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

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ABSTRACT

Interest in methods to provide 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. This paper explores the issue of whether or not the substantial federal investment in health-related research and development (R&D) entitles the public to commensurate consideration in prices charged for any resulting drugs. It is intended to provide the reader with an understanding of the rationale for government support of R&D and subsequent efforts to facilitate private sector commercialization of new technologies generated from such work. Concerns surrounding innovation in pharmaceuticals and biotechnology are discussed within the broader context of the federal role in facilitating technological progress. The report will be updated if events warrant such action.

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

Summary

Interest in methods to provide 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 20 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.

However, questions are being raised as to whether or not the current balance is adequate, particularly with respect to drug discovery. The particular nature of health-related R&D and the $15.7 billion federal investment in this area has focused attention on the manner in which the National Institutes of Health undertakes research and development 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 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 drug pricing will change the nature of the current approach to government-industry-university cooperation.

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

Overview

Interest in methods to provide 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 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 interest 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 R&D are realized when innovations are available in the marketplace. In recognition of this, the Congress has passed legislation to facilitate the commercialization of new technologies.

The Stevenson-Wydler Technology Innovation Act and the Bayh-Dole Act (as discussed below) 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.

However, 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 ($15.7 billion in funding by the National Institutes of Health alone in FY1999), has led critics of the current system to argue that the necessity of incentives contained in current legislation 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 Orphan Drug Act. Therefore, some maintain, a more direct payback should be required including 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.[1] Instead, the report looks at the manner in which the National Institutes of Health (NIH) supports R&D to encourage the development of new pharmaceuticals and therapeutics, particularly through cooperative activities among academia, industry, and government. The goal is to offer insights into the discussion on whether 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

Rationale

The argument for special government consideration in pricing stems, in part, from the fact that the federal government substantially invests in research and development necessary for new drugs. It is thus important to determine the rationale behind such support to assess the validity of this justification. Traditionally, the U.S. 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

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[1] For a discussion of drug pricing see: Congressional Research Service, *Prescription Drugs: Factors Influencing Their Pricing*, by David J. Cantor, CRS Report 96-296, February 3, 1998 and Congressional Research Service, *The Cost of Prescription Drugs for the Uninsured Elderly and Legislative Approaches*, by the Transportation and Industry Analysis Section, November 24, 1999.

the benefits that can be captured by any one firm performing it.[2] "Government support of basic scientific research represents an example of the government furnishing a good, scientific knowledge, that improves social well-being. . . a good that cannot be sold because those who do not pay receive the benefits anyway."[3] Estimates of a social rate of return on R&D spending over twice that of the rate of return to the inventor 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.

Over the past 20 years, 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. 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.[5] 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 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. It is an activity that may involve, among other things, idea origination, research, development, engineering, commercialization, and diffusion throughout the marketplace. A concept can become an innovation without evolving through those separate steps. An invention becomes an innovation when it has been integrated into the economy such that the knowledge created is applied in production to increase productivity and quality, or results in a new or improved product or service that can

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[2] Edwin Mansfield, "Social Returns From R&D: Findings, Methods, and Limitations," *Research/Technology Management*, November-December 1991, 24.

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

be sold in the marketplace. It is only in that phase that a significant stimulus to economic growth occurs.

Research and development are important to technological progress in many ways. Some have argued that the innovations arising from R&D are the most important ones.[6] 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. In addition, R&D contributes to economic growth by its impact on productivity. For more than two decades various experts studying the effects of research and development have found that productivity growth in an industry or a firm is directly and significantly related to the amount spent previously on R&D in that industry or company.[7] Studies estimate that one-half of productivity increases (output per person) are the result of investments in research and development.[8]

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.

