Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship

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November 30, 2012

Congressional Research Service
7-....
www.crs.gov
RL32324

CRS Report for Congress
Prepared for Members and Committees of Congress

Summary

Public interest in approaches that might provide prescription drugs at lower cost, particularly for the elderly, has rekindled discussion over the role the federal government plays in facilitating the creation of new pharmaceuticals for the marketplace. In the current debate, some argue that the government's financial, scientific, and/or clinical support of health-related research and development (R&D) entitles the public to commensurate considerations in the prices charged for any resulting drugs. Others view government intervention in price decisions based upon initial federal funding as contrary to a long-term trend of government promotion of innovation, technological advancement, and the commercialization of technology by the business community leading to new products and processes for the marketplace.

The government traditionally funds R&D to meet the mission requirements of the federal departments and agencies. It also supports work in areas where there is an identified need for research, primarily basic research, not being performed in the private sector. Over the past 25 or more years, congressional initiatives have expanded the government's role to include the promotion of technological innovation to meet other national needs, particularly the economic growth that flows from the use of new and improved goods and services. Various laws facilitate commercialization of federally funded R&D through technology transfer, cooperative R&D, and intellectual property rights. The legislated incentives are intended to encourage additional private sector investments often necessary to further develop marketable products. The current approach to technology development attempts to balance the public sector's interest in new and improved technologies with concerns over providing companies valuable benefits without adequate accountability or compensation.

Some question whether or not the current balance is appropriate, particularly with respect to drug discovery. The particular nature and expense of health-related R&D have focused attention on the manner in which the National Institutes of Health (NIH) undertakes research activities. Critics maintain that any need for technology development incentives in the pharmaceutical and/or biotechnology sectors is mitigated by industry access to government-supported work at no cost, monopoly power through patent protection, and additional regulatory and tax advantages such as those conveyed through the Hatch-Waxman Act, the Biologics Price Competition and Innovation Act, and the Orphan Drug Act. Supporters of the existing approach argue that these incentives are precisely what are required and have given rise to robust pharmaceutical and biotechnology industries. It remains to be seen whether or not decisions related to federal involvement in issues related to pharmaceutical R&D will change the nature of the current approach to government-industry-university cooperation.

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Overview

Public interest in approaches that might provide prescription drugs at lower cost, particularly for the elderly, has rekindled discussion over the role the federal government plays in facilitating the development and marketing of new pharmaceuticals. In the current debate, some argue that the government's financial, research, and/or clinical support of health-related R&D entitles the public to commensurate considerations in the prices charged for any resulting drugs. Others view government intervention in price decisions based upon initial federal funding of basic research as contrary to a long-term trend of government promotion of innovation, technological advancement, and the commercialization of technology by the business community leading to new products and processes for the marketplace.

The federal involvement in R&D stems, in part, from the understanding that technological advancement is a key element in economic growth. Many of the innovations that stimulate technological progress are rooted in basic research. However, because the returns to basic research accrue to society as a whole and often can not be captured by the firm performing the work, there tends to be underinvestment in these activities. Thus, the government typically funds fundamental research as a "public good." Concurrently, the government has an interest in ensuring that the results of this enterprise are applied to generate new goods and services to meet the demands of citizens. The benefits of research emerge when innovations are available in the marketplace. In recognition of this, Congress has passed legislation to facilitate the commercialization of new technology.

Government policies implemented over the past 25 or more years include incentives to increase private sector investment in technology development through technology transfer, cooperative R&D, and intellectual property rights. The intent is to encourage academia and industry to commit the necessary, and often substantial, resources required to take the results of federally supported R&D and generate products or processes to meet market demand. Utilizing patent ownership and facilitating collaborative government-university-industry efforts, the current legislative approach attempts to balance the public's need for new technologies and techniques with concerns over providing companies valuable benefits without adequate accountability or compensation. The reservation of certain rights for the government that permit federal intervention in specific circumstances associated with health and safety concerns are intended to act as safeguards for the public.

Some Members of Congress have questioned the adequacy of the current balance between public and private needs. The particular nature of health-related research and development, and the substantial federal investment in this area (over $30.8 billion was appropriated to NIH for medical research in FY2012),[1] has led critics of the current system to argue that the necessity of incentives is mitigated by such factors as free access to the results of federally funded work; by the monopoly power permitted by patent protection; and by other regulatory and tax advantages such as those conveyed by the Hatch-Waxman Act, the Biologics Price Competition and Innovation Act, or the Orphan Drug Act. Therefore, some commentators maintain, a more direct payback should be required including recoupment of public sector financial support or government involvement in price decisions. Other experts counter that these inducements have

[1] See http://officeofbudget.od.nih.gov/pdfs/FY12/FY%202012%20Consolidated%20%20Appropriations%20Act%20PL%20112-74_revised%201-30-2012.pdf.

played an important role in making the U.S. pharmaceutical and biotechnology industries innovative, productive, and competitive. They point out that while the government contributed to development of the Internet, as well as to the telecommunications, semiconductor, and aviation industries, no one is advocating federal involvement in cost considerations in these areas as they are in the health field.

This paper explores the reasons behind government funding of research and development and subsequent efforts to facilitate private sector commercialization of the results of such work. It does not address issues associated with drug costs or pricing. Instead, the report looks at the manner in which the National Institutes of Health (NIH) supports research to encourage the development of new pharmaceuticals and therapeutics, particularly through cooperative activities among academia, industry, and government. The goal is to offer insights concerning the discussion on whether or not use of the results of the federal R&D enterprise warrants government input into price decisions made by the private sector. Concerns surrounding innovation in health-related areas will be explored within the broader context of the government's role in facilitating technological progress.

Government Support for R&D

The U.S. government is expected to spend an estimated $138.9 billion in FY2012 on research and development to meet the mission requirements of the federal departments and agencies.[2] Traditionally, the government funds R&D to meet the mission requirements of the federal departments and agencies (e.g., defense, public health, environmental quality). It also supports work in areas where there is an identified need for research, primarily basic research, not being performed in the private sector. Federal funding reflects a consensus that while basic research is the foundation for many innovations, the rate of return to society as a whole generated by investments in this activity is significantly larger than the benefits that can be captured by any one firm performing it.[3] "Government support of basic scientific research represents an example of the government furnishing a good, scientific knowledge, that improves social well-being ... a good that cannot be sold because those who do not pay receive the benefits anyway."[4] Estimates of a social rate of return on R&D spending over twice that of the rate of return to the inventor of the product often lead to underinvestment by the business community.[5] In addition, incentives for private sector financial commitments are dampened by the fact that spending for R&D runs a high risk of failure. The rewards of basic research tend to be long term, sometimes are not marketable, and are not always evident.

[2] Office of Management and Budget, *Fiscal Year 2013 Analytical Perspectives, Budget of the U.S. Government*, 370, available at http://www.whitehouse.gov/sites/default/files/omb/budget/fy2012/assets/spec.pdf.

[3] Edwin Mansfield, "Social Returns From R&D: Findings, Methods, and Limitations," *Research/Technology Management*, November-December 1991, 24. See also: Charles I. Jones and John C. Williams, "Measuring the Social Return to R&D," *Quarterly Journal of Economics*, November 1998, 1119 and Richard R. Nelson and Paul M. Romer, "Science, Economic Growth, and Public Policy," in Bruce R. Smith and Claude E. Barfield, eds. *Technology, R&D, and the Economy*, (Washington, The Brookings Institution and the American Enterprise Institute, Washington, 1996), 57.

[4] Baruch Brody, "Public Goods and Fair Prices," *Hastings Center Report*, March-April 1996, 8.

[5] For a list of relevant research in this area see Council of Economic Advisors. *Supporting Research and Development to Promote Economic Growth: The Federal Government's Role*, (October 1995), 6-7.

Congressional initiatives have expanded the government's role in R&D to include the promotion of technological innovation to meet other national needs, particularly the economic growth that flows from the commercialization and use of new products and production processes by the private sector.[6] Technological advancement is an important factor in the nation's economic growth. Experts widely accept that technical progress is responsible for up to one-half the growth of the U.S. economy and is one principal driving force for increases in our standard of living.[7] Historically, industrial expansion was based on the use of technology to exploit natural resources. Today, such growth tends to be founded on scientific discoveries and engineering knowledge (e.g., biomedical applications, electronics) and is even more dependent than before on the development and use of technology. Technology can help drive the economy because it contributes to the creation of new goods and services, new industries, new jobs, and new capital. It can expand the range of services offered and extend the geographic distribution of those services. The application of technologies also can contribute to the resolution of those national problems that are amenable to technological solutions.

Technological progress is achieved through innovation, a process by which industry provides new and improved products, manufacturing processes, and services. Research and development are important to this technological advancement in many ways. R&D contributes to economic growth by its impact on productivity. For more than two decades various experts studying the effects of research and development have found that productivity growth in an industry or a firm is generally directly and significantly related to the amount spent previously on R&D in that industry or company.[8] Analysts estimate that one-half of productivity increases (output per person) are the result of investments in research and development.[9] Others argue that innovations arising from R&D are the most important ones.[10] Profound changes in our society have been brought about by advances in research, resulting in new products and processes in the areas of medicine, semiconductors, computers, and materials, to name just a few.

To leverage the substantial federal investment in R&D, government policies and practices provide incentives for private sector utilization of the results of this endeavor to make products and processes for the marketplace. Legislative initiatives (discussed below) facilitate the commercialization of government-funded research and development through mechanisms that encourage government-industry-university collaboration. Joint federal efforts with the private sector offer a means to get government-generated research and technical know-how to the business community where it can be developed, commercialized, and made available for use to meet the needs of government agencies or to stimulate economic growth vital to the nation's

[6] For information on relevant legislation see CRS Report RL33528, *Industrial Competitiveness and Technological Advancement: Debate Over Government Policy*, by (name redacted).

[7] Gregory Tassey, *The Economics of R&D Policy* (Connecticut, Quorum Books, 1997), 54. See also Edwin Mansfield, "Intellectual Property Rights, Technological Change, and Economic Growth," in: *Intellectual Property Rights and Capital Formation in the Next Decade*, eds. Charls E. Walker and Mark A. Bloomfield (New York, University Press of America, 1988), 5.

[8] Alden S. Bean, "Why Some R&D Organizations Are More Productive Than Others," *Research/Technology Management*, January-February 1995, 26. See also: Edwin Mansfield, "How Economists See R&D," *Harvard Business Review*, November-December 1981, 98.

[9] Zvi Griliches, "The Search for R&D Spillovers," *Scandinavian Journal of Economics*, 1992, 29-47. Cited in: Council of Economic Advisors, *Supporting Research and Development to Promote Economic Growth: The Federal Government's Role*, October, 1995, 1.

[10] Ralph Landau, "Technology, Economics, and Public Policy," in: *Technology and Economic Policy*, eds. Ralph Landau and Dale W. Jorgenson (Cambridge, Ballinger Publishing Co. 1986), 5.

welfare and security. In addition, cooperative ventures among government institutions, companies, and academia allow for R&D to cross traditional boundaries of knowledge and experience. Ideas, expertise, and know-how are combined, facilitating a mix that may lead to more creativity and invention.

