NIH: MOVING RESEARCH FROM THE BENCH TO THE BEDSIDE

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BEFORE THE

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mechanisms underlying disease, and design and develop therapeutic strategies for treating and preventing disease.

Mr. BILIRAKIS. Thank you very much, Dr. Lindberg. And, of course, there will be questions, and so you will have that opportunity.

Dr. Rohrbaugh, please proceed, sir.

STATEMENT OF MARK L. ROHRBAUGH

Mr. ROHRBAUGH. Chairman Bilirakis and members of the subcommittee, I am pleased to present to you a synopsis of NIH technology transfer activities both within the National Institutes of Health and at institutions receiving NIH funds.

First, I would like to speak to the NIH mission, which is to uncover new knowledge that will lead to better health for everyone. In furtherance of this mission, we conduct our technology transfer activities with the following goals in mind—to expand fundamental knowledge about the nature and behavior of living systems; to improve and develop strategies for the diagnosis, treatment, and prevention of disease; and to communicate the results of research to the scientific community and the public at large with the goal of improving public health.

One of the greatest challenges to realizing the promise of the NIH mission is the ability to translate basic research findings into drugs and therapies for patients. Translating a new drug discovery from the laboratory to an initial clinical evaluation in patients requires navigation of a multi-step review process involving several critical implementation issues over the course of 6 to 10 years.

This "bench to bedside" pathway often begins with the transfer of an early stage technology developed in the course of federally funded research to a private sector partner. While this is but one step in a lengthy and expensive process, it is often the step that jump starts the development of a new therapeutic product.

The overwhelming majority of the NIH budget—over 80 percent—is devoted to the support of scientists at approximately 1,700 organizations. This is what is known as our extramural program. A much smaller portion of our budget—slightly less than 10 percent—supports research and training conducted by the Federal scientists at NIH facilities. This is known as our intramural research program. I believe it is important to make this distinction while discussing technology transfer activities, because these two areas are governed by different legislative authorities.

In its broadest sense, technology transfer is the movement of information and technologies from research findings to practical application, whether for further research purposes or commercial products. At the NIH, we transfer technology through publications of research results, exchange of data, sharing materials, public-private partnerships, as well as the patenting and licensing of technologies.

The NIH Office of Technology Transfer administers over 1,500 active licenses and approximately 2,400 patents and patent applications. In fiscal year 2002, we received more than $51 million in royalties from licensees. This accounts for about two-thirds of the royalties collected by all Federal laboratories combined.

About 200 products have reached the market that include technologies licensed from the NIH; 17 of these are vaccines and therapeutics. We view these products as the best and ultimate measure of our success in facilitating the transfer of technologies that the private sector develops into products that benefit the public health.

This leads me to a brief discussion of the Bayh-Dole Act of 1980, which applies to recipients of Federal funds. As you mentioned, Mr. Chairman, the Act provides incentives to move federally funded inventions to the private sector where they benefit the public. With a few exceptions, the legislation does not prescribe methods to be used in the licensing of these inventions, but the institutions must agree to pursue practical application of inventions, and to provide the U.S. Government with a royalty-free right to use the inventions for government purposes.

That Federal Government right does not extend from the federally funded technology to the final product, except in those rare cases where the technology is the final product. Moreover, this government right applies only to the patent—that is, the intellectual property—not to the materials themselves that constitute the physical embodiment of the invention. In most cases, a federally funded technology is combined with other intellectual property or know-how, often proprietary to a company, to develop the final product.

NIH-funded technology is usually at the earliest stage of development and requires much further investment to bring the technology to the marketplace. Thus, technology transfer is a high-risk venture, and few inventions ultimately result in products that reach the marketplace, yet the NIH has been fortunate in having a number of its technologies licensed and incorporated into methods of making, administering, or as components of new products.