Cooperative R&D

While the federal investment in R&D is significant (approximately $79 billion a year), application of the results of this endeavor typically is the responsibility of the private sector and/or the university community. This tenet is reflected in legislative initiatives to facilitate the commercialization of government-funded research and development through mechanisms that encourage government-industry-university collaboration. Joint federal efforts with the private sector offers a means to get government-generated technology 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, joint ventures among government institutions, companies, and academia allow for R&D that crosses traditional boundaries of knowledge and experience. Ideas, expertise, and know-how are combined, facilitating a mix that may lead to more creativity and invention. It appears

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[6] 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.

[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.

that "merging technological knowledge and skills from different companies improves the innovation process."[9]

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 10% yearly increase in company support for such work between 1997 and 1999.[10] The rising expense of research and development has been juxtaposed with increasing international competition and shareholder demands for short-term returns. Thus, partnerships are a result of ". . .today's complex technologies, intense competition, and information overload [that] have required new approaches" beyond the funding of scientists to pursue their own interests.[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 recent 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. During 1996, firms funded $5 billion in outside R&D, 4.7% of the total in-house work performed. This amount is higher than the 3.6% displayed in the early 1990s and the under 2% in the early 1980s.[14] An estimated 20% of the largest U.S. corporations outsource technology development.[15]

It should be noted that joint ventures are not always successful due, in part, to cultural differences between companies or organizations, as well as managerial and financial issues or conflicting goals and objectives. However, studies by Coopers & Lybrand (now PriceWaterhouseCoopers) identify numerous benefits that have

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

[10] National Science Foundation, *Research and Development in Industry: 1998 [Early Release Tables]* [http:www.nsf.gov] March 29, 2000.

[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 Newletter* [http:www.barometersurveys.com] March 13, 2000.

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

[15] *Let's Order Out for Technology*, 47.

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. Coopers and Lybrand concluded that ". . .collaborative growth firms are spending more on new product development while focusing more on bigger winners and on innovation. . .[and]. . .are not reluctant to go outside their organization to work with others in the development of their innovative new products."[16]

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 advancements is 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 Edwin Mansfield of the 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."[17] Over 90% of life science companies in the United States have had a cooperative relationship with universities.[18]

Universities also are expanding their interaction with the private sector through licensing of inventions generated within academia. It is estimated that 19% of university research is done in conjunction with industry partnership efforts.[19] One way of measuring this interaction is through the number of patents licensed by academic institutions. Between FY1991 and FY1995, university invention disclosures increased 29%, patent applications increased 53%, and licenses and options executed increased 66%.[20] The increases are more pronounced between FY1995 and FY1998. The number of inventions disclosed increased 59% (from 7,427 in FY1995 to 11,784 in FY1998), the number of new patent applications rose 103% (2,373 to 4,808), and 71% more licenses were signed (2,142 to 3,668) over this time period.[21] According to the Association of University Technology Managers, in FY1998 alone, 364 new companies were established based on university R&D,

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[16] Coopers and Lybrand, L.L.P., "Partnerships Pay off for Growth Companies," *Trend Setter Barometer*, 6 January, 1997.

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

[18] David Blumenthal, Nancyanne Causino, Eric Campbell, and Karen Seashore Louis, "Relationships Between Academic Institutions and Industry in the Life Sciences — An Industry Survey," *The New England Journal of Medicine*, 8 February, 1996, 369.

[19] Wes Cohen, Richard Florida, and Richard Goe, "University-Industry Research Centers in the United States," Report to the Ford Foundation, 1993 referenced in Rosenberg and Nelson, *American Universities and Technical Advance in Industry*, 323.

[20] Association of University Technology Managers, "Licensing Survey FY1991-FY1995, Executive Summary," [http://www.autm.net] March 31, 2000.

[21] Association of University Technology Managers, FY98 AUTM Survey, [http://www.autm.net] March 31, 2000.

academic licensing generated $33.5 billion in economic activity, and 280,000 jobs were dependent on these inventions.