Industrial R&D

Industry also has an interest in cooperative efforts with government and/or academia. As new technologies are generated and their impact more widespread, industry has had to commit an increasing amount of resources to the performance of R&D. Concurrently, shortened product cycles have led to expanded demands for new technology and higher costs for technology development as reflected in the 43.5% increase in company support for such development work between 1998 and 2008 (using constant 2000 dollars).[11] The rising expense of research and development has been juxtaposed with increasing international competition and shareholder demands for short-term returns. Thus, partnerships are a result of "today's complex technologies, intense competition, and information overload [that] have required new approaches" beyond the funding of scientists to pursue their own interests.[12] Cooperative R&D permits work to be done which is too expensive for one company to fund or of marginal value for any given firm.

Companies have developed alternative means of acquiring new technologies while controlling the requisite costs. External alliances allow access to innovations without the expense and risks of generating them independently. Thus, collaboration permits firms to acquire the basic research they need from outside organizations. Experts argue that, for certain industries, the more extensive a firm's emphasis on external sources of technical knowledge, the greater its total factor productivity growth.[13] A survey undertaken by PriceWaterhouseCoopers found "businesses that outsource [their R&D] are growing faster, larger, and more profitable than those that do not."[14] The perceived benefits to this approach are reflected in increasing company support for external R&D. In 2007, U.S. companies contracted out 7.8% of their R&D expenditures, up from the 4.5% contracted out in 1997.[15] In the early 1980s, just after the passage of the Bayh-Dole Act, less than 2% of industry funding was directed at extramural research.[16]

It should be noted that joint ventures are not always successful due, in part, to failed concepts, cultural differences between companies or organizations, managerial and financial issues, or conflicting goals and objectives. However, studies by PriceWaterhouseCoopers identify numerous benefits that have resulted from partnering including increased sales of existing products; improved competitive position; increased productivity; development of more new products or business lines; and better operations or technology. Of the fastest-growing U.S. firms, 56% had partnered in the prior three years "resulting in more innovative products, more profit

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[11] National Science Board, *Science and Engineering Indicators, 2010* (Washington, National Science Foundation, 2010), Appendix table 4-6, available at http://www.nsf.gov/statistics/seind10/c4/at04-06.pdf.

[12] John Carey, "What Price Science?" *Business Week*, 26 May, 1997, 168.

[13] Alden S. Bean, "Why Some R&D Organizations Are More Productive Than Others," *Research/Technology Management*, January-February 1995, 26.

[14] PriceWaterhouseCoopers, *Trendsetter Newsletter,* March 13, 2000, available at http://www.barometersurveys.com.

[15] *Science and Engineering Indicators, 2010,* Appendix table 4-39, available at http://www.nsf.gov/statistics/seind10/append/c4/at04-39.pdf.

[16] John E. Jankowski, "R&D: Foundation for Innovation," *Research/Technology Management*, March-April 1998, 17.

opportunities—and significantly higher growth rates."[17] An earlier survey undertaken by the company concluded that "collaborative growth firms are spending more on new product development while focusing more on bigger winners and on innovation ... [and] ... are not reluctant to go outside their organization to work with others in the development of their innovative new products."[18] More recent work by Battelle found that

> Fully 81% of U.S. manufacturing survey respondents indicated their involvement in some type of collaborative R&D activity.... More than 60% viewed these technology collaborations as important to the growth of their organizations, with 39% planning to expand their collaborative efforts beyond existing levels.[19]

This trend is reflected in the pharmaceutical industry. There are an increasing number of alliances, particularly between large businesses and small biotech companies.[20] According to Ernst & Young, the number of strategic alliances in this sector more than doubled from 2005 to 2006,[21] while "2007 and 2008 were exceptionally strong years" for alliances.[22] Later analysis from Ernst & Young found that in 2010, U.S. strategic alliances between pharmaceutical firms and biotech companies increased for the "third consecutive year."[23] Data from the National Science Foundation indicate a 119.2% increase in R&D expenditures contracted out in the United States by the pharmaceutical and medicine industries between 2000 and 2005.[24]

Research indicates the benefits to alliances and "positive effects on R&D performance."[25] One study found that "nearly a third of new pharmaceutical products are now developed through alliances."[26] Another analysis indicated that "drugs developed in alliances are more likely to succeed in clinical trials."[27] Similarly, Wheaton College Professor Kejun Song argues that:

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[17] PriceWaterhouseCoopers, "Partnerships Have Big Payoffs for Fast-Growth Companies," *Trendsetter Barometer*, August 26, 2002, available at http://www.barometersurveys.com.

[18] Coopers and Lybrand, L.L.P., "Partnerships Pay off for Growth Companies," *Trend Setter Barometer*, 6 January, 1997, available at http://www/barometersurveys.com.

[19] Battelle, *2012 Global R&D Funding Forecast*, December 2011, 13, available at http://www.battelle.org.

[20] Patricia M. Danzon, Sean Nicholson, Nuno Sousa Pereira, *Productivity in Pharmaceutical-Biotechnology R&D: The Role of Experience and Alliances*, National Bureau of Economic Research, Working Paper 9615, April 2003, 5 available at http://www.nber.org/papers. See also, Nadine Roijakkers and John Hagedoorn, "Inter-firm R&D Partnering in Pharmaceutical Biotechnology since 1975: Trends, Patterns, and Networks," *Research Policy*, April 2006, 444.

[21] Ernst & Young, *Beyond Borders, Global Biotechnology Report 2007*, 29, available at http://www.ey.com/beyondborders.

[22] Ernst & Young, *Beyond Borders, Global Biotechnology Report 2010*, 76, available at http://www.ey.com/Publication/vwLUAssets/Beyond_borders_2010/$File/Beyond_borders_2010.pdf.

[23] Ernst & Young, *Beyond Borders, Global Biotechnology Report 2011,* 80, available at http://www.ey.com/Publication/vwLUAssets/Beyond_borders_global_biotechnology_report_2011/$FILE/Beyond_borders_global_biotechnology_report_2011.pdf.

[24] *Science and Engineering Indicators, 2010*, Appendix table 4-40, available at http://www.nsf.gov/statistics/seind10/append/c4/at04-40.pdf.

[25] Henry Grabowski and Margaret Kyle, "Mergers and Alliances in Pharmaceuticals: Effects on Innovation and R&D Productivity," in Klaus Gugler and B.Burcin Yurtoglu, eds., *The Economics of Corporate Governance and Mergers*, (Edward Elgar, Northampton, MA, 2008), 273.

[26] Jon Hess and Elio Evangelista, "Pharma-Biotech Alliances," *Contract Pharma*, September 2003, available at http://www.contractpharma.com/articles/2003/09/pharmabiotech-alliances.

[27] Patricia M. Danzon, Sean Nicholson, Nuno Sousa Pereira, "Productivity in Pharmaceutical-Biotechnology R&D: The Role of Experience and Alliances," *Journal of Health Economics* 24, 2005, 319.

> Concentrating talents through co-development alliances may be good news, as it would speed up commercialization of innovations in the drug industry. Finer specialization in R&D may improve the success rate in these highly risky endeavors as well.[28]

Thus, it appears that "merging technological knowledge and skills from different companies improves the innovation process."[29]

In addition to joint projects among companies, industry-university cooperation in R&D provides another important means to facilitate technological innovation. Traditionally, much of the basic research integral to certain technological advancement is funded by the government but performed in academia. Companies are increasingly looking toward this community to provide the underlying knowledge necessary for the development of commercial products without financing the large overhead costs associated with in-house research. According to David Blumenthal at the Harvard School of Medicine, by the mid to late 1990s, over 90% of life science companies in the United States had a cooperative relationship with universities.[30] Later analysis found that in 2007 52.8% of academic life science faculty had a relationship with industry and "were more productive than faculty without such support on virtually every measure."[31] A 2006 survey of medical schools and large independent teaching hospitals indicated that 67% of academic departments had established relationships with pharmaceutical companies.[32]

The value of these interactions has been documented. A study by the late Professor Edwin Mansfield demonstrated that "over 10% of the new products and processes introduced in [the 8 industries explored] could not have been developed (without substantial delay) in the absence of recent academic research."[33] More recent analysis reported that "during the past 40 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through research carried out in PSRIs [public-sector research institutions]."[34] This same study indicated that between "9.3 and 21.2% of all drugs involved in new-drug applications approved during the period from 1990 through 2007," were the result of work performed by PSRIs.[35] Additional research based on the 252 new drugs approved by the FDA between 1998 and 2007

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[28] Kejun Song, Drug R&D Alliances and Innovation: A Two-sided Matching Model of the Licensing Market in the Biotechnology-Pharmaceutical Industry, August 11, 2009, 34, available at http://www.economics.uci.edu/files/economics/docs/phdcandidates/08-09/Kejun%20Song/songpaper1.pdf.

[29] Francis Bidault and Thomas Cummings, "Innovating Through Alliances: Expectations and Limitations," *R&D Management*, January 1994, 33.

[30] David Blumenthal, "Academic-Industrial Relationships in the Life Sciences," *The New England Journal of Medicine*, December 18, 2003, 2453.

[31] Darren E. Zinner, Dragana Bolcic-Jankovic, Brian Clarridge, David Blumenthal, and Eric G. Campbell, "Participation of Academic Scientists in Relationships with Industry," *Health Affairs*, November/December 2009, 1814.

[32] National Research Council, *Conflict of Interest in Medical Research, Education, and Practice*, (Washington, DC, National Academies Press, 2009), 101.

[33] Edwin Mansfield, "Academic Research and Industrial Innovation: An Update of Empirical Findings," *Research Policy* 26, 1998, 775.

[34] Ashley J. Stevens, Jonathan J. Jensen, Katrine Wyller, Patrick C. Kilgore, Sabarni Chatterjee, and Mark L. Rohrbaugh, "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *The New England Journal of Medicine*, February 10, 2011, 535.

[35] Ibid., 540.

established that 31% of the 118 drugs considered "scientifically novel" were the result of research originally performed in universities.[36]

Patents

Much of this cooperative work, whether government-industry, government-university, industry-university, or industry-industry, is facilitated by the patent system. Patents protect the inventor's investments in generating the knowledge that is the basis for innovation. The U.S. Constitution states that patents are intended to promote "the progress of science and the useful arts." As research and development become more expensive, ownership of title to inventions has been used by the federal government as a means to foster increased private sector activities to generate new and improved products and processes for the marketplace. In an academic setting, the possession of title is expected to provide motivation for the university to license the technology to industry for further refinement and application in expectation of royalty payments.