In summary, the field of technology transfer facilitates the movement of research findings to promote further research or to develop them further into products of use to the public. It is through our statutory framework, unique institutions, and public-private partnerships that the Nation has created the most envied research enterprise in the world.

I can assure you, Mr. Chairman, and members of the subcommittee, that the NIH is committed to its mission of improvement of public health and will utilize all of the mechanisms it has to achieve this mission.

I thank you for the opportunity to come before you today, and I welcome any questions you may have.

[The prepared statement of Mark L. Rohrbaugh follows:]

PREPARED STATEMENT OF MARK L. ROHRBAUGH, DIRECTOR, OFFICE OF TECHNOLOGY TRANSFER, OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chairman Bilirakis and Members of the Subcommittee, I am pleased to present to you a synopsis of NIH technology transfer activities both within the National Institutes of Health (NIH) and at institutions receiving NIH funds. I would also like to refer the Subcommittee to a report developed by the NIH, with input from patient advocacy groups, academia, and industry, on ensuring that the taxpayers' interests are protected. This report, titled "A Plan to Ensure Taxpayers' Interests are Protected," was submitted to the Senate Appropriations Committee in July 2001 and provides excellent background information on the nature of Government-funded research and drug discovery, the history of Federal agency technology transfer legislation, including the Bayh-Dole Act, and the ways in which the NIH ensures that the American taxpayers benefit from our technology transfer activities.

First, I would like to speak to the NIH mission, which is to uncover new knowledge that will lead to better health for everyone. In furtherance of this mission, we conduct our technology transfer activities with the following goals in mind: (1) to expand fundamental knowledge about the nature and behavior of living systems; (2) to improve and develop strategies for the diagnosis, treatment, and prevention of disease; and (3) to communicate the results of research to the scientific community and the public at large with the goal of improving public health.

One of the greatest challenges to realizing the promise of the NIH mission is the ability to translate basic research findings into drugs and therapies for patients. Translating a new discovery from the laboratory to an initial clinical evaluation in patients requires navigation of a multi-step review process involving several critical implementation issues over the course of six to ten years. These include issues relating to preclinical efficacy evaluation, drug production, preclinical safety assessment, regulatory documentation and approval, protocol design and approval, and a range of logistical issues regarding execution of the trial itself. This "bench to bedside" pathway often begins with the transfer of an early-stage technology developed in the course of federally-funded research to a private-sector partner. While this is but one step in a lengthy and expensive process, it is often the step that "jump-starts" the development of a new therapeutic product.

Our success in meeting the goals of our technology transfer activities depends on the ability to disseminate and share research findings with the research community and, when possible, to transfer findings into research and diagnostic tools and devices, and to assist in the development of therapeutic drugs and vaccines. Despite the lengthy and expensive process to bring research findings to use by the research community and the public, the NIH and federally-funded institutions have been able to bring new technologies forward to enhance the research enterprise and public health. This is due in part to the enactment of legislation to overcome a number of the issues that hampered research and development and the licensing of federally funded technologies for further development into products. Prior to the passage of the Bayh-Dole Act in 1980, many inventions arising out of government research sat on the shelf and were never commercialized into products to treat patients. Since 1980, these incentives have paved the way for the development of many new drugs, vaccines, and medical devices. These activities have also stimulated economic development and the creation of new jobs in the United States. My remarks will provide you with several examples of NIH technologies that have been of benefit to public health, and other speakers will be able to enumerate the successes they have been able to produce with Federal research funds.

The overwhelming majority of the NIH budget, over 80%, is devoted to the support of more than 200,000 scientists and their collaborators in the extramural research community who are affiliated with approximately 1700 organizations, including universities, medical schools, hospitals, and other non-profit and for-profit research facilities located in all 50 states, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and points abroad. This is what is known as our extramural program. A much smaller portion of our budget, slightly less than 10%, supports research and training conducted by Federal scientists at NIH facilities. This is known as our intramural research program. I believe it is important to make this distinction when discussing technology transfer activities, because these two areas are governed by different legislative authorities.