The use of academic research by industry 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. . . ."[22] In the pharmaceutical industry, over one-quarter of new drugs depended on academic research for timely commercialization.[23] 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.[24] Work prepared for the National Science Foundation by Francis Narin and his associates 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."[25] Of the papers cited in patents granted 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. And the biomedical community relies on this basic work more heavily than other industries with 79% of drug and medicine patents citing public science.[26]

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 Constitution states that patents are intended to promote "the progress of science and the useful arts." As research and development become more expensive, ownership of title to inventions has been used by the federal government as a means to foster increased private sector activities to generate new and improved products and processes for the marketplace. In an academic setting, the possession of title is expected to provide motivation for the university to license the technology to industry for further refinement in expectation of royalty payments.

The patent system is grounded in Article I, Section 8, Clause 8 of the U.S. Constitution and is intended to stimulate new discoveries and their reduction to

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[22] 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.

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

[24] 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.

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

[26] Francis Narin, Kimberly S. Hamilton, and Dominic Olivastro, "The Increasing Linkage Between U.S. Technology and Public Science," Research Policy, 1997, 328.

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 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.[27]

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 resulting patents are more detailed in their claims and therefore easier to defend.[28] In contrast, one study found that in the aircraft and semiconductor industries patents are not 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.[29] 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."[30] In certain industries, patents significantly raise the costs incurred by nonpatent holders wishing to use the idea or invent around the patent — an estimated 40% in the pharmaceutical sector, 30% for major new chemical products, and 25% for typical chemical goods — and are thus viewed as important. However, in other industries, patents have much smaller impact on the costs associated with imitation (e.g. in the 7%-15% range for electronics), and may be considered less successful in protecting resource investments.[31]

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[27] For more information see: Congressional Research Service, *Patents and Innovation: Issues in Patent Reform*, by Wendy H. Schacht, CRS Report 97-599, updated 24 August 1999, and Congressional Research Service, *R&D Partnerships and Intellectual Property: Implications for U.S. Policy*, by Wendy H. Schacht, CRS Report 98-862, 21 October 1998.

[28] 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. See also: Mansfield, Edwin. Intellectual Property Rights, Technological Change, 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), 12 and 13.

[29] *Appropriating the Returns for Industrial Research and Development*, 253.

[30] Ibid., 269.

[31] Mansfield, Edwin, Mark Schwartz, and Samuel Wagner. Imitation Costs and Patents: An Empirical Study, *The Economic Journal*, December 1981, in *The Economics of Technical Change*, 270.

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), as amended, and P.L. 96-517, Amendments to the Patent and Trademark Act (commonly referred to as "Bayh-Dole" after its two main sponsors, former Senators Birch Bayh and Robert Dole), 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 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.[32]

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.[33] 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 possibly several 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.[34] 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. Bayh-

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[32] For a detailed discussion of the legislative provisions of the Stevenson-Wydler Act and the Bayh-Dole Act see: *Congressional Research Service, Patent Ownership and Federal Research and Development (R&D): A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act*, by Wendy H. Schacht, CRS Report RL30320, September 28, 1999.

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

[34] *Government Patent Policy*, 5.

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

In enacting P.L. 96-517, the Congress accepted the proposition that vesting title in a contractor will encourage commercialization and that this should be used to foster innovation in specific segments of the economy. As stated in the law:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally-supported research and development; . . . to promote collaboration between commercial concerns and nonprofit organizations, including universities; . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; [and] to ensure that the Government obtains sufficient rights in federally-supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions. . . .[35]

The anticipated paybacks to the country through increased revenues from taxes on profits, new jobs created, improved productivity, and economic growth were seen by Congress as a balance for the initial cost of the technology to the government or any potential unfair advantage to any recipient.

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."[36] 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."[37]

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

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[35] 35 U.S.C. §200

[36] Ibid.

[37] *Report to Accompany H.R. 6933,* 3.

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. §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."

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 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 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.[38]

It should be noted here 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.

NIH-University-Industry Collaboration: The Results

Implementation of the Laws

The primary mission of the National Institutes of Health (NIH) ". . .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 $15.7 billion of both in-house and extramural R&D (11% of this total is for work within NIH laboratories and 82% goes to contractors, primarily universities and non-profit research institutions). Simultaneously, the Stevenson-Wydler Technology Innovation Act, as amended, 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."[39] Thus,

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[38] 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.

