DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

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NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected

July, 2001

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

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**A. Executive Summary**

*Issue*

The Committee Report for the FY 2001 DHHS Appropriation contained the following instruction to the NIH:

> "The conferees have been made aware of the public interest in securing an appropriate return on the NIH investment in basic research. The conferees are also aware of the mounting concern over the cost to patients of therapeutic drugs. By July, 2001, based on a list of such therapeutic drugs which are FDA approved, have reached $500 million per year in sales in the United States, and have received NIH funding, NIH will prepare a plan to ensure that taxpayers' interests are protected." (p. 142)

*Process*

- A comprehensive cross-analysis of all 47 FDA-approved drugs meeting the $500M/year threshold yielded four that have been developed in part with technologies from NIH funding.

- NIH reviewed studies that have examined the impact of federally supported biomedical research and the return on investment that such research generates. For example, in May 2000, the U.S. Congressional Joint Economic Committee (JEC) issued The Benefits of Medical Research and the Role of NIH, which states that the benefit of increased life expectancy in the U.S. as a result of advances in health care creates annual net gains of about $2.4 trillion (in 1992 dollars). The Committee concludes that, "if only 10 percent of these increases in value ($240 billion) are the result of NIH-funded medical research, it indicates a payoff of about 15 times the taxpayers' annual NIH investment of $16 billion".

- NIH encountered difficulty in being able to cross-reference NIH grants and contracts that gave rise to inventions with any patents or licenses covering the final product, as well as an inability to identify other federal and/or non-federal sources of funds that contribute to an inventive technology.

- NIH contacted a number of sources to obtain information that may be useful in developing a plan, including:
  Council of Governmental Relations
  Association of University Technology Managers
  Biotechnology Industry Organization

Pharmaceutical Research and Manufacturers Association
Companies with whom NIH has ongoing business relationships
Other federal agencies with active technology transfer programs

- Feedback from Universities:

  Revenues derived from licensing income and other equity are being used to defray the costs of patenting, licensing and related legal and infrastructure expenses associated with technology transfer.

  If additional revenue is produced, it is used to fund new research programs, to support biomedical science training, and to cover research expenses not provided under overhead rates.

  However, most university technology transfer programs have very few, if any, products in the market. Given the investment in patent prosecution costs, operating expenses, and revenue sharing with inventors as provided by law, many universities operate their technology transfer programs at a net loss.

  These organizations stress the fact that most of the technologies are very early stage and, consequently, often have little licensing appeal. A relatively small number of technologies provide most of the licensing income they receive, because very few products are true "blockbusters".

*NIH Plan*

- Modify existing policies to ensure that grantees and contractors report to the agency the name, trademark or other appropriate identifiers of a therapeutic drug that embodies technology funded by the NIH once it is FDA-approved and reaches the market.

- Develop a web-based database that will identify the NIH grants or contracts that funded, in whole or in part, the inventive research, the date of the first disclosure to the government, the licensee, the date of the first commercial sale, and the product's commercial name.

- Propose standardized language to simplify the reporting requirements for NIH funded inventions, including an appropriate format for providing the information to NIH.

- Include in the database any FDA-approved therapeutic drugs arising from technologies developed by the intramural research program.

- Identify a group that includes representatives from Government, academic and other research entities, private industry, and other interested parties to establish a thoughtful dialogue on the appropriate returns to the public.

**B. Introduction**

The National Institutes of Health (NIH) is composed of 27 Institutes and Centers whose collective mission is to sponsor and conduct medical research and research training that leads to better health for all Americans. In this manner, the NIH expands fundamental knowledge about the nature and behavior of living systems; improves and develops new strategies for the diagnosis, treatment, and

prevention of disease; reduces the burdens of disease and disability; and assures a continuing cadre of outstanding scientists for future advances. In FY 2001, the NIH received $20.3 billion in support of its mission. Of that amount, nearly 84 percent supports non-Federal researchers working in universities, medical centers, hospitals, and research institutions throughout the country and abroad (collectively referred to as extramural research), and about 10 percent is allocated to in-house research laboratories located on the NIH campus and several off-campus sites (referred to as intramural research).

The Committee Report for the FY 2001 DHHS Appropriation contained the following instruction to the NIH:

> "The conferees have been made aware of the public interest in securing an appropriate return on the NIH investment in basic research. The conferees are also aware of the mounting concern over the cost to patients of therapeutic drugs. By July, 2001, based on a list of such therapeutic drugs which are FDA approved, have reached $500 million per year in sales in the United States, and have received NIH funding, NIH will prepare a plan to ensure that taxpayers' interests are protected." (p. 142)

**C. Background**

1. Commercialization of Government Owned and Government Funded Technologies

In 1980, in response to concerns about U.S. competitiveness in the global economy, Congress enacted two laws that encourage government owned and government funded research laboratories to pursue commercialization of the results of their research. These laws are known as the Stevenson-Wydler Act and the Bayh-Dole Act. Their goal is to promote economic development, enhance U.S. competitiveness, and benefit the public by encouraging the commercialization of technologies that would otherwise not be developed into products due to lack of incentives.

P.L. 96-480, the Stevenson-Wydler Technology Innovation Act of 1980 established the basic federal technology policies. This legislation enables NIH and other federal agencies to execute license agreements with commercial entities that promote the development of technologies discovered by government scientists. The Act also provides a financial return to the public in the form of royalty payments and related fees. In 1986, the directives of this Act were augmented by its amendment, the Federal Technology Transfer Act of 1986 (FTTA), which authorizes federal agencies to enter into cooperative research and development agreements (CRADA) with non-federal partners to conduct research.

The Patent and Trademark Amendments of 1980 (P.L. 96-517), known as the Bayh-Dole Act, was designed to address the barriers to development and promote the necessary synergy to advance federally funded inventions toward commercialization. The Bayh-Dole Act was enacted to allow federal agencies to secure patent rights and convey them to commercial entities through licensing, thereby promoting the transfer of federally funded technologies to the public and enhancing economic development. A key provision of the Act is that it provides grantees and contractors, both for-profit and not-for-profit, the authority to retain title to government-funded inventions, and charges them with the responsibility to use the patent system to promote utilization, commercialization, and public availability of inventions.

If the grantee or contractor institution declines title or elects not to pursue practical application of the technology, the federal agency can elect or decline title to the invention. By law, the funding agency retains residual interest in grant- and contract-supported inventions, such as a royalty-free, paid-up license to use the technology for government purposes. This right does not extend to a licensee's final commercial product, nor does it extend to proprietary information or trade secrets that belong to another party and may be incorporated in the final product.

2. The Process under Bayh-Dole

Recipients of NIH research funds, the NIH, and industry have now had twenty years' experience in technology transfer under Bayh-Dole. To accomplish the transfer of technology, NIH and NIH-funded recipients typically seek patent protection for inventions arising out of this basic research and license the rights to private entities to promote commercialization. Thus, private entities interested in practicing an invention in which they have no ownership may obtain rights to use and commercialize the invention by entering into a licensing agreement with the patent owner.

A license is a contract with binding commitments on each party, usually involving compensation (i.e. royalties, milestone payments, etc.). A license does not grant title, or ownership, to the invention. A license can be exclusive, when only one party is permitted to use or commercialize the technology; co-exclusive, when a limited number of parties have rights to use or commercialize the technology; or, non-exclusive, when more than one party is allowed to use or commercialize such rights.

a. Extramural Technology Transfer

Federally funded extramural laboratories establish their own licensing procedures and policies and obtain revenues from patent licensing agreements with industrial developers[1]. Universities also establish their own policies, in compliance with federal statute (Bayh-Dole and its regulations), for the distribution and use of proceeds from academic license agreements. Typically, revenues are allocated to inventors as a reward or incentive, and to laboratories, departments, and schools to support the research mission; however, the amounts provided to each are variable and subject to institutional policies.

Some measure of the financial returns associated with the Bayh-Dole Act may be gleaned from data that the Association of University Technology Managers (AUTM) has collected from its constituency for the past nine years. The latest available survey (FY1999) elicited responses from 190 U.S. and Canadian universities, teaching hospitals, research institutes and patent commercialization companies. The AUTM institutions that responded to the survey received 71 percent of NIH extramural dollars in FY 1999 (Appendix 1).

The survey includes information on patents and licenses in the fields of healthcare products, software programs, physics, copyrights and agricultural products as well as research reagents and tools used by industry and academia for various research, development and

commercial purposes. However, it does not separate biomedical technologies from the whole, nor does it separate income from federally funded projects from other sources of support; therefore, it is possible to draw only general conclusions from it. Further, this annual survey is designed to examine how basic academic discovery drives economic development, as intended by Bayh-Dole, but is not designed with the intent of exploring the issue of financial return on research investment.

As noted in the AUTM survey, in FY 1999 the gross income received from all active licenses and options held by U.S. universities, hospitals, research institutes and other entities amounted to $935 million. Of this income, 83 percent was earned on royalties from product sales, and the remainder consisted of cashed-in equity, milestone payments, and other fees. The survey also reports a total sponsored research activity of $25.7 billion in FY 1999, $16.3 billion of which was federal support[2]. If return on investment is presumed to be proportional, the AUTM data suggest a direct gross cash return on its federally funded research of approximately 5.5 percent annually. However, the AUTM survey collects very little data on the costs of the respondents' technology transfer programs. Therefore, it is not possible to determine from this information whether there is a "net profit" to the institution from technology transfer.

As a part of this report, NIH asked the Council on Governmental Relations (COGR), the AUTM, the Association of American Universities (AAU) and the Association of American Medical Colleges (AAMC) to provide information from their members on their use of royalty income. University officials consistently reported that the revenues derived from licensing income and other equity are being used to defray the costs of patenting, licensing and related legal and infrastructure expenses associated with technology transfer. In addition, according to COGR, net revenue is shared between the inventor and the university, and the inventors' share is in the range, on average, of 30-35 percent of net income received.

If additional revenue is produced, it is used to fund new research programs, to support biomedical science training, and to cover research expenses not provided under capped overhead rates. However, most university technology transfer programs have very few, if any, products in the market. Given the investment in patent prosecution costs, operating expenses, and revenue sharing with inventors as provided by law, many universities operate their technology transfer programs at a net loss. These organizations stress the fact that very few products are true "blockbusters," and that a relatively small number of technologies provide most of the licensing income they receive, since most of the technologies are very early stage and, consequently, often have little licensing appeal (see Appendix 2).

NIH does not have jurisdiction over the extramural technology transfer programs of academic institutions that use federal funds for inventive research. Indeed, the provisions of the Bayh-Dole Act do not give the funding agencies, including NIH, title to grants- and contracts-supported research discoveries, nor does it authorize the funding agency to dictate licensing and/or commercialization terms for these technologies.

b. Intramural Technology Transfer

As dictated by law, and under regulations from the Department of Commerce, NIH and other federal agencies carry out their technology transfer mandate by retaining title to the inventions developed internally by federal laboratories and licensing these inventions to ensure utilization, commercialization and public availability. As is the case with licensing programs in the extramural community, these technologies are negotiated on a case-by-case basis and in a manner consistent with rates and practices in private industry. For more details on NIH patenting and licensing policies and strategy, please see Appendix 3.

In FY2000, the NIH technology transfer program generated $52 million from its intramural licensing activity; in the past five years, license revenues have totaled approximately $200 million. In a 1999 study conducted by the General Accounting Office (GAO), NIH accounted for 95.1% of the royalty revenue received by the six agencies examined between 1996 and 1998, and was the most active program among the six.

NIH distributes the royalty income in accordance with federal law and NIH policy. By law, federal inventors must receive the first $2,000 of income received by the agency and at least 15 percent thereafter, up to a maximum of $150,000 per year in royalties from all licensed technologies in which they are inventors. The NIH formula modifies the amount of sharing to modestly increase the inventors' share, by providing them with 25% of the income after $50,000 in royalties is attained, up to the statutory maximum. In FY 2000 the inventors of NIH intramural technologies received, as a group, 13.5 percent of total NIH royalty revenue, and 28 NIH inventors currently receive the maximum $150,000 annual royalty.

The income remaining after the inventors' share goes to the Institute or Center within NIH in which the technology was developed. As provided by law, the funds are used for the following purposes:

- to reward scientific, engineering, and technical employees of the laboratory;
- to further scientific exchange among the laboratories of the agency;
- to educate and train employees consistent with the research and development missions and objectives of the agency or laboratory,
- to support other activities that increase the potential for transfer of the technology of the laboratories of the agency;
- to pay expenses incidental to the administration and licensing of intellectual property by the agency or laboratory with respect to inventions made at the laboratory, including the fees or other costs for the services of other agencies, persons, or organizations for intellectual property management and licensing services; or
- to support scientific research and development consistent with the research and development missions and objectives of the laboratory.

3. The Nature of Federally Funded Technology

The role of federally funded basic discovery and a fair rate of return on this investment must also be considered in the context of what occurs following the initial invention. In their paper *Proofs and Prototypes for Sale: The Tale of University Licensing*, Jensen and Thursby analyzed 62 of the top 135 U.S. universities to determine the impact of Bayh-Dole on the commercial application and diffusion of inventions from federally funded research. They found that most inventions came from research in the schools of science, engineering, medicine and nursing. They reported that research leading to 63 percent of all inventions was federally funded, while 17 percent was sponsored by industry and 18 percent was not sponsored. Of all inventions disclosed within these universities, fewer than half of the inventions were licensed. In what the authors of the study consider their most remarkable finding, they determined that over 75 percent of licensed inventions were no more than a proof of concept[3]. Consequently, these inventions represented an extremely high-risk venture for those companies that did seek to develop the technologies.

Jensen and Thursby further describe the difficulty of finding willing developers of such early stage technology. During the reporting period of the survey, an average of 1178 licenses were executed annually. Only 22 percent of executed licenses had multiple bidders[4]. In addition, the top five inventions licensed in each university accounted for 78 percent of gross license revenue, demonstrating the high risk and variable commercial outcome of such early stage technologies.

4. The Road to Innovation

To determine the return on investment, it is critical to ascertain costs associated with the basic research and development that gave rise to a particular technology. However, the path that research takes is determined by the results of series of experiments, and the best science can veer dramatically from the plan. Therefore, the factors that make scientifically curious minds appropriately alter research plans also make determining a starting point for assigning costs to a particular technology difficult.

An inventive technology is most likely one piece of a very large research project; and, it may be tangential to the main focus as well. For example, technical obstacles are common impediments in biomedical research; they frustrate, but they also inspire. Overcoming the obstacle may lead an investigator to develop an alternative technology, which may or may not be a distinct piece of research. Rather, it may be a necessary sidestep within the larger project, and the costs of development are, for the most part, very difficult to isolate.

In addition, biomedical laboratories generally conduct their research with multiple complementary goals. Within an overarching research mission, a laboratory is typically divided into separate units, each of which is responsible for conducting research on a particular piece of a broad

hypothesis, and each of which receives a variable piece of the laboratory budget as progress warrants. Some projects are designed to develop fundamental data or techniques that are necessary for a particular line of investigation; these techniques can be, and often are, useful for a number of unrelated studies.

Attempting to determine the costs of biomedical discovery is also complicated by the fact that new research almost always builds upon the work of predecessor scientists. Determining what part of a preceding budget or what part of a multi-purpose technique contributes to an inventive technology is, at best, extremely difficult, if not impossible.

5. Return on Investment

The question of the taxpayers' return on investment in biomedical research was debated in 1980 in consideration of the Bayh-Dole Act. At that time, concerns that the proposed legislation would permit private industry to profit from the taxpayers' investment in basic discovery led to proposals to recover the federal investment in basic research from any profits. Until shortly before its passage, the Bayh-Dole Act contained language to recoup the federal investment for federally funded technologies that reach commercialization. The proposed language included a formula for the repayment process. The Government would receive 15 percent of income over $70,000 gross income after a patent application was filed and up to an additional 5 percent if the gross income exceeded $1 million, up to the amount of government contributions under the funding agreement, pegged to the Consumer Price Index.

The Bayh-Dole Act was passed after Conferees made two changes in the language, in response to concerns that the process for determining repayment was threatening to cause an impasse in deliberations. First, several attempts to develop a mechanism for collecting repayment funds failed because there was no agreement on whether the funds would be returned to the agencies or to general revenue, or how the collection and auditing functions would be conducted. There were also fears that the costs of the infrastructure required to administer such a program would exceed the amounts collected.

To obtain passage of the legislation, members of Congress agreed that recoupment provisions would be dropped. However, due to concerns of some members of Congress that large companies would benefit from public dollars without a return to the taxpayer, large companies were removed from eligibility in the final bill. With these changes, the bill was passed and the Act today remains applicable to universities, nonprofit organizations and small businesses. In 1983, by Presidential Memorandum, President Ronald Reagan extended the implementation to large companies. And, in 1987, implementation of the Act was extended to these companies as part of an Executive Order issued by President Reagan.

6. The NIH "Reasonable Pricing" Clause Experience

In the years following passage of Bayh-Dole, members of Congress continued to express concerns about an appropriate monetary return for taxpayers' investment in biomedical research. In response to those concerns, in 1989 the NIH adopted a policy stating that there should 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." It was applied in Cooperative Research and Development Agreement (CRADA) negotiations between NIH intramural laboratories and potential private collaborative partners interested in engaging in collaborative research. The "reasonable pricing" clause was required in exclusive licenses to inventions made under NIH CRADAs. Shortly after the policy of "reasonable pricing" was introduced, industry objected to it, considering it a form of price control. Many companies withdrew from any further interaction with NIH because of this stipulation.

Both NIH and its industry counterparts came to the realization that this policy had the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the Bayh-Dole Act. To study the impasse caused by "reasonable pricing," the NIH convened panels that included scientists and administrators in Government, industry, academia, and patient advocacy groups to review the policy. In exploring the matter, the panels considered two key questions:

- First, what kind of return on the public investment is appropriate?

  The panels agreed on the following hierarchy, from most-to-least important: fostering scientific discoveries; rapid transfer of discoveries to the bedside; accessibility of resulting products to patients; and royalties.

- Second, how much return on investment is appropriate?

