seragen Corporation. The university itself, individual members of its board of trustees, the president of the university, and members of its faculty own substantial equity in this company, which also is funding research at the university.45

Reduced trust in academic life science enterprise. Real or apparent changes in the norms and behavior of academic life science researchers have led in turn to governmental initiatives that have fueled anxieties about the long-term effect of academic/industry relationships on the legitimacy of academic biomedical science. Under pressure from congressional critics, NIH published proposed guidelines in 1989 on conflicts of interest among grantees.46 These initial guidelines were withdrawn because of protests from the biomedical research community and legal challenges, but new guidelines have been drawn up and are under review by the Clinton administration. The GAO concluded in a 1992 report that growing interactions between universities and businesses increased the potential for conflicts of interest and recommended new policies governing federal grantees and agencies.47 An internal NIH task force was formed in the following year to review procedures for implementing the Bayh-Dole Act among NIH grantees. The task force is committed to reporting to Congress within one year.48

Prospects For Future Academic/Industry Relationships

The question now is whether this increased scrutiny of academic/industry relationships and their associated problems represents merely a necessary midcourse correction to refine federal policy toward these col-
laborations, or whether current federal attempts to regulate these relationships presage more worrisome trends. One theory is that the federal government will increasingly demand that universities serve short-term definitions of the public interest—including the need for local and national economic development—by working closely with industries and state and national governments on economic development programs. At the same time, the resulting economic entanglements among universities and professors will compound other developments—highly publicized examples of scientific misconduct, disputes between scientists over title to intellectual property, allegations of misuse of federal grant monies—that will cause the public and its elected representatives to see the university biomedical research enterprise as not only fallible but self-interested. The associated loss of public trust in the university might then result in a different social contract between academia and society in which academic biomedical labs are viewed as a species of government contractor, like the defense industry, whose fates rise and fall with perceived external threats and the vagaries of public opinion.

An equally plausible prediction is that universities will prove capacious and durable enough to accommodate academic/industry relationships in the biomedical sciences while preserving a fundamental commitment to open, disinterested inquiry. According to this scenario, the public’s faith in medical progress will cause the federal government to maintain support for university-based biomedical research without demanding unreasonable, short-term results.

Whatever the future holds, the stakes are substantial. The postwar partnership between government and the academic life sciences has fundamentally affected the course of human development at a cost that seems, by historical standards, relatively small. In recasting that partnership, universities, industries, voters, and policymakers must carefully consider whether its new terms will permit that progress to continue.
NOTES

4. Ibid.
5. Strickland, Politics, Science, and Dread Disease.
17. Ibid.
18. B. Healy, Statement before the House Small Business Subcommittee on Regulation, Business Opportunities, and Technology (17 June 1993).
33. Blumenthal et al., “University-Industry Relationships in Biotechnology.”
36. OTA, Biotechnology in a Global Economy.
38. Etzkowitz, “Entrepreneurial Science in the Academy.”
40. Etzkowitz, “Regional Industrial and Science Policy in the United States.”
41. Healy, Statement before the House Small Business Subcommittee on Regulation, Business Opportunities, and Technology.
42. Blumenthal et al., “University-Industry Relationships in Biotechnology.”
47. GAO, Controlling Inappropriate Access to Federally Funded Research Results.
48. Healy, Statement before the House Small Business Subcommittee on Regulation, Business Opportunities, and Technology.
49. Etzkowitz, “Enterprises from Science.”