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CRS Report for Congress

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

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Prepared for Members and
Committees of Congress

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

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 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 has focused attention on the manner in which the National Institutes of Health (NIH) undertakes research activities. Critics maintain that the 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 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. This report will be updated as events warrant.

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

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, the Congress has passed legislation to facilitate the commercialization of new technology.

Government policies implemented over the past 25 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 (NIH will have funded approximately \$27 billion for medical research in FY2006¹), 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 or the Orphan Drug Act. Therefore, some maintain, a more direct payback should be required including recoupment of public sector financial support or government involvement in price decisions. Others counter that these inducements have 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 \$133.7 billion for research and development in FY2006 (according to the National Science Foundation). 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.² “Government support of basic scientific research represents an example of the

¹ Information from [<http://www.nih.gov/about/budget.htm>].

² 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, (continued...)”

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.”³ 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 leads to underinvestment by the business community.⁴ 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 not marketable, and not always evident.

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.⁵ 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.⁶ 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, the 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

² (...continued)

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.

³ Baruch Brody, “Public Goods and Fair Prices,” *Hastings Center Report*, March-April 1996, 8.

⁴ 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.

⁵ For information on relevant legislation see CRS Report RL33528, *Industrial Competitiveness and Technological Advancement: Debate Over Government Policy*, by Wendy H. Schacht.

⁶ Gregory Tasse, *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.

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.⁷ Analysts estimate that one-half of productivity increases (output per person) are the result of investments in research and development.⁸ Others argue that innovations arising from R&D are the most important ones.⁹ 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, just to name 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 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 37% increase in company support for such work between 1997 and 2003 (using current dollars).¹⁰ The rising expense of research and development has been juxtaposed with

⁷ Alden S. Bean, "Why Some R&D Organizations Are More Productive Than Others," *Research/Technology Management*, Jan.-Feb. 1995, 26. See also: Edwin Mansfield, "How Economists See R&D," *Harvard Business Review*, Nov.-Dec. 1981, 98.

⁸ 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.

⁹ 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.

¹⁰ National Science Foundation, *Research and Development in Industry: 2002*, Table 1, available at [<http://www.nsf.gov/statistics/nsf06322/pdf/tab1.pdf>] and National Science Foundation, *InfoBrief: Increase in U.S. Industrial R&D Expenditures Reported for 2003* (continued...)

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.¹¹ 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.¹² A survey undertaken by PriceWaterhouseCoopers found “businesses that outsource are growing faster, larger, and more profitable than those that do not.”¹³ The perceived benefits to this approach are reflected in increasing company support for external R&D. In 2003, companies funded \$10.2 billion in outside research and development, 5% of the total firm financed R&D, up from 2.5% in 1997.¹⁴ In the early 1980s, just after the passage of the Bayh-Dole Act, less than 2% of industry funding was directed at extramural research.¹⁵

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% have partnered in the past three years “resulting in more innovative products, more profit opportunities - and significantly higher growth rates.”¹⁶ In an earlier survey undertaken by the company they concluded that “collaborative growth firms are spending more on new product development while focusing more on bigger winners

¹⁰ (...continued)

Makes Up for Earlier Decline, December 2005 available at [<http://www.nsf.gov/sbe/srs>].

¹¹ John Carey, “What Price Science?” *Business Week*, 26 May, 1997, 168.

¹² Alden S. Bean, “Why Some R&D Organizations Are More Productive Than Others,” *Research/Technology Management*, January-February 1995, 26.

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

¹⁴ *InfoBrief: Increase in U.S. Industrial R&D Expenditures Reported for 2003 Makes Up for Earlier Decline*, 3.

¹⁵ John E. Jankowski, “R&D: Foundation for Innovation,” *Research/Technology Management*, March-April 1998, 17.

¹⁶ PriceWaterhouseCoopers, “Partnerships Have Big Payoffs for Fast-Growth Companies,” *Trendsetter Barometer*, August 26, 2002 available at [<http://www.barometersurveys.com>].

and on innovation...[and]...are not reluctant to go outside their organization to work with others in the development of their innovative new products.”¹⁷

This trend is reflected in the pharmaceutical industry. There are an increasing number of alliances, particularly between large businesses and small biotech companies: “For example, the 20 largest pharmaceutical firms signed an average of 1.4 alliances per year with a biotech company during 1988-1990, but 5.7 such alliances per year in 1997-1998.”¹⁸ Studies show that large firms have a higher rate of success in developing compounds they obtain through licensing than in compounds they generate in house.¹⁹ It appears that “merging technological knowledge and skills from different companies improves the innovation process.”²⁰

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. A study by the late Edwin Mansfield (University of Pennsylvania Wharton School of Business) 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.”²¹ 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.²²

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

¹⁷ Coopers and Lybrand, L.L.P., “Partnerships Pay off for Growth Companies,” *Trend Setter Barometer*, 6 January, 1997, available at [<http://www.barometersurveys.com>].