The patent system is grounded in Article I, Section 8, Clause 8 of the Constitution and is intended to stimulate new discoveries and their reduction to practice, commonly known as innovation. The grant of a patent provides the inventor with a means to capture returns to his invention through exclusive rights on its practice for 20 years from date of filing. This is designed to encourage those investments necessary to further develop an idea and generate a marketable technology. At the same time, the process of obtaining a patent places the concept on which it is based in the public domain. In return for a time limited monopoly right to specific applications of the knowledge generated, the inventor must publish the ideas covered in the patent. Proponents argue that, as a disclosure system, the patent can, and often does, stimulate other firms or individuals to invent "around" existing patents to provide for parallel technical developments or meet similar and expanded demands in the marketplace.[37]

Innovation produces new knowledge. One characteristic of this knowledge is that it is a "public good," a good that is not consumed when it is used. This "public good" concept underlies the U.S. patent system. As Professor John Shoven points out, "The use of an idea or discovery by one person does not, in most cases, reduce the availability of that information to others."[38] Therefore the marginal social cost of the widespread application of that information is near zero because the stock of knowledge is not depleted. This is why the federal government funds basic research. "Ordinarily, society maximizes its welfare through not charging for the use of a free good."[39] However, innovation typically is costly and resource intensive. Patents permit novel concepts or discoveries to become "property" when reduced to practice and therefore allow for control over

[36] Robert Kneller, "The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs," *Nature Reviews/Drug Discovery*, November 2010, 869.

[37] For more information see CRS Report 97-599, *Patents and Innovation: Issues in Patent Reform*, and CRS Report 98-862, *R&D Partnerships and Intellectual Property: Implications for U.S. Policy*, both by Wendy Schacht.

[38] John B. Shoven, "Intellectual Property Rights and Economic Growth," in eds. Charls Walker and Mark A. Bloomfield, *Intellectual Property Rights and Capital Formation in the Next Decade* (New York, University Press of America, 1988), 46.

[39] Robert P. Benko, "Intellectual Property Rights and New Technologies," in *Intellectual Property Rights and Capital Formation in the Next Decade*, 27.

their use. They "create incentives that maximize the difference between the value of the intellectual property that is created and used and the social cost of its creation."[40]

The patent process is designed to resolve the problem of appropriability. If discoveries were universally available without a means for the inventor to realize a return on investments, most commentators are convinced that there would result a "much lower and indeed suboptimal level of innovation."[41] Although research is often important to innovation, it appears that, on average, it constitutes approximately 25% of the cost of commercializing a new technology or technique, thus requiring the expenditure of a substantial amount of additional resources to bring most products or processes to the marketplace. The grant of a patent provides the inventor with a mechanism to capture the returns to his invention through exclusive rights on its practice for 20 years from date of filing. That is intended to encourage those investments necessary to further develop an idea and generate a marketable technology.

The utility of patents to companies varies among industrial sectors. Patents are perceived as critical in the drug and chemical industries. That may reflect the nature of R&D performed in these sectors, where the results often are relatively easy to reproduce.[42] Others have pointed out that drug patents are more detailed in their claims and therefore easier to defend.[43] In contrast, studies have found that in many other industries the protection offered by patents is diminished by the ability to invent around the patent and limited by the disclosure of vital information in the patent itself.[44] In the aircraft and semiconductor industries patents have not been the most successful mechanism for capturing the benefits of investments. Instead, lead time and the strength of the learning curve were determined to be more important.[45] According to one study, in the semiconductor and related equipment industry, secrecy and lead time were deemed significantly more important than patents. Similar findings characterize the aerospace and machine tool industries, among others.[46] The degree to which industry perceives patents as effective has been characterized as "positively correlated with the increase in duplication costs and time associated with patents."[47]

The patent system has dual policy goals—providing incentives for inventors to invent and encouraging inventors to disclose technical information.[48] Disclosure requirements are factors in

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40 Stanley M. Besen and Leo J. Raskind, "An Introduction to the Law and Economics of Intellectual Property," *Journal of Economic Perspectives*, Winter 1991, 5.

41 Kenneth W. Dam, "The Economic Underpinnings of Patent Law," *Journal of Legal Studies*, January 1994, 247.

42 Henry Grabowski, "Patents, Innovation and Access to New Pharmaceuticals," *Journal of International Economic Law*, December 2002, 849.

43 Levin, Richard C. and Alvin K Klevorick, Richard R. Nelson, and Sidney G. Winter. Appropriating the Returns for Industrial Research and Development, *Brookings Papers on Economic Activity*, 1987, printed in *The Economics of Technical Change*, ed. Edwin Mansfield and Elizabeth Mansfield. (Vermont, Edward Elgar Publishing Co., 1993), 255 and 257.

44 Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, National Bureau of Economic Research, February 2000, available at http://www.nber.org/papers/w7552.

45 *Appropriating the Returns for Industrial Research and Development*, 253.

46 *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, Table 1.

47 *Appropriating the Returns for Industrial Research and Development*, 269.

48 Robert P. Merges, "Commercial Success and Patent Standards: Economic Perspectives on Innovation," *California Law Review*, July 1988, 876.

achieving a balance between current and future innovation through the patent process, as are limitations on scope, novelty mandates, and nonobviousness considerations.[49] Patents can give rise to an environment of competitiveness with multiple sources of innovation, which is viewed by some experts as the basis for technological progress. This is important because, as Professors Robert Merges and Richard Nelson found in their studies, in a situation where only "a few organizations controlled the development of a technology, technical advance appeared sluggish."[50]

The patent system has long been subject to criticism, however. Some observers have asserted that the patent system is unnecessary due to market forces that already suffice to create an optimal level of innovation. The desire to obtain a lead time advantage over competitors, as well as the recognition that technologically backward firms lose out to their rivals, may well provide sufficient inducement to invent without the need for further incentives.[51] Other commentators believe that the patent system encourages industry concentration and presents a barrier to entry in some markets.[52] Still other observers believe that the patent system too frequently attracts speculators who prefer to acquire and enforce patents rather than engage in socially productive activity.[53]

When analyzing the validity of these competing views, it is important to note the lack of rigorous analytical methods available for studying the effect of the patent law upon the U.S. economy as a whole. The relationship between innovation and patent rights remains poorly understood. As a result, current economic and policy tools do not allow us to calibrate the patent system precisely in order to produce an optimal level of investment in innovation. Thus, each of the arguments for and against the patent system remains open to challenge by those who are unpersuaded by their internal logic.

Legislative Initiatives

Reflecting the importance of cooperative R&D to the government, a series of legislative provisions use intellectual property rights to foster collaboration between all the parties in the research and development enterprise leading to the generation of new and improved products and processes for the marketplace. Both P.L. 96-480, the Stevenson-Wydler Technology Innovation Act (known as the "Stevenson-Wydler Act"),[54] as amended, and P.L. 96-517, Amendments to the Patent and Trademark Act (commonly referred to as the "Bayh-Dole Act" after its two main sponsors, former Senators Birch Bayh and Robert Dole),[55] are the basis for efforts at using patents

[49] *The Economic Underpinnings of Patent Law*, 266-267. Scope is determined by the number of claims made in a patent. Claims are the technical descriptions associated with the invention. In order for an idea to receive a patent, the law requires that it be " ... new, useful [novel], and nonobvious to a person of ordinary skill in the art to which the invention pertains."

[50] Robert P. Merges and Richard R. Nelson, "On the Complex Economics of Patent Scope," *Columbia Law Review*, May 1990, 908.

[51] Frederic M. Sherer, *Industrial Market Structure and Economic Performance* (Rand McNally & Co., 1970), 384-387.

[52] (name redacted), "Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties," *University of Illinois Law Review* (2001), 305.

[53] Ibid.

[54] 15 U.S.C. §3701 and following.

[55] 35 U.S.C. §200 and following.

and licensing to facilitate cooperative R&D, technology transfer, and the commercialization of technology supported by the federal government. These laws affect the way the National Institutes of Health, and other government agencies, interact with the academic community and industry in the R&D arena. It is in this area where the sometimes competing goals of prescription drug cost containment and encouragement of technology-based innovations may conflict.

While the result of different legislative histories and concerns, the Stevenson-Wydler Act and the Bayh-Dole Act were passed to encourage the use of technologies funded by and/or developed by the federal government in pursuit of the departments' and agencies' mission requirements. However, they address intellectual property issues that arise from different R&D relationships. The Stevenson-Wydler Act contains provisions concerning assignment of title to inventions arising from collaborative work between federal laboratories and outside cooperating parties where no direct federal funding is involved. The Bayh-Dole Act primarily addresses the distribution of patents resulting from federally funded research and development performed by outside organizations and prescribes the licensing of government-owned inventions.[56]

The Stevenson-Wydler Technology Innovation Act

P.L. 96-480, the Stevenson-Wydler Act, as amended, was enacted to encourage use of technologies developed in the federal laboratory system. This is to be accomplished by technology transfer, the process by which technology generated in one organization, in one area, or for one purpose is applied in another organization, in another area, or for another purpose. In the defense and space arenas it is often called "spin-off." The original act provided federal departments and agencies with a mandate to transfer technology as well as established mechanisms by which to accomplish this goal. P.L. 99-502, the Federal Technology Transfer Act of 1986, and P.L. 101-189, the FY1990 Department of Defense Authorizations, amended the law and created cooperative research and development agreements (CRADAs) as a means to undertake the transfer activity.

A CRADA is a specific legal document (not a procurement contract) that defines the collaborative venture. It is intended to be developed at the laboratory level, with limited agency review. The work performed must be consistent with the laboratory's mission. In pursuing these joint efforts, the laboratory may accept funds, personnel, services, and property from the collaborating party and may provide personnel, services, and property to the participating organization. The government can cover overhead costs incurred in support of the CRADA, but is expressly **prohibited** from providing **direct** funding to the industrial partner.

The act does not specify the dispensation of patents derived from the collaborative work, allowing agencies to develop their own policies. At the least, the law permits the non-federal collaborating party the "option to choose an exclusive license for a pre-negotiated field of use for any such invention under the agreement." The laboratory director also may negotiate licensing agreements for related government-owned inventions previously made at that laboratory to facilitate cooperative ventures.

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[56] For a detailed discussion of the legislative provisions of the Stevenson-Wydler Act and the Bayh-Dole Act see CRS Report RL33527, *Technology Transfer: Use of Federally Funded Research and Development*; CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*; and CRS Report RL30320, *Patent Ownership and Federal Research and Development (R&D): A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act*, all by (name redacted).

In all cases, the government retains certain rights, including a "nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes." Under "exceptional circumstances," the government may exercise its right to require a party, to which it assigned title or granted exclusive license to an invention, to license the technology to another organization if it is necessary to address health and safety needs not being addressed; to meet requirements for public use specified by federal regulation not being met; or if the cooperating party has not performed its obligations as specified in the agreement.

Preference in determining CRADAs is given to small businesses, companies that will manufacture in the United States, or foreign firms from countries that permit American companies to enter into similar arrangements. According to the Senate report that accompanied the legislation (S.Rept. 99-283), "the authorities conveyed by [the section dealing with CRADAs] are permissive" to promote the widest use of this arrangement.[57]

It should be noted that CRADAs are only one form of cooperative activity, but because they can be easily identified and quantified they tend to be the most visible. Other mechanisms include personnel exchanges and visits; licensing of patents; work for others; educational initiatives; information dissemination; the use of special laboratory facilities and centers set up in particular technological areas; cooperative assistance to state and local programs; and the spinoff of new firms. Currently, federal laboratories legislatively are prohibited from competing with the private sector and can only offer the use of expertise and equipment which is not readily available elsewhere. Technology transfer and cooperative efforts are expressly forbidden to interfere with the laboratories' R&D mission-related activities.