[39] Information on NIH patent and licensing procedures in this section, unless otherwise noted, (continued...)

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."[40] 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.

The National Institutes of Health, in its cooperative ventures, has attempted to take into account some of the concerns arising specifically from the health-related field. Therefore, the NIH approach to cooperative research and development agreements differs from that of other federal laboratories. Although CRADAs are exempt from disclosure under the Freedom of Information Act, "[c]onsistent with our mission responsibilities, . . . NIH declines to protect the results of CRADA research as trade secrets for collaborators. This allows the results of CRADA research to join intramural research results in being communicated broadly to the scientific and medical community."[41] Open dissemination of research data is promoted with the agency reserving the right to publish information on R&D generated by NIH even under a cooperative research and development agreement.

The articulated policy of the Public Health Service (the parent agency of NIH) is to obtain ownership of inventions arising from agency funded R&D within the provisions of the law (as discussed above) and to transfer the technology through the use of licensing whenever possible instead of assignment of patent title. Under a CRADA, ". . .the producing Party will retain ownership of and title to all Subject Inventions, all Subject Data and all Research Materials produced solely by their investigators. Jointly developed Subject Inventions, Subject Data and Research Materials will be jointly owned." 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 invention, the relative contributions of the Parties to the invention and the CRADA, the risks incurred by the Collaborator and the costs of

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[39] (...continued)
taken from: [http://www.nih.gov/od/ott].

[40] 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.

[41] House Committee on Science, Space, and Technology, *Transfer of Technology from Federal Laboratories: Hearings*, 102nd Cong., 1st sess., May 30,1991, 158.

subsequent research and development needed to bring the invention to the marketplace."

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

Figures provided by NIH show a general increase in the number of licenses executed each year and in the amount of royalties collected. Between FY1986 and FY1999, the number of licenses granted increased over 500% while the royalties paid to NIH in FY1999 were 10 times the amount paid in FY1987. In the past 5 years alone, royalties have grown 141% from $18,487,000 (FY1994) to $44,590,000 (FY1999). Overall, the number of patents issued have also expanded from 103 in FY1994 to 163 in FY1999.

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.[42]

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

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[42] NIH News, Press Release and Backgrounder, April 11, 1995, 7.

medication."[43] No other federal department or agency, with the exception of the Bureau of Mines, established such a requirement.

The clause was removed in 1995 at the request of Dr. Harold Varmus, 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."[44] 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."[45] 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.[46] Opponents of the clause argued that the uncertainty of the pricing clause exacerbated a process already fraught with risk. According to industry sources, not knowing what the determination of "fair" pricing would be at the end of a long and expensive research, development, and commercialization process was a strong deterrent to entering into cooperative arrangements. Many of the pharmaceutical and biotechnology companies declined to undertake CRADAs. Some firms even declined opportunities for joint clinical trials with NIH in anticipation of future price control demands. At the public hearings most of the patient advocacy groups called for repeal of the fair pricing clause.

NIH reportedly was reluctant to make definitive decisions on pricing. At that time, reasonable pricing was defined as a price within the range of existing therapies.[47] 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."[48]

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[43] Ibid., 4.

[44] Ibid., 1.

[45] Ibid., 3.

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

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

[48] 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.

The reluctance of a federal laboratory to enter into determinations of "fair" pricing may be understood within the context of the wide range of variables that might need to be taken into consideration. Among these are: (1) What is the value of the federal contribution? (2) Under a CRADA the government is specifically prohibited from providing direct funding; how can the federal investment be determined? (3) What is the cost of government-sponsored research in relation to the total costs incurred by the company (including research, development, clinical trials, FDA approval, production, distribution, marketing)? (4) What costs were incurred in related work that did not result in a marketable product or process? (5) Who owns the intellectual property rights and what is their value to the company? (6) What is the value of other intellectual property the collaborating party brought to the endeavor? (7) What are the costs of not having the drug available? (8) What are the replacement and/or substitution costs associated with the therapeutic?