¹⁸ 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>].

¹⁹ *Ibid*, 7

²⁰ Francis Bidault and Thomas Cummings, “Innovating Through Alliances: Expectations and Limitations,” *R&D Management*, January 1994, 33.

²¹ Edwin Mansfield, “Academic Research and Industrial Innovation: An Update of Empirical Findings,” *Research Policy* 26, 1998, 775.

²² David Blumenthal, “Academic-Industrial Relationships in the Life Sciences,” *The New England Journal of Medicine*, December 18, 2003, 2453.

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. 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.²³

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 are relatively easy to reproduce.²⁴ Others have pointed out that drug patents are more detailed in their claims and therefore easier to defend.²⁵ 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.²⁶ 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.²⁷ According to one recent study, in the semiconductor and related equipment industry,

²³ 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 H. Schacht.

²⁴ Henry Grabowski, “Patents, Innovation and Access to New Pharmaceuticals,” *Journal of International Economic Law*, December 2002, 849.

²⁵ 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.

²⁶ 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)*, NBER, February 2000, available at [<http://www.nber.org/papers/w7552>].

²⁷ *Appropriating the Returns for Industrial Research and Development*, 253.

secrecy and lead time were deemed significantly more important than patents. Similar findings characterize the aerospace and machine tool industries, among others.²⁸ 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.”²⁹

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 of Stanford University 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.”³⁰ 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.”³¹ 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 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.”³²

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.”³³ While research is often important to innovation, studies have shown that, on average, it constitutes only 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.

²⁸ *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, Table 1.

²⁹ *Appropriating the Returns for Industrial Research and Development*, 269.

³⁰ John B. Shoven, “Intellectual Property Rights and Economic Growth,” in eds. Charles Walker and Mark A. Bloomfield, *Intellectual Property Rights and Capital Formation in the Next Decade*, (New York, University Press of America, 1988), 46.

³¹ Robert P. Benko, “Intellectual Property Rights and New Technologies,” in *Intellectual Property Rights and Capital Formation in the Next Decade*, 27.

³² Stanley M. Besen and Leo J. Raskind, “An Introduction to the Law and Economics of Intellectual Property,” *Journal of Economic Perspectives*, Winter 1991, 5.

³³ Kenneth W. Dam, “The Economic Underpinnings of Patent Law,” *Journal of Legal Studies*, January 1994, 247.

The patent system thus has dual policy goals — providing incentives for inventors to invent and encouraging inventors to disclose technical information.³⁴ Disclosure requirements are factors in achieving a balance between current and future innovation through the patent process, as are limitations on scope, novelty mandates, and nonobviousness considerations.³⁵ Patents 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 Robert Merges (Boston University) and Richard Nelson (Columbia University) found in their studies, in a situation where only “a few organizations controlled the development of a technology, technical advance appeared sluggish.”³⁶

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. 96-418, the Stevenson-Wydler Technology Innovation Act (known as the “Stevenson-Wydler Act”),³⁷ 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),³⁸ are the basis for efforts at using patents 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

³⁴ Robert P. Merges, “Commercial Success and Patent Standards: Economic Perspectives on Innovation,” *California Law Review*, July 1988, 876.

³⁵ *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.”

³⁶ Robert P. Merges and Richard R. Nelson, “On the Complex Economics of Patent Scope,” *Columbia Law Review*, May 1990, 908.

³⁷ 15 U.S.C. sec. 3701 and following

³⁸ 35 U.S.C. sec. 200 and following

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.³⁹

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.

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

³⁹ 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: A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act*, all by Wendy H. Schacht.

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 Senate report 99-283 that accompanied the legislation, “the authorities conveyed by [the section dealing with CRADAs] are permissive” to promote the widest use of this arrangement.⁴⁰

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.⁴¹ 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.⁴² 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 patents arising from federally-funded R&D, offers an incentive for cooperative work and commercial application. Royalties derived from intellectual property rights provides the academic community an alternative way to support further research and

⁴⁰ 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.