The Bayh-Dole Act

P.L. 96-517, the Bayh-Dole Act, evolved out of congressional interest in developing a uniform federal patent policy to promote the utilization of inventions made with the support of the federal research establishment.[58] Such action was deemed necessary because, at the time the legislation was under consideration, only 5% of federally owned patents were being used. While there were several possible reasons for such a low level of utilization (including no market applications), this was thought by many to be one consequence of the practice by most agencies of taking title to all inventions made with government funding while only permitting the nonexclusive licensing of contractor inventions.[59] Without title to inventions, or at least exclusive licenses, companies may be less likely to engage in and fund the additional R&D necessary to bring an idea to the marketplace. The Bayh-Dole Act, by providing universities, nonprofit institutions, and small businesses with ownership of certain patents arising from federally funded R&D, offers an incentive for cooperative work and commercial application. Royalties derived from intellectual property rights provide the academic community an alternative way to support further research and the business sector a means to obtain a return on their financial contribution to the endeavor.

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[57] Senate Committee on Commerce, Science, and Transportation, *Federal Technology Transfer Act of 1986, Report to Accompany H.R. 3773*, 99th Cong. 2nd sess., 1986, S.Rept. 99-283, 10.

[58] House Committee on Science and Technology, *Government Patent Policy*, 95th Cong., 2nd sess., May 1978, H.Rept. Prt. 4.

[59] Ibid., 5.

Each nonprofit organization (including universities) or small business is permitted to elect (within a reasonable time) to retain title to a "subject invention" made under federally funded R&D.[60] (According to a recent Supreme Court decision in *Stanford University v. Roche Molecular Systems Inc.*, "The Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions." The act only clarifies "the order of priority of rights between the Federal Government and a federal contractor in a federally funded invention that already belongs to the contractor" and that certain conditions must be met before the invention belongs to the contractor.)[61] The institution must commit to commercialization within a predetermined, agreed upon, time frame. However, the government may keep title under "exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter." Additionally, the government may withhold title if the contractor "is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government," in situations associated with national security, or when the work is related to the naval nuclear propulsion or weapons programs of the Department of Energy.[62]

Certain other rights are reserved for the government to protect the public interest. The government retains "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world." The government also retains "march-in rights" that enable the federal agency to require the contractor (whether he owns title or has an exclusive license) to "grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants" with due compensation, or to grant a license itself under certain circumstances. The special situation necessary to trigger march-in rights involves a determination that the contractor has not made efforts to commercialize within an agreed upon time frame or that the "action is necessary to alleviate health or safety needs" that are not being met by the contractor.[63]

The Bayh-Dole Act also addresses the licensing of inventions to which the government retained title typically because of past agency practices or because of a public interest. Title 35 U.S.C. Section 209 proscribes the licensing of this type of invention. The law permits federal departments to offer nonexclusive, exclusive, or partially exclusive licenses under certain conditions and with specific rights retained by the government. These include the right to terminate the license if commercialization is not pursued as provided in the business plan or if the government needs the license for public use. The agencies are required to inform the public about the availability of a patent for licensing. Notices are to be published in the *Federal Register* for a period of three months and if a company displays intent to license, the laboratory must place an additional notice and offer 60 days for objections. In providing licenses, small businesses are given preferences and licensees must agree that "any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States."

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[60] 35 U.S.C. §202.

[61] Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al., __U.S.__(June 6, 2011).

[62] 35 U.S.C. §202.

[63] 35 U.S.C. §203.

NIH-University-Industry Collaboration: The Results

The primary mission of the National Institutes of Health "is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability."[64] To achieve this, NIH funds over $30.9 billion of both in-house and extramural R&D; less than 10% of this total is for work within NIH laboratories and more than 80% goes to contractors, primarily universities and non-profit research institutions.[65] Simultaneously, the Stevenson-Wydler Technology Innovation Act and the Bayh-Dole Act provide the agency with the "statutory mandate to ensure that new technologies developed in those laboratories are transferred to the private sector and commercialized in an expeditious and efficient manner."[66] Thus, NIH is faced with two interrelated goals: "promoting the health of the American people and all mankind through research in the biosciences, and fostering a vigorous domestic biotechnology industry."[67] While the legislation discussed in this paper provides a general framework within which to achieve some of these objectives, there are specific issues associated with health research that have generated concerns not raised in other industrial sectors. Given the particular interest in health-related R&D, the increased commercial potential, and cost considerations, questions are being raised within Congress as to the adequacy of current arrangements. Most experts agree that closer cooperation can augment funding sources (both in the public and private sectors), increase technology transfer, stimulate additional innovation, lead to new products and processes, and expand markets. Yet, others point out that collaboration may provide an increased opportunity for unfair advantages, excessive private sector profits at the expense of the public, conflicts of interest, redirection of research, and less openness in sharing of scientific discovery.

Intramural Research

Intramural research performed at the National Institutes of Health accounts for approximately 10% of the NIH budget. Typically, NIH keeps title to inventions made in its laboratories. In FY2012, NIH (and FDA) scientists filed 352 invention disclosures and 147 new U.S. patent applications, while 130 patents were issued. During the fiscal year, 198 licenses were executed and $111.2 million in royalties collected on existing licenses. This is in contrast to 10 years earlier in FY2002, when 331 inventions were disclosed, 173 patent applications filed, and 99 patents issued. At that time, 231 licenses were executed and royalty payments totaled $51.0 million. Over the FY2002-FY2012 time period, $917.7 million in royalties were generated from licenses on NIH-owned patents.[68]

To date, NIH has identified 26 FDA approved products that have been developed with technology from the NIH *intramural* research program.[69] It should be noted that NIH did not develop the

[64] National Institutes of Health, *About NIH*, available at http://www.nih.gov/about/.

[65] See http://www.nih.gov/about/budget.htm.

[66] Office of Technology Transfer, National Institutes of Health, *Public Health Service (PHS) Patent Policy*, available at http://ott.nih.gov/policy/phspat_policy.html.

[67] President's Council of Advisors on Science and Technology. *Achieving the Promise of the Bioscience Revolution: The Role of the Federal Government*. Washington, December 1992. Introductory letter, no page number.

[68] Information on NIH patent and licensing procedures in this section, unless otherwise noted, is available at http://ott.nih.gov/about_nih/statistics.aspx.

[69] National Institutes of Health, FDA Approved Therapeutic Drugs and Vaccines Developed with Technologies From (continued...)

final product; technologies derived from NIH supported research are involved in producing or administering the product.[70] According to the General Accounting Office (now the Government Accountability Office), NIH was responsible for 95% of the royalties collected by six agencies (Department of the Army, Department of the Navy, Department of the Air Force, Department of Energy, and the National Aeronautics and Space Administration) studied between 1996 and 1998. In addition, NIH had the largest number of licensing agreements during this time.[71] A 2011 report by the Department of Commerce, National Institute of Standards and Technology, found that income from technologies licensed by the Department of Health and Human Services (HHS) accounted for 55.1% of the total amount of license fees collected by all federal laboratories during FY2009.[72]

Policies

The articulated policy of the Public Health Service (PHS), the parent agency of NIH, as well as the Food and Drug Administration, and the Centers for Disease Control, is to "ensure that new technologies developed in those laboratories are transferred to the private sector and commercialized in an expeditious and efficient manner" while protecting the public interest.[73] The policies associated with the patenting and licensing of inventions made within NIH are designed to "balance new product development with appropriate market competition."[74]

Cooperative Research and Development Agreements (CRADAs) must reflect the mission requirements of NIH and not divert resources from the agency's mandate.[75] It also is expected that scientific input from the collaborating party will advance the capabilities of government scientists in their work. In this environment, ideas and results are to be discussed openly. Publication of the knowledge generated by NIH-supported research is required, after providing time to apply for patent protection. To support the transfer of technology and the widespread use of the intellectual property, as well as to further

> a longstanding tradition of scientific freedom, PHS research results are published freely. Publication of research is not to be significantly delayed for the purpose of either filing patent applications on patentable subject matter, or conducting further research to develop patentable subject matter.[76]

(...continued)

the Intramural Research Program at the National Institutes of Health, available at http://ott.nih.gov/about_nih/fda_approved_products.aspx.

[70] Mark L. Rohrbaugh, *NIH: Moving Research from the Bench to the Bedside*, Testimony before the House Committee on Energy and Commerce, Subcommittee on Health, July 10, 2003, available at http://ott.nih.gov.

[71] General Accounting Office, *Technology Transfer: Number and Characteristics of Inventions Licensed by Six Federal Agencies*, GAO/RCED-99-173, June 1999, 6, 7.

[72] National Institute of Standards and Technology, U.S. Department of Commerce, *Federal Laboratory Technology Transfer, Fiscal Year 2009,* March 2011, 16-17, available at http://www.nist.gov/tpo/publications/upload/Federal-Lab-TT-Report-FY2009.pdf.

[73] *Public Health Service (PHS) Patent Policy*.

[74] National Institutes of Health, *A Plan to Ensure Taxpayers' Interests are Protected,* "Technology Transfer Mission Statement," Appendix A-3.3, July 2001, available at http://ott.nih.gov/policy/policy/policy_protect_text.html.

[75] Office of Technology Transfer, National Institutes of Health, Cooperative Research and Development Agreements (CRADAs) and Material Transfer Agreements (MTAs), available at http://ott.nih.gov/cradas/model_agree.aspx.

[76] *Public Health Service (PHS) Patent Policy*.

NIH practice is to patent inventions arising from intramural R&D within the provisions of the law and to transfer the technology through the use of licensing whenever possible instead of assignment of patent title to the outside entity. The organization "will seek patent protection on biomedical technologies only when a patent facilitates availability of the technology to the public for preventive, diagnostic, therapeutic, or research use, or other commercial use."[77] Under a CRADA,

> the producing Party will retain sole ownership of and title to all CRADA Subject Inventions, all copies of CRADA Data, and all CRADA Materials produced solely by its employee(s). The Parties will own jointly all CRADA Subject Inventions invented jointly and all copies of CRADA Data and all CRADA Materials developed jointly.[78]

Typically, the collaborating party has the option to elect an exclusive (or nonexclusive) license to any subject invention not made solely by an employee of this collaborating entity. Accordingly, the terms of the license

> will fairly reflect the nature of the CRADA Subject Invention, the relative contributions of the Parties to the CRADA Subject Invention and the CRADA, a plan for the development and marketing of the CRADA Subject Invention, the risks incurred by the Collaborator, and the costs of subsequent research and development needed to bring the CRADA Subject Invention to the marketplace.[79]

Decisions on licensing are to be made to "ensure development of each technology for the broadest possible applications, optimizing the number of products developed from PHS technology." Thus, non-exclusive or co-exclusive licenses are used if possible; exclusive licenses are to be for specific indications or fields of use. When a mandatory exclusive license is used as under a CRADA, NIH requires that the licensee grant sublicenses to "broaden the development possibilities when necessary for the public health." The resulting technology is to be made available for research purposes. Technologies licensed to industry are required to be expeditiously commercialized, "offered and maintained for sale, and made reasonably accessible to the public." The public interest is maintained through efforts to encourage development of competing products and through royalty-bearing licenses that reflect "a fair financial return on the public's research investment."[80]

Fair Pricing Clause

Prior to 1995, NIH had included what was known as a "fair pricing clause" in its cooperative research and development agreements and many licensing arrangements. In 1989, the Public Health Service (PHS) instituted a policy addressing the pricing of products resulting from a government-owned patent licensed by NIH on an *exclusive* basis to industry or an invention jointly developed with industry under a CRADA and then licensed *exclusively* to the collaborator. The language used in the contract stated:

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[77] Ibid.