  The panels acknowledged the importance of monetary return in the form of licensing and license execution fees, royalties, and recovery of patent prosecution expenses, but concluded that the question of royalties and monitoring returns is less important than the issue of expeditious new product development and accessibility of the products to those who need them.

  The panels' evaluation of the issue supported the view that the intangible benefits of rapid development of technologies as effective therapeutics, and the assurance of access to those products for all who need them, are so significant that they override monetary return considerations[5].

  The panels concluded that the policy did not serve the best interests of technology development and recommended to the Director, NIH, that the language be rescinded. The Director, NIH, accepted the recommendation, and the policy was revoked in 1995.

The consequences of NIH's "reasonable pricing clause" policy can be seen in the relatively flat growth rate of CRADAs that occurred between 1990 and 1994, and the subsequent rebound in CRADAs following revocation of the policy (see Appendix 4).

7. Additional Studies Considering the Return on Investment

Several groups have recently revisited the issue of federally supported research and its value. For instance, the National Science Foundation estimates that the rate of return on the Government's investment for basic research can be as high as 40 percent when all the numbers are totaled, including taxes generated from product development[6].

In May 2000, the U.S. Congressional Joint Economic Committee (JEC) issued *The Benefits of Medical Research and the Role of NIH*, which examined the role of federal funding for medical research and the benefits that derive from that research. The Committee report states that, although the rate of return on publicly funded research is difficult to quantify, the benefit of increased life expectancy in the U.S. as a result of advances in health care creates annual net gains of about $2.4 trillion (using 1992 dollars). The Committee concluded, "if only 10 percent of these increases in value ($240 billion) are the result of NIH-funded medical research, it indicates a payoff of about 15 times the taxpayers' annual NIH investment of $16 billion"[7].

The JEC report also cites estimates that have been made in econometric studies that place the economy-wide rate of return on publicly funded research on the order of 25 to 40 percent a year. Development of biomedical discoveries also contributes to the national economy by providing therapeutics that reduce what the JEC termed "the economic costs of illness." This includes lost wages due to morbidity and mortality, expenditures associated with health care and treatment of disease, and the intangible costs of pain and suffering caused by disease. The JEC calculated that these costs amount to approximately $3 trillion annually, far exceeding the taxpayers' investment.

The Mary Woodward Lasker Charitable Trust's initiative called "Funding First," commissioned nine distinguished economists to conduct a comprehensive examination of the true economic value of our national investment in medical research. The report, Exceptional Returns: The Economic Value of America's Investment in Medical Research, published in May 2000, concluded that the likely returns from medical research are so extraordinarily high that the payoff from any plausible "portfolio" of investments in research would be enormous. For example, the reductions in

mortality from cardiovascular disease alone averaged $1.5 trillion annually during the period 1970-1990. If just one-third of this gain is a result of medical research, the return on investment averaged $500 billion. As the report notes: "That's on the order of 20 times as large as average annual spending on medical research — by any benchmark an astonishing return for the investment[8]."

The conclusions of these and other studies on the issue of return on investment are consistent and comparable in that they assert that there are both monetary and intangible benefits of remarkable value that are gained from federally funded biomedical research[9].

**D. Methodology, Findings and Discussion**

As noted in the Introduction, in FY 2001 Congress asked the NIH to assess appropriate return to the taxpayers when a therapeutic drug, developed from technology funded by NIH, reached annual product sales of $500 million per year, making it a "blockbuster" drug.

To address Congress' request, the NIH analysis focused on patent rights, since it is only through such rights that a financial interest can be established for a product. NIH determined which therapeutic drugs currently on the market met the Congressionally established criteria. NIH also studied the process by which technologies reach the market. To augment its analysis, NIH reviewed other studies that have examined one or more aspects of the impact of federally supported biomedical research and the return on investment that such research generates.

NIH also held discussions with a number of leaders in the academic, not-for-profit and government sectors, as well as representatives of for-profit entities to explore all of the issues relevant to developing a plan to ensure that taxpayers' interests are protected (see Appendix 5).

There is no existing database that captures all the elements required for this analysis; therefore, NIH undertook an exhaustive compilation of data from a number of individual sources of information, and then conducted a cross-analysis to obtain a list that meets the specifications in the Congressional instruction. NIH reviewed information in the Food and Drug Administration (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations List (known as the Orange Book). This list identifies drug products approved on the basis of safety and effectiveness by FDA under the Federal Food, Drug, and Cosmetic Act and provides a list of patents that cover the approved product. The patent history of each drug was examined using the U.S. Patent and Trademark Office (USPTO) computerized data bank. This search was used to determine if NIH, the Department of Health and Human Services (DHHS) or the Public Health Service (PHS) held rights in or was designated as having an interest on the patents. Finally, the NIH queried the Edison database. Edison is a NIH-developed interactive system, through which grantee and contractor organizations report information on inventions developed with NIH funding, as required by the Bayh-Dole Act (see Appendix 6).

Analysis of the pharmaceutical company sales data for 1999 (the latest date for which data are available) yielded a total of 47 FDA- approved drugs that met the $500 million/year threshold (see Appendix 7). For each drug listed, NIH sought to determine whether the agency, directly, or through a grantee or contractor, held any patent rights to the drugs.

From the comprehensive cross-analysis of all 47 drugs, it was determined that NIH has Government use or ownership rights to patented technologies used in the development of four of those drugs. Those four are Taxol®, Epogen®, Procrit®, and Neupogen®.

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.

1. Analysis

As mentioned in the Background section, discussions on the appropriate return on the taxpayers' investment have been part of public policy deliberations for many years. Macroeconomics studies addressing this issue have been conducted repeatedly over the past thirty years and clearly show the direct and positive impact of public funding for health-related basic research and the wisdom of such investment of taxpayers' funds for public benefit. These studies, however, have generally focused on the broader impact of such research on quality of life, improvement of health and economic competitiveness.

It is important to note 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. This is due to many factors.

First, the technologies developed in basic research laboratories are nascent, requiring extensive further development.

Second, not all technologies arising from NIH funded research lead to therapeutic drugs; indeed, new chemical entities that could lead to therapeutic products are hard to discover, as pharmaceutical and biotechnology companies can attest.

Third, the likelihood that a compound will reach the market is very low. Consider the following statistics: for one drug to be approved by the FDA, a company typically needs to screen between 5,000 and 10,000 compounds. Of these, an average of 250 compounds survive pre-clinical testing, only five compounds are approved for clinical testing, and only one succeeds in obtaining FDA approval[10].

Fourth, development and production of a FDA-approved therapeutic drug occurs, on average, eight to twelve years after a license is signed, and a license offers no guarantee that a product will ever reach the market. Given this lag time, most

investigators and universities are unaware when licensing milestones are reached unless they have a very active license-monitoring program or until they receive royalty payments pursuant to the license agreements.

NIH also found that the actual financial return to grantees and contractors was relatively low. Indeed, while universities and industry stressed that the current system under Bayh-Dole has been highly successful and a model now emulated by the world, they cautioned that the great majority of these patents do not generate significant revenues or even sufficient revenues to compensate the patenting expenses (see Appendices 2, 8, 9, and 10). The university and industrial communities clearly noted that the current system of innovation under Bayh-Dole has achieved its goal and promoted utilization of technologies for public benefit that otherwise would lie fallow. It was further noted that recoupment strategies, while well intentioned, would have a chilling effect on the technology transfer process and fail to address the key concern of access to therapeutic drugs. These constituencies expressed deep concern that changes in the system would be counter to the Bayh-Dole Act and would destabilize a successful balance between public and private needs for innovation and development.

NIH explored the notion of possible royalty redirection for "blockbuster" drugs under licenses arising from the Bayh-Dole Act. This suggestion was met with strong resistance from the academic community because it was perceived as a tax that would, at best, have no net effect on the price of a therapeutic drug and, at worst, increase its cost. Further, it was argued that such redirection of royalties would undermine the research enterprise, drain funds for academic development, and discourage faculty members from embarking in the technology transfer process. Moreover, there is concern that any movement to extract a direct financial return for the investment would dampen, if not destroy, industry's willingness to establish agreements with academic institutions, as was the case when NIH imposed the reasonable pricing clause in its CRADAs.

The university community gives strong support for broad access to prescription drugs and health care services at reasonable rates. However, the universities noted that neither NIH nor universities have a role in drug pricing.

NIH is aware that in the future other potential "blockbuster" drugs may result from Bayh-Dole related activities and, therefore, keenly appreciates the importance of thoughtful analysis of the advantages and disadvantages of potential models of return on investment, and the importance of a continued dialogue on this matter. However, it should be noted that even if these strategies were to be considered appropriate, NIH has no authority to impose such measures.

It has taken two decades since the enactment of Bayh-Dole for federally funded institutions to develop a royalty stream, and NIH realizes that future events may change the situation that exists today. This dynamic environment makes it even more important to be able to track how the link from invention to patent to license to royalty develops, and to be able to examine these links at a later date. It is also clear from our current efforts that such information is not readily accessible at the present time.

For example, analysis of the 47 therapeutic drugs that have reached annual sales in

the U.S. of $500 million, and determination of which of these had intellectual property that ties back to federal funding, was particularly difficult. This is due to the fact that implementing regulations of the Bayh-Dole Act do not require that investigators provide such information to the funding agency, and it is generally not provided. As a result, tracking down the "pedigree" of these drugs had to be done manually and on a case-by-case basis.

From a more practical and direct perspective, NIH found that a key obstacle to systematic analysis on this matter is the lack of solid and consistent data on which to base the discussion. This lack of information has also been identified by members of the public, and specifically addressed in the letter from the Pharmaceutical Research and Manufacturers of America (see Appendix 10).

**E. The Plan**

It is clear that information relating to inventive discoveries and their commercial development is reported neither systematically nor consistently. Currently, significant information is not required by the implementing regulations under Bayh-Dole. As a result, it is not possible to cross-reference NIH grants and contracts that funded inventions with any patents or licenses embodied in the final product. Nor is it possible to identify other federal and/or non-federal sources of funds that contribute to an inventive technology. To address this deficiency, NIH will:

**First**, modify its existing extramural policy manuals to ensure that grantees and contractors report to the agency the name, trademark or other appropriate identifiers of a therapeutic drug that embodies technology funded by the NIH once it is FDA-approved and reaches the market;

**Second**, make this information available to the public in a web-based database. The database will identify the NIH grants or contracts that funded, in whole or in part, the inventive research, the date of the first disclosure to the government, the licensee and the product's commercial name;

**Third**, develop standardized language to simplify the reporting requirements. This language will include an appropriate format for providing the information to NIH; and,

**Fourth**, comply with these same requirements so that all FDA-approved therapeutic drugs developed in the NIH intramural program will also be listed in the publicly accessible database.

The availability of these data will make the research discovery and development process transparent; as a result, it will permit the tracking of a drug's technological pedigree and serve as a resource for the public.

Additionally, the NIH recognizes the need for continued dialogue on this important matter. To do so, it is necessary to identify a group of stakeholders, with representation from Government, academic and research entities, private industry,

and other appropriate interested parties, which would participate in a thoughtful and constructive discussion on the appropriate returns to the public. It is envisioned that the data collected under this Plan, and the information gathered from the broader stakeholder discussion, will aid in the evaluation of the costs and benefits of technology transfer to the taxpayers and inform future decisions by NIH on policies and practice.

**F. Conclusion**

On the basis the information gathered for this report, NIH believes that its stewardship of the federal resources that support biomedical research has protected the taxpayers' interests. NIH and its recipient institutions apply the provisions of Bayh-Dole to best advantage in seeking the optimal return on investment in terms of public health benefit.

NIH also concludes that contravening the provisions of Bayh-Dole may have a deleterious effect on biotechnology development. Current practices in technology transfer have yielded a dramatic return to the taxpayer through the discovery of new technologies that extend life and improve the quality of life and through the development of products that, without the successful public-private relationship, might not be available. The transfer of federally funded technology has also resulted in financial returns from licensing activity, and such funds are used to buttress the biomedical research enterprise that has made the U.S. the world leader in this field.

Requiring direct financial recoupment of the federal investment in biomedical research can potentially impede the development of promising technologies by causing industry to be unwilling to license federally funded technologies. The "reasonable pricing" provisions that NIH once required in all CRADA and exclusive license negotiations did just that. Of even greater concern should be the potential that the economic disincentives of recoupment will make it expedient for industry to move research outside the federal milieu. Such action would diminish the strides made under the Bayh-Dole Act and have the unintended consequence of removing the research from federal oversight, a particular concern when the research involves lines of investigation that are especially critical or sensitive.

It is impossible to overstate the achievements or the global macroeconomic impact of U.S. taxpayer-supported biomedical research. Federally funded biomedical research, aided by the economic incentives of Bayh-Dole, has created the scientific capital of knowledge that fuels medical and biotechnology development. American taxpayers, whose lives have been improved and extended, have been the beneficiaries of the remarkable medical advances that have come from this enterprise.

**G. References**

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**H. Appendices:**
http://www.nih.gov/news/wydenreportappendices2001.pdf

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1. Large and small businesses eligible for government-funded grants and contracts are subject to the Bayh-Dole Act. These entitites typically commercialize technologies directly or through agreements with other commercial partners.

2. Association of University Technology Managers, *AUTM Licensing Survey, FY 1999*, p. 34

3. Jensen and Thursby, *Proofs and Prototypes for Sale: The Tale of University Licensing*, p. 5

4. Jensen and Thursby, p. 8

5. *Report of the NIH Panels on Cooperative Research and Development Agreements*, July 21 and September 8, 1994, p. 27

6. Washington Fax, October 17, 2000, p. 2

7. The Joint Economic Committee, U.S. Senate. May 2000. *The Benefits of Medical Research and the role of the NIH*, available on the Joint Economic Committee webste http://jec.senate.gov

8. Exceptional Returns: The Economic Value of America's Investment in Medical Research. Report of the Mary Woodward Lasker Charitable Trust's initiative *Funding First*, May 2000.

9. NIH Contributions to Pharmaceutical Development. Administrative document prepared by NIH Staff, February 2000.

10. Convergence: Ernst and Young's Biotechnology Industry Report, Millennium Edition, p. 47

# Appendix 1

Attachment E

(Ranked by FY 1999 Total Sponsored Research Expenditures)

| U.S. UNIVERSITIES: Name of Institution | Year 0.5 Prof. FTE Devoted to Tech. Transfer | FY 1999 Total Sponsored Research Expenditures | FY 1999 Invention Disclosures Received | FY 1999 Total U.S. Patent Applications Filed | FY 1999 Licenses & Options Executed | FY 1999 Adjusted (*) Gross License Income Received | FY 1999 Licenses & Options Yielding License Income | FY 1999 Legal Fees Expended | FY 1999 Legal Fees Reimbursed | FY 1999 U.S. Patents Issued | FY 1999 Start-up Companies Formed |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Univ. of California System | 1979 | $1,864,901,000 | 818 | 670 | 219 | $74,133,000 | 715 | $12,500,000 | $7,500,000 | 281 | 13 |
| Johns Hopkins University | 1973 | $1,010,088,334 | 250 | 256 | 106 | $10,353,453 | 137 | $3,288,453 | $1,344,461 | 111 | 7 |
| Massachusetts Inst. of Technology (MIT) | 1940 | $725,600,000 | 381 | 341 | 95 | $16,131,334 | 346 | $5,933,157 | $2,284,627 | 154 | 17 |
| Univ. of Michigan | 1982 | $499,722,000 | 158 | 147 | 42 | $3,472,671 | 90 | $2,764,309 | $1,116,081 | 56 | 2 |
| Univ. of Washington/Wash. Res. Fndtn. | 1983 | $479,654,994 | 226 | 114 | 115 | $27,878,900 | 185 | $1,338,024 | $457,327 | 36 | N.A. |
| Univ. of Pennsylvania | 1986 | $477,000,000 | 244 | 151 | 57 | $2,984,000 | 55 | $1,677,000 | $1,399,000 | 82 | 6 |
| W.A.R.F./Univ. of Wisconsin-Madison | 1925 | $421,600,000 | 278 | 162 | 106 | $18,011,400 | 191 | $2,850,000 | $177,000 | 79 | 4 |
| Univ. of Minnesota | 1957 | $417,556,493 | 219 | 99 | 71 | $5,662,088 | 153 | $1,940,733 | $1,091,233 | 55 | 5 |
| Stanford University | 1970 | $417,037,000 | 236 | 237 | 147 | $27,699,355 | 339 | $2,674,594 | $958,879 | 90 | 19 |
| North Carolina State University | 1984 | $413,369,278 | 148 | 62 | 83 | $7,761,000 | 60 | $936,145 | $735,545 | 30 | 8 |
| SUNY Research Foundation | 1979 | $405,238,284 | 201 | 123 | 46 | $13,538,619 | 149 | $1,671,656 | $133,999 | 53 | 3 |
| Texas A&M University System | 1992 | $402,203,000 | 145 | 85 | 53 | $5,180,510 | 155 | $879,302 | $457,362 | 19 | 0 |
| Harvard University | 1977 | $401,849,500 | 109 | 186 | 48 | $9,886,404 | 166 | $3,150,532 | $2,298,884 | 72 | 2 |
| Penn State University | 1989 | $393,462,000 | 188 | 231 | 40 | $2,830,448 | 64 | $897,517 | $458,299 | 46 | 3 |
| Cornell Research Fndtn., Inc. | 1979 | $376,784,000 | 172 | 147 | 150 | $6,070,000 | 199 | $2,900,000 | $2,200,000 | 70 | 4 |
| Univ. of Illinois, Urbana, Champaign | 1993 | $358,247,000 | 104 | 53 | 39 | $2,856,207 | 84 | $578,089 | $8,116 | 14 | 4 |
| Duke University | N.A. | $334,505,814 | 115 | 111 | 41 | $1,566,195 | 73 | $1,241,331 | $565,312 | 43 | 2 |
| Washington University | 1985 | $333,196,000 | 104 | 78 | 114 | $6,999,971 | 107 | $1,168,144 | $939,485 | 39 | 4 |
| Univ. of Colorado | 1993 | $331,579,000 | 79 | 63 | 10 | $3,127,303 | 10 | $329,300 | $26,778 | 27 | 1 |
| Univ. of Arizona | 1988 | $320,244,777 | 97 | 40 | 11 | $314,299 | 31 | $118,494 | $116,028 | 8 | 3 |
| Yale University | 1982 | $315,953,000 | 70 | 110 | 23 | $40,695,606 | 28 | $1,186,852 | $322,924 | 37 | 3 |
| Univ. of Pittsburgh | 1992 | $311,200,000 | 107 | 70 | 16 | $608,851 | 23 | $1,636,874 | $421,008 | 30 | 3 |
| Univ. of Florida | 1983 | $280,408,217 | 136 | 127 | 10 | $21,649,577 | 45 | $2,937,299 | $793,876 | 58 | 2 |
| Columbia University | 1982 | $279,275,674 | 182 | 109 | 98 | $89,159,556 | 212 | $4,030,556 | $1,152,913 | 77 | 5 |
| Univ. of Iowa Research Fndtn. | 1975 | $259,514,262 | 79 | 83 | 21 | $3,464,565 | 80 | $1,530,469 | $728,514 | 32 | 2 |
| Univ. of Texas at Austin | 1988 | $258,122,000 | 81 | 49 | 31 | $1,929,390 | 24 | $553,213 | $330,953 | 17 | 1 |
| Ohio State University | 1990 | $257,950,000 | 100 | 35 | 26 | $1,626,000 | 34 | $545,000 | $112,000 | 18 | 0 |
| Univ. of Southern California | 1971 | $254,811,651 | 156 | 101 | 57 | $450,568 | 55 | $650,668 | $190,757 | 13 | 4 |
| Purdue Research Foundation | 1988 | $253,018,364 | 102 | 81 | 76 | $2,149,000 | 201 | $1,070,000 | $548,000 | 24 | 4 |