⁴¹ House Committee on Science and Technology, *Government Patent Policy*, 95th Cong., 2nd sess., May 1978, H.Rept. Prt. 4.

⁴² *Government Patent Policy*, 5.

the business sector a means to obtain a return on their financial contribution to the endeavor.

Each nonprofit organization (including universities) or small business is permitted to elect (within a reasonable time frame) to retain title to any “subject invention” made as a result of R&D funded by the federal government; except 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.”⁴³ The owner of the intellectual property must commit to commercialization of the patent within a predetermined time frame agreed to by the supporting agency and the performing organization. As stated in the House report to accompany the bill, “the legislation establishes a **presumption** [emphasis added] that ownership of all patent rights in government funded research will vest in any contractor who is a nonprofit research institution or a small business.”⁴⁴

Certain 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 (15 U.S.C. sec. 203).

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. §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.”

⁴³ *Ibid.*

⁴⁴ *Federal Technology Transfer Act, Report to Accompany H.R. 6933, 3.*

NIH-University-Industry Collaboration: The Results

The primary mission of the National Institutes of Health “is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people.” To achieve this, NIH funds \$27 billion of both in-house and extramural R&D; 10% of this total is for work within NIH laboratories and 80% goes to contractors, primarily universities and non-profit research institutions.⁴⁵ 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.”⁴⁶ 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.”⁴⁷ 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 FY2006, NIH scientists filed 367 invention disclosures and 173 new patent applications, while 93 patents were issued to NIH. During that year, 254 licenses were executed and \$82.7.7 million in royalties collected on existing licenses. This is in contrast to 10 years earlier in FY1996 when 196 inventions were disclosed, 136 patent applications filed, and 127 patents issued. At that time, 184 licenses were executed and royalty payments totaled \$27 million. Over the FY1996-FY2006 time period, \$586.9 million in royalties were generated on NIH-owned patents that were licensed⁴⁸.

⁴⁵ Information can be found at [<http://www.nih.gov/about/budget.htm>].

⁴⁶ Office of Technology Transfer, National Institutes of Health, *Public Health Service (PHS) Patent Policy*, available at [http://ott.od.nih.gov/policy/phspat_policy.html].

⁴⁷ 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.

⁴⁸ Information on NIH patent and licensing procedures in this section, unless otherwise noted, is available at [http://ott.od.nih.gov/about_nih/statistics.html].

As of December 2006, NIH has identified 25 FDA approved products that have been developed with technology from the NIH *intramural* research program.⁴⁹ It should be noted that NIH did not develop the final product; technologies derived from NIH supported research are involved in producing or administering the product.⁵⁰ 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.⁵¹ A report by the Department of Commerce found that income from technologies licensed by the Department of Health and Human Services (HHS) accounted for 56% of the total amount of license fees collected by all federal laboratories during FY2003. The number of licenses issued by HHS comprised 21% of the total number of licenses, second only to the Department of Energy.⁵²

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.⁵³ The policies associated with the patenting and licensing of inventions made within NIH are designed to “balance new product development with appropriate market competition.”⁵⁴

Cooperative Research and Development Agreements (CRADAs) must reflect the mission requirements of NIH and not divert resources from the agency’s mandate.⁵⁵ 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

⁴⁹ National Institutes of Health, *FDA Approved Therapeutic Drugs and Vaccines Developed with Technologies From the Intramural Research Program at the National Institutes of Health*, available at [<http://ott.od.nih.gov>].

⁵⁰ 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.od.nih.gov>].

⁵¹ General Accounting Office, *Technology Transfer: Number and Characteristics of Inventions Licensed by Six Federal Agencies*, GAO/RCED-99-173, June 1999, 6, 7.

⁵² Office of the Secretary, U.S. Department of Commerce, *Summary Report on Federal Laboratory Technology Transfer*, December 2004, 10 and 11, available at [http://www.technology.gov/reports/TechTrans/2004_Sum.pdf]

⁵³ *Public Health Service (PHS) Patent Policy*

⁵⁴ 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].

⁵⁵ Office of Technology Transfer, National Institutes of Health, *Cooperative Research and Development Agreements (CRADAs) and Material Transfer Agreements (MTAs)*, available at [http://ott.od.nih.gov/cradas/model_agree.html].