[78] Office of Technology Transfer, National Institutes of Health, *PHS Model CRADA*, 2009, available at http://www.ott.nih.gov/forms_model_agreements/forms_model_agreements.aspx.

[79] Ibid.

[80] Office of Technology Transfer, National Institutes of Health, *Public Health Service (PHS) Licensing Policy*, available at http://ott.nih.gov/policy/phslic_policy.aspx.

> Because of [NIH's] responsibilities and the public investment in research that contributes to a product licensed under a CRADA, DHHS [Department of Health and Human Services] has a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for the NIH intellectual property rights may require that this relationship be supported by reasonable evidence.[81]

While there was no statutory requirement mandating this type of clause, it was instituted in response to public and political pressures resulting from concern over the cost of AZT, a drug used in the treatment of HIV infection. However, according to the NIH, "AZT was not developed under a CRADA or exclusive license nor, to date, has it been determined that the government has a patentable interest in this medication."[82] No other federal department or agency, with the exception of the Bureau of Mines, had established such a requirement.

The clause was removed in 1995 at the request of Dr. Harold Varmus, then Director of NIH, after a review of the situation and several public hearings. He concluded that the evidence indicated "the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public."[83] While sharing concerns over the "potential inaccessibility" of drugs due to costs, "NIH [agreed] with the consensus of the advisory panels that enforcement of a pricing clause would divert NIH from its primary research mission and conflict with its statutory mission to transfer promising technologies to the private sector for commercialization."[84] A study by the Department of Health and Human Services Inspector General found that companies viewed the clause as a major problem in the NIH CRADA approach.[85] Opponents of the clause argued that the uncertainty of the pricing clause exacerbated a process already fraught with risk. According to industry sources, not knowing what the determination of "fair" pricing would be at the end of a long and expensive research, development, and commercialization process was a strong deterrent to entering into cooperative arrangements. Many of the pharmaceutical and biotechnology companies declined to undertake CRADAs. Some firms even declined opportunities for joint clinical trials with NIH in anticipation of future price control demands. At the public hearings most of the patient advocacy groups called for repeal of the fair pricing clause.

NIH reportedly was reluctant to make definitive decisions on pricing. At that time, reasonable pricing was defined as a price within the range of existing therapies.[86] However, a differentiation was made between the reasonable pricing clause and "price setting:" the latter was seen as regulation and had been considered inappropriate for NIH. According to 1991 testimony of Dr. Bernadine Healy, then Director of NIH, the laboratory was "probably ... unqualified" to undertake drug pricing because it has not been involved in such activities. Instead, NIH "should approach fair pricing as a co-inventor of a fundamental discovery and use ... leverage as an agency that

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[81] National Institutes of Health, "Press Release and Backgrounder," *NIH News*, April 11, 1995, 7.

[82] Ibid., 4.

[83] Ibid., 1.

[84] Ibid., 3.

[85] Reginald Rhein, "Will NIH's Fair Price Clause Make CRADAs Crumble?," *The Journal of NIH Research*, March 1994, 41.

[86] NCI Seeking Prices for CRADA Products in Line with Existing Therapies; Indigent Care Important, *The Blue Sheet*, January 27, 1993, 10.

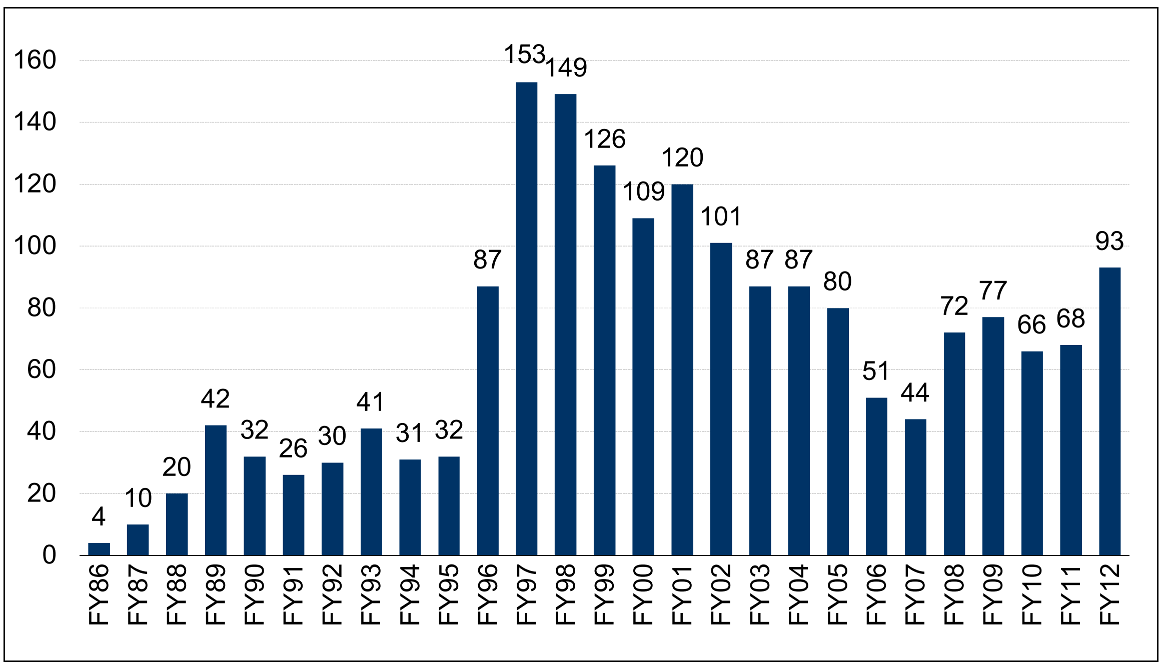
knows what we brought to the table." Dr. Healy maintained that the laboratory should not be "too intrusive" or get "too involved in the financial and proprietary activities of companies."[87]

The effect of abandoning the clause was immediate. Subsequent to rescission of the clause in April 1995, the number of CRADAs executed by NIH increased substantially (see **Figure 1**).

Extramural Research

Extramural research, primarily at universities or medical centers, comprises the major portion of NIH research funding (approximately 84% of the total). Under law mandated by the Bayh-Dole Act, federal departments and agencies do not retain title to inventions made with government funding when the research is performed by an outside contractor. Since the federal organization does own the patent, it does not receive royalty payments for any licensing agreements. Nor does the agency have direct say, other than as provided in the Bayh-Dole Act, in the way these technologies are commercialized.[88]

Figure 1. NIH CRADAs



Source: National Institutes of Health, Office of Technology Transfer http://www.ott..nih.gov/about_nih/statistics.html.

Across *all* technology areas, the Bayh-Dole Act appears to be successful in facilitating the commercialization of technology.[89] The latest licensing survey by the Association of University Technology Managers (AUTM) found that in FY2011, 591 new commercial products were

[87] House Committee on Small Business, *The National Institutes of Health and Its Role in Creating U.S. High-Technology Industry Growth and Jobs, Hearing*, 100th Cong., 1st sess., December 9, 1991, 22-23.

[88] *A Plan to Ensure Taxpayers' Interests are Protected.*

[89] For a detailed discussion of the impact of this legislation across the federal government see CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, by (name redacted).

brought to market, 671 new companies were created, and 6051 new licenses/options were granted as a result of technology transfer from the academic community.[90] In 1980, 390 patents were awarded to universities;[91] by 2009, this number increased to 3,088.[92] While these figures include all types of R&D, funding for university research in the life sciences comprises by far the largest portion of academic research support. In 2009, 51.7% of total R&D expenditures at academic institutions went to finance the medical and biological sciences. The federal government remains the primary source of this funding.[93]

The use of this academic research, funded in large part by the federal government, appears to be particularly important to the business community. Studies have found that "growth companies with university ties have productivity rates almost two-thirds higher than peers."[94] In the pharmaceutical industry, research indicated that over one-quarter of new drugs depended on academic research for timely commercialization.[95] Recent work published in the *New England Journal of Medicine* indicates that drugs discovered in public-sector research institutions (including universities) "are expected to have a disproportionately large therapeutic effect."[96] Other experts have noted that "NIH funded basic research makes a positive and significant contribution to pharmaceutical product innovation."[97]

Further, there is evidence demonstrating that public science, "research performed in and supported by governmental, academic and charitable research institutions," plays a crucial role in private sector technology development.[98] Recent analysis confirms this: "public-sector research has an important impact on drug development" and drugs that had a public-sector patent appeared to be the "most innovative drugs-those receiving priority review."[99] Work prepared for the National Science Foundation indicated that "public science plays an essential role in supporting U.S. industry, across all the science-linked areas of industry, amongst companies large and small, and is a fundamental pillar of the advance of U.S. technology."[100] This study demonstrated that of the papers cited in patents granted to U.S. companies during the years 1987-1988 and 1993-1994,

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90 Association of University Technology Managers, *U.S. AUTM Licensing Survey: FY2010*, available at http://www.autm.net/AM/Template.cfm?Section=FY_2010_Licensing_Survey&Template=/CM/ContentDisplay.cfm&ContentID=6874.

91 National Science Board, *Science and Engineering Indicators—1993* (Washington, National Science Foundation, 1993), 430.

92 National Science Board, *Science and Engineering Indicators, 2012* (Washington, National Science Foundation, 2010), Appendix table 5-48, available at http://www.nsf.gov/statistics/seind12/append/c5/at05-48.pdf.

93 Ibid., Appendix table 5-5, available at http://www.nsf.gov/statistics/seind12/append/c5/at05-05.pdf.

94 Coopers and Lybrand L.L.P., "Growth Companies with University Ties Have Productivity Rates Almost Two-Thirds Higher Than Peers," *Trend Setter Barometer*, January 26, 1995, 1.

95 Nathan Rosenberg and Richard R. Nelson, "American Universities and Technical Advance in Industry," *Research Policy*, May 1994, 344.

96 *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 535.

97 Andrew Toole, *The Impact of Public Basic Research on Industrial Innovation: Evidence from the Pharmaceutical Industry*, May 9, 2008, 4, available at https://editorialexpress.com/cgi-bin/conference/download.cgi?db_name=IIOC2008&paper_id=115.

98 G. Steven McMillian, Francis Narin, and David L. Deeds, "An Analysis of the Critical Role of Public Science in Innovation: The Case of Biotechnology," *Research Policy*, 2000, 1.

99 Bhaven N. Sampat and Frank R. Lichtenberg, "What Are the Respective Role of the Public and Private Sectors in Pharmaceutical Innovation?" *Health Affairs*, February 2011, 333 and 335.

100 Francis Narin, Kimberly S. Hamilton, and Dominic Olivastro, *The Increasing Linkage Between U.S. Technology and Public Science*, paper presented to the House Committee on Science, March 17, 1997, 15.