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(Ranked by FY 1999 Total Sponsored Research Expenditures)

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|---|---|---|---|---|---|---|---|---|---|---|---|
| Baylor College of Medicine | 1983 | $239,000,000 | 89 | 39 | 35 | $12,280,879 | 110 | $621,363 | $117,324 | 25 | 0 |
| Univ. of Georgia | 1979 | $237,493,000 | 72 | 44 | 32 | $3,208,427 | 64 | $878,682 | $681,680 | 21 | 5 |
| Northwestern University | N.A. | $236,668,615 | 80 | 71 | 14 | $2,758,450 | 38 | $416,895 | $264,301 | 35 | 0 |
| Georgia Institute of Technology | 1990 | $223,641,675 | 127 | 143 | 18 | $2,038,078 | 46 | $833,832 | $106,136 | 23 | 3 |
| Univ. of Missouri System | 1987 | $212,238,803 | 62 | 37 | 16 | $1,544,985 | 21 | $399,971 | $231,806 | 22 | 1 |
| Indiana University (ARTI) | 1991 | $209,154,093 | 59 | 38 | 14 | $1,040,092 | 39 | $632,995 | $201,458 | 18 | 1 |
| Michigan State University | 1992 | $207,912,000 | 85 | 82 | 33 | $23,711,867 | 48 | $1,187,038 | $245,446 | 63 | 1 |
| Univ. of Massachusetts, All Campuses | 1995 | $206,382,231 | 112 | N.A. | 19 | $4,105,000 | 41 | N.A. | N.A. | 32 | 2 |
| Emory University | 1985 | $205,600,000 | 89 | 50 | 13 | $15,257,565 | 35 | $915,425 | $500,948 | 44 | 4 |
| Univ. of North Carolina/Chapel Hill | 1985 | $198,081,333 | 116 | 74 | 70 | $1,696,786 | 47 | $956,393 | $564,159 | 41 | 0 |
| Univ. of Virginia Patents Fndtn. | 1977 | $197,046,500 | 154 | 155 | 25 | $4,185,446 | 62 | $569,024 | $179,877 | 23 | 6 |
| Iowa State University | 1935 | $186,700,000 | 160 | 106 | 163 | $1,812,870 | 298 | $854,852 | $335,317 | 49 | 2 |
| Univ. of Rochester | 1980 | $185,488,000 | 85 | 53 | 5 | $2,994,170 | 17 | $329,000 | $33,000 | 14 | 1 |
| Univ. of Maryland, College Park | 1987 | $185,036,200 | 84 | 113 | 61 | $968,144 | 109 | $430,190 | $196,120 | 12 | 3 |
| Univ. of Utah | 1968 | $182,753,466 | 172 | 98 | 25 | $3,257,026 | 58 | $939,807 | $256,946 | 40 | 8 |
| Univ. of Texas Southwestern Med. Ctr. | 1990 | $179,709,069 | 80 | 63 | 23 | $4,856,751 | 57 | $996,890 | $422,397 | 27 | 1 |
| Case Western Reserve University | 1986 | $176,519,336 | 59 | 37 | 10 | $505,192 | 16 | $284,243 | $24,463 | 17 | 3 |
| Univ. of Miami | 1989 | $175,600,000 | 27 | 9 | 9 | $432,937 | 22 | $211,404 | $66,344 | 8 | 0 |
| Univ. of Illinois at Chicago | 1985 | $175,093,000 | 61 | 35 | 20 | $1,839,290 | 45 | $355,451 | $209,792 | 13 | 2 |
| Univ. of Alabama/Birmingham | 1987 | $171,831,840 | 121 | 113 | 40 | $1,568,587 | 58 | $804,313 | $150,935 | 24 | 2 |
| Univ. of Tennessee Research Corp. | 1983 | $170,896,000 | 75 | 54 | 7 | $602,053 | 24 | $612,123 | $81,813 | 17 | 1 |
| Virginia Tech Intellectual Properties, Inc. | 1985 | $169,250,000 | 65 | 58 | 41 | $1,328,343 | 74 | $180,830 | $42,396 | 37 | 3 |
| Carnegie Mellon University | 1992 | $167,675,342 | 104 | 36 | 23 | $5,892,284 | 51 | $1,183,217 | $35,600 | 30 | 5 |
| Univ. of Kansas | 1994 | $167,575,000 | 67 | 22 | 7 | $885,000 | 39 | $129,000 | $65,000 | 10 | 1 |
| Rutgers, The State University of NJ | 1989 | $165,872,573 | 112 | 103 | 60 | $4,304,616 | 73 | $1,026,345 | $801,421 | 31 | 3 |
| Vanderbilt University | 1990 | $165,200,000 | 87 | 51 | 31 | $1,100,579 | 44 | $440,251 | $216,718 | 17 | 2 |
| Univ. of Chicago-ARCH Dev. Corp. | 1986 | $162,805,000 | 65 | 74 | 14 | $1,868,392 | 40 | $1,635,106 | $746,700 | 33 | 1 |
| Univ. of South Florida | 1990 | $161,300,000 | 48 | 53 | 13 | $490,408 | 18 | $385,579 | $84,444 | 24 | 8 |
| Univ. of Hawaii | 1987 | $151,809,406 | 41 | 36 | 0 | $171,877 | 19 | $235,501 | $17,269 | 11 | 0 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| California Institute of Technology | 1978 | $150,000,000 | 143 | 212 | 21 | $6,500,000 | 35 | $1,150,000 | $33,000 | 62 | 7 |
| New York University | 1989 | $149,000,000 | 50 | N.A. | N.A. | $10,700,000 | 18 | $1,000,000 | $700,000 | 30 | 2 |
| Univ. of New Mexico/Sci. & Tech. Corp. | 1995 | $148,600,000 | 47 | 53 | 3 | $400,200 | 9 | $374,500 | $85,200 | 15 | 2 |
| Colorado State University | 1970 | $147,664,283 | 30 | 17 | 9 | $386,990 | 18 | $98,177 | $32,258 | 13 | 4 |
| Wayne State University | 1988 | $147,000,000 | 39 | 18 | 3 | $458,000 | 12 | $106,000 | $15,000 | 18 | 1 |
| Oregon State University | 1980 | $145,665,138 | 38 | 25 | 17 | $825,283 | 45 | $201,382 | $117,569 | 6 | 1 |
| Boston University | 1976 | $142,515,956 | 56 | 52 | 17 | $263,095 | 18 | $764,966 | $422,999 | 22 | 7 |
| Florida State University | 1996 | $132,664,855 | 23 | 15 | 8 | $57,313,014 | 14 | $160,282 | $104,883 | 5 | 1 |
| Univ. of Maryland, Baltimore | 1989 | $131,484,606 | 62 | 44 | 7 | $116,681 | 16 | $281,886 | $93,120 | 12 | 2 |
| Univ. of Nebraska-Lincoln | 1996 | $131,046,000 | 32 | 28 | 8 | $796,894 | 24 | $253,173 | $0 | 9 | 2 |
| Mount Sinai School of Medicine of NYU | 1991 | $123,404,735 | 36 | 35 | 12 | $1,012,061 | 14 | $781,672 | $51,168 | 9 | 0 |
| Univ. of Cincinnati | 1983 | $115,025,000 | 47 | 36 | 15 | $3,905,945 | 16 | $145,033 | $29,687 | 6 | 4 |
| Virginia Commonwealth University | 1994 | $113,000,000 | 88 | 68 | 17 | $459,200 | 21 | $131,124 | $63,005 | 14 | 3 |
| Univ. of Texas Houston Hlth. Sci. Ctr. | 1985 | $107,035,788 | 20 | 12 | 8 | $343,050 | 9 | $223,230 | $0 | 6 | 0 |
| Univ. of Connecticut | 1987 | $105,800,000 | 45 | 32 | 12 | $481,134 | 10 | $304,600 | $6,000 | 11 | 2 |
| Princeton University | 1987 | $102,000,000 | 60 | 61 | 14 | $1,480,000 | 20 | $1,650,000 | $1,265,000 | 26 | 2 |
| Clemson University | 1987 | $99,340,766 | 29 | 7 | 7 | $4,648,141 | 10 | $72,274 | $0 | 2 | 1 |
| Tufts University | 1978 | $98,567,533 | 51 | 32 | 12 | $506,149 | 21 | $625,216 | $299,375 | 11 | 0 |
| Oklahoma State University | 1995 | $88,900,000 | 19 | 9 | 1 | $154,946 | 7 | $141,088 | $52,726 | 4 | 0 |
| Tulane University | 1985 | $87,324,000 | 13 | 17 | 9 | $7,572,483 | 19 | $235,000 | $130,215 | 7 | 0 |
| Oregon Health Sciences University | 1989 | $86,822,525 | 32 | 45 | 11 | $291,131 | 32 | $359,302 | $187,466 | 15 | 1 |
| Univ. of Oklahoma-All Campuses | 1984 | $85,584,836 | 30 | 45 | 6 | $110,265 | 7 | $281,455 | $181,981 | 8 | 2 |
| Thomas Jefferson University | 1984 | $85,400,000 | 87 | 80 | 17 | $742,515 | 24 | $338,970 | $91,867 | 27 | 1 |
| Univ. of Texas Medical Branch | 1988 | $85,000,000 | 30 | 38 | 4 | $108,857 | 10 | $376,655 | $258,549 | 21 | 0 |
| Univ. of Kentucky Research Fodtn. | 1984 | $83,743,077 | 65 | 32 | 9 | $2,496,786 | N.A. | $520,270 | $63,016 | 24 | 2 |
| Medical Univ. of South Carolina | N.A. | $81,246,129 | 40 | 24 | 5 | $121,627 | 11 | $272,517 | $69,718 | 8 | 3 |
| Dartmouth College | 1985 | $81,055,083 | 18 | 26 | 7 | $491,302 | 47 | $173,977 | $117,601 | 20 | 0 |
| Auburn University | 1988 | $80,544,000 | 25 | 13 | 5 | $186,738 | 6 | $213,994 | $53,200 | 12 | 0 |
| Utah State University | 1987 | $80,539,784 | 27 | 7 | 4 | $227,929 | 15 | $84,884 | $16,634 | 6 | 1 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| Univ. of Texas Hlth Sci Ctr San Antonio | 1990 | $80,020,875 | 21 | 41 | 14 | $3,660,638 | 32 | $516,571 | $38,768 | 13 | 0 |
| Wake Forest University | 1985 | $78,351,866 | 36 | 19 | 6 | $2,788,987 | 9 | $798,320 | $130,239 | 3 | 1 |
| Brown University Research Fndtn. | 1983 | $76,330,000 | 40 | 36 | 4 | $1,009,516 | 13 | $157,041 | $93,222 | 17 | 1 |
| Univ. of South Carolina | 1993 | $69,819,000 | 36 | 26 | 7 | $175,187 | 12 | $88,264 | $10,813 | 4 | 0 |
| Univ. of Delaware | 1997 | $64,872,678 | 20 | 29 | 4 | $470,303 | 8 | $122,683 | $7,910 | 3 | 2 |
| Univ. of Arkansas, Fayetteville | 1990 | $63,110,717 | 26 | 21 | 2 | $259,883 | 21 | $187,862 | $38,423 | 13 | 1 |
| New Mexico State University | 1990 | $63,037,606 | 12 | 10 | 3 | $1,792 | 3 | $115,770 | $17,031 | 2 | 0 |
| West Virginia University | 1999 | $62,000,000 | 9 | 3 | 1 | $41,800 | 5 | $83,500 | $0 | 2 | 0 |
| Arizona State University | 1985 | $60,091,584 | 49 | 47 | 11 | $1,274,145 | 18 | $547,472 | $172,444 | 12 | 1 |
| Univ. of New Hampshire | 1997 | $60,015,544 | 6 | 5 | 6 | $34,696 | 5 | $14,336 | $0 | 0 | 0 |
| Univ. of Oregon | 1992 | $58,616,598 | 9 | 11 | 10 | $232,000 | 20 | $86,858 | $90,000 | 5 | 1 |
| Univ. of Louisville | 1996 | $53,258,000 | 30 | 9 | 3 | $48,632 | 4 | $30,869 | N.A. | 2 | 1 |
| Kansas State University Research Fndtn. | 1942 | $52,597,214 | 28 | 16 | 7 | $258,063 | 31 | $216,370 | $135,589 | 12 | 2 |
| Univ. of Vermont | 1998 | $52,500,000 | 25 | 11 | 6 | $338,000 | 3 | $182,000 | $88,000 | 2 | 0 |
| Idaho Research Fndtn./Univ. of Idaho | 1986 | $50,345,178 | 18 | 7 | 2 | $140,500 | 6 | $299,413 | $199,388 | 3 | 0 |
| Montana State University | 1980 | $49,741,400 | 15 | 12 | 7 | $243,700 | 18 | $203,630 | $159,890 | 7 | 1 |
| Temple University | 1986 | $45,456,670 | 19 | N.A. | 5 | $493,947 | 16 | $213,892 | $0 | N.A. | 0 |
| North Dakota State University | 1995 | $44,696,000 | 23 | 6 | 7 | $1,059,797 | 38 | $93,041 | $6,596 | 4 | 0 |
| Rice University | 1998 | $44,500,000 | 20 | 33 | 8 | $21,000 | 4 | $117,000 | $9,000 | 1 | 1 |
| Louisiana State University, Agric. Ctr. | 1989 | $44,318,252 | 17 | 7 | 7 | $1,091,787 | 17 | $153,265 | N.A. | 3 | 1 |
| Univ. of North Dakota | N.A. | $43,131,073 | 2 | 1 | 0 | $0 | 0 | $8,578 | $0 | 0 | 0 |
| Brandeis University | 1982 | $42,666,882 | 17 | 18 | 6 | $120,126 | 21 | $184,820 | $180,411 | 9 | 3 |
| New Jersey Institute of Technology | 1990 | $42,500,000 | 35 | 8 | 2 | $22,500 | 3 | $175,000 | $0 | 4 | 0 |
| Univ. of Houston | 1996 | $42,002,331 | 40 | 7 | 5 | $120,831 | 8 | $294,601 | $71,072 | 5 | 0 |
| Univ. of Maine | N.A. | $41,453,000 | 6 | 3 | 2 | $0 | 0 | $30,301 | $0 | 4 | 0 |
| Univ. of Rhode Island | 1991 | $41,400,000 | 12 | 7 | 11 | $823,385 | 10 | $123,447 | $666 | 3 | 0 |
| San Diego State University | 1998 | $40,624,000 | 7 | 3 | 4 | $82,000 | 2 | $50,000 | $0 | 1 | 2 |
| Syracuse University | 1989 | $39,500,000 | 10 | 4 | 1 | $112,529 | 16 | $181,628 | $129,483 | 5 | 0 |
| Univ. of Dayton | 1984 | $37,039,132 | 28 | 9 | 2 | $567,535 | 5 | $246,160 | $129,197 | 8 | 1 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| George Mason University | 1996 | $32,376,000 | 13 | 11 | 0 | $753 | 1 | $10,360 | $0 | 3 | 0 |
| Loyola University Medical Center | N.A. | $29,778,103 | 4 | 3 | 10 | $567,500 | 10 | $86,252 | $0 | 0 | 0 |
| Michigan Technological University | 1988 | $28,073,860 | 20 | 11 | 11 | $222,272 | 18 | $174,275 | $2,500 | 2 | 0 |
| St. Louis University | 1998 | $27,817,000 | 19 | 15 | 3 | $788,472 | 22 | $160,157 | $83,590 | 6 | 0 |
| Univ. of South Alabama | 1995 | $27,252,916 | 5 | 11 | 0 | $7,178 | 3 | $131,031 | $0 | 6 | 0 |
| Creighton University | 1992 | $25,700,000 | 17 | 3 | 2 | $123,717 | 4 | $27,779 | $0 | 2 | 0 |
| Lehigh University | N.A. | $25,312,458 | N.A. | N.A. | N.A. | $117,661 | 7 | $26,000 | $0 | N.A. | N.A. |
| Southern Illinois Univ./Carbondale | 1993 | $23,655,654 | 15 | 6 | 6 | $48,245 | 9 | $149,877 | $30,163 | N.A. | 0 |
| Kent State University | 1989 | $23,472,249 | 12 | 5 | 3 | $147,159 | 7 | $221,087 | $119,488 | 4 | 1 |
| Univ. of Montana | 1995 | $22,996,357 | 5 | 2 | 3 | $67,000 | 4 | $54,422 | $0 | 2 | 0 |
| New York Medical College | 1994 | $22,821,758 | 16 | 3 | 3 | $87,589 | 8 | $43,133 | $25,030 | 3 | 2 |
| Wright State University | N.A. | $22,753,000 | 2 | 1 | 4 | $18,525 | 6 | $6,254 | $0 | 1 | 0 |
| Univ. of New Orleans | 1999 | $22,297,000 | 6 | 6 | 1 | $13,770 | 2 | $39,881 | $5,000 | 2 | 0 |
| Univ. of Maryland, Baltimore County | 1994 | $21,854,000 | 26 | 9 | 1 | $39,117 | 2 | $100,525 | $0 | 6 | 0 |
| Univ. of Maryland Biotech Institute | 1995 | $20,387,312 | 17 | 14 | 4 | $335,000 | 2 | $367,328 | N.A. | 4 | 0 |
| Brigham Young University | 1986 | $17,226,876 | 71 | 12 | 21 | $3,961,971 | 51 | $215,310 | $29,633 | 4 | 1 |
| Ohio University | 1991 | $16,492,896 | 13 | 8 | 0 | $617,805 | 3 | $174,515 | $119,272 | 4 | 0 |
| Univ. of Northern Iowa | 1998 | $13,148,015 | 0 | 2 | 0 | $1,268 | 1 | $13,364 | $0 | 2 | 0 |
| Medical College of Ohio | 1983 | $11,895,179 | 7 | 2 | 0 | $22,991 | 6 | $75,664 | $21,701 | 6 | 0 |
| Portland State University | N.A. | $11,735,117 | 3 | 0 | 0 | $0 | 0 | $0 | $0 | 0 | 0 |
| California State Polytechnic University | 1999 | $11,575,000 | 1 | 2 | 2 | $10,000 | 2 | $47,000 | $0 | 1 | 0 |
| Univ. of Akron | 1995 | $10,193,500 | 29 | 20 | 7 | $244,056 | 15 | N.A. | N.A. | 11 | 1 |
| East Carolina University | 1995 | $8,360,000 | 10 | 6 | 1 | $76,000 | 0 | $46,836 | $3,984 | 2 | 0 |
| **TOTAL U.S. UNIVERSITIES** | | **$23,565,568,068** | **10,052** | **7,612** | **3,295** | **$641,000,108** | **6,663** | **$100,438,800** | **$42,438,911** | **3,079** | **275** |