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.⁵⁶

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.”⁵⁷ Under a CRADA,

the producing Party will retain 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.⁵⁸

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 invention to the marketplace.⁵⁹

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

⁵⁶ *Public Health Service (PHS) Patent Policy*

⁵⁷ *Ibid.*

⁵⁸ Office of Technology Transfer, National Institutes of Health, *PHS Model CRADA*, 2005, available at [<http://ott.nih.gov/doc/CRADAModel2005.doc>].

⁵⁹ *Ibid.*

development of competing products and through royalty-bearing licenses that reflect “a fair financial return on the public’s research investment.”⁶⁰

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:

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.⁶¹

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.”⁶² 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.”⁶³ 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.”⁶⁴ 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.⁶⁵ Opponents

⁶⁰ Office of Technology Transfer, National Institutes of Health, *Public Health Service (PHS) Licensing Policy*, available at [http://ott.od.nih.gov/policy/phslic_policy.html].

⁶¹ National Institutes of Health, “Press Release and Backgrounder,” *NIH News*, April 11, 1995, 7.

⁶² *Ibid.*, 4.

⁶³ *Ibid.*, 1.

⁶⁴ *Ibid.*, 3.

⁶⁵ Reginald Rhein, “Will NIH’s Fair Price Clause Make CRADAs Crumble?,” *The Journal* (continued...)

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.⁶⁶ 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 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 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.”⁶⁷

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 Table 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.⁶⁸

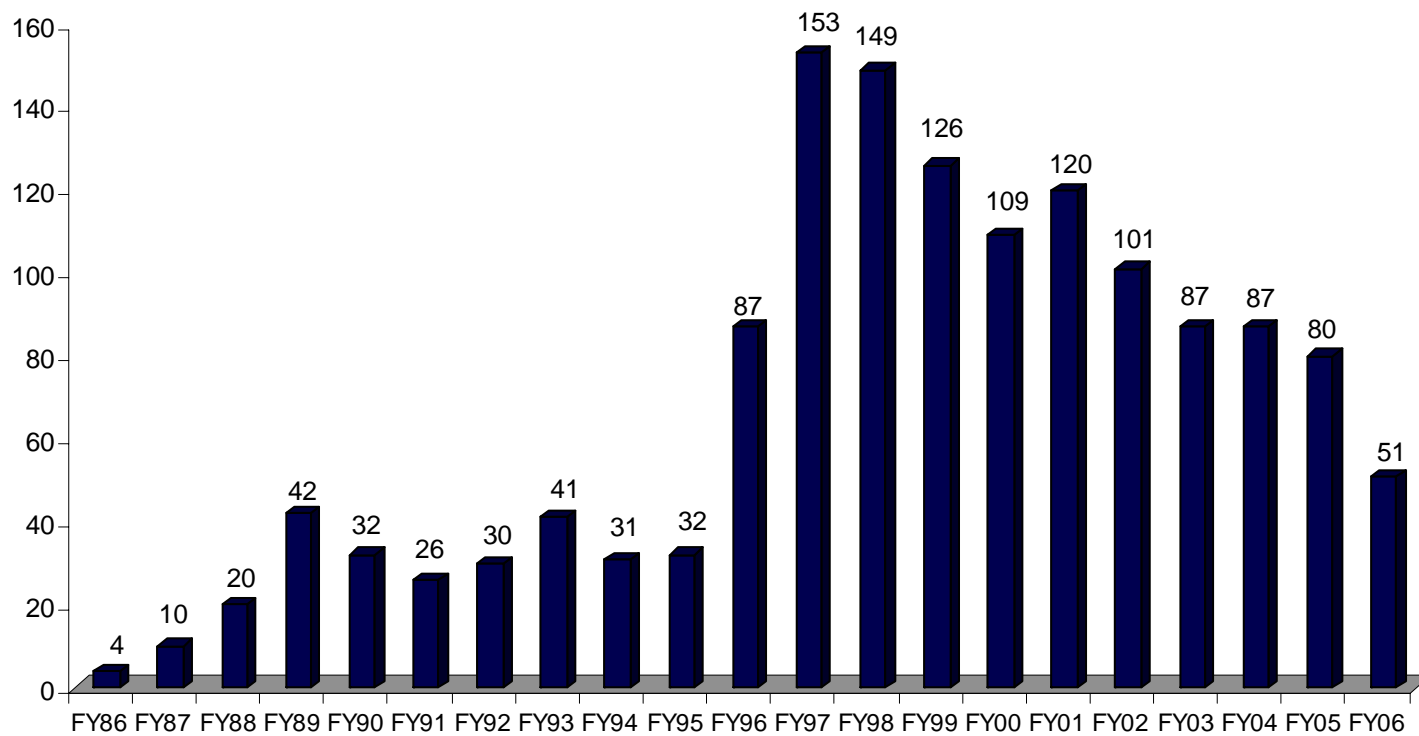
⁶⁵ (...continued)
of *NIH Research*, March 1994, 41.