73% were authored at academic, governmental, and other public facilities (domestic or foreign) as compared with 27% from industrial sources. Similarly, research by Professors Cohen, Nelson, and Walsh found "that public research importantly affects industrial R&D in a broad range of industries" and "the share of R&D projects affected by public research is likely even greater than that which makes use of either the research findings or the techniques and instruments generated by public research."[101] The biomedical community relies on this basic work more heavily than other industries with 79% of drug and medicine patents citing the results of public science.[102]

A May 2000 internal study on *NIH Contributions to Pharmaceutical Development* and a U.S. Congress, Joint Economic Committee report on *The Benefits of Medical Research and the Role of the NIH* issued the same time, document the part government funded research plays in drug development.[103] Scientists supported by the government "contributed by discovering basic phenomena and concepts, developing new techniques and assays, and participated in clinical applications of the drugs."[104] While it is often many years before the research is utilized to generate marketable results, top selling pharmaceuticals "are the result of a great deal of basic research on the disease mechanism which allowed more specific targeting of the underlying problem."[105] Federal funding is also important in the search for new and additional uses for existing drugs since private sector firms will not use a technology covered by a patent because of infringement issues.[106]

Results of a study by Professor Andrew Toole demonstrated that "federally funded basic research is a positive and significant contributing factor in pharmaceutical product innovation."[107] However, it is often particularly difficult to exactly identify the government's contribution to a new drug, particularly since a product typically embodies more than one patent. Generally, there are multiple sources of input from multiple parties in drug development. This is demonstrated by NIH's detailed analysis of the top five drugs with sales of over $1 billion in 1994 and 1995 cited in the paragraph above. In its 2000 case study, NIH found that:

> Research may be targeted to the cure of a particular disease, or aimed at understanding basic mechanisms and gaining knowledge for which no immediate application is apparent. Disease-targeted research can be effective in fueling progress in a given area. However, just as often results from other fields of research led to breakthroughs in disease concepts or in drug discovery. These five drugs all arose from both disease-specific and unrelated fields of research.[108]

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[101] Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, "Links and Impacts: The Influence of Public Research in Industrial R&D," *Management Science*, January 2002, 21.

[102] Francis Narin, Kimberly S. Hamilton, and Dominic Olivastro, "The Increasing Linkage Between U.S. Technology and Public Science," *Research Policy*, 1997, 328. See also G. Steven McMillan, Francis Narin, and David Deeds, "An Analysis of the Critical Role of Public Science in Innovation: The Case of Biotechnology," *Research Policy*, 2000, 1.

[103] National Institutes of Health, *NIH Contributions to Pharmaceutical Development, Case Study Analysis of the Top-Selling Drugs*, May 2000, administrative document and U.S. Congress, Joint Economic Committee, *The Benefits of Medical Research and the Role of the NIH*, May 2000, available at http://jec.senate.gov.

[104] *NIH Contributions to Pharmaceutical Development, Case Study Analysis of the Top-Selling Drugs.*

[105] Ibid.

[106] *The Benefits of Medical Research and the Role of the NIH.*

[107] Andrew A. Toole, *The Impact of Public Basic Research on Industrial Innovation: Evidence From the Pharmaceutical Industry*, Discussion Paper, Stanford Institute for Economic Policy Research, November 2000, available at http://siepr.stanford.edu/home.html.

[108] *NIH Contributions to Pharmaceutical Development*.

In response to congressional direction, the National Institutes of Health looked at 47 FDA-approved drugs that had sales of $500 million or more a year to determine the role of NIH-sponsored technologies in their development. As described in the resulting July 2001 report, *A Plan to Ensure Taxpayers' Interests are Protected*, "NIH sought to determine whether the agency, directly, or through a grantee or contractor, held any patent rights to the drugs."[109] NIH funded technologies were found to have been used in the development of four of these pharmaceuticals:

> Epogen® and Procrit® are based on different uses of a patented process technology developed at Columbia University with support from NIH grants. Columbia licensed their technology to Amgen for Epogen® and to Johnson & Johnson for Procrit®.
>
> Neupogen® is manufactured by Amgen using patented technologies for a process and a composition licensed from Memorial Sloan-Kettering Cancer Center (MSKCC). These technologies were developed with NIH grant support.
>
> Taxol® is manufactured by Bristol Myers Squibb (BMS) using a patented process technology developed by Florida State University (FSU) with NIH grant funds. In addition, the NIH has rights to an underlying technology arising from a NIH CRADA collaboration with BMS. The NIH has received from BMS tens of millions of dollars in royalties from FY1997 to FY2000 under the license to the NIH technology.[110]

A 2003 study by GAO found that government financial support of extramural research and development had resulted in inventions that "were used to make only 6 brand name drugs associated with the top 100 pharmaceuticals that VA [the Veteran's Administration] procured for use by veterans and 4 brand name drugs associated with the top 100 pharmaceuticals that DOD dispensed in 2001."[111] What these, and other reports document is that "while NIH's federally funded research has contributed in a substantial, dramatic, yet general, way to advances in medicine and biology, the direct contributions to a final therapeutic product as a consequence of the Bayh-Dole process is limited and difficult to determine."[112] In addition to multiple sources of innovation, tracking the federal contribution is made more difficult by the fact that the government does not retain ownership of inventions made by contractors.

Issues and Options

The actual and expected benefits flowing from the biomedical community go beyond economic consideration of the importance of technological progress to the nation. The potential life saving quality of many of the products associated with this type of R&D provides an additional dimension. In addition to the opportunities to generate profits on sales of products, provide jobs, and stimulate investments, advances in biotechnology and pharmaceuticals also can facilitate economic growth through improvements in productivity resulting from a healthier population.

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[109] *A Plan to Ensure that Taxpayers' Interests are Protected.*

[110] Ibid.

[111] General Accounting Office, *Technology Transfer, Agencies' Rights to Federally Sponsored Biomedical Inventions*, July 2003, GAO-03-536, 2.

[112] *A Plan to Ensure that Taxpayers' Interests are Protected.*

Professor Frank Lichtenberg suggests that the benefits of new drugs include "longer life, better quality of life, and reductions in total medical expenditure."[113]

Pricing Decisions and Recoupment

Federal support for health-related R&D amounts to approximately 21.5% (FY2010) of the total federal R&D budget, second only to the R&D funding spent for defense.[114] The sizable public sector investment has raised the issue of a more direct return to the federal government and taxpayers for their support of R&D. The significant portion of public resources spent by the government in this arena, and provided to the private sector at no cost, has prompted some observers to call for government involvement in the establishment of some pharmaceutical prices. Others argue that the government should "recoup" its investment from firms using federally supported R&D after profits are generated.

Such suggestions are based on several factors. In addition to funding research performed by individual companies, under certain circumstances, the government furnishes the private sector ownership of the intellectual property resulting from this public investment. Patent protection gives firms monopoly rights on these innovations for a specified amount of time. Concurrently, the government has conveyed added and substantial financial, regulatory, and tax advantages through legislation such as the Hatch-Waxman Act and the Orphan Drug Act. According to one commentator, "the drug industry was able to grow rapidly not only because its structure evolved in an atmosphere relatively free from close examination, but also because it developed in a fairly unrestrictive regulatory setting."[115] Another critic of existing policy, Daniel Zingale, formerly the executive director of AIDS Action, offered the following analogy: "imagine if General Motors could get the American taxpayer to heavily subsidize its research and development, fund government programs that purchase half of its cars and then get many of those same taxpayers to buy a new car each and every year."[116]

In the late 1990s, an investigation of health-related R&D by the *Boston Globe*'s Spotlight Team led them to conclude that pharmaceutical companies are "piggybacking on government research" and then charging "onerous prices."[117] In the article it was argued that "by funding the early stages of research and testing, NIH assumes great risk while reaping few financial rewards." The *Globe*'s research indicated that 45 of 50 top-selling drugs resulted from government funding of approximately $175 million. "The average net profit margin of the companies making those drugs was 14 percent in 1997, more than double the 6 percent average for industrial companies in the Standard & Poor's 500."

The government typically funds basic research because the resulting knowledge is considered a public good. It is often assumed that incentives, including patent protection, encourage firms to

113 Frank Lichtenberg, "Cipro and the Risks of Violating Pharmaceutical Patents," *National Center for Policy Analysis, Brief Analysis No. 380*, November 15, 2001, available at http://www.ncpa.org/pub/ba/ba38.PDF.

114 National Science Foundation, *Federal R&D Funding by Budget Function Fiscal Years 2009-2011,* Table 2, available at http://www.nsf.gov/statistics/nsf10323/pdf/nsf10323.pdf.

115 Mary T. Griffin, "AIDs Drugs and the Pharmaceutical Industry: A Need for Reform," *American Journal of Law and Medicine*, 1991, 6.

116 Adriel Bettelheim, "Drugmakers Under Siege," *CQ Outlook*, September 25, 1999, 10.

117 Alice Dembner and the Globe Spotlight Team, "Public Handouts Enrich Drug Makers, Scientists," *The Boston Globe*, April 5, 1998.

take steps to bring the results of this fundamental research to market. However, it also has been argued that health care has both public and private benefits and is therefore not a classical public good.[118] By providing patent protection to the results of federally funded research, a company receives an individual benefit based upon public investments. According to one observer, the suggestion that incentives for drug development, particularly patent protection, are necessary for innovation in this field may be "exaggerated, given governmental subsidization of research and development costs."[119] The public investment in R&D "replaces some portion of the patent-conferred incentives that are necessary to encourage companies to undertake privately financed research."[120] For example, it has been argued that the high prices associated with AIDS-related drugs can not be attributed to the high cost of R&D and a lengthy regulatory process because of the substantial federal investment in such research and fast track approval of these drugs.[121]

Proponents of recoupment and/or federal cost controls assert that the monopoly power of patents should be modified by "public subsidization."[122] They contend that the public has a right to a return on its investment. However, certain observers claim that "this right is not preserved under the patent system, which ascribes solely to the patent holder all proprietary rights and interests in the patented product or process." The "extraordinary gains" generated by prices on the resulting drugs "cannot be explained by the usual 'incentives' rationale for conferring patent monopolies." Instead, those who favor government input into price decisions maintain that the prices of the resulting pharmaceuticals and therapeutics should reflect the public contribution to these products and processes. "In other words, public support of quasi-public goods must be balanced by some degree of public sharing in the fruits of the investment, as well as input into the nature of that sharing."

Critics of policies to recoup federal research support or government involvement in pricing decisions argue that advocates of such actions misunderstand the actual nature of the NIH role in research and pharmaceutical development. They maintain that federal support for basic research reflects a consensus that such work is critical because it is the foundation for many new innovations and that any returns created by this activity are generally long term, sometimes not marketable, and not always evident. Yet the rate of return to society as a whole generated by investments in research is significantly larger than the benefits that can be captured by the firm performing the work. According to a study by Professors Iain Cockburn and Rebecca Henderson, the rate of return to government funded biomedical research may be 30% a year, a figure that may actually be higher because calculations do not account for the broader effects of pharmaceutical innovation on health and well-being.[123]

The National Institutes of Health funds "basic research aimed at understanding biological mechanisms and gaining knowledge for which no immediate application is apparent has been a vital supply of new ideas, and can only be sustained through public support."[124] This fundamental

[118] Steven R. Salbu, "Aids and Drug Pricing: In Search of a Policy," *Washington University Law Quarterly,* Fall 1993, 13-14.