* *Reports prior to FY 1998 reflect Gross License Income Received (see footnote x).*

(Ranked by FY 1999 Total Sponsored Research Expenditures) Attachment E

| U.S. HOSPITALS & RESEARCH INSTITUTES: Name of Institution | Year 0.5 Prof. FTE Devoted to Tech. Transfer | FY 1999 Total Sponsored Research Expenditures | FY 1999 Invention Disclosures Received | FY 1999 Total U.S. Patent Applications Filed | FY 1999 Licenses & Options Executed | FY 1999 Adjusted (*) Gross License Income Received | FY 1999 Licenses & Options Yielding License Income | FY 1999 Legal Fees Expended | FY 1999 Legal Fees Reimbursed | FY 1999 U.S. Patents Issued | FY 1999 Start-up Companies Formed |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Massachusetts General Hospital | 1976 | $247,034,000 | 174 | 170 | 40 | $6,603,343 | 60 | $3,547,170 | $1,801,539 | 85 | 4 |
| Mayo Foundation | 1986 | $240,500,000 | 119 | 72 | 31 | $4,361,548 | 124 | $994,627 | $261,310 | 31 | 0 |
| Brigham & Women's Hospital | 1986 | $196,289,000 | 81 | 70 | 28 | $3,149,675 | 70 | $1,067,008 | $617,477 | 26 | 4 |
| M.D. Anderson Cancer Center | 1987 | $155,126,396 | 67 | 36 | 17 | $3,169,420 | 60 | $682,882 | $443,687 | 20 | 0 |
| Fred Hutchinson Cancer Res. Ctr. | 1988 | $141,372,000 | 26 | 12 | 21 | $2,103,483 | 75 | $253,336 | $67,712 | 14 | 2 |
| Beth Israel Deaconess Medical Ctr. | 1997 | $117,327,557 | 63 | 41 | 21 | $1,171,033 | 32 | $1,137,489 | $916,925 | 29 | 3 |
| Sloan Kettering Institute for Cancer Res. | 1981 | $100,982,132 | 36 | 24 | 22 | $43,065,502 | 44 | $816,603 | $140,000 | 7 | 1 |
| Dana-Farber Cancer Institute | 1990 | $94,477,120 | 47 | 22 | 21 | $2,268,182 | 65 | $865,000 | $257,201 | 33 | 0 |
| Children's Hospital, Boston | 1991 | $85,000,000 | 75 | 82 | 13 | $2,616,923 | 30 | $1,191,938 | $389,981 | 27 | 1 |
| Health Research, Inc. | 1986 | $75,800,000 | 19 | 7 | 7 | $6,996,742 | 35 | $266,619 | $22,771 | 14 | 0 |
| St. Jude Children's Research Hospital | 1995 | $73,778,337 | 32 | 16 | 16 | $619,921 | 43 | $391,634 | $168,050 | 6 | 0 |
| Medical College of Wisconsin | 1984 | $72,500,000 | 10 | 6 | 9 | $469,265 | 20 | $89,735 | $59,383 | 3 | 1 |
| City of Hope National Medical Ctr. | 1986 | $65,890,000 | 40 | 31 | 0 | $23,752,074 | 24 | $0 | $0 | 10 | 0 |
| Woods Hole Oceanographic Inst. | 1993 | $62,118,319 | 1 | 0 | 0 | $118,300 | 2 | $9,920 | $9,800 | 0 | 0 |
| Children's Hospital of Philadelphia | N.A. | $58,348,000 | 21 | 15 | 4 | $101,160 | 7 | $131,051 | $39,557 | 2 | 0 |
| Children's Hospital, Cincinnati | 1996 | $55,419,771 | 20 | 12 | 3 | $315,459 | 9 | $401,060 | $71,949 | 2 | 0 |
| Fox Chase Cancer Center | 1984 | $54,242,489 | 31 | 23 | 37 | $331,676 | 26 | $314,522 | $0 | 2 | 1 |
| Salk Institute | 1969 | $51,416,000 | 45 | 38 | 23 | $2,521,687 | 68 | $1,700,056 | $1,220,374 | 21 | 0 |
| National Jewish Med. and Res. Ctr. | 1994 | $34,234,123 | 9 | 12 | 3 | $510,864 | 18 | $113,724 | $47,845 | 7 | 0 |
| Wistar Institute | 1991 | $23,974,000 | 10 | 33 | 15 | $2,482,000 | 53 | $290,391 | $73,526 | 7 | 0 |
| Oklahoma Medical Research Fndtn | 1990 | $23,777,502 | 17 | 19 | 2 | $586,988 | 20 | $461,711 | $64,819 | 5 | 0 |
| Hospital for Special Surgery | 1996 | $18,515,000 | 8 | 5 | 0 | $5,587,603 | 9 | N.A. | N.A. | 2 | 0 |
| Institute of Paper Science and Tech. | 1997 | $15,599,000 | 17 | 11 | 2 | $0 | 0 | $110,977 | $87,223 | 4 | 0 |
| New York Blood Center | 1975 | $14,000,000 | 9 | N.A. | 6 | $35,000,000 | 30 | $600,000 | $100,000 | 14 | 0 |
| California Pacific Medical Ctr. Res. Inst. | N.A. | $12,751,706 | 4 | 1 | 0 | $0 | 0 | $87,696 | $47,450 | 0 | 0 |
| Schepens Eye Research Institute | 1997 | $10,599,003 | 6 | 7 | 0 | $125,375 | 3 | $252,830 | $54,119 | 3 | 0 |
| Torrey Pines Inst. for Molecular Studies | 1997 | $5,386,000 | 2 | 2 | 8 | $125,000 | 1 | $41,300 | $33,000 | 3 | 0 |
| St. Elizabeth's Medical Center of Boston | 1995 | $4,500,000 | 6 | 5 | 3 | $0 | 0 | $83,000 | $61,500 | 1 | 0 |
| Cleveland Clinic Foundation | 1989 | N.A. | 111 | 29 | 3 | $1,995,522 | 29 | $458,321 | $74,029 | 20 | 0 |
| **TOTAL U.S. HOSPITALS & RESEARCH INSTITUTES** | | **$2,110,957,455** | **1,106** | **801** | **355** | **$150,148,745** | **957** | **$16,360,600** | **$7,131,227** | **398** | **17** |

* *Reports prior to FY 1998 reflect Gross License Income Received (see footnote x).*

Attachment E

(Ranked by FY 1999 Total Sponsored Research Expenditures)

| CANADIAN INSTITUTIONS: Name of Institution | Year 0.5 Prof. FTE Devoted to Tech. Transfer | FY 1999 Total Sponsored Research Expenditures (U.S. $) | FY 1999 Invention Disclosures Received | FY 1999 Total U.S. Patent Applications Filed | FY 1999 Licenses & Options Executed | FY 1999 Adjusted (*) Gross License Income Received (U.S. $) | FY 1999 Licenses & Options Yielding License Income | FY 1999 Legal Fees Expended (U.S. $) | FY 1999 Legal Fees Reimbursed (U.S. $) | FY 1999 U.S. Patents Issued | FY 1999 Start-up Companies Formed |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Univ. of Toronto | 1980 | $209,121,012 | 90 | 25 | 17 | $844,175 | 21 | $308,452 | $150,997 | 6 | 5 |
| Univ. de Montreal | 1990 | $133,658,635 | 37 | 22 | 15 | $362,229 | 16 | $187,347 | $73,738 | 13 | 8 |
| McGill University | 1990 | $125,454,301 | 95 | N.A. | 24 | $539,433 | 38 | $363,653 | $269,289 | 17 | 8 |
| Univ. of Alberta | 1987 | $115,918,697 | 59 | 47 | 15 | $2,434,907 | 20 | $400,699 | $93,718 | 11 | 4 |
| Univ. of British Columbia | 1984 | $95,341,717 | 126 | 95 | 14 | $788,209 | 55 | $1,030,188 | $780,024 | 50 | 6 |
| UTI, Inc./Univ. of Calgary | 1985 | $71,519,412 | 77 | 37 | 29 | $1,871,917 | 53 | $383,075 | $220,728 | 15 | 3 |
| Univ. of Western Ontario | 1995 | $60,573,428 | 29 | 14 | 7 | $43,556 | 16 | $92,421 | $0 | 4 | 5 |
| McMaster University | 1987 | $53,059,239 | 29 | 3 | 9 | $365,589 | 13 | $19,904 | $5,707 | 2 | 0 |
| Queen's University | 1984 | $46,556,737 | 38 | 17 | 8 | $674,660 | 27 | $307,177 | $192,474 | 12 | 0 |
| Hospital for Sick Children Research | 1985 | $41,024,364 | 33 | 11 | 24 | $461,031 | 37 | $205,950 | $43,074 | 7 | 2 |
| Univ. of Waterloo | 1990 | $38,026,652 | 8 | 7 | 17 | $459,348 | 56 | $85,779 | $21,718 | 6 | 0 |
| Univ. of Manitoba | 1983 | $31,192,381 | 22 | 39 | 15 | $969,731 | 28 | $204,244 | $3,692 | 7 | 0 |
| Univ. de Sherbrooke | 1986 | $26,921,524 | 21 | 4 | 22 | $2,692,152 | 54 | $316,921 | $151,670 | 3 | 2 |
| Carleton University | 1986 | $18,425,175 | 20 | 1 | 2 | $97,698 | 2 | $13,023 | $1,905 | 0 | 1 |
| Simon Fraser University | 1985 | $15,601,834 | 17 | 15 | 6 | $556,350 | 5 | $70,692 | $2,509 | 5 | 4 |
| Univ. of Ottawa Heart Institute | 1989 | $12,814,423 | 5 | 0 | 0 | $0 | 0 | $35,038 | $18,023 | 0 | 0 |
| Ottawa Civic Hospital Loeb Res. Inst. | 1995 | $10,768,610 | 5 | 3 | 0 | $333,300 | 2 | $71,865 | $65,000 | 0 | 0 |
| Concordia University | 1997 | $10,624,157 | 3 | 4 | 1 | $15,130 | 3 | $7,137 | $0 | 2 | 1 |
| ecole De Technologie Superieure | 1996 | $3,005,324 | 3 | 1 | 2 | $15,345 | 1 | $4,711 | $0 | 0 | 1 |
| akehead University | 1995 | $2,779,608 | 0 | 0 | 0 | $0 | 0 | $108 | $0 | 0 | 0 |
| **OTAL CANADIAN INSTITUTIONS** | | **$1,122,387,230** | **717** | **345** | **227** | **$13,524,760** | **447** | **$4,108,384** | **$2,094,266** | **160** | **50** |

*Reports prior to FY 1998 reflect Gross License Income Received (see footnote x).*

Attachment E

(Ranked by FY 1999 Total Sponsored Research Expenditures)

| PATENT MANAGEMENT FIRMS<br>Name of Institution | Year 0.5 Prof. FTE Devoted to Tech. Transfer | FY 1999 Total Sponsored Research Expenditures | FY 1999 Invention Disclosures Received | FY 1999 Total U.S. Patent Applications Filed | FY 1999 Licenses & Options Executed | FY 1999 Adjusted (*) Gross License Income Received | FY 1999 Licenses & Options Yielding License Income | FY 1999 Legal Fees Expended | FY 1999 Legal Fees Reimbursed | FY 1999 U.S. Patents Issued | FY 1999 Start-up Companies Formed |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Competitive Technologies, Inc. (CTI) | N.A. | N.A. | 23 | 13 | 9 | $3,463,176 | 73 | $128,887 | $0 | 3 | 0 |
| Research Corporation Technologies | 1987 | N.A. | 426 | 31 | 28 | $54,199,100 | 168 | N.A. | N.A. | 21 | 2 |
| **TOTAL PATENT MNGMNT. FIRMS** | | **N.A.** | **449** | **44** | **37** | **$57,662,276** | **241** | **$128,887** | **$0** | **24** | **2** |

** Reports prior to FY 1998 reflect Gross License Income Received (see footnote x).*

Attachment E

| ALL RESPONDENTS: | FY 1999 Total Sponsored Research Expenditures | FY 1999 Invention Disclosures Received | FY 1999 Total U.S. Patent Applications Filed | FY 1999 Licenses & Options Executed | FY 1999 Adjusted (*) Gross License Income Received | FY 1999 Licenses & Options Yielding License Income | FY 1999 Legal Fees Expended | FY 1999 Legal Fees Reimbursed | FY 1999 U.S. Patents Issued | FY 1999 Start-up Companies Formed |
|---|---|---|---|---|---|---|---|---|---|---|
| U.S. UNIVERSITIES | $23,565,568,068 | 10,052 | 7,612 | 3,295 | $641,000,108 | 6,663 | $100,438,800 | $42,438,911 | 3,079 | 275 |
| U.S. HOSPITALS & RESEARCH INSTITUTES | $2,110,957,455 | 1,106 | 801 | 355 | $150,148,745 | 957 | $16,360,600 | $7,131,227 | 398 | 17 |
| CANADIAN INSTITUTIONS (U.S. $) | $1,122,387,230 | 717 | 345 | 227 | $13,524,760 | 447 | $4,108,384 | $2,094,266 | 160 | 50 |
| PATENT MANAGEMENT FIRMS | N.A. | 449 | 44 | 37 | $57,662,276 | 241 | $128,887 | $0 | 24 | 2 |
| **TOTAL ALL RESPONDENTS** | **$26,798,912,753** | **12,324** | **8,802** | **3,914** | **$862,335,889** | **8,308** | **$121,036,671** | **$51,664,404** | **3,661** | **344** |

** Reports prior to FY 1998 reflect Gross License Income Received (see footnote x).*

# Appendix 2

# COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Avenue, N.W., Suite 320, Washington, D.C. 20005
(202) 289-6655/(202) 289-6698 (FAX)


June 5, 2001

Dr. Wendy Baldwin
Deputy Director
Extramural Research
National Institutes of Health
Building 1, Room 114
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Baldwin:

As you requested, we asked COGR member universities that receive substantial funding from HHS for information about their use of royalty returns from intellectual property. The results confirm that relatively few universities derive substantial revenues from royalty returns. They also confirm that universities are reinvesting their share of royalty returns for a wide variety of research and educational purposes, in furtherance of the objectives of the Bayh-Dole Act.

Key points are summarized below, followed by more detailed discussion of the information and data that we received.

Summary

- Institutions reported a wide variety of uses of royalty income. Most frequent uses included research and educational expenses of graduate students, start-up research costs for new or junior faculty, seed money for innovative new projects or initiatives, computer equipment and laboratory facilities renovation.

- A number of universities reported special uses of royalty income including a summer program for female undergraduate students interested in science careers; a technical assistance program providing high technology urban planning and architectural visualization services to inner city communities based on the agricultural extension service model; and a new laboratory building to support the demands of 21st century medical research.

- All the institutions shared royalty revenues received with the inventor(s), consistent with Bayh-Dole Act requirements. Most institutions also distributed a percentage of royalties to the inventor's department and/or research laboratory.

- For all the universities, the percentage of income received from royalties was small as compared to their total federal funding or total sponsored research expenditures. For

at least half of the universities that responded to us, revenues from royalties were low by almost any standard of comparison. For one university, the overall costs of operating its technology management office greatly exceeded its gross royalty revenues. Other responses noted that many universities operate their technology transfer programs at a loss.

- University use of royalty returns is complex and diverse. However, our responses confirm that universities are reinvesting these funds for broad research, education, and associated infrastructure purposes, as contemplated by the Bayh-Dole Act.

Background

We asked COGR member universities for information about the formula used by the university for royalty distribution, the annual university share of royalty income, the uses of royalty income by the university, and any special programs or projects funded by royalty revenues. We received responses from 23 of the top 25 HHS-funded institutions (as identified in the NSF federal funding data for FY99).