⁶⁶ NCI Seeking Prices for CRADA Products in Line with Existing Therapies; Indigent Care Important, *The Blue Sheet*, January 27, 1993, 10.

⁶⁷ 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.

⁶⁸ *A Plan to Ensure Taxpayers' Interests are Protected*

Figure 1. NIH CRADAs



Across *all* technology areas, the Bayh-Dole Act appears to be successful in facilitating the commercialization of technology.⁶⁹ The latest licensing survey by the Association of University Technology Managers (AUTM) found that in FY2004, 567 new commercial products were brought to market, 462 new companies were created, and \$1.4 billion in royalties were generated as a result of technology transfer from the academic community.⁷⁰ In 1980, 390 patents were awarded to universities;⁷¹ by 2003, this number increased to 3,259.⁷² 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 2004, 51% of total R&D expenditures at academic institutions went to finance the medical and biological sciences.⁷³ The federal government remains the primary source of this funding.

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....”⁷⁴ In the pharmaceutical industry, over one-quarter of new drugs depended on academic research for timely commercialization.⁷⁵ 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.⁷⁶ 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.”⁷⁷ This research demonstrated that of the papers cited in patents granted

⁶⁹ For a detailed discussion of the impact of this legislation across the federal government see *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*.

⁷⁰ Association of University Technology Managers, *AUTM Licensing Survey: FY2004*, available at [<http://www.autm.net/events/File/04AUTMSurvey>] Sum-USpublic.pdf.

⁷¹ National Science Board, *Science and Engineering Indicators - - 1993*, National Science Foundation, Washington, 430.

⁷² National Science Board, *Science and Engineering Indicators - - 2006*, National Science Foundation, Washington, A5-148.

⁷³ National Science Foundation, *Academic Research and Development Expenditures: Fiscal Year 2004*, Table 4 available at [<http://www.nsf.gov/statistics/nsf06323/pdf/tab4.pdf>].

⁷⁴ Coopers and Lybrand L.L.P., “Growth Companies with University Ties Have Productivity Rates Almost Two-Thirds Higher Than Peers,” *Trend Setter Barometer*, 26 January, 1995, 1.

⁷⁵ Nathan Rosenberg and Richard R. Nelson, “American Universities and Technical Advance in Industry,” *Research Policy*, May 1994, 344.

⁷⁶ 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.

⁷⁷ Francis Narin, Kimberly S. Hamilton, and Dominic Olivastro, “The Increasing Linkage Between U.S. Technology and Public Science,” paper presented to the House Committee (continued...)

to U.S. companies during the years 1987-1988 and 1993-1994, 73% were authored at academic, governmental, and other public facilities (domestic or foreign) as compared with 27% from industrial sources. 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.⁷⁸

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.⁷⁹ 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.”⁸⁰ 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.”⁸¹ 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.⁸²

Results of a study by Andrew Toole at Stanford University demonstrated that “federally funded basic research is a positive and significant contributing factor in pharmaceutical product innovation.”⁸³ 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 5 drugs with sales of over \$1 billion in 1994 and 1995 cited above. In its 2000 case study, NIH found that

[r]esearch 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

⁷⁷ (...continued)

on *Science*, 17 March, 1997, 15.

⁷⁸ Francis Narin, Kimberly S. Hamilton, and Dominic Olivastro, “The Increasing Linkage Between U.S. Technology and Public Science,” *Research Policy*, 1997, 328.

⁷⁹ 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>].

⁸⁰ *NIH Contributions to Pharmaceutical Development, Case Study Analysis of the Top-Selling Drugs*.

⁸¹ *Ibid.*

⁸² *The Benefits of Medical Research and the Role of the NIH*

⁸³ 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>].

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.⁸⁴

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."⁸⁵ 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.⁸⁶

A later 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."⁸⁷ 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."⁸⁸ 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.