In its broadest sense, technology transfer is the movement of information and technologies from research findings to practical application, whether for further research purposes or commercial products. At the NIH we transfer technology through publications of research results, exchange of data, sharing of materials, public-private partnerships, as well as patenting and licensing technologies. Technologies licensed from the NIH include the HIV Test Kit, marketed by several companies including Abbott; Videx (ddI), marketed by Bristol-Myers Squibb for the treatment of HIV/AIDS; Vitravene, marketed by Isis Pharmaceuticals for the treatment of cytomegalovirus infections of the eye and the first product of its class; Zenapax, manufactured by Hoffman La Roche for the treatment of non-Hodgkin's lymphoma and the first radioimmunotherapy to be approved; and Fludara, marked by Berlex as a treatment for chronic lymphocytic leukemia (CLL).

I direct the central technology transfer office at the NIH, which is located in the NIH's Office of the Director. Our responsibilities can be viewed as twofold. First, we are responsible for the identification, evaluation, protection, marketing, and licensing of technologies arising out of NIH laboratories to achieve the agency's mission. As a part of that activity, we monitor our licensees' progress and collect royalties from licensed technologies. Secondly, we provide policy direction to the agency and to scientists and administrators receiving NIH funding. We also represent the Department of Health and Human Services on technology transfer matters. Other

technology transfer transactions, such as the negotiation of agreements to transfer materials and collaborations with private institutions, are conducted by technology transfer staff who are employed by the individual Institutes and Centers at NIH.

The activities of the Office of Technology Transfer are carried out by a well-qualified staff and supported by contractors, including 11 patent law firms. Members of our professional staff generally have at least one advanced degree, such as Ph.D., J.D., or M.B.A., and many have more than one advanced degree. Our staff administers over 1500 active licenses and approximately 2,400 patents/patent applications. In Fiscal Year 2002, we had 331 Employee Invention Disclosures, 173 patent applications filed in the United States, and 88 patents issued, and we executed 231 license agreements.

While we have these metrics as outputs of our activity, we have initiated through the GPRA process the development of a new metric to measure the ultimate outcomes of our activities. We have developed a system of case studies for technologies developed at the NIH and licensed to private sector partners for further development and commercialization. To date, we have completed two case studies: Havrix, the first vaccine against Hepatitis A; and Synagis, a therapeutic for a lower respiratory tract infection in infants and small children. This new metric provides a more complete view of the technology transfer process by providing a time line for the development of a technology into a final product, a description of the respective roles of the NIH and its private sector partner, and the impact of that new product on public health. It is that final measure that, we believe, provides the best indicator of success, since it addresses the NIH mission to improve public health. We expect to have three additional studies on our web site by the end of the calendar year, and we will be contracting for support to accelerate this process for all of products and materials that have reached the market utilizing at least in part technologies licensed from the NIH.

NIH intramural research technology transfer activities, as is the case for all federal research and development technology transfer activities, are governed by the Stevenson Wydler Act, the Federal Technology Transfer Act, and subsequent legislation. The original legislation was enacted in 1980 as part of an economic stimulation package for the U.S. economy. The legislation calls for the Federal laboratories to review their research findings to determine if they constitute new inventions, whether patent protection should be sought, and finally to use mechanisms such as licensing to move these new technologies to the private sector for further development and commercialization.

Our license agreements provide rights to use NIH technologies in return for royalty fees and, in the case of commercialization licenses, a commitment to bring the technology to the market. Fees are assessed usually on an annual basis throughout the term of the license or when certain milestones are reached. When a product reaches the market, our licenses call for a negotiated percentage of sales to be paid to the NIH. We have been able to generate strong returns from licensing activities. In Fiscal Year 2002, NIH generated $51M in royalty income. That amount represented about two-thirds of the royalty income generated by all the Federal laboratories combined. Over the past 9 years, we have generated over $325M in royalty income. By law, we pay a prescribed portion of royalty income to inventors, and the remainder of royalty income is used for technology transfer activities and for further research.