It is important to note that these 23 universities do not correspond to the top group of institutions in terms of income received from licensing of intellectual property. In fact, according to the annual licensing survey of the Association of University Technology Managers, Inc. (AUTM), some of them are in the "second 50" in terms of license income received. While some of the universities that responded to us rank very high in the AUTM survey, the overall sample is not biased in terms of the top royalty receiving institutions.

Also of significance is that neither our information nor the AUTM data identify royalty income specifically from drug-related inventions. A substantial amount of the royalties received by the institutions that responded to us may be related to inventions in fields of science and engineering other than the biomedical areas supported by NIH. While universities track and report sponsorship of inventions in accordance with federal requirements, they are not required to separately identify royalty income by individual sponsor, nor is such data reported to AUTM.

The responses we received with regard to distribution of royalty income by the universities and the use(s) made of this income are summarized below.

Distribution Formula

1. All 23 institutions reported that they employed a distribution formula for sharing of the revenues received, consistent with Bayh-Dole Act requirements. The formula varied among the institutions, and in some cases was based on a sliding scale depending on the level of income received. However, in all cases, royalties received from federally-supported inventions were shared between the inventor(s) and the institution, as required by Bayh-Dole. In most cases, a deduction was made from gross revenues to reimburse the university's technology transfer function for direct legal expenses incurred in

patenting or licensing the subject invention. Net revenue then was shared between the inventor and the university, with the university's share reinvested for support of research and education.

2. Most, but not all of the institutions provided us with the specific percentage share paid to the inventor. Most typically, the inventor's share was in the 30-35% range of net income received.

3. The remaining balance of net income was apportioned to the institution. These revenues were redistributed for research and education purposes and for expenses associated with the university's administration of inventions, consistent with the Bayh-Dole guidelines. Most institution formulas provided for distribution of a percentage to the inventor's department and/or research laboratory, and a percentage share to the university. In some cases, the university ultimately returned all or most of its share to the inventor's school, department or laboratory. Some public institutions redistributed a portion of their share to other campuses included in the state university system for research and education purposes. Finally, some institutions allocated a share for administration of the invention or technology management function. Practices varied, with some institutions deducting a portion of gross revenues for this purpose while others allocated a percentage of net.

University Share of Royalty Income

All 23 institutions provided us with data as to royalty income received. However, the data was not provided to us in uniform categories. Some institutions provided us gross revenues only, requiring us to estimate the university share based on the distribution formula used by the institution.

We compared the information provided us with the data reported in the annual AUTM licensing survey. The comparisons presented some difficulties.[1] Nevertheless, in most cases we were able to reconcile the numbers reported to us with the AUTM data reasonably well.

We focused on FY99, since that is the most recent year for which comparable AUTM data are available. It also is the most recent year reported by NSF in its federal funding survey. (It should be noted that the government fiscal year reported by NSF differs from most university fiscal years as reported to us and reflected in the AUTM data). We estimated the total aggregate university share of royalty income received, with payments to inventors and direct legal expenses subtracted; we also subtracted expenses for the administration of the invention or technology management function where paid from gross revenues and not

[1] The AUTM survey reports gross license income received, broken down into several different categories (running royalties, cashed-in equity, and other types). AUTM does not report the distribution of royalty income. In some cases the distributions reported to us by the institutions exceeded the gross income reported to AUTM due to differences in reporting periods (i.e. institutions may distribute in one year income reported to AUTM in a previous year). To fully understand these differences would require much further analysis and comparisons of aggregate data over time, which was beyond the scope of this effort.

allocated as part of the "university share." We estimate that for the 23 reporting institutions, the FY99 aggregate university share was $208,450,000. For the 23 institutions, this averages to a little over $9,000,000 per institution. However, only 6 of the 23 reported university revenue in excess of $9,000,000. If the royalties of these universities are subtracted, the total royalties for the other 17 universities drops to $54,732,000, with an average share of $3,220,000.

We compared the revenues received by the 23 institutions with their total Federal obligations for science and engineering reported in the NSF survey data for FY99. The total Federal funding was $6,620,548,000. The university share of royalty revenue was approximately 3.1% of the total Federal funding. As another comparison, total sponsored research expenditures in FY99 (AUTM survey data, which corresponds more closely to the universities' fiscal years) for these institutions (less several campuses of the University of California, which is reported by AUTM at a consolidated system level) were $7,260,418,000. The university royalty share was approximately 2.6% of total sponsored research expenditures. These percentages would be even lower if the 6 institutions that received more than $9M in royalties were excluded.

These data should be considered preliminary estimates in need of considerably more refinement. However, they do suggest that for most universities, royalty income does not represent a significant source of revenue in comparison with Federal funding or total sponsored research expenditures. It is worth noting that even for the University of California System, which in past years typically has led research universities in terms of royalty income generated by its technology transfer program, the royalty income is small as compared with UC research expenditures. In fact, UC's royalty income is approximately 3% of UC research expenditures, which is comparable to the 2.6% of total sponsored research expenditures noted above for the non-UC institutions.

At least half the universities in our sample do not appear to be deriving substantial revenues from royalty income by almost any standard of comparison. For 10 of the institutions the university share of royalty income in FY99 was below $3M; 2 were in the $3-4M range; and 2 more in the $4-5M range. In fact, one university indicated that the overall costs of operating its technology management office and related legal expenses exceeded its gross revenues by a factor of 3 in FY99. The University of California System in their response to us noted, "...although UC is fortunate to have a long established program that has enjoyed considerable success in shepherding the commercialization of many important technologies, at times many of the UC campuses operate their technology transfer programs at a loss." The latter point was reflected in other institution responses as well.

Where universities are deriving more substantial income from their share of royalties, that success often tends to be associated with one particular invention. Also, there appear to be substantial annual fluctuations in income received. We chose to present FY99 data for the reasons indicated above. We also received data for FY00 from most of the institutions. While some institutions reported considerably higher revenues in FY00, for others the

opposite was the case. One institution reported a court settlement in FY00 which quadrupled its gross income from each of the previous two years. One-time occurrences of this sort can result in very large perturbations in the numbers. For these and the other reasons indicated above, this data needs to be approached with caution. Returns of royalties to universities are neither constant nor predictable.

Uses of Royalty Income

Institutions reported a wide variety of uses of royalty income. At the department level these uses tend to cluster in several areas. Those mentioned most frequently are graduate student research-related expenses (e.g., travel), start-up research costs for new or junior faculty, computer equipment and laboratory facilities renovation. Other uses mentioned in more than one response were guest speakers or visiting scholars, postdoctoral research expenses and incentives for faculty retention.

No institution that responded to us appears to systematically track use of royalty returns at the department or laboratory level. Thus we received no information as to the amounts associated with any particular use. Institutions tend to track use of the university share to a greater extent. However, in many cases a significant amount of the university share is redistributed to the school or department level, so information as to the end use of such revenues also is lacking.

A number of institutions mentioned use of all or part of the university share of royalty returns for intramural research competition. Often a special fund is established for this purpose. These are referred to by a variety of names: "Royalty Research Fund," "Science Development Fund," "University Enrichment Fund," "University Research Foundation or Endowment," "Research Incentive Fund," etc. They tend to be geared to support expenses such as start-up costs for new science faculty, seed money for innovative new projects or initiatives, and research expenses for graduate students and postdocs. A number of these funds also provide for graduate fellowship support. With one exception, we did not receive a specific accounting of these particular uses. [2]

University use of royalty returns clearly is complex and diverse. However, from the responses we received, there seems little doubt that universities are reinvesting these funds in a broad variety of research and educational activities, as contemplated by Bayh-Dole.

[2] The exception is the Wisconsin Alumni Research Foundation (WARF), perhaps the longest-established of these funds. WARF publishes annual reports that provide detailed information on WARF expenditures, both each year and over time. However, a substantial portion of WARF distributions involve non-royalty income (endowment, etc.); the distribution of royalty income is not broken down separately.

Special Uses

A number of institutions reported using royalty income for special programs or initiatives. An example is a department at Vanderbilt University which used some of its royalty money to help support a program called "Women in Science;" a summer program for 4-5 female non-Vanderbilt undergraduate students interested in science careers. The students were placed in university labs and mentored for the summer. The royalty money helped to pay for their housing on campus during this time since few were able to come without some assistance. Columbia University reported a number of special uses of royalty income. These include the Columbia Earth Institute, which seeks to link Columbia's research and educational activities relating to the complex systems of Earth and the urgent need for human action designed to maintain Earth's sustainability, with the activities of like-minded knowledge institutions outside the University; the Digital Media and Information Technology program which comprises a range of activities designed to prepare Columbia to be a national leader in the interactive future; and the Urban Technical Assistance Program, which provides high-technology urban planning and architectural visualization services to neighborhood communities in New York City modeled on the agricultural extension programs of the public land-grant universities. Finally, Yale University has started construction of a new laboratory building to support the demands of 21st century medical research, which has been financed in part by royalty income. The new building will furnish six floors of laboratories for disease oriented research, as well as core research resources and teaching facilities, e.g. a transgenic mouse facility capable of housing up to 74,000 mice, and a new MRI Center. Nine research programs are slated to move into the new building.

Conclusions

There are many limitations to this data, as noted above. It also is important to reiterate that universities are not required to track royalty revenues associated with specific research sponsors. We did not receive any overall data on the share of royalty income associated specifically with NIH-funded inventions. One institution in our sample that has tracked NIH-funded invention royalties is the University of California. In FY99 only 33% of the royalties received by the University of California were derived from inventions associated with NIH-funded research. Our information otherwise does not indicate what percentage of royalties received by a university may be related to NIH support in biomedical areas. In some cases this may represent a substantial portion of revenues; in others the royalties may be more related to information technology or inventions in other fields of science or engineering.[3] The data also do not break out inventions related to support from federal vs. non-federal sponsors.

[3] At one time AUTM did report the proportion of royalties paid for "life sciences" vs. "physical sciences." For universities the life sciences percentage was in the 80% range. However, the AUTM survey no longer breaks down license income by scientific disciplines, apparently at least in part because of difficulties experienced by institutions in breaking down income data this way. Licensing income associated with the life sciences of course is not necessarily related to NIH funding, and could arise from inventions funded totally or in part by industry sponsors.

It also is important to recognize that inventions typically represent the culmination of research conducted over many years, often with the support of multiple sponsors. The primary mission of universities is knowledge, rather than product, creation. For these reasons, it is inherently problematic to attempt to relate specific federal agency investments in university research to returns resulting from that investment in the form of royalties paid on inventions that usually are developed many years later.

Despite the limitations, we believe our data represent reasonable estimates, and that further refinements are unlikely to result in order of magnitude differences. Clearly some universities do much better than others in terms of royalty revenues. For these institutions in particular, we believe our information confirms that the incentives provided by Bayh-Dole are working in the manner intended. Universities are commercializing technology developed with federal support and reinvesting the royalty returns in the research and education enterprise. However, both our information and the AUTM data confirm that relatively few universities are deriving substantial revenues from royalties. The information should help dispel the notion of "windfall profits" being reaped by most universities.

Please let us know if you have questions or would like to discuss any of this information further.

Sincerely,

Katharina Phillips.

Katharina Phillips
President

Cc: Dr. Maria Freire

**Appendix 3.1, 3.2, 3.3**

# United States Public Health Service
# Technology Transfer Manual
# Chapter No. 200

PHS Patent Policy

## A. PURPOSE

This Manual Chapter sets forth policy for the initiation and prosecution of patents on technologies developed in Public Health Service (PHS) laboratories.

## B. BACKGROUND

The primary mission of PHS research laboratories is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. In 1986, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) were given a 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. PHS is cognizant of its role in protecting the public interest as NIH, FDA, and CDC technologies are transferred.

Realization of the considerable anticipated health benefits inherent in PHS conducted and supported biomedical research will depend in large part on the ability and willingness of private sector technology transfer partners to commercialize new technologies. For potential preventive, diagnostic, and therapeutic products, that willingness almost invariably hinges on the existence of patent protection in the United States and foreign countries for the technology in question.

The United States Patent and Trademark Office (PTO) and courts with jurisdiction over patent matters are the only entities that can make a definitive determination in the United States of the patentability of biomedical research discoveries, including human genetic material. Foreign countries similarly determine the scope and subject matter of patent protection within their boundaries. These determinations require a careful analysis of the particular facts and circumstances of each patent application.

Whether or not to file for patent protection on a given technology is a policy decision made at the discretion of the agency in which a Federal employee inventor works. Accordingly, the PHS has established the following policy to guide its agencies in the pursuit and maintenance of U.S. and foreign patent protection for PHS-owned biomedical technology.

## C. POLICY

- The PHS 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. Generally, a patent is necessary to facilitate and attract investment by commercial partners for further research and commercial development of the technology, such as where the utility of the patentable subject matter is as a potential preventive, diagnostic, or therapeutic product. However, a patent also might be necessary to encourage a commercial partner to make available for research use important materials or products.

- Patent protection generally will not be sought by the PHS where further research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic, or preventive uses are not reasonably anticipated. For example, PHS generally will not seek patent protection for commercially valuable research tools (knock-out mice, receptors, cell lines) for the sole purpose of excluding others from using the patentable subject matter without a license. Such materials can be licensed under biological materials licenses or distributed to the research community without further compensation.

- PHS generally will not seek patent protection on a technology unless the commercial or public health value of the technology warrants the expenditure of funds for patenting. If PHS determines that a technology is patentable, but declines to seek patent protection due to low public health or commercial priority, waiver of patent rights to the employee-inventor of the technology may be appropriate and may be considered in accordance with applicable policies and procedures.

- When commercialization and technology transfer can best be accomplished without patent protection, such protection will not be sought. For example, some technologies may be commercialized through non-patent licensing, and some technologies are transferred to the private sector most expeditiously through publication. For those best transferred through publication, patenting and licensing are unnecessary and could inhibit broad dissemination and

application of the technology. Methods of performing surgical procedures, for example, could fall within this category.

- With regard to the patenting of research results arising under a Cooperative Research and Development Agreement (CRADA), PHS will evaluate whether to file for patent protection in accordance with these principles, to the extent consistent with the terms of the CRADA and the collaborative relationship.

- In accordance with 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.

- With regard to the patenting of research results which are in early stages of development, PHS will file for patent protection only on research that has a practical utility or a reasonable expectation of future practical utility. Practical utility for this purpose is based on the reasonable expectation of at least one commercial or public health use that is directly and specifically related to the research results in question. For example, the practical utility of a cDNA sequence is determined according to whether a potential use is directly a consequence of the particular sequence, not a use common to all DNA.

- Once initiated, prosecution of patent applications and maintenance of issued patents will continue only as long as there exists a reasonable expectation of transferring the patent rights to a commercial partner through licensing.

- PHS will enforce and defend its patents, where appropriate, either through its own resources, by granting its licensees the right of enforcement and defense as provided by 35 U.S.C. 207 (a)(2), or by referring the matter directly to the Department of Justice. In any case, no litigation may be undertaken in the Federal Court system without approval of the Department of Justice.

## E. EFFECTIVE DATE

The policies and procedures set forth in this Manual Chapter are effective immediately.

## F. ADDITIONAL INFORMATION

Questions about this Manual Chapter may be directed to Ms. Barbara McGarey, Deputy Director, Office of Technology Transfer, on (301) 496-7057.

# United States Public Health Service
# Technology Transfer Manual
# Chapter No. 300

PHS Licensing Policy

## A. PURPOSE

This Manual Chapter sets forth the policy for licensing technologies developed in Public Health Service (PHS) laboratories.

## B. BACKGROUND

The primary mission of PHS research laboratories is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. In 1986, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) were given a 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. PHS is cognizant of its role in protecting the public interest as NIH, FDA, and CDC technologies are transferred.

Realization of the considerable anticipated health benefits inherent in PHS conducted and supported biomedical research will depend in large part on the ability and willingness of private sector technology transfer partners to commercialize new technologies. For potential preventive, diagnostic, and therapeutic products, that willingness almost invariably hinges on the existence of patent protection in the United States and foreign countries for the technology in question.

## C. POLICY

PHS generally seeks to patent and license biomedical technologies when a patent will facilitate and attract investment by commercial partners for further research and commercial development of the technology. This is critical where the utility of the patentable subject matter is as a potential preventive, diagnostic, or therapeutic product. However, it also could occur when a patent is necessary to encourage a commercial partner to keep important materials or products available for research use.

Patent protection generally is not sought by PHS where further research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic, or preventive uses are not reasonably anticipated. For example, PHS generally will not seek patent protection for research tools, such as transgenic mice, receptors, or cell lines. Such materials can be licensed effectively in the absence of patent protection, under royalty-bearing biological materials licenses, or distributed to the research community through nonroyalty-bearing material transfer agreements. For research tools, the public interest is served primarily by ensuring that the tool is widely available to both academic and commercial scientists to advance further scientific discovery. Secondarily, a financial return to the public is obtained through royalties on the rare research tool that has significant commercial value.

In addition, when commercialization and technology transfer can best be accomplished without patent protection, such protection will not be sought. For example, some technologies may be transferred to the private sector most expeditiously through publication. For such technologies, patenting and licensing are unnecessary and could inhibit broad dissemination and application of the technology. Methods of performing surgical procedures, for example, could fall within this category.

In contrast, for technologies with potential preventive, diagnostic, or therapeutic uses, where some type of exclusivity (and therefore patent protection) is necessary for product development, licensing of the patent rights is the primary vehicle for transferring the technology to commercial partners. Due to the importance of effective patent licensing to the development and availability of new products arising from PHS technology, the PHS licensing program is governed by the following principles in marketing, negotiating, executing, and monitoring licenses to PHS patents:

- PHS seeks to ensure development of each technology for the broadest possible applications, optimizing the number of products developed from PHS technology. This is accomplished first and foremost through diligent assertion of inventorship (and thus ownership) rights to PHS technologies in accordance with current patent law. Second, PHS policy is to retain those ownership rights for transfer to the private sector through licensing instead of assignment. This strategy allows PHS to engage in licensing negotiations which ensure the broadest and most expeditious development of new products. Assignment of rights to the commercialization partner would inhibit the ability of PHS to have a meaningful role in monitoring and ensuring the development of the technology.