The effect of abandoning the clause was immediate. As demonstrated below, subsequent to recission of the clause in April 1995, the number of CRADAs increased substantially:

NIH Executed CRADAS

FY1986 - - 4	FY1991 - - 26	FY1996 - - 87
FY1987 - - 10	FY1992 - - 30	FY1997 - - 153
FY1988 - - 20	FY1993 - - 41	FY1998 - - 149
FY1989 - - 42	FY1994 - - 31	FY1999 - - 126
FY1990 - - 32	FY1995 - - 32	

Issues and Options

Arguments advocating greater federal involvement in setting some pharmaceutical prices are based, in part, on the substantial public investment in generating new information and expertise through health-related R&D. The government supports basic research because of the perceived benefits of funding selected work that individual companies are unable or unwilling to finance. Innovation typically is knowledge-driven — dependent on the application of knowledge, whether it is scientific, technical, experiential, or intuitive. Innovation also 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."[49] 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

[49] John B. Shoven, "Intellectual Property Rights and Economic Growth," in Walker, et. al., *Intellectual Property Rights and Capital Formation in the Next Decade*, 46.

funds basic research. "Ordinarily, society maximizes its welfare through not charging for the use of a free good."[50] 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."[51]

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, there would result a ". . . much lower and indeed suboptimal level of innovation."[52] 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.

Issuance of a patent furnishes the inventor with a limited-time monopoly that is influenced by other mitigating factors, particularly the requirements for information disclosure, the length of the patent, and the scope of rights conferred. The process of obtaining a patent places the concept on which it is based in the public domain. In return for a monopoly right to the application 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 market needs.

The patent system thus has dual policy goals — providing incentives for inventors to invent and encouraging inventors to disclose technical information.[53] 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.[54] Patents give rise to an environment of

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

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

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

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

[54] Dam , *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

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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."[55]

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 health of these sectors.[56] American pharmaceutical firms have ". . .consistently maintained a competitive edge in international markets" and lead in new drug discoveries. The U.S. investment in health-related R&D exceeds all other countries.[57] American biotechnology companies generated $13.4 billion in product sales and employed 153,000 people in 1998. This was a 15% increase in sales over 1997 and a 9% growth in workers. An industry that did not exist 20 years ago, biotechnology has provided new products and processes for the international marketplace, including more than 350 drugs and vaccines, with vast potential for many more advances.[58]

Federal support for health-related R&D amounts to approximately 20% of the total federal R&D budget, second only to the research funding spent for defense. According to the last relevant survey conducted by NIH, in FY1995 the federal government provided 37% of the total national support for health R&D or $13.4 billion, industry supplied 52% or $18.6 billion, and private non-profits (4% or $1.3 billion), as well as state and local government (7% or $2.4 billion), funded the remainder.[59] These figures show a change from ten years earlier when the federal government provided 46% of national health-related R&D while industry funded 42% of the total amount spent.

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. In addition to

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[54] (...continued)
art to which the invention pertains." See footnote 12, p. 7.

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

[56] Iain Cockburn, Rebecca Henderson, Luigi Orsenigo, and Gary P. Pisano, "Pharmaceuticals and Biotechnology," *U.S. Industry in 2000*, National Academy Press, Washington, 1999, 365.

[57] Department of Commerce, International Trade Administration, *U.S. Industry &Trade Outlook '99*, (McGraw-Hill, 1998), 11-12.

[58] Biotechnology Industries Organization, *About BIO*, [http://www.bio.org/aboutbio/guidetoc.html] January 7, 2000.