Our licensing policies, including the manner in which we grant licenses and structure the terms of those agreements, are also designed to promote the overall mission of the NIH. Exclusive licenses, which constitute a small portion of our total license portfolio, are granted when necessary as an incentive for a company to invest in the high-risk, long-term commercial development of a particular technology. While our statutory authorities for licensing inventions prescribe the conditions under which we can grant exclusive licenses, we go a step further in ensuring that exclusive licenses encourage the broadest development of new technologies for the public good. For example, the scope of a license to a single technology with broad applicability is usually limited to include only those aspects of the technology the company intends to develop and demonstrates the capability to develop. Thus, multiple aspects of a single technology may be exclusively licensed to multiple parties. For example, a technology for treating a variety of cancers might be licensed to one company for lung cancer therapeutics and to another for liver and pancreatic cancer therapeutics. In addition, we require licensees to provide a plan to ensure the rapid development of the technology. Our monitoring group has post-licensure responsibilities to ensure that the company reasonably complies with these terms.

This leads me to a brief discussion of the Bayh-Dole Act, which applies to recipients of Federal funds. This 1980 Act brought about a major change in governmental operations by permitting institutions receiving Federal funding for research and de-

velopment, as grantees and contractors, to retain title to any invention developed with the use of Federal funds. Prior to this time, title to these inventions generally reverted to the U.S. Government, where they rarely were moved to the private sector and thus did not benefit the public.

In return for the right to hold title to inventions developed with Federal funding, institutions agree to pursue practical application of those inventions and to provide the U.S. Government with a royalty-free right to use the invention for Government purposes. That Federal Government right does not extend from the federally-funded technology to the final product, except in those rare cases where the technology is a final product. Moreover, this Government license right applies to only the patent, that is, the intellectual property, not the tangible property that constitutes the physical embodiment of the invention.

The legislation did not prescribe methods to be used in the licensing of those inventions, with a few exceptions. Institutions electing title are required to give preference to small, U.S. businesses in licensing their technologies; exclusive licensees are required to manufacture their product substantially within the US when a product is to be used or sold in the US; licensing terms should not encumber future research and discovery; and non-profit organizations must obtain Government approval to assign title to third parties.

In most instances, NIH-funded technology, both in our intramural and extramural activities, is at the very early stage of development and requires much further research and development to bring the technology to the marketplace. The discovery may be a basic research finding without any animal testing or human clinical trials, a method for making or using a material, or a material that is only a part of the total technology that must be brought together to create a new product. As early stage technologies, they are highly risky projects for anyone to pursue and require a great deal of time and money to bring them to fruition. The closer a technology is to the marketplace, the lower the risk and cost to the licensee, and the more valuable the technology from a royalty standpoint.

However, in both academia and Federal laboratories, technology transfer is a high-risk venture, and few inventions ultimately result in products that reach the marketplace. The NIH has been fortunate in having a number of its technologies licensed and incorporated into the process of manufacturing, administering, or as one of the ingredients in making new prescription drugs, therapeutics, and vaccines. In most cases, a federally-funded technology is combined with other intellectual property or know how, often proprietary to a company, to develop a final product.

Due to the regulatory requirements on technologies that involve products used in humans, the development of biomedical technologies may take from 7 to 10 years to reach the market, if it ever reaches the market due to a high failure rate. This makes the biomedical technology development process expensive and risky.

The NIH has been quite successful in its pursuit of technology transfer activities and is viewed by many as one of the premier biomedical technology transfer operations in the world. We are pleased to report that NIH technologies have been licensed as part of the development of 17 prescription drugs and vaccines approved by the FDA. Again, we have not developed the final products; our technology is only a part of the process for making or administering the product or ingredients incorporated in the product. Overall, about 200 products are sold utilizing, at least in part, technologies licensed from the NIH.