[119] Ibid., 6.

[120] Ibid., 7.

[121] *AIDS Drugs and the Pharmaceutical Industry: A Need for Reform*, 11.

[122] Information and quotes in this paragraph from: *Aids and Drug Pricing: In Search of a Policy,* 5-20.

[123] Ian M. Cockburn and Rebecca M. Henderson, *Publicly Funded Science and the Productivity of the Pharmaceutical Industry*, NBER Conference on Science and Public Policy, April 2000, available at http://www.nber.org.

[124] National Institutes of Health, *NIH Contributions to Pharmaceutical Development, Case Study Analysis of the Top-* (continued...)

knowledge contributes to the general pool of knowledge which industry may use to generate specific products. In the health-related arena, NIH supports research, primarily at universities, directed at the underlying mechanisms of disease: research and knowledge that are applied by the private sector to develop specific treatments for disease.[125] Studies demonstrate the "important role that the public sector plays in providing fundamental insights in basic knowledge as a basis for drug discovery."[126] The basic research "feeds an independent step in the discovery process called the 'drug concept' or 'rock turning' period ... [which] is the very first point in the pharmaceutical innovative process and necessarily precedes chemical synthesis."[127] This research generally is composed of work supported by the government and publicly available as well as knowledge resulting from internal firm R&D.[128] The information and concepts generated by this research have a "substantial impact" on pharmaceutical R&D.[129] According to NIH:

> The research supported and conducted by the NIH is sometimes mischaracterized as necessarily resulting in the commercialization of drug products. In truth, much of NIH funding supports the exploration of fundamental biological mechanisms that would otherwise not be pursued due to the lack of market incentives. Such research can lead to early-stage findings and provide clues that may eventually lead to medical advancements for diseases for which existing methods of therapy are nonexistent, inefficient, or suitable only for a select population.[130]

This is not to imply that the private sector does little in relation to the government in the pharmaceutical arena. Pharmaceutical companies spend more than NIH on R&D, primarily for applied research and development directed at generating new drugs for the marketplace. Some analysts argue that the federal role is overstated because existing studies use citations as a measure of each sector's contribution to drug development. This, critics maintain, skews the results because the government encourages, and even requires, publication of research results while industry often discourages such practices.[131]

What appears to be the case is that benefits move in both directions between the government and the private sector.[132] A comprehensive study by NIH of five top selling drugs demonstrated "that public and private sector biomedical research are interwoven, complementary parts of the highly successful U.S. biomedical science endeavor."[133] Taking the results of this study further, Janice Reichert and Christopher-Paul Milne of the Tufts Center for the Study of Drug Development at Tufts University noted that for the set of drugs looked at by NIH, the government's involvement

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Selling Drugs, Administrative document, May 2000.

[125] Ibid.

[126] *Publicly Funded Science and the Productivity of the Pharmaceutical Industry*.

[127] *The Impact of Public Basic Research on Industrial Innovation: Evidence From the Pharmaceutical Industry.*

[128] Ibid.

[129] Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, "Links and Impacts: The influence of Public Research on Industrial R&D," *Management Science*, January 2002.

[130] National Institutes of Health, *Report to Congress on the Affordability of Inventions and Products*, July 2004, 3, available at http://ott.od.nih.gov/policy/policies_and_guidelines.html.

[131] Janice M. Reichert and Christopher-Paul Milne, "Public and Private Sector Contributions to the Discovery and Development of 'Impact' Drugs," *American Journal of Therapeutics*, 2002, 543-555. See also Charles G. Smith and John R. Vane, "The Discovery of Captopril," *The FASEB Journal*, 2003, 788-789.

[132] *Publicly Funded Science and the Productivity of the Pharmaceutical Industry.*

[133] *NIH Contributions to Pharmaceutical Development, Case Study Analysis of the Top-Selling Drugs.*

> was greatest in the preclinical and clinical development of drugs that were treatments for serious or life-threatening diseases ... [where] there was clearly a public health benefit derived from facilitating the development of these drugs. The NIH was also involved in the discovery and/or development of compounds that were in the "public domain" (i.e., knowledge of the existence and method of preparation of the compounds was publicly available before therapeutic potential was identified) ... These types of compounds initially might not have been of interest to the pharmaceutical industry, because possible patent claims were limited.[134]

Those who oppose changes in the current approach to intellectual property ownership of the results of federally funded R&D argue that the promise of a large return on investment "is precisely the tool sanctioned by the Constitution to promote the progress of science."[135] It is because pharmaceuticals and biotechnology are so research intensive that they rely heavily on patents. Intellectual property is important because the "costs of drug innovation are very high while the costs of imitation are relatively low."[136] The domestic pharmaceutical industry typically reinvests 8% to 20% of its revenues in R&D, and oftentimes substantially more, in contrast to other industries where the rates are about 3% to 4%, according to testimony presented by Dr. Arthur Levinson, CEO of Genentech.[137] Ownership of intellectual property is particularly important to biotechnology companies that typically are small and do not have profits to finance additional R&D. According to the Biotechnology Industry Organization, most of these firms finance research and development from equity capital not profits. Only 5% of biotech companies have sales and therefore depend on venture capital and IPOs.[138] Industry advocates maintain the patents are a necessity for raising this equity capital and that price controls would deter investors.[139] Thus, some experts maintain that "the ability of companies to control their discoveries through the establishment of intellectual property rights is fundamental to the competitiveness of [such] industry."[140]

Elimination of the incentives associated with technology transfer and increased R&D through patent ownership and control over intellectual property would reduce innovation according to many experts. Columbia University's Frank Lichtenberg states that "weakening patent protection (e.g. by government violation of patents) may have a chilling effect on private R&D investment, and therefore reduce the health and wealth of future generations."[141] A similar opinion was expressed by John E. Calfee of the American Enterprise Institute. Noting that, "one of the least-

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134 *Public and Private Sector Contributions to the Discovery and Development of "Impact" Drugs*.

135 Evan Ackiron, "Patents for Critical Pharmaceuticals: The AZT Case," *American Journal of Law and Medicine*, 1991, 18.

136 *Patents, Innovation and Access to New Pharmaceuticals.*

137 U.S. Congress, Joint Economic Committee, Putting *a Human Face on Biotechnology: A Report on the Joint Economic Committee's Biotechnology Summit*, February 23, 2000, 5 available at http://www.senate.gov/~jec/bio_report.htm. See also Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, October 2006, 9, available at http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf; and Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2010, inside front cover, available at http://www.phrma.org/sites/phrma.org/files/attachments/Profile_2010_FINAL.pdf.

138 Information derived from: Richard Pops, *BIO 2004 CEO and Investors Conference Keynote Speech*, February 25, 2004, and Biotechnology Industry Organization, *Biotechnology Industry Statistics*, both available at http://www.bio.org.

139 *Drugmakers Under Siege*.

140 U.S. Department of Commerce, Office of Technology Policy, *Meeting the Challenge: U.S. Industry Faces the 21st Century, The U.S. Biotechnology Industry* (Washington, July 1997), 16.

141 *Cipro and the Risks of Violating Pharmaceutical Patents.*

appreciated effects of faster research and development is to quicken the competitive process itself," Calfee argues that "although the scientific effort required for new drugs costs a great deal of money, the drugs are worth far more than they cost. Eliminate the financial reward, however, and you cut off the supply."[142]

Dr. M. Kathy Behrens, a director of the National Venture Capital Association, testified at hearings before the Joint Economic Committee on September 29, 1999, that "health care proposals which impose drug price controls, or Medicare drug benefits which provide marginal reimbursement, can create a perception or reality that the industry's potential return is limited or at greater risk."[143] Other experts concur with this assessment. Research undertaken by Professor John Vernon found "that pharmaceutical price regulation has a negative effect on firm R&D investment ... [and] could impose a very high cost in terms of foregone medical innovation."[144] One study has suggested that the threat of price controls during the first Clinton Administration had a detrimental effect on private sector support of pharmaceutical research and development.[145]

Actual experience and cited studies suggest that companies which do not control the results of their investments—either through ownership of patent title, exclusive license, or pricing decisions—tend to be less likely to engage in related R&D. This likelihood is reflected in the provisions of the Bayh-Dole Act (as well as other laws). Providing universities, nonprofit institutions, and small businesses with title to patents arising from federally funded R&D offers an incentive for cooperative work and commercial application. Royalties derived from intellectual property rights provide the academic community an alternative way to support further research and the business sector a means to obtain a return on its financial contribution to the endeavor. While the idea of recoupment was considered by Congress in hearings on the legislation prior to the act's passage in 1980, it was rejected as an unnecessary obstacle, one which would be perceived as an additional burden to working with the government. Policy makers thought such a program to be particularly difficult to administer.[146] Instead, Congress accepted as satisfactory the anticipated payback to the country through increased revenues from taxes on profits, new jobs created, improved productivity, and economic growth. For example, according to the MIT Technology Licensing Office, in 1998, 15% of the sales of licensed products derived from federally funded university research was returned to the government in the form of income taxes, payroll taxes, capital gains taxes, and corporate income taxes. This was estimated to be six times the royalties paid by companies to the universities.[147] The emergence of the biotechnology industry and the development of new therapeutics to improve health care are often cited indications of such benefits.

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142 John E. Calfee, "Why Pharmaceutical Price Controls are Bad for Patients," *AEI On the Issues*, March 1999 available at http://www.aei.org/oti.

143 *Putting a Human Face on Biotechnology: A Report on the Joint Economic Committee's Biotechnology Summit*, 8.

144 John A. Vernon, "Drug Research and Price Controls," *Regulation*, Winter 2002-2003, 25.

145 *Cipro and the Risks of Violating Pharmaceutical Patents*.

146 For example see U.S. House of Representatives, Committee on Science and Technology, *Government Patent Policy*, Hearings, September 23, 27, 28, 29, and October 1, 1976, 94th Cong. 2nd sess., 1976; United States Senate, Select Committee on Small Business, *Government Patent Policies*, Hearings, December 19, 20, and 21, 1977, 95th Cong. 1st sess., 1978; and U.S. Senate, Committee on Commerce, Science, and Transportation, *Patent Policy*, Hearings, July 23 and 27, and October 25, 1979, 96th Cong. 1st sess., 1979.

147 Kenneth D. Campbell, "TLO Says Government Research Pays Off Through $3 billion in Taxes, *MIT Tech Talk*, April 15, 1998, available at http://web.mit.edu.

Research Tools

The focus on intellectual property ownership of the results of federally funded R&D has led some critics to charge that the patenting of fundamental research prevents further biomedical innovation. Law professors Rebecca Eisenberg and Arti Rai argue that due to implementation of the Bayh-Dole Act "proprietary claims have increasingly moved upstream from the end products themselves to the ground-breaking discoveries that made them possible in the first place."[148] While patents are designed to spur innovation, Rai and Eisenberg maintain that certain patents hinder the process. From their perspective, permitting universities to patent discoveries made under federal funding, the Bayh-Dole Act "draws no distinction between inventions that lead directly to commercial products and fundamental advances that enable further scientific studies."[149] These basic innovations are generally known as "research tools."