- PHS seeks to ensure that a licensee obtains the appropriate scope of rights necessary to develop a potential application of the technology. This ensures that as many companies as possible can obtain commercial development rights, resulting in the concurrent development of many potential applications. This is accomplished through:

  --Negotiating non-exclusive or co-exclusive licenses whenever possible. This allows more than one company to develop products using a particular technology, products which may ultimately compete with each other in the marketplace. PHS recognizes that companies typically need an exclusive market position to offset the risk, time, and expense of developing biomedical diagnostic or therapeutic products, however, companies do not necessarily need to achieve that position by exclusively licensing a government technology used to develop that product. Instead, they frequently are able to add their own proprietary technologies to the technology licensed from the government to ultimately achieve some level of uniqueness and exclusivity for the final product.

  --Negotiating and awarding exclusive licenses for specific indications or fields of use, based on the license applicant's commercial development ability at the time of application. This prevents one company from tying up license rights to applications that could be concurrently developed by another company.

  --Negotiating provisions for mandatory sublicensing by exclusive licensees, particularly where a broad exclusive license is granted, as under a CRADA. CRADA exclusive licenses are granted to patents arising under the CRADA based on the scope of the CRADA research. The research, and therefore the patents, can be broad. Because CRADA partners obtain options to exclusive licenses at the onset of the CRADA, it is usually not appropriate to narrow the field of use to such licenses beyond the original scope of the CRADA research. Thus, PHS requires exclusive licensees to grant sublicenses to broaden the development possibilities when necessary for the public health.

  --Negotiating requirements for continuing availability of the technology for further research. Although a technology has been licensed for commercial development, PHS seeks to maintain the availability of that technology for further research uses only by non-profit and for-profit entities. This advances science and stimulates further commercial development.

- PHS seeks to ensure that commercial partners expeditiously develop the licensed technology. This is accomplished through:

--granting license rights only to fields of use for which the company has submitted an acceptable commercial development plan to bring the technology to practical application. PHS typically does not grant license rights to venture capitalists, brokers, or other entities that are not in a position to develop the technology directly.

--negotiating specific commercial development milestones and benchmarks with proposed licensees so that development can be assessed and monitored;

--negotiating license execution fees, minimum annual royalty payments, milestone payments, and reimbursement of patent expenses in addition to earned royalty payments. Requiring a company to pay royalties "out of pocket" to acquire and keep the technology ensures that a company is committed to developing the technology and has not licensed the technology merely for competitive advantage.

- PHS seeks to ensure that technologies commercialized under PHS licenses are brought to practical application, offered and maintained for sale, and made reasonably accessible to the public. PHS enhances public access to the benefits of its technology by fostering the development of competing products for the same or similar applications. For example, PHS currently has several CRADAs and licenses which combine the significant expertise of its scientists with the knowledge and resources of different private partners for the development of two types of therapy (gene therapy and recombinant enzyme replacement therapy) for an inherited disease. The only therapy currently on the market to treat this disease is an expensive enzyme replacement regimen derived from placental tissue.

- PHS seeks to obtain a fair financial return on the public's research investment through negotiating royalty-bearing licenses and obtaining payment of patent expenses from licensees.

- PHS seeks to negotiate and obtain public benefits from licensees that are appropriate and consistent with expeditious commercial development and accessibility of the technology.

- PHS monitors the performance of PHS licensees and ensures that its licensed technology is fully developed, through the modification or termination of a license in the event that a licensee is unable to fully develop the rights granted. Modifying an exclusive license to a non-exclusive one, or narrowing the fields of use, allows PHS to license the technology to other companies for further development and sale. This is accomplished through:

--Negotiating specific grounds for modification or termination of the license. The PHS model exclusive license specifies nine grounds, including failure to meet commercialization benchmarks, failure to keep the licensed technology reasonably accessible to the public, and failure to reasonably meet unmet health care needs.

--Monitoring the commercial development activities of the licensees to determine compliance with the terms of the license agreement.

--Initiating administrative action to modify or terminate license rights where necessary.

## E. EFFECTIVE DATE

The policies and procedures set forth in this Manual Chapter are effective immediately.

## F. ADDITIONAL INFORMATION

Questions about this Manual Chapter may be directed to Ms. Barbara McGarey, Deputy Director, Office of Technology Transfer, on (301) 496-7057.

## NIH Technology Transfer Mission Statement

The Department of Health and Human Services (DHHS) has designated the National Institutes of Health (NIH) as the lead agency for technology transfer for the Public Health Service (PHS). Within the NIH, the Office of Technology Transfer (OTT) has primary responsibility for technology transfer. This Office evaluates, protects, monitors, and manages the NIH invention portfolio to carry out the mandates of the Federal Technology Transfer Act of 1986. This is largely accomplished through overseeing patent prosecution, negotiating and monitoring licensing agreements, and providing oversight and central policy review of Cooperative Research and Development Agreements. OTT also manages the patent and licensing activities for the Food and Drug Administration (FDA). OTT is responsible for the central development and implementation of technology transfer policies for three research components of the PHS—NIH, FDA, and the Centers for Disease Control and Prevention.

To the extent that current law permits, NIH has made deliberate efforts to return benefit to the taxpayers who support its research. NIH has developed and implemented a number of licensing strategies that balance new product development with appropriate market competition:

1. NIH negotiates non-exclusive or co-exclusive licenses whenever possible, so that more than one company can develop products in competition with one another. In FY 2000, 84 percent of all commercial development licenses executed by the NIH were non-exclusive; these represent the majority of diagnostic and research tool technologies in the NIH portfolio. The remaining 16 percent that were exclusive represent a majority of the therapeutic and vaccine technologies in the NIH portfolio.

2. NIH negotiates exclusive licenses for specific indications or fields of use, based on the license applicant's commercial development ability at the time of application. This prevents one company from tying up license rights to applications that could be concurrently developed by another company.

3. NIH negotiates requirements for continuing availability of the technology for further research. In this way, technologies that are licensed remain accessible to research personnel to advance science and stimulate further commercial development.

4. All NIH licenses can be terminated for failure to comply with the terms of the license, and NIH negotiates specific commercial development milestones and benchmarks with licensees so that development can be assessed and monitored.

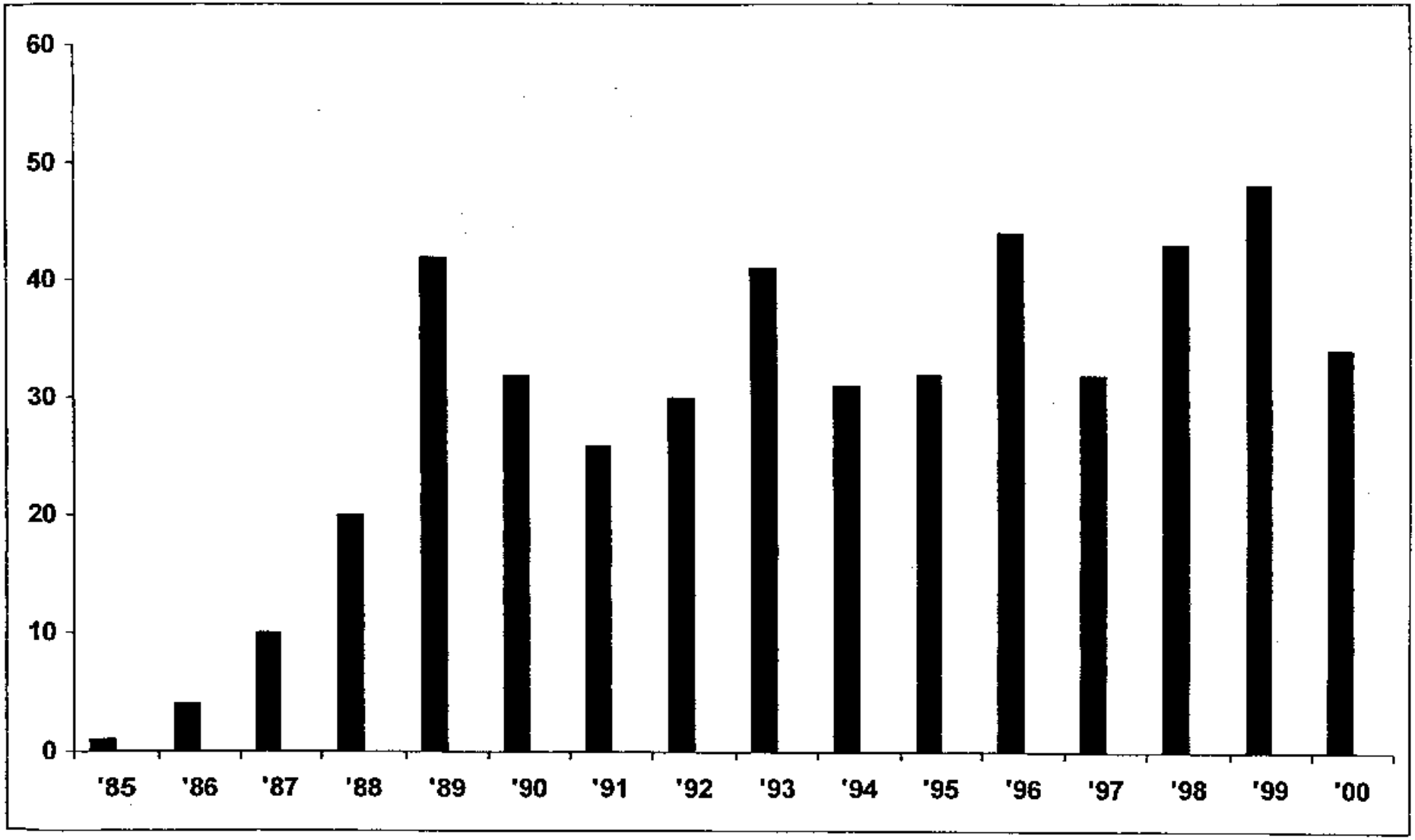
5. NIH does not seek patent protection on a technology for which further research and development is not necessary to realize the technology's primary use. The NIH will seek patent protection for therapeutic, diagnostic or preventive uses and when a technology requires further research and development to bring a technology to practical application.

6. Where a broad exclusive license is granted, NIH negotiates provisions for mandatory sublicensing by exclusive licensees to broaden the development possibilities when necessary for the public health. Some exclusive licenses emanate from Cooperative Research and Development Agreements (CRADA). By law, CRADA partners can obtain an exclusive license to technology developed under a CRADA.

7. NIH includes public benefit provisions in its license agreement, when appropriate, such as a requirement that the drug developer provide a specified amount of the product, if one is commercialized, to indigent populations, or that the company establish a website to provide information on the disease for which the drug is being developed.

# Appendix 4

# NIH Executed Standard CRADAs



# Appendix 5

## List of Groups Consulted

The Council on Governmental Relations (COGR) - an association that develops policies and practices for administering federally sponsored research and training in universities.

The Association of University Technology Managers (AUTM) - an organization representing the technology managers and business executives in universities, research institutions, teaching hospitals, companies and federal agencies.

The Pharmaceutical Research and Manufacturers of America (PhRMA) – an organization that represents the country's leading research-based pharmaceutical and biotechnology companies.

Biotechnology Industry Organization (BIO) – an organization that represents the biotechnology industry.

The Association of American Medical Colleges (AAMC) - a non-profit association founded to work for reform in medical education. The Association now comprises medical schools, academic and professional societies, and the nation's medical students and residents.

The Association of American Universities (AAU) – an organization founded to advance the international standing of U.S. research universities, and representing sixty-three North American public and private universities.

# Appendix 6

# Interagency Edison: A Common Electronic Way to Meet Statutory Reporting Requirements Across The Government

## A Business Case for the Edison System

Passage of the Bayh-Dole Act in 1980 resulted in statutory regulations that mandate reporting by award recipients of all inventions and patents derived through federal funding agreements: grants, cooperative agreements, and contracts. Every year, NIH-sponsored research yields thousands of inventions, such as biological agents, new drugs, laboratory equipment, and scientific processes. Some grantee/contractor organizations may have a single invention to report in a year, while others, such as large research universities, may have several hundred each year. The need to accurately receive and track reports for such subject inventions was emphasized in a Congressional inquiry held in August, 1994. Observations by Congress were followed by a report from the Office of Inspector General, DHHS issued that year, entitled, "NIH Oversight of Extramural Research Inventions." The report recommended a timely and decisive move to redefine the level of responsibility on the part of NIH for overseeing grantee/contractor compliance with Federal regulations concerning invention reporting and utilization. In response to the Inspector General's recommendations, the NIH Office of Policy for Extramural Research Administration moved to provide grantee/contractor organizations with a more accessible and efficient mechanism for submitting and tracking information about inventions and patents derived from NIH support.

The mechanism chosen to meet this need was unveiled in 1995 as "Edison", an interactive Web site for reporting, monitoring, and tracking inventions derived from federally-funded research. Specifically, Edison is a relational database system from which either representatives of extramural grantee/contractor organizations or federal agency staff can create, access, and modify records in a common file. Submission and monitoring of information in the Edison system permits grantee/contractor organizations to comply electronically with mandated invention reporting requirements.

## Edison System Technology and Adoption by the Extramural Community

When introduced, Edison was one of the first innovative government systems to use interactive web technology to support the exchange of confidential information. Its use of the Internet as a platform avoided compatibility obstacles inherent in proprietary software design, and also provided accessibility for diverse populations of grantee/contractor institutions that include start-up companies with single users via public Internet providers as well as research institutions and for-profit corporate contractors.

As a system responsible for the submission and tracking of invention and patent information, confidentiality was a critical element in Edison's design. Institutions are required to register, and individual user accounts provide for authenticated sessions. Use of either of the most

popular Internet browsers, Netscape Navigator™ or Microsoft Internet Explorer™, ensures that information being transmitted remains confidential by the use of encryption technology. Unauthorized access to secondary screens in the Edison system is prevented by session-specific transient internal passwords that are completely transparent to the user.

From its introduction, grantee/contractor organizations have increasingly opted to use the Edison system. By the beginning of 2001, nearly 300 institutions have registered to use Edison. Given the fact that only a fraction of the approximately 2,000 grantee/contractor institutions ever develop inventive technologies from their research, projections suggest that the institutions now using Edison constitute more than 90 percent of prospective routine users.

## Interagency Edison – A Government-Wide Invention Reporting System

Statutory regulations require the reporting of inventions derived through funding agreements with any federal agency. The desire to achieve a uniform reporting system throughout government suggested the use of the Edison system as a common gateway whereby grantee/contractors could submit reports to any agency through a single site.

In 1997, this vision was first realized through the addition of the National Science Foundation (NSF) to the Edison system. A separate database was established and, by simply identifying either NIH or NSF as the source of funding for inventive technologies, all reported information was routed into the appropriate database. With this expansion, the system renamed "Interagency Edison", and a high level Internet domain name, http://iedison.gov, was granted by the General Services Administration. This single gateway concept has been well received by the NIH and NSF grantee/contractor community as has now been adopted by 14 federal agencies whose grantees/contractors develop inventive technologies. NIH continues to support maintenance and operations of the overall system without charge to the other agencies.

Interagency Edison has now become the model for a similar distributed computing approach that is being pursued for electronic grants administration across the federal government in the "Federal Commons" initiative. The unqualified success of the Interagency Edison system has been demonstrated through its enthusiastic support by grantee/contractors and federal agencies. Use of the system has been estimated to reduce as many as 15 cycles of paper correspondence to an almost completely electronic business process, while setting a standard for meeting government-wide requirements through a single site. In recognition of meeting these objectives, the Edison system was recognized as a semi-finalist for the National Information Infrastructure Awards in 1996, and the design team received a prestigious Golden Hammer Award from Vice President Gore's National Performance Review in 1997.

