

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Report to Congress on
Affordability of Inventions and Products

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Affordability of Inventions and Products

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Affordability of Inventions and Products

Executive Summary

In Section 218 of the Conference Report on H.R. 2673, Consolidated Appropriations Act 2004, the Committee on Appropriations requested that the National Institutes of Health (NIH) prepare and submit a report addressing the affordability of inventions and products developed with Federal funds. The following is submitted in response to the request.

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. The goals of the agency are as follows: 1) foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to advance significantly the Nation's capacity to protect and improve health; 2) develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease; 3) expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and 4) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

The NIH recognizes the importance of finding an equitable solution to the issue of affordability of inventions and products. However, any role it might assume in the affordability discourse would, of necessity, be limited by the fact that the Federal Government has rights in only a very small number of commercialized products and inventions. It is also important to consider the effect of taking any actions that might result in fewer new products that might improve public health reaching the market.

The NIH contributes to the affordability of inventions and products by conducting and funding medical research that may eventually lead to the development of new drugs and devices and, ultimately, significant improvements in human health and the quality of life.

Introduction

In Section 218 of the Conference Report on H.R. 2673, Consolidated Appropriations Act 2004, the Committee on Appropriations stated:

SEC. 218. Not later than 90 days after the date of enactment of this Act, the Director of the National Institutes of Health shall submit to the appropriate committees of Congress a report that shall--

- (1) Contain the recommendations of the Director concerning the role of the National Institutes of Health in promoting the affordability of inventions and products developed with Federal funds; and
- (2) Specify whether any circumstances exist to prevent the Director from promoting the affordability of inventions and products developed with Federal funds.

This report addresses the issues contained in the legislative committee request. While the report requests the NIH Director to address the role of the NIH in promoting the affordability of inventions and products developed with Federal funds, we are, of course, only in a position to address inventions funded by our agency.

Recommendations of the NIH Director Regarding the Affordability of Products Made Using Federally Funded Inventions

The NIH Director believes that the optimal approach that the NIH can legitimately pursue in promoting the affordability of inventions and products developed with NIH funds is through the conduct and support of outstanding health-related research relevant to the American people. The NIH was established with the mission of science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. In those instances when such research leads to a novel technology, it is the role of the NIH and recipients of NIH funds to disseminate the research findings and, as appropriate, pursue further development to bring technologies to practical application to benefit the public.

The NIH has a role to play in the early-stage development of technologies that are later brought to market by its licensees or commercial collaborators. The final product, whether it is a therapeutic, a diagnostic, or a medical device, is often the result of a host of discoveries contributed over the years by numerous university, government, or commercial laboratories. The NIH typically contributes to the understanding of basic and clinical biology (such as the pathogenesis of a disease, the immunological or genetic processes associated with a disease, etc.) that helps in guiding translational research toward producing a cure or therapy. NIH investigators often create research tools that are used in the path to drug discovery by private industry.

Even in those few cases in which an NIH-invented technology is an identifiable part of a final product, the invention would typically be one of numerous components that would go into building that product. Such invention components may range from a novel method of administering the prescription drug to an active ingredient combined with other compounds to make the final drug. A good analogy would be that of an automobile, where different components are invented and manufactured by a variety of entities. Just as the provider of any one component of an automobile cannot dictate the cost of the final vehicle, the provider of a single technology in the development of a therapeutic drug cannot dictate the final cost of the drug.

The research supported and conducted by the NIH is sometimes mischaracterized as necessarily resulting in the commercialization of drug products. In truth, much of NIH funding supports the exploration of fundamental biological mechanisms that would otherwise not be pursued due to the lack of market incentives. Such research can lead to early-stage findings and provide clues that may eventually lead to medical advancements for diseases for which existing methods of therapy are nonexistent, inefficient, or suitable only for a select population. For example, original research on hormones conducted in the 1960s uncovered the mechanism by which a specific protein, the G-protein, allowed cells to signal each other. Building upon those early studies, researchers discovered that bacterial and viral agents cause disease by acting on G-proteins and, as a result, G-proteins are now the target of 65 percent of all prescription drugs invented primarily, if not entirely, by the commercial sector.

Any possible NIH role in the affordability debate would be limited strictly to the small fraction of commercialized products developed with Federal funds. The July 2003 GAO Report to Congressional Committees entitled "Technology Transfer Agencies' Rights to Federally Sponsored Biomedical Inventions" found that of the top 100 pharmaceuticals procured by the Department of Veterans Affairs in fiscal year 2001, only five implicated Government rights. Additionally, of the top 100 pharmaceuticals dispensed by the Department of Defense between July 1, 2001 and June 30, 2002, only three had active Government rights.

About one-third of the NIH grants awarded support a robust clinical research program. The NIH Roadmap for medical research in the 21st century, announced in September 2003 (<http://nihroadmap.nih.gov/>), includes plans for enhancing the manner in which NIH conducts and supports research leading to improvements in public health. For example, the plan for "Re-engineering the Clinical Research Enterprise" is designed to build a stronger clinical research infrastructure that facilitates the translation of basic research to clinical application, including the development of technologies to improve the assessment of clinical outcomes. Another goal is to work within the Federal system of clinical research oversight to promote coordination of policies, requirements, and procedures concerning clinical research and, where appropriate, to help create streamlined approaches. (Also see Dr. Zerhouni's testimony to the Subcommittee on Health of the Committee on

Energy and Commerce, House of Representatives, March 25, 2004; and Zerhouni, E.: The NIH Roadmap, *Science*, Vol. 302, pp. 64, 72, October 3, 2003). Other efforts include collaborations between the NIH and the Food and Drug Administration to facilitate the development and use of better cancer treatments including efforts to reduce the time it takes for promising new drugs to be reviewed for testing in clinical trials (see the National Cancer Institute's press release of November 12, 2003, <http://www.nci.nih.gov/newscenter/pressreleases/FriendsFDANCI>).