I would also like to bring to your attention our biomedical research resources policy, known as our Research Tools policy. It is an important part of NIH's role to serve as a provider of technical assistance to NIH and recipient institution scientists and administrators. This policy arose from concerns in the scientific community that there appeared to be reluctance on the part of some institutions and researchers to share unique research tools at all or at least under reasonable terms. These tools include cells lines, strains of mice, reagents, monoclonal antibodies, and in some instances software. In response to the concern, the NIH asked a subgroup of the Advisory Committee of the Director to conduct a review. Their review found that these concerns were well founded and consequently recommended that the NIH develop guidelines for the research community to follow in combating the problem.

In 1999, NIH issued a document entitled, "Sharing of Biomedical Research Resources, Principles and Guidelines for Recipients of NIH Research Grants and Contracts." The policy applies to research tools developed with NIH funds and calls for the sharing of these tools among non-profit organizations with minimal terms and impediments. In the passage of the Technology Transfer Commercialization Act of 1999, P.L. 106-404, language was added in support of the tools guidelines when they amended the Bayh-Dole Act's purpose. The language was changed to state that inventions made under Federal funding are to be brought to practical application in

a manner to promote free competition and enterprise *without unduly encumbering future research and discovery.*

This policy is now a term and condition of NIH grants, and the latest information we have gathered indicates that this policy has significantly improved the sharing of materials between non-profit institutions, has improved sharing between non-profit institutions and for-profit entities, and reportedly has also improved the sharing by for-profits with non-profit entities. We continue to monitor this area to ensure that our recipients are complying with the intent of the policy.

While my comments have centered mostly on licensing activities, I have mentioned other technology transfer mechanisms including public-private partnerships, such as Cooperative Research and Development Agreements (CRADAs) and Clinical Trial Agreements. I would be pleased to provide information on these mechanisms if the Subcommittee so desires.

In summary, the field of technology transfer combines legal, business, and scientific skills to bring about the movement of research findings to promote further research or to develop them further into products of use to the public. It is through our statutory framework, unique institutions, and public-private partnerships that the Nation has created the most envied research enterprise in the world. I can assure you, Mr. Chairman and members of this Subcommittee, that the NIH is committed to its mission of improvement of public health and will utilize all of the mechanisms it has to achieve that mission. I thank you for the opportunity to come before you today and I welcome any questions you may have.

Mr. BILIRAKIS. Thank you very much, Doctor.

Dr. Barker?

STATEMENT OF ANNA BARKER

Ms. BARKER. Good morning. Thank you, Mr. Chairman and members, for the opportunity to be here today to discuss a new task force that the NCI has established with the Food and Drug Administration. I have the privilege of co-chairing that task force, along with Dr. Mullin, who will speak after me.

Before highlighting the mission and work of this task force, I would like to focus just briefly on the stunning advances in biomedical research over the past few years that recently led our Director at the National Cancer Institute, Andy von Eschenbach, to challenge the cancer community with a goal, and that goal is to eliminate suffering and death due to cancer and to do it by 2015.

That is a daunting and challenging goal for all of us. Why do we believe that that is a feasible goal, even though it is a major challenge? The reason is that progress in research over the past few years has led to unimagined advances across the entire research continuum of discovery, development, and delivery. As a result, we have reached an inflection point in research, meaning that progress from this point forward can be unprecedented and nearly unimagined.

The sequencing of the human genome, which you heard about from Francis Collins recently, and associated progress in new areas such as genomics and proteomics, are allowing us to dissect out the genetic changes and mechanisms that actually produce cancer. We now understand that cancer is a process—a process with multiple opportunities to develop new, more effective interventions to detect, treat, and prevent this disease.

The development of targeted therapies and preventives for cancer is really within our grasp. For the first time in our national effort to conquer this devastating