# Appendix 7

# LIST OF THERAPEUTIC DRUGS

| # | NAME | US SALES | CHEMICAL | COMPANY | USE | APP_DATE |
|---|---|---|---|---|---|---|
| 1. | PRILOSEC | 4,183,490 | Omeprazole | AstraZeneca Plc. | Ulcers | 02/14/88 |
| 2 | LIPITOR | 2,997,636 | Atorvastin calcium | Warner Lambert & Pfizer Inc. | Hypercholesterolemia | 12/17/96 |
| 3 | PROZAC | 2,567,168 | Flupxetine hydrocloride | Eli Lilly & Co. | Depression | 12/29/87 |
| 4 | PREVACID | 2,360,649 | Lansoprazole | Tap Holdings Inc. | Ulcers | 05/10/95 |
| 5 | ZOCOR | 2,298,527 | Simvastatin | Merck & Co. | Hypercholesterolemia | 12/23/91 |
| 6 | EPOGEN | 1,834,434 | Epoetin alfa | Amgen Inc. | Anemia | 06/01/89 |
| 7 | ZOLOFT | 1,735,380 | Sertalle hydrocloride | Pfizer Inc. | Depression | 12/30/91 |
| 8 | CLARITIN | 1,531,361 | Loretadine | Schering-Plough Corp. | Allergic rhinitis | 04/12/93 |
| 9 | PAXIL | 1,512,677 | Paroxetine hydrocloroe | SmithKline Beecham Plc. | Depression | 12/29/92 |
| 10 | ZYPREXA | 1,491,700 | Olanzapine | Eli Lilly & Co. | Schizophrenia | 09/30/96 |
| 11 | NORVASC | 1,480,924 | Amlodipine besylate | Pfizer Inc. | Hypertension | 07/31/92 |
| 12 | CELEBREX | 1,416,229 | Celecoxib | Pharmacia Corp. & Pfizer Inc. | Osteoarthritis & rheumatoid arthritis | 12/31/98 |
| 13 | GLUCOPHAGE | 1,316,193 | Metformin hydrocloride | Bristol-Myers Squibb Co. | Type 2 diabetes | 12/29/94 |
| 14 | PROCRIT | 1,260,499 | Epoetin alfa | Johnson & Johnson | Anemia | 12/31/90 |
| 15 | PRAVACHOL | 1,179,812 | Pravastatin sodium | Bristol-Myers Squibb Co. | Hypercholesterolemia | 10/31/91 |
| 16 | AUGMENTIN | 1,162,217 | Amoxicillin & clavulante potassium | SmithKline Beecham Plc. | Bacterial infections | 08/06/84 |
| 17 | PREMARIN | 1,080,221 | Conjugated estrogens | American Home Products Corp. | Vasomotor symptoms associated with menopause | 1942 |
| 18 | RISPERDAL | 1,034,431 | Risperidone | Johnson & Johnson | Schizophrenia | 12/29/93 |
| 19 | NEUPOGEN (SORBITOL) | 991,462 | Filgrastim | Amgen Inc. | Neutropenia | 02/21/91 |
| 20 | IMITREX | 946,531 | Sumatriptan succinate | Glaxo Wellcome Plc. | Migraine | 12/28/92 |
| 21 | CIPRO | 920,261 | Ciprofloxacin hydrocloride | Bayer AG | Bacterial infections | 10/22/87 |
| 22 | VASOTEC | 852,012 | Enalapril maleate | Merck & Co. | Hypertension | 12/24/85 |
| 23 | NEURONTIN | 851,361 | Gabapentin | Warner-Lambert Co. | Epilepsy | 12/29/93 |
| 24 | TAXOL SEMI-SYN | 846,487 | Paclitaxel | Bristol-Myers Squibb Co. | Ovarian cancer & AIDS-related Kaposi's sarcoma | 12/29/92 |
| 25 | REZULIN | 772,723 | Troglitazone | Warner-Lambert Co. & Sankyo Parke Davis | Type 2 diabetes | 01/29/97 |
| 26 | DEPAKOTE | 746,796 | Divalproex sodium | Abbott Laboratories | Bipolar disorder, seizures, & migraine | 03/10/83 |
| 27 | CARDIZEM CD | 732,396 | Diltiazem hydrocloride | Aventis SA | Angina | 11/05/82 |
| 28 | ZESTRIL | 724,059 | Lisinopril | AstraZeneca Plc. | Hypertension | 12/30/87 |
| 29 | PEPCID | 719,949 | Famotidine | Merck & Co. | Ulcers | 10/15/86 |
| 30 | ZITHROMAX Z-PAK | 712,605 | Azithromycin | Pfizer Inc. | Bacterial infections | 11/04/91 |
| 31 | BIAXIN | 693,578 | Clarithromycin | Abbott Laboratories | Bacterial infections | 10/31/91 |
| 32 | FOSAMAX | 671,466 | Alendronate sodium | Merck & Co. | Osteoporosis | 12/29/95 |
| 33 | VIAGRA | 666,695 | Sildenafil citrate | Pfizer Inc. | Erectile dysfunction | 03/27/98 |
| 34 | PROCARDIA | 626,492 | Nifedipine | Pfizer Inc. | Hypertension & angina | 09/06/89 |
| 35 | AMBIEN | 613,503 | Zolpidem tartrate | Searle | Chronic Insomnia | 12/16/92 |
| 36 | PREMPRO | 610,189 | Conjugated estrogens | American Home Products Corp. | Vasomotor symptoms associated with menopause | 1942 |
| 37 | OXYCONTIN | 602,605 | Oxycodone hydrocloride | Purdue Pharma LP | Pain reliever | 12/12/95 |
| 38 | BUSPAR | 591,899 | Buspirone hydrocloride | Bristol-Myers Squibb Co | Anxiety disorders | 09/29/96 |
| 39 | WELLBUTRIN | 583,343 | Bupropion hydrocloride | Glaxo Wellcome Plc. | Depression | 10/04/96 |
| 40 | ZYRTEC | 580,245 | Cetirizine hydrocloride | Pfizer Inc. | Allergic rhinitis & chronic idiopathic urticaria | 12/08/95 |
| 41 | PROPULSID | 558,172 | Cisapride | Johnson & Johnson | Gastroesophageal reflux disease | 07/29/93 |
| 42 | ROCEPHIN | 556,707 | Sterile ceftriaxone sodium | F. Hoffman-La Roche Ltd. | Bacterial infections | 12/21/84 |
| 43 | ALLEGRA | 553,099 | Fexofenadine hydrocloride | Aventis SA | Allergic rhinitis | 07/25/96 |
| 44 | REBETRON | 547,799 | Ribavirin & interferon alfa-2b, recombinant | Schering-Plough Corp. | Hepatitis C | 07/03/98 |
| 45 | HYTRIN | 540,693 | Terazosin hydrocloride | Abbott Laboratories | Benign prostatic hypertrophy and hypertension | 08/07/87 |
| 46 | LEVAQUIN | 533,554 | Levofloxacin | Johnson RW | Bacterial infections | 12/20/96 |
| 47 | ZOFRAN | 532,752 | Ondansetron hydrocloride | Glaxo Wellcome Plc. | Nausea and vomiting | 01/04/91 |

# Appendix 8

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
2450 N STREET, NW, WASHINGTON, DC 20037-1127
PHONE 202-828-0400 FAX 202-828-1125
HTTP://WWW.AAMC.ORG

**Congressional Directive to NIH for "Return on Investment"**

The conference report to appropriations legislation funding the National Institutes of Health and other agencies in FY 2001 contained the following language:

> The conferees have been made aware of the public interest in securing an appropriate return on the NIH investment in basic research. The conferees are also aware of the mounting concern over the cost to patients of therapeutic drugs. By July 2001, based on a list of such therapeutic drugs which are FDA approved, have reached $500,000,000 per year in sales in the United States, and have received NIH funding, NIH will prepare a plan to ensure that taxpayers' interests are protected.[1]

This language reflects a compromise to an amendment introduced by Sen. Ron Wyden (D-Oregon) on June 23, 2000[2] and proposals by Sen. Paul Wellstone (D-Minn.) and Rep. Bernie Sanders (I-Vermont) relating to "reasonable pricing" of pharmaceuticals. NIH is expected to complete its directive in July.

According to the NIH Office of Technology Transfer, 47 FDA-approved therapeutic drugs under patent currently generate U.S. sales of more than $500 million annually. In discussions with Congress, the NIH has agreed to draft a plan that focuses on the "return on investment" of public funding supporting drug development.

NIH-funded research has generated thousands of patents held by universities and other institutions.[3] Only *one* of the 47 FDA-approved drugs identified as generating $500 million or more in sales has been determined by NIH to be derived directly from a patent generated by NIH-funded research. Although several more "blockbuster" drugs from patents issued on NIH-sponsored research may soon become available, the agency is currently developing its plan on the basis of the single major-selling drug developed from a university-held patent. The specifics of the NIH plan under development are as yet uncertain.

**Background:** Sen. Wyden's original amendment proposed to require, "as a condition of receiving a grant or contract from the National Institutes of Health," assurance from an academic institution or other entity to transfer to the NIH director a percentage of funds made available from licenses or sales of a broad range of pharmaceuticals. Assumedly,

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[1] Report 106-1033, Conference Report to accompany H.R. 4577, Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 2001. December 15, 2000.
[2] See Appendix 1, attached.
[3] See NIH Office of Technology Transfer and "Edison" database, http://www.iedison.gov/.

the requirement was presented as a "pay-back" for the original NIH research grant or contract awards. The threshold of $500 million in annual sales applied to "any pharmaceutical, pharmaceutical compound or drug delivery mechanism (including biologics and vaccines) approved by the Food and Drug Administration" resulting from an award.

The Conference Report language is the latest in a series of Congressional actions touching on concerns about the price of pharmaceuticals derived in part from publicly funded research. An earlier initiative, the reasonable pricing clause, focused directly upon industry partnerships under NIH Cooperative Research and Development Agreements (CRADAs). In the 1990s, expressions of interest from industry in NIH CRADAs plunged following introduction of the reasonable pricing clause, and the clause was subsequently rescinded.

The sentiments reflected in the conference report were articulated by the new chair of the subcommittee overseeing NIH appropriations:

> The Senate Labor/HHS appropriations subcommittee [May 23, 2001] held a hearing on the NIH budget. During the session, ranking member (and soon to be chairman) Tom Harkin (D-IA) asked about the support NIH had provided for research on a new anti-leukemia drug, Gleevec, which the Food and Drug Administration approved two weeks ago. National Cancer Institute director Rick Klausner responded that NIH had made grants totaling $4 million for specific work on the drug, and that much of the underlying research--which went back decades--had also been supported by NIH. Harkin responded that the cost of this drug to consumers was $2,000 to $3,000 a month, and said he "wondered about the pricing, and about re-capturing some of the costs." "We need to figure this one out, how to get some of the money to come back to NIH," he said. "This is an issue that will be coming down the road."[4]

**Analysis:** The conference language contravenes several prevailing and critical aspects of federal science and technology policy, including the Bayh-Dole Act and related legislation. To promote the dissemination of useful knowledge, federal policy has generally sought to encourage academic institutions receiving federal research awards to transfer technology arising from this research to the private sector through licensing arrangements or other agreements.

The vast majority of the NIH's extramural research is performed by academic institutions (more than $12 billion in FY 2001) and published and broadly disseminated without monetary returns to the institutions or to NIH. However, federal statutes (the Bayh-Dole, Stevenson-Wydler, and other Acts) and policies direct academic and other non-profit awardee institutions, where advisable, to seek patents on inventions arising from federally sponsored research in order to catalyze commercial development.

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[4] Reported by the American Association of Universities, AAU CPR Update 01-#96, May 24, 2001.

The origin of the Bayh-Dole Act (P.L. 96-517) arose from concerns of the 1960s and 1970s that many potential research products were "lying fallow" in academic institutions because of a lack of sufficient incentive for commercializing research inventions. Moreover, the Federal policies on patenting and licensing of sponsored research at that time relied greatly on non-exclusive licensing and other conditions that further discouraged partnerships with private sector firms. In order to encourage more efficient transfer of technology from federal research grants to broad public or commercial application, the Bayh-Dole Act of 1980 permits academic institutions to retain rights and title to inventions produced under federally sponsored research without seeking prior approval from federal agencies. With passage of the Bayh-Dole Act, patents issued to universities and other non-profit institutions have risen from fewer than 250 in 1980 to more than 2000 annually.[5] Many of the patents generated with federal support are attributable to NIH research.

Many commentators attribute the Bayh-Dole Act's remarkable success to its explicit promulgation of incentives for academic and other non-profit institutions to pursue commercial licensing of inventions arising from research. In fact, such incentives had existed prior to passage of the act. The significance of Bayh-Dole was that it required federal research awardees to pursue the application of their research into products and practice, and it removed the federal government as a party to negotiations. The act thereby encouraged commercial entities and venture capitalists to negotiate licensing arrangements with academic institutions without fear of federal intercession.[6]

The Bayh-Dole Act's key objective, as stated in its preamble (35 USC § 200), is to encourage dissemination and utilization of technology. The act does not seek to promote a commercial return to federal agencies or academic institutions on research investment.

In fact, while the number of patents issued to universities and other non-profit institutions has increased dramatically since passage of the act, the great majority of these patents do not generate significant revenues or even sufficient revenues to compensate the patenting expenses.[7] The information contained in these patents nevertheless remains publicly available within the records of the U.S. Patent and Trademark Office. The conference report language, by focusing on the rare (<1:1000) sub-class of university-owned patents that are commercially successful, does not take into consideration the great number of patents obtained by universities at their own risk and expense that never succeed commercially. Further, the act requires institutions to reinvest licensing income back into research, which the institutions do. The conference language's direction to NIH runs contrary to the express intentions of Bayh-Dole and would represent a major departure from prevailing federal policy.

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[5] AUTM survey.

[6] Testimony of Howard Bremer, Ph.D., October 25, 1993. From Council on Governmental Relations, Washington DC.

[7] See, for the example of one major research institution, Katherin Ku, Effect of Patenting and Technology Transfer on Commercialization, presentation to the National Academies, April 17, 2001. Available at: http://www.nationalacademies.org/ip, accessed June 8, 2001.

There is currently a substantial return on investment from NIH and other federally funded biomedical and scientific research.

The fundamental rationale of federal science policy since the end of World War II has been to invest tax dollars in basic research to promote the societal returns of improved health, strengthened national security, and enhanced economic performance. This has been the central argument advanced in the Congress for funding NIH and other science agencies, and has been echoed by the advocacy community:

> Federal support for basic science is an aspect of spending that has a payback, and a massive one at that. It puts money out and gets back new products, healthier people and cash....significantly increasing our federal investment in basic medical and scientific research will pay handsome dividends in the 21st Century.[8]

In the 1950s, economist Robert Solow demonstrated that more than half of the U.S. annual growth in GNP was attributable to new technologies and new knowledge, as opposed to increases in land, labor, or other "traditional" capital inputs.[9] Solow, a Nobel laureate and MIT faculty member, believed that university-based research along with industry R&D was a substantial component of this growth. The relationship of academic research with industrial innovation and prosperity was further established by Edwin Mansfield,[10] Nathan Rosenberg and Richard Nelson[11], and numerous other leading economists. Joseph Stiglitz, serving on the President's Council of Economic Advisors, reported estimates of a social rate of return on federally funded research between 25% and 50% annually. He summarized his views to the National Science Board: "Advances in knowledge are essential to spurring economic growth. There are only a few things that economists really agree upon, and this is one of them."[12]

Improvements to health from medical and other research have been documented in numerous ways. Many of these have focused on case studies of the role of (primarily basic) academic research leading to development of specific products or therapies[13,14] In studies of health outcomes, the demographer Kenneth Manton and colleagues have measured declining rates of disability and generally improved quality of life indicators among older Americans, which directly correlate with innovations from biomedical research.[15] Improved levels of day-to-day functioning of older Americans have welcome

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[8] Peter Lynch, financial analyst, quoted in Exceptional Returns: the Economic Value of America's Investment in Medical Research. Funding First, Washington, DC, May 2000.

[9] Solow has produced numerous reviews of this "growth accounting" research, including, Technical change, capital formation and economic growth. American Economic Review, 1962; 52:76-86.

[10] Mansfield E. Academic research and industrial innovation, Research Policy 1991: 1-12.

[11] Rosenberg N, Nelson RR. American universities and technical advance in industry. Research Policy 1994; 23: 323-348.

[12] Transcript of National Science Board meeting, open session, March 23, 1995.

[13] Comroe JH, Dripps RD. The top ten clinical advances in cardiovascular-pulmonary medicine and surgery. Final report, January 31, 1977. NIH NHLBI contract 1-HO-1-2327.

[14] Dustin HP, Roccella EJ, Garrison HG. Controlling hypertension: a research success story. Archives of Internal Medicine, 1996;156:1926-35.

[15] Manton KG., Corder KS, Stallard E. Monitoring changes in the health of the U.S. elderly population: correlates with biomedical research and clinical innovations. FASEB Journal, 1997; 11:923-930.

implications for the financial burden of care placed on families and federal programs, such as Medicare.[16] These studies do not purport to measure speculative "cost savings" from specific innovations in medical care resulting from medical research; they do demonstrate significant improvements in health care correlated with biomedical research.

Americans widely recognize the generative effects of academic research on the electronic and computer science industries, as seen in Silicon Valley, Boston's I-128 corridor, and North Carolina's Research Triangle. Similarly, federal investments in biomedical research, which led directly to the development of the biotechnology industry, are reflected in the geographic concentration of biotechnology firms near leading biomedical research centers in the San Francisco Bay area, Southern California, New England, Maryland, and elsewhere. The growth of high technology industries near universities and research centers is the result of interactions with leading academic scientists, ideas, and pools of university trained personnel.[17] Comparatively little, if any, of the commercial value of these enterprises remunerates universities directly. Rather, these industries provide a foundation for job creation, economic growth, and improved quality-of-life that are highly prized by state and local governments and their Congressional delegations.

The annual survey of the Association of University Technology Managers (AUTM) reports that licensing by member academic institutions (including major teaching hospitals) "contributed over $40 billion in economic activity and supported more than 270,000 jobs in fiscal year 1999."[18] *They estimate this activity to have generated $5 billion in U.S. tax revenues for federal, state, and local government.* More than 60% of licenses and option agreements by AUTM members were made to small businesses, which are leading sources of job growth and economic development.

**Summary:** the AAMC objects to the conference report language on the grounds that it proposes to tax a rare source of unrestricted university revenues. These revenues are reinvested in basic research and training to help pay for the infrastructure necessary to be a competitive research institution, and to help support the significant cost-sharing that federal research funding presently obligates.[19]

The conference report's language is unwise policy. American taxpayers currently receive an extraordinary return on their investment in biomedical and other scientific research, through a system of governmental, academic, and industrial interaction that other nations are struggling to emulate. The historic success of these policies, together with new scientific opportunities and public health needs, are the basis of our advocacy for an expanded NIH budget and support of other federal science agencies.

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[16] Ibid.

[17] For an analysis of the role of "star scientists" in biotechnology, see Zucker LG, Darby MR. The economists' case for biomedical research, in The Future of Biomedical Research. Washington, DC: American Enterprise Institute, 1997.

[18] AUTM Licensing Survey: FY 1999, Survey Summary.

[19] See also Appendix 2, editorial by Donald Kennedy in Science, June 8, 2001.

**Recommendations:**

- The AAMC, working closely with the university and research community, should reaffirm the nation's commitment to existing federal science policies, which yield substantial returns to society on public investment in research and development.

- The AAMC should oppose any proposal to redirect institutions' income in a manner other than that already required by the Bayh-Dole Act and current regulation.

## Appendix 1: Original Wyden Amendment

WYDEN AMENDMENT NO. 3616 -- (Senate - June 23, 2000)

[Page: S5750]

(Ordered to lie on the table.)

Mr. WYDEN submitted an amendment intended to be proposed by him to the bill, H.R. 4577, supra; as follows:

On page 33, line 16, strike the period and insert the following: ``: Provided further, That the Director of the National Institutes of Health shall ensure, with respect to funds appropriated under this Act, that--

``(1) an entity that receives a grant or contract, made available with the appropriated funds by the National Institutes of Health, to conduct research shall provide the Director, at intervals of time determined appropriate by the Director, with information relating to--

``(A) any pharmaceutical, pharmaceutical compound or drug delivery mechanism (including biologics and vaccines) approved by the Food and Drug Administration that is manufactured from a technology that--

``(i) is developed, in whole or in part, using the results of such research; and

``(ii) has been licensed, sold or transferred by the grantee or contractor to an organization for manufacturing purposes;

``(B) the utilization of each such technology that has been licensed, sold or transferred to another entity;

``(C) the amount of royalties, other payments, or other forms of reimbursement collected by the grantee or contractor with respect to the license, sale or transfer of each such technology; and

``(D) the aggregate amount of the specific grants or contracts that were used in the development of such transferred technology.