⁸⁴ *NIH Contributions to Pharmaceutical Development*

⁸⁵ *A Plan to Ensure that Taxpayers' Interests are Protected*

⁸⁶ *Ibid.*

⁸⁷ General Accounting Office, *Technology Transfer, Agencies' Rights to Federally Sponsored Biomedical Inventions*, July 2003, GAO-03-536, 2.

⁸⁸ *A Plan to Ensure that Taxpayers' Interests are Protected*

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. Frank Lichtenberg (Columbia University Graduate School of Business) suggests that the benefits of new drugs include “longer life, better quality of life, and reductions in total medical expenditure.”⁸⁹

Pricing Decisions and Recoupment

Federal support for health-related R&D amounts to approximately 23% of the total federal R&D budget, second only to the R&D funding spent for defense.⁹⁰ 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.”⁹¹ 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

⁸⁹ 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>].

⁹⁰ National Science Foundation, *Federal R&D Funding by Budget Function Fiscal Years 2004-2006*, Table 2, available at [<http://www.nsf.gov/statistics/nsf06317/pdf/tab2.pdf>].

⁹¹ Mary T. Griffin, “AIDs Drugs and the Pharmaceutical Industry: A Need for Reform,” *American Journal of Law and Medicine*, 1991, 6.

programs that purchase half of its cars and then get many of those same taxpayers to buy a new car each and every year.”⁹²

Several years ago, 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.”⁹³ 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 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.⁹⁴ 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.”⁹⁵ 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.”⁹⁶ 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.⁹⁷

Proponents of recoupment and/or federal cost controls assert that the monopoly power of patents should be modified by “public subsidization”⁹⁸ 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

⁹² Adriel Bettelheim, “Drugmakers Under Siege,” *CQ Outlook*, September 25, 1999, 10.

⁹³ Alice Dembner and the Globe Spotlight Team, “Public Handouts Enrich Drug Makers, Scientists,” *The Boston Globe*, April 5, 1998.

⁹⁴ Steven R. Salbu, “Aids and Drug Pricing: In Search of a Policy,” *Washington University Law Quarterly*, Fall 1993, 13-14.

⁹⁵ *Ibid.*, 6.

⁹⁶ *Ibid.*, 7.

⁹⁷ *AIDs Drugs and the Pharmaceutical Industry: A Need for Reform*, 11.

⁹⁸ Information and quotes in this paragraph from: *Aids and Drug Pricing: In Search of a Policy*, 5-20.

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. Federal support for basic research reflects a consensus that such work is critical because it is the foundation for many new innovations. However, 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 Iain Cockburn of Boston University and Rebecca Henderson of MIT, 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.⁹⁹

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.¹⁰⁰ This fundamental 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.¹⁰¹ Studies demonstrate the “important role that the public sector plays in providing fundamental insights in basic knowledge as a basis for drug discovery.¹⁰² 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.”¹⁰³ This basic research generally is composed of work supported by the government and publicly available and knowledge resulting from internal firm R&D.¹⁰⁴ The information and concepts

⁹⁹ 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>].

¹⁰⁰ National Institutes of Health, *NIH Contributions to Pharmaceutical Development, Case Study Analysis of the Top-Selling Drugs*, Administrative document, May 2000.

¹⁰¹ *Ibid.*

¹⁰² *Publicly Funded Science and the Productivity of the Pharmaceutical Industry*.

¹⁰³ *The Impact of Public Basic Research on Industrial Innovation: Evidence From the Pharmaceutical Industry*.

¹⁰⁴ *Ibid.*

generated by this research have a “substantial impact” on pharmaceutical R&D.¹⁰⁵ 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.¹⁰⁶

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.¹⁰⁷

What appears to be the case is that benefits move in both directions between the government and the private sector.¹⁰⁸ A comprehensive study by NIH of 5 top selling drugs demonstrated “that public and private sector biomedical research are interwoven, complementary parts of the highly successful U.S. biomedical science endeavor.”¹⁰⁹ 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

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” (ie, knowledge of the existence and method of preparation of the compounds was publicly available before therapeutic potential

¹⁰⁵ Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, “Links and Impacts: The influence of Public Research on Industrial R&D,” *Management Science*, Jan. 2002.

¹⁰⁶ National Institutes of Health, *Report to Congress on Affordability of Inventions and Products*, July 2004, 3, available at [http://ott.od.nih.gov/policy/policies_and_guidelines.html]

¹⁰⁷ 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.

¹⁰⁸ *Publicly Funded Science and the Productivity of the Pharmaceutical Industry*.