Eisenberg and Professor Richard Nelson argue that ownership of research tools may "impose significant transaction costs" that result in delayed innovation and possible future litigation.[150] It also can stand in the way of research by others:

> Broad claims on early discoveries that are fundamental to emerging fields of knowledge are particularly worrisome in light of the great value, demonstrated time and again in history of science and technology, of having many independent minds at work trying to advance a field. Public science has flourished by permitting scientists to challenge and build upon the work of rivals.[151]

Similar concerns were expressed by Harold Varmus, president of Memorial Sloan-Kettering and former director of the National Institutes of Health. In July 2000 prepared testimony, he spoke to being "troubled by widespread tendencies to seek protection of intellectual property increasingly early in the process that ultimately leads to products of obvious commercial value, because such practices can have detrimental effects on science and its delivery of health benefits."[152] While the Bayh-Dole Act and scientific advances have helped generate a dynamic biotechnology industry, there have been changes that "are not always consistent with the best interests of science."[153]

However, as Varmus and others acknowledge, the remedies to this situation are not necessarily associated with the Bayh-Dole Act or its implementation by NIH. Yale President Richard Levin notes that while some research should be kept in the public domain, including research tools, the fact that it is privatized is not the result of the Bayh-Dole Act, but rather the result of patent law made by the courts and Congress. Therefore, he believes that changes to the act are not the appropriate means to address the issues.[154]

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148 Arti K. Rai and Rebecca S. Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine," *American Scientist*, January-February 2003, 52.

149 Ibid.

150 Rebecca S. Eisenberg and Richard R. Nelson, "Public vs. Proprietary Science: A Fruitful Tension?," *Daedalus*, Spring 2002.

151 Ibid.

152 U.S. Congress, House Committee on the Judiciary, Subcommittee on Courts and Intellectual Property, *Hearings on Gene Patents and Other Genomic Inventions*, July 13, 2000, available at http://www.house.gov/judiciary/seve0713.htm.

153 Ibid.

154 National Academy of Sciences, Board on Science, Technology, and Economic Policy, *Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research*, April 17, 2001 [transcript], 262 (continued...)

Current law, as reaffirmed by court decisions, permits the patenting of research tools. However, there have been efforts to encourage the widespread availability of these tools. Marie Freire, formerly director of the Office of Technology Transfer at NIH, testified that the value to society is greatest if the research tools are easily available for use in research. She asserted that there is a need to balance commercial interests with public interests.[155] To achieve this balance, the National Institutes of Health has developed guidelines for universities and companies receiving federal funding that make clear research tools are to be made available to other scientists under reasonable terms.[156] In 1999, NIH issued a policy paper, *Sharing of Biomedical Research Resources, Principles and Guidelines for Recipients of NIH Research Grants and Contracts,* which "calls for the sharing of [research] tools among non-profit organizations with minimal terms and impediments."[157] This approach, now included as a requirement in NIH grants, is reflective of subsequent changes to the Bayh-Dole Act that stated the results of the federal R&D enterprise should be achieved "without unduly encumbering future research and discovery."[158] In addition, the U.S. Patent and Trademark Office made changes in the guidelines used to determine the patentability of biotechnology discoveries.

A study by Professors John Walsh, Ashish Arora, and Wesley Cohen found that although there are now more patents associated with biomedical research, and on more fundamental work, there is little evidence that work has been curtailed due to intellectual property issues associated with research tools.[159] According to this view, scientists are able to continue their research by "licensing, inventing around patents, going offshore, the development and use of public databases and research tools, court challenges, and simply using the technology without a license (i.e., infringement)." According to the authors of the report, private sector owners of patents permitted such infringement in academia (with the exception of those associated with diagnostic tests in clinical trials) "partly because it can increase the value of the patented technology."

Government Rights: Royalty Free Licenses and Reporting Requirements

The government retains certain rights under the Bayh-Dole Act to protect the public interest. The act states that the government is provided a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world." This license, commonly known as a "royalty free license," has been the subject of some discussion including whether or not this permits government purchasers to obtain discounts on products developed from federally funded R&D, particularly pharmaceuticals. A July 2003 GAO report addressed this issue and concluded that the license entitles the government to practice or have practiced the invention on the government's behalf, but "does not give the

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available at http://www.nas.edu.

[155] U.S. Congress, Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education and Related Agencies, *Hearings*, August 1, 2001.

[156] Available on the NIH website at http://www.nih.gov.

[157] *NIH: Moving Research From the Bench to the Bedside*.

[158] Ibid., see also P.L. 106-404, §6.

[159] John P. Walsh, Ashish Arora, Wesley M. Cohen, "Working Through the Patent Problem," *Science*, February 14, 2003, 1021, see also John P. Walsh, Charlene Cho, Wesley M. Cohen, "View for the Bench: Patents and Material Transfers," *Science*, September 23, 2005, 2002-2003.

federal government the far broader right to purchase, 'off the shelf' and royalty free (i.e. at a discounted price), products that happen to incorporate a federally funded invention when they are not produced under the government's license."[160] The study states that rights in one patent do not "automatically" permit rights in subsequent, related patents.[161] Because the government apparently holds few licenses on the biomedical products it purchases (generally through the Veteran's Administration and the Department of Defense),[162] federal officials indicated that procurement costs were best reduced by use of the Federal Supply Schedule and national contracts.[163] Government licenses are used primarily in the performance of research in the biomedical area.[164]

A related issue is that of tracking the government's interest in patents resulting from federally funded research and development. Under the Bayh-Dole Act, grantees are required to report annually on the utilization of any invention arising from federally funded R&D. The Code of Federal Regulations (37 CFR 404.14(h)) states that these "reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and *such other data and information the agency may reasonably specify*." [emphasis added] In an August 1999 study, GAO noted that federal contractors and grantees were not meeting the reporting requirements associated with the Bayh-Dole Act, making it difficult to identify and assess what licenses the government retained, among other things.[165] Three years later, in a follow-up report, GAO stated that four of the five agencies had taken steps to insure improved compliance with the law including several new monitoring systems, although more needed to be done.[166] To keep track of inventions subject to the Bayh-Dole Act, in 1995 NIH created Interagency Edison (iEdison), an Internet-based reporting system (that is also used by other federal agencies). In response to the findings of GAO, suggestions by the NIH Interagency Edison Working Group, and recommendations contained in the report *A Plan to Ensure Taxpayers' Interests are Protected*, new reporting requirements were implemented effective January 1, 2002, that include "the commercial name of any FDA-approved products, utilizing any subject invention, which have reached the market during the annual reporting period."[167]

Concluding Observations

To date, the U.S. system of research, development, and commercialization has had a clear impact on the pharmaceutical and biotechnology industries. Policies concerning funding for research, intellectual property protection, and cooperative R&D have played an important part in the economic success of these sectors.[168] American pharmaceutical firms have "consistently

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[160] *Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions*, 7.

[161] Ibid., 8.

[162] Ibid.

[163] Ibid., 12.

[164] Ibid., 10.

[165] General Accounting Office, *Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision*, August 1999, GAO/RCED-99-242, 2.

[166] General Accounting Office, *Intellectual Property: Federal Agency Efforts in Transferring and Reporting New Technology*, October 2002, GAO-03-47, 29.

[167] National Institutes of Health, *Changes in Grantee/Contractor Reporting of Intellectual Property Utilization*, Notice NOT-OD-02-019, December 13, 2001.

[168] Iain Cockburn, Rebecca Henderson, Luigi Orsenigo, and Gary P. Pisano, "Pharmaceuticals and Biotechnology," (continued...)

maintained a competitive edge in international markets" and lead in new drug discoveries.[169] According to industry sources, U.S. investment in health-related R&D exceeds all other countries[170] and has demonstrated a pattern of R&D investment that has increased at approximately twice the rate of R&D growth in Europe.[171]

Incentives for innovation in the industrial community clearly have contributed to substantial research and development by the pharmaceutical and biotechnology sectors. In 2010, research and development spending by the biopharmaceutical industry in the United States totaled between $67.4 billion and $68.0 billion.[172] Domestic R&D spending for members of the Pharmaceutical Research and Manufacturers of America (PhRMA) was an estimated $37.4 billion, with 20.3% of domestic sales reinvested in research and development.[173] The industry employs approximately 291,000 individuals in highly skilled jobs.[174] Public U.S. biotechnology companies spent $17.6 billion on R&D, generated $52.6 billion in product sales, and produced $61.6 billion in revenue during 2010.[175] An industry that did not exist 25 years ago, U.S. biotechnology has provided new products and processes for the international marketplace, including more than 200 biotech drugs and vaccines, with potential for many more advances.

Some observers question whether or not there are unintended consequences to current policies and programs related to innovation that may need to be addressed. As discussed in this paper, the current legislative approach promotes the private sector use of the results of federally funded research and development, particularly through incentives to cooperative activities among government, industry, and academia. This approach attempts to balance the public's interest in new or improved products and processes for the marketplace with concerns over providing companies valuable benefits without adequate accountability or compensation. In general, incentives for the commercialization of government-supported R&D have been created in response to the argument that the economic benefits to the nation's research investment occur when new goods and services are available to meet public demand, create new jobs, improve productivity, and increase our standard of living. To date, these potential benefits have been considered more important than the initial cost to the government.

However, the particular nature of health-related R&D and the substantial federal investment in this area have caused uncertainty over whether or not the present balance is appropriate. Critics of the current approach argue that the need for technology development incentives in the pharmaceutical and/or biotechnology sectors is mitigated by industry access to government-

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U.S. Industry in 2000 (National Academy Press, Washington, 1999), 365.

169 Department of Commerce, International Trade Administration, *U.S. Industry &Trade Outlook 2000* (McGraw-Hill, 2000), 11-16.

170 PhRMA, *Pharmaceutical Industry Profile 2006*, 48, available at http://www.phrma.org.

171 PhRMA, *Pharmaceutical Industry Profile 2003*, 16, available at http://www.phrma.org.

172 *2011 Global R&D Funding Forecast*, 9 and Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry 2011 Profile,* inside cover, available at http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf, and CMR International, "2011 Pharmaceutical R&D Factbook," as noted in *Drug Dropout in Clinical Trials is at Unsustainable Levels, According to Thomson Reuters, CMR International*, June 27, 2011 Press Release, available at http://thomsonreuters.com/content/press_room/science/R+D-CMR-factbook-2011.

173 *Pharmaceutical Industry 2011 Profile,* inside front cover and 50.

174 Bureau of Labor Statistics, U.S. Department of Labor, *Career Guide to Industries, 2006-07 Edition, Pharmaceutical and Medicine Manufacturing*, available at http://www.bls.gov/oco/cg/cgs009.htm.

175 *Beyond Borders, Global Biotechnology Report 2011*, 39.

supported R&D at no cost, monopoly power through patent protection, and other regulatory and tax advantages. They maintain that the benefits to industry are such that the public has the right to expect a more direct financial return for the federal investment and, therefore, the government should be permitted to provide input into certain drug pricing decisions. Those who disagree point out that the collaborative public-private environment created by federal policies and practices has generated extraordinary innovation in the pharmaceutical and biotechnology industries. These sectors have provided significant benefits to the health and well-being of the nation. It remains to be seen if changes will be made and if the nature of government-industry-university cooperation will be altered.

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