Overall improvements in efficiency and time and reduction in risk to industry in bringing drugs to the marketplace should result in not only new and better drugs for the American public but also permit industry to price the drugs lower than they would otherwise.

Circumstances Preventing the Director from Promoting the Affordability of Products Developed Using Federally Funded Inventions

The Bayh-Dole Act (Public Law 96-517) and the Stevenson-Wydler Technology Innovation Act (Public Law 96-480), as amended by the Federal Technology Transfer Act of 1986, provide the statutory framework and authority for federally funded technology transfer operations. The former addressed the barriers to the development and commercialization of federally funded inventions, while the latter established the basic Federal technology policies. Neither provided the NIH with the legislative authority to specify commercialization terms in the agreements of its grantees and contractors.

The cost of prescription drugs is a legitimate public concern that exists whether or not a drug was developed from a technology arising from federally funded research. NIH, however, has neither the mandate nor the authority to be the arbiter of drug affordability.

It is the mission of the NIH to advance research with the goal of improving public health (42 U.S.C. § 281). The NIH focuses on support of research, training, and health information dissemination and other programs associated with a particular NIH Institute's specific mission (42 U.S.C. § 285), consistent with Department of Health and Human Services authority for conducting research and investigations (42 U.S.C. § 241). NIH's legislative authority, however, does not extend to the affordability of products (42 U.S.C. §§ 281-282).

Central to both Stevenson-Wydler and Bayh-Dole was the concept of using the patent system as an incentive to private industry to participate in the further research and development needed to bring early-stage Federal innovations to practical application in the marketplace. Responsibility for managing intellectual property rights, as well as the rewards derived from their commercialization, was provided to funding recipients under Bayh-Dole.

Bayh-Dole permits only limited oversight of technology transfer operations by the funding agency. For example, the NIH must approve assignment of ownership to third parties or foreign manufacture of products for use in the United States (35 U.S.C. § 202(c)(7) and 35 U.S.C. § 204, respectively). Should a critical public health emergency arise, the NIH may require mandatory licensing or sublicensing if it determines that a technology is not being moved to practical application (35 U.S.C. § 203). Bayh-Dole, however, does not provide authority for the NIH to control the pricing of products resulting from inventions made by funding recipients.

Affordability of health inventions and products is a relative term involving numerous interactive market forces including accessibility, intellectual property rights, and insurance reimbursement options. Affordability is a function of the individual person's ability to bear the cost of a particular drug. Many companies, therefore, have indigent patient programs to supply drugs to some patients on a discounted or no cost basis, thereby making them affordable to those patients.

In fact, the issue of drug affordability is often a matter of access. Access to drugs and vaccines, etc., may be influenced by a number of factors. For example, generic versions of drugs that have passed the term of patent protection are almost always cheaper than the original. Furthermore, drugs purchased from wholesalers are less expensive than those from retailers and distributors. Adding to this complexity are the vagaries operative in reimbursement and insurance mechanisms that may affect the accessibility and, hence, the perception of affordability of a therapy.

A case in point is that of Synagis® used to treat Respiratory Syncytial Virus (RSV) infections, particularly in children (<http://ott.od.nih.gov/newpages/techdev.pdf>). This therapeutic was developed in part from an NIH technology. Prior to the arrival of this therapeutic in the market, the most effective treatment available against RSV required a hospital stay. Synagis® now provides a solution in the doctor's office at a total cost much less than the cost for hospitalization. The actual out-of-pocket cost to the patient in obtaining this in-house treatment, however, is higher than the cost of hospitalization. This is due to insurance reimbursement policies that require the patient to pay a portion of the total cost for this in-office treatment, while little or no cost is incurred by the patient in the case of hospitalization. As this example illustrates, the issues surrounding the affordability of drugs and therapeutics are very complex and beyond the scope of the authority of the NIH.

In the July 2001 NIH report entitled "A Plan to Ensure Taxpayers' Interests Are Protected," the issue of "reasonable pricing" of federally funded inventions was discussed in depth. As part of the evaluation done for the report, a special panel was convened that included scientists and administrators from government, industry, academia, and patient advocacy groups. The panel concluded that the descending hierarchy of importance of return on public investment in NIH research should be fostering scientific discoveries, rapid development of technologies as

effective therapeutics, accessibility of resulting products to patients and, lastly, royalties. The report also described the "chilling effect" that the imposition of requirements for price controls had on collaborations between NIH and industry and came to the conclusion that such price controls were, in fact, contrary to the tenets of the Bayh-Dole Act.

Conclusion

Although establishing standards for the affordability of drugs and therapies is beyond the agency's mission or authority, the NIH contributes to affordability through research that leads to the development of a wider selection of drugs or new drugs, where no drugs were available. More alternatives can translate into more choices for the public, greater market competition, affordability and, ultimately, overall return to society by the improvement of the quality of life. Thus, as long as NIH continues to focus on its core mandate, namely conducting and funding broad-based research that could lead to the development of new drugs and therapies in the future, we believe that the NIH is acting as a responsible partner in the national enterprise to improve the quality of life for the public and to make drugs more affordable.