¹⁰⁹ *NIH Contributions to Pharmaceutical Development, Case Study Analysis of the Top-Selling Drugs*.

was identified)...These types of compounds initially might not have been of interest to the pharmaceutical industry, because possible patent claims were limited.¹¹⁰

Those who oppose changes in the current approach to intellectual property ownership of the results of federally funded R&D maintain that the promise of a large return on investment “is precisely the tool sanctioned by the Constitution to promote the progress of science.”¹¹¹ 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.”¹¹² 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.¹¹³ 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.¹¹⁴ Industry sources maintain the patents are a necessity for raising this equity capital and that price controls would deter investors.¹¹⁵ 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.”¹¹⁶

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

¹¹⁰ *Public and Private Sector Contributions to the Discovery and Development of “Impact” Drugs.*

¹¹¹ Evan Ackiron, “Patents for Critical Pharmaceuticals: The AZT Case,” *American Journal of Law and Medicine*, 1991, 18.

¹¹² *Patents, Innovation and Access to New Pharmaceuticals.*

¹¹³ 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].

¹¹⁴ 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>].

¹¹⁵ *Drugmakers Under Siege.*

¹¹⁶ 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.

health and wealth of future generations.”¹¹⁷ A similar opinion was expressed by John E. Calfee of the American Enterprise Institute. Noting that, “one of the least-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.”¹¹⁸

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.”¹¹⁹ Other experts concur with this assessment. Research undertaken by John Vernon (University of Pennsylvania) 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.”¹²⁰ Other work 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.¹²¹

Actual experience and cited studies point to the conclusion 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 fact 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 their financial contribution to the endeavor. While the idea of recoupment was considered by the 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. 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, 15% of the sales of licensed products derived from federally funded university research is returned to the government in the form of income taxes, payroll taxes, capital gains taxes, and corporate income taxes. This is estimated to be 6 times the royalties paid by

¹¹⁷ *Cipro and the Risks of Violating Pharmaceutical Patents.*

¹¹⁸ John E. Calfee, “Why Pharmaceutical Price Controls are Bad for Patients,” *AEI On the Issues*, March 1999 available at [<http://www.aei.org/oti>].

¹¹⁹ *Putting a Human Face on Biotechnology: A Report on the Joint Economic Committee’s Biotechnology Summit*, 8.

¹²⁰ John A. Vernon, “Drug Research and Price Controls,” *Regulation*, Winter 2002-2003, 25.

¹²¹ *Cipro and the Risks of Violating Pharmaceutical Patents.*

companies to the universities.¹²² The emergence of the biotechnology industry and the development of new therapeutics to improve health care are other cited indications of such benefits. These benefits generally have been considered more important than the initial cost of the technology to the government or any potential unfair advantage.

Research Tools

The focus on intellectual property ownership of the results of federally funded R&D has led critics to charge that the patenting of fundamental research prevents further biomedical innovation. Law professors Rebecca Eisenberg (University of Michigan) and Arti Rai (University of Pennsylvania) argue that due to implementation of the Bayh-Dole Act “[p]roprietary claims have increasingly moved upstream from the end products themselves to the ground-breaking discoveries that made them possible in the first place.”¹²³ 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.”¹²⁴ These basic innovations are generally known as “research tools.”

Eisenberg and Richard Nelson of Columbia University argue that ownership of research tools may “impose significant transaction costs” that result in delayed innovation and possible future litigation.¹²⁵ 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.¹²⁶

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

¹²² 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>].

¹²³ Arti K. Rai and Rebecca S. Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine,” *American Scientist*, Jan.- Feb. 2003, 52.

¹²⁴ *Ibid.*

¹²⁵ Rebecca S. Eisenberg and Richard R. Nelson, “Public vs. Proprietary Science: A Fruitful Tension?,” *Daedalus*, Spring 2002.

¹²⁶ *Ibid.*

detrimental effects on science and its delivery of health benefits.”¹²⁷ 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.”¹²⁸

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 the Congress. Therefore, he believes that changes to the act are not the appropriate means to address the issues.¹²⁹

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.¹³⁰ 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.¹³¹ 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.”¹³² 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....”¹³³ 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 (University of Illinois, Chicago), Ashish Arora (Carnegie Mellon University), and Wesley Cohen (Duke University) found that

¹²⁷ 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>].

¹²⁸ *Ibid.*

¹²⁹ 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 available at [<http://www.nas.edu>].