[59] Information from the NIH web site available at: [http://grants.nih.gov/grants/award/trends96/CONTENTS.HTM]

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 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."[60] One critic of the present policy, Daniel Zingale, formerly the executive director of AIDS Action, has offered the following analogy: "imagine if General Motors could get the American taxpayer to heavily subsidize its research and development, fund government programs that purchase half of its cars and then get many of those same taxpayers to buy a new car each and every year."[61]

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."[62] 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." Similarly, Ralph Nader and James Love asserted in 1993 testimony that drugs developed with federal funding were priced "considerably" higher than those developed without such support.[63] According to their studies of FDA approved "new molecular entities," those pharmaceuticals generated with federal support were priced between $368 and $546,000 (per full year or completed course of treatment, whichever is less) compared to those with no government investment which were priced between $321 and $2,376 (per full year or completed course of treatment, whichever is less).

As noted previously, 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

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

[61] Adriel Bettelheim, *Drugmakers Under Seige*, CQ on the Web: [http://ww.cq.com]

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

[63] Ralph Nader and James Love, *Federally Funded Pharmaceutical Inventions*, testimony before the Special Committee on Aging, United States Senate, February 24, 1993 available at [http://www.cptech.org]

has both public and private benefits and is therefore not a classical public good.[64] By providing patent protection to the results of federally-funded research, a company receives an individual benefit based upon public investments. According to Steven Salbu, 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."[65] 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."[66] For example, Mary Griffin argues 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.[67]

Proponents of federal cost controls assert that the monopoly power of patents should be modified by "public subsidization"[68] They contend that the public has a right to a return on its investment. However, it is claimed 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 therefore ". . .cannot be explained by the usual 'incentives' rationale for conferring patent monopolies." Instead, those who favor government input into price decisions maintain that the prices of the resulting pharmaceuticals and therapeutics should reflect the public contribution to these products and processes. "In other words, public support of quasi-public goods must be balanced by some degree of public sharing in the fruits of the investment, as well as input into the nature of that sharing."

However, those who oppose changes in the current approach maintain that the promise of large returns on investments ". . .is precisely the tool sanctioned by the Constitution to promote the progress of science."[69] From their perspective, it is because pharmaceuticals and biotechnology are so research intensive that they rely heavily on patents. 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.[70] During 1995, the 5 firms with the highest

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

[65] Ibid., 6.

[66] Ibid., 7.

[67] Griffin, 11.

[68] Information and quotes in this paragraph from Salbu, 5-20.

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

[70] Joint Economic Committee, "Putting a Human Face on Biotechnology: A Report on the Joint Economic Committee's Biotechnology Summit," available at: [http://www.senate.gov/~jec/bio_report.htm] February 23, 2000., 5.

R&D budget per employee were U.S. biotechnology companies.[71] Therefore, 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."[72]

It is argued that eliminating the incentives associated with technology transfer and increased R&D through patent ownership and control over intellectual property would weaken innovation. John E. Calfee of the American Enterprise Institute maintains, "one of the least-appreciated effects of faster research and development is to quicken the competitive process itself." He states 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."[73]

In addition to the pharmaceutical industry, ownership of intellectual property is particularly important to biotechnology companies that are typically 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 3.5% of biotech companies have sales and therefore depend on venture capital and IPOs.[74] Industry sources maintain the patents are a necessity for raising this equity capital and that price controls would deter investors.[75] 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."[76]

Incentives to innovation in the industrial community clearly have contributed to substantial R&D in the pharmaceutical and biotechnology sectors. Yet, there are questions as to whether or not there are unintended consequences that 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

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[71] Biotechnology Industry Organization, testimony submitted April 1999.

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

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

[74] Biotechnology Industry Organization, "Contributions to New Medicine from Government-Funded Basic Biomedical Research," testimony submitted to the Senate Appropriations Subcommittee on Labor, Health, and Human Services, Education, and Related Agencies, April 1999, [http://www.bio.org].

[75] Adriel Bettelheim, "Drugmakers Under Siege," *CQ Outlook*, September 25, 1999, 10.

[76] Joint Economic Committee, "Putting a Human Face on Biotechnology: A Report on the Joint Economic Committee's Biotechnology Summit," 8.

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. It remains to be seen if changes will be made and if the nature of government-industry-university cooperation will be altered.