``(2) an annual report is prepared and submitted to the appropriate committees of Congress that contains a summary of the information provided to the Director under paragraph (1) for the period for which the report is being prepared;

``(3)(A) as a condition of receiving a grant or contract from the National Institutes of Health to conduct research, an entity shall provide assurances to the Director that such entity will, as a part of any agreement that is entered into by the entity to license, sell, or

transfer any technology that is developed, in whole or in part, using the results of such research, require the repayment by the licensee, purchaser, or transferee (or the entity if the entity is using the technology in a manner described in this subparagraph) to the Director of an amount (determined under subparagraph (B)) of the funds made available through the grants or contracts as reported by the entity under paragraph (1)(D), if the licensee, purchaser, or transferee uses the technology to manufacture a pharmaceutical, pharmaceutical compound, or drug delivery mechanism (including biologics and vaccines) that is approved by the Food and Drug Administration;

''(B) the amount of the funds made available through the grant or contract to be repaid under subparagraph (A) shall be determined according to a fee schedule that--

''(i) is established by the Director; and

''(ii) shall ensure that--

''(I) the amount is based on a percentage of the net sales of the pharmaceutical, pharmaceutical compound, or drug delivery mechanism (including biologics and vaccines) that is referred to in subparagraph (A); and

''(II) the aggregate amount is limited to the aggregate amount of the funds made available through the grants or contracts involved; and

''(C) the amount described in subparagraph (B) shall be repaid to the Director, who shall deposit any such amount in an account and distribute funds from the account to the various offices of the National Institutes of Health for research conducted by the various offices, according to the scientific merit presented by the research projects involved; and

''(4)(A) with respect to an entity that is required to repay funds under paragraph (3), if the net sales of the pharmaceutical, pharmaceutical compound, or drug delivery mechanism (including biologics and vaccines) involved exceed $500,000,000 (or the increased or decreased amount determined under subparagraph (B)) in any calendar year, the entity shall pay to the Director (as a return on the investment made by the Director through the grant or contract involved) for

[Page: S5751]

such year an amount equal to 1 percent of the amount by which such net sales exceed $500,000,000 (or such increased or decreased amount) in such year; and

''(B) the $500,000,000 amount referred to in subparagraph (A) shall be increased or decreased, for each calendar year that ends after December 31, 2000, by the same percentage as the percentage by which the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from the Index for September of 2000."

## Appendix 2: Editorial from *Science*, June 8, 2001

### Drug Prices: Real Problem, Wrong Solution

Donald Kennedy

Drug pricing has been an important political issue, off and on, ever since the Kefauver hearings in the late 1950s, and it now reappears in a strange disguise. After several failed efforts at passing "reasonable pricing" legislative amendments, Congress now will be asked to consider targeting--guess what?--not the drug companies, but U.S. research universities. Senator Ron Wyden (D-OR) has introduced language instructing the National Institutes of Health (NIH) to submit to Congress a plan whereby, if a drug produces half a billion dollars or more in sales and was developed from NIH-supported work in universities, the government should recover some of the profits. That would undercut a long-standing government policy that encourages technology transfer and has produced a rich harvest of innovation.

The concern is easy to understand: Drug pricing now threatens to block medical rescue for some of the world's most afflicted people. The African AIDS epidemic has awakened consciences across the developed world. Some of the promising but costly therapies were developed from basic research conducted at universities, which own patents on the discoveries and have been collecting royalties from commercial licensees. Angry students at Yale and Minnesota have been protesting those payments, and their anguish is understandable: To have workable but unaffordable therapies for this disease is difficult to accept. Thus, intense political scrutiny has been focused on the universities as well as the drug companies.

Just as hard legal cases can make bad law, emerging crises often make bad policies. Senator Wyden wants to attack the problem by reaching for the most available handle--the universities. His approach rests on persuasive-sounding logic: NIH has made substantial investments in basic research in universities; that research has led to successful drugs developed by pharmaceutical companies; and universities are receiving large royalty payments in return. All of this is true and reflects exactly what was intended by the Bayh-Dole Amendments in 1980. That legislation permitted universities to develop intellectual property protection for their inventions even when federal funding supported the work, thus encouraging the transfer of inventions to commercial developers. As university technology licensing offices become more sophisticated at negotiating terms with industry, royalty revenue streams have become large enough to attract political attention, although they contribute only trivially to a drug's price.

Does that mean that the government should get some of that revenue back? That's what Wyden thinks. Leaving NIH some room to be creative, he has offered two different recoupment proposals. One would have NIH receive some fraction of each royalty stream--in effect, garnishing the payments to the university. The other would require that

universities return the value of the grant that led to the product. The agency now must develop a response, due in July 2001, telling Congress what it proposes to do.

NIH and its congressional overseers should consider two problems. One is practical: The scientific and economic history of innovation tells us that its trajectory is tortuous and often obscure. To demonstrate that one particular grant gave rise to a discovery that in turn enabled the development of a specific drug will not be easy. The second is economic: Long before Bayh-Dole (indeed, back when Vannevar Bush presided over the conversion of military research into the plowshare of basic academic work), it was understood that the role of federal funding was to promote discoveries that would then attract the risk capital necessary for subsequent product development. The public would then benefit not only from the products themselves but also from the new employment and tax revenue they would generate.

Before Congress contemplates such a radical reformulation of Bayh-Dole, it should conduct a careful study of the present returns to the government from past basic research support. The guess here is that such an analysis will demonstrate that the economic benefits are very large indeed. If that is true, it would be a serious policy error to risk diminishing the incentives for technology transfer in order to divert some of the same income that helps support further university research. If the eggs really are golden, why punish the goose? As for the universities, they might think again about whether it's wise to press for continued royalty payments on real "blockbuster" drugs, especially those serving the most vulnerable populations. Sometimes it's politically wiser to let enough be enough.

Volume 292, Number 5523, Issue of 8 Jun 2001, p. 1797.

# Appendix 9

BIO
BIOTECHNOLOGY INDUSTRY ORGANIZATION

June 11, 2001

Maria Freire, Ph.D.
Director
Science & Technology
Office of Intramural Research
National Institutes of Health
6011 Executive Blvd., Suite 325
Rockville, MD 20852-3804

Dear Dr. Freire: Maria

Thank you for taking the time to meet with several representatives of Biotechnology Industry Organization (BIO) and its companies regarding the report to Congress on appropriate return on investment as requested in last year's Appropriations conference report. BIO believes that the National Institutes of Health and its Office of Technology Transfer have done a remarkable job of achieving their mission and providing the taxpayers the kind of return on investment they expect and deserve.

Dealing with government agencies can be frustrating, but we find that for all the requirements faced by the Office of Technology Transfer (OTT), you and your agency are extremely adept and competent in licensing technologies and negotiating CRADAs with our companies. While speeding up the process would provide incentives to our industry to do more, we recognize the larger public interest you must consider. OTT's serious and energetic approach to licensing has been successful in achieving its ultimate mission of improving public health.

This leads us directly to point one: NIH is a government agency, not a business. Its mission is to serve the broader public good, not conduct research for profit. The fact that you license technologies and negotiate CRADAs as an equal partner to industry is a tribute to your abilities, experience and commitment to protecting the public interest.

If monetary income is not the purpose of NIH and your office, then an appropriate return on investment needs to be measured in parameters other than dollars returned to NIH. First and foremost, the basic science performed and supported by NIH leads to greater scientific knowledge throughout the world. This, in turn, leads to additional research, both NIH-sponsored and private. This research yields lifesaving therapeutics and diagnostics -- an unequivocal appropriate return on investment.

Another clear return on investment is that the scientific training provided by the NIH leads to the development of the best scientists in the world. The United States is the

1625 K STREET, N.W., SUITE 1100
WASHINGTON, D.C. 20006-1604
202-857-0244
FAX 202-857-0237
http://www.bio.org

cradle of scientific research. NIH scientists and scientists who have had the benefit of NIH funding for research play a part in driving the economy.

According to the 1999 Ernst and Young report, the biotech industry employed 162,000 people and paid nearly $10 billion in taxes, including income, corporate and other federal, state and local taxes. This thriving segment of our modern economy provides a myriad of returns to the taxpayers for their generous and forward thinking-investment in basic medical research.

The biotechnology industry continues to lose $5.1 billion per year. Of nearly 1,500 companies, only 15 currently have profitable biologics on the market. We continue to be a high-risk long-term investment. NIH and university licensed research is still "early stage" research with no guarantee of success. As a result, companies can risk only limited investments in licensed science and technologies. If fees or royalty requirements increase, companies must demand greater returns, given the risk.

Some companies look to license research tools rather than technologies that could lead directly to FDA-approved prescription biologics. These tools can provide a method or a portion of the process for discovering or producing a therapy, but are not a part of the treatment itself. They are not guaranteed to be successful. Thus, many of NIH's licensable technologies cannot be expected to result in sizable monetary returns. NIH has established a policy that research tools should be made as widely available as possible so that as many researchers as possible can take advantage of the NIH investment. NIH has made the determination, consistent with its mission, that a public health benefit will be derived from wide distribution of its research tools.

Licensing fees for these tools, or for any technology, does provide NIH with a direct monetary return on its investment. The negotiations for these licensing agreements ensure an appropriate return because your office does not sign an agreement without appropriate licensing and royalty clauses. Likewise, if the licensing and royalty requirements were too harsh, companies would walk away from the deal. The fact that you are licensing technology and negotiating a substantial number of CRADAs shows you are able to balance a monetary return to NIH with the public need to transfer the technology for applied research in order to achieve the ultimate goal of improved treatments and public health.

Similarly, the public good is served through the licensing accomplished by universities. Bayh/Dole agreements have been very successful at transferring the NIH-supported research to the private sector for applied research. These agreements, like the CRADAs, are high-risk investments for private companies and often do not pan out. Several universities have done well with the royalties paid by companies that have had success. This has provided the incentive for greater activity in attempting to forge such agreements. Not only is the science developed further, which may lead to new products,

agreements. Not only is the science developed further, which may lead to new products, but a portion of the fees and royalties paid to universities gets turned back into additional research, giving a double "bang" for the appropriated "buck."

Companies paid $390 million in royalties and $725 million in license fees to U.S. universities on nearly 7,500 licenses/options in 1998 (according to AUTM FY 98 Survey Summary). The NIH received $52 million in royalties in 1999. Our companies believe that these payments provide a rate of return to the government comparable to the rate of return on technology transferred between and among companies.

There is no standard "royalty" built into technology, Bayh/Dole or CRADA licenses. The science licensed is often at different stages. The earlier the stage the greater the risk to the company, and therefore the lower the royalty. No one can predict which idea will lead to a blockbuster drug. There is no clause stipulating that if the license leads to failure the private sector will receive a refund. This is the risk of the marketplace. In fact, of all CRADAs, only one has led to a product with greater than $500 million in sales per year. This one drug had many unique factors in leading up to the CRADA and development, including some clinical trials done by NIH. Yet even here, there continued to be a risk of failure as the company pursued additional clinical trials.

For one drug to be approved by the FDA, a company typically needs to screen between 5,000 and 10,000 compounds. Of those, an average 250 lead to pre-clinical testing. Only about 5 of these make it to clinical testing, and with 80% passing Phase I, another 30% pass Phase II and then another 80% pass Phase III clinical testing. Each stage of research and development is high risk and has even higher costs. Even if companies could license potential compounds that had completed Phase II clinical trials, there would continue to be substantial risk of failure. Additionally, Phase III clinical trials are associated with the highest costs.

Negotiating licenses and royalties is a part of establishing a business relationship and negotiating a business transaction. The government should not establish pre-set royalty fees. If such fee schedules are established, and companies find them burdensome, it will only drive away companies from transferring the technology generated by NIH grants, thereby reducing the rate of return to the general public on the NIH research.

Establishing a royalty for a blockbuster drug is questionable, too, because "blockbuster" status is so rare. Should the percent go up or down? With university agreements it varies. Should a percentage be set aside for indigent care instead? Most universities and all companies with FDA-approved products already provide for this. Setting aside a portion of the blockbuster drug for this purpose could offset the "out-of-pocket" expenses already being set aside for indigent care.

In summary, entities that obtain licenses to further develop technology initially supported by NIH currently pay licensing fees to initiate such research and often pay royalties on sales when and if the entities obtain FDA approval. Additional remuneration comes to the federal government via taxable income on sales of such products. More importantly, the public and taxpayers see the best return on investment through improved patient care obtained through advances in drug and biologic development. Long-term effects of breakthroughs in drug and biologic development also improve the quality of life and enable individuals to maintain participation in the labor force, thereby contributing to Federal and state tax revenues.

We understand why Congress has inquired about an appropriate return on investment in NIH. All taxpayers, individual and corporate, want to know that their tax dollars are being spent wisely and achieving the public good for which they were collected. In fact, this issue can be raised about all of the research and development done or supported by government, whether it be the airline industry, the high-tech internet or communications industries, or NASA and the aerospace industry.

Finally, we refer you to the May 2000 report from the Office of the Chairman of the Joint Economic Committee entitled, "The Benefits of Medical Research and the Role of NIH." The Executive Summary states, "Publicly funded research in general generates high rates of return to the economy, averaging 25 to 40 percent a year." This Congressional report clearly defines the purpose of NIH and its valuable return on investment. NIH needs to be evaluated as a whole, not just by the results of the OTT and not on any single division or department. In short, Congress has answered its own question; the taxpayer receives an appropriate return.

We believe that the investment in NIH and scientific research has achieved every goal Congress could have desired. Our industry has been spurred by that investment and we are proud to give back so much in potential public health outcomes as well as what we return to the economy in general.

Sincerely,

Carl B. Feldbaum
President
Biotechnology Industry Organization

CBF:mbl

# Appendix 10

Alan F. Holmer
PRESIDENT AND CHIEF EXECUTIVE OFFICER

PhRMA

July 3, 2001

Maria Freire, Ph.D.
Director
Science & Technology
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804

Dear Dr. Freire:

The history of biomedical science in the Twentieth Century is one of remarkable accomplishments and advances in the treatment of many diseases and conditions. A major role in these developments has been the collaborations between NIH intramural researchers and their colleagues in the innovative pharmaceutical companies of America. The Congress and Administrations of both political parties have consistently encouraged these collaborations. Virtually all policy makers in the past two decades have recognized the fundamental truth that the maximum benefit to the American people is the creation of increased scientific knowledge and its rapid dissemination through commercial products developed by the private sector.

We appreciate the singular contributions to the public health and welfare made by you and your colleagues at the Department of Health and Human Services and the National Institutes of Health. The partnership between our industry and the NIH has well served the interests of the American people.

Recently, some concern has been expressed about whether the Federal government is obtaining optimal benefits from technology transfer with respect to certain pharmaceutical products. This letter will attempt to respond to that concern by analyzing it in its discrete elements.

There are two different types of research undertaken using NIH funding; intramural and extramural. With respect to the research undertaken at the NIH by NIH researchers, the record is clear and unequivocal. The NIH leads the Federal government – and indeed the world – in the commercialization of its research

product. Your office has consistently negotiated with the private sector to advance the interests of patients. You have sought to secure licensing terms that are comparable to commercial arrangements when such arrangements are appropriate. You have also sought to advance both scientific knowledge and patient benefits when non-exclusive licenses are appropriate in platform technologies.

With respect to the extramural research funded by the NIH, that work is generally designed to advance the level of understanding of basic scientific questions. According to one major university system, these grants rarely produce patentable and licensable technologies. It is not common for these licenses to produce substantial royalty or other income. Thus, as tempting as it might appear to seek return of a portion of the NIH funds, such a proposal would likely be extremely difficult to implement and could ultimately cause significant harm to universities and their research programs.

Current practice of technology transfer between universities and the private sector has worked remarkably well. It has helped to create dramatic new industries in the life sciences including biotechnology, genomics, and bioinformatics. These technology transfers have played a central role in stimulating the growth of economic clusters in Silicon Valley, the Route 128 corridor, Houston, Texas, and Research Triangle Park, North Carolina. Imposing new hurdles to this kind of technology transfer will likely stifle those developments.

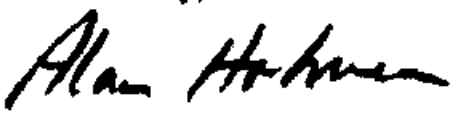
We respectfully suggest two measures that could increase the transparency of licensing arrangements. First, we suggest that the NIH provide some additional data in the annual report to the Congress and the public in order to outline the success you have had in securing positive results in technology transfer. Specifically, this report could detail the manner in which you negotiate and obtain licenses on commercially viable terms. In addition, the report could focus on the criteria you apply in determining when and whether to seek an exclusive or nonexclusive license. Finally, the report could provide a comprehensive assessment of the public health and socio-economic benefits of technology transfer.

Second, with respect to extramural research, we recognize that there is a need to have the grantees comply with the terms of the Bayh Dole Act of 1980 and to utilize the funds that they receive for scientific and educational purposes. The reports you have received from the academic community indicate the richness and variation of uses of royalty or licensing income for public health purposes. One impediment to meaningful evaluation of this process, however, is the lack of comprehensive data. Much of the information about the licensing practices of universities is not immediately transparent, nor are the uses of the funds derived from royalties or licensing as clear as possible. There are two

steps that could improve this situation. The NIH Director could convene a conference of affected parties that would permit compilation of a better set of data on these issues. Such a conference could also permit universities to learn from each other the best practices in place at sister institutions. In addition, we recommend that the pending Institute of Medicine Study of the Future of Academic Health Centers be asked to look at the role of technology transfer as part of its mandate.

In sum, we appreciate the partnership we have enjoyed with the NIH and its grantees. We believe that this partnership has produced tremendous public health benefits. We stand ready and willing to work with you and your colleagues to further advance the interests of patients and economic development by improving the technology transfer process.

Sincerely,



Alan F. Holmer