¹³⁰ U.S. Congress, Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education and Related Agencies, *Hearings*, Aug. 1, 2001.

¹³¹ Available on the NIH website at [<http://www.nih.gov>].

¹³² *NIH: Moving Research From the Bench to the Bedside*.

¹³³ *Ibid.*, see also: P.L. 106-404, Section 6.

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.¹³⁴ 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 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.”¹³⁵ The study states that rights in one patent do not “automatically” permit rights in subsequent, related patents.¹³⁶ Because the government apparently holds few licenses on the biomedical products it purchases (generally through the Veteran’s Administration and the Department of Defense),¹³⁷ federal officials indicated that procurement costs were best reduced by use of the Federal Supply Schedule and national contracts.¹³⁸ Government licenses are used primarily in the performance of research in the biomedical area.¹³⁹

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

¹³⁴ John P. Walsh, Ashish Arora, Wesley M. Cohen, “Working Through the Patent Problem,” *Science*, Feb. 14, 2003, 1021.

¹³⁵ *Technology Transfer: Agencies’ Rights to Federally Sponsored Biomedical Inventions*, 7.

¹³⁶ *Ibid.*, 8.

¹³⁷ *Ibid.*, 8.

¹³⁸ *Ibid.*, 12.

¹³⁹ *Ibid.*, 10.

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.¹⁴⁰ Two 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.¹⁴¹ 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.”¹⁴²

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 well-being of these sectors.¹⁴³ American pharmaceutical firms have “consistently maintained a competitive edge in international markets” and lead in new drug discoveries.¹⁴⁴ The U.S. investment in health-related R&D exceeds all other countries¹⁴⁵ and has demonstrated a pattern of R&D investment that has increased at approximately twice the rate of R&D growth in Europe.”¹⁴⁶

Incentives for innovation in the industrial community clearly have contributed to substantial research and development by the pharmaceutical and biotechnology

¹⁴⁰ General Accounting Office, *Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision*, August 1999, GAO/RCED-99-242, 2.

¹⁴¹ General Accounting Office, *Intellectual Property: Federal Agency Efforts in Transferring and Reporting New Technology*, October 2002, GAO-03-47, 29.

¹⁴² National Institutes of Health, *Changes in Grantee/Contractor Reporting of Intellectual Property Utilization*, Notice NOT-OD-02-019, December 13, 2001.

¹⁴³ Iain Cockburn, Rebecca Henderson, Luigi Orsenigo, and Gary P. Pisano, “Pharmaceuticals and Biotechnology,” *U.S. Industry in 2000*, (National Academy Press, Washington, 1999), 365.

¹⁴⁴ Department of Commerce, International Trade Administration, *U.S. Industry & Trade Outlook 2000*, (McGraw-Hill, 2000), 11-16.

¹⁴⁵ PhRMA, *Pharmaceutical Industry Profile 2006*, 48, available at [<http://www.phrma.org>].

¹⁴⁶ PhRMA, *Pharmaceutical Industry Profile 2003*, 16 available at [<http://www.phrma.org>].

sectors. Pharmaceuticals companies (that are members of the Pharmaceutical Researchers and Manufacturers Association/PhRMA) spent \$39.4 billion on R&D in 2005, \$31.44 billion for research performed within the United States.¹⁴⁷ PhRMA estimates that total pharmaceutical R&D totaled \$51.3 billion in 2005. The industry employs approximately 223,000 individuals in highly skilled jobs.¹⁴⁸ Prescription drug sales by PhRMA members in the United States totaled \$164.2 billion in 2005.¹⁴⁹ American biotechnology companies generated \$33.3 billion in product sales and \$46 billion in revenue during 2004, as well as employed over 187,000 people.¹⁵⁰ An industry that did not exist 25 years ago, U.S. biotechnology has provided new products and processes for the international marketplace, including approximately 330 biotech drugs and vaccines, with potential for many more advances.

Yet, 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. 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 results 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-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 obligation 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.

¹⁴⁷ *Pharmaceutical Industry Profile 2006*, 44 and 52.

¹⁴⁸ *Pharmaceutical Industry Profile 2003*, 17.

¹⁴⁹ *Pharmaceutical Industry Profile 2006*, 49.

¹⁵⁰ Biotechnology Industry Organization, *Biotechnology Industry Statistics*, available at [<http://www.bio.org/speeches/pubs/er/statistics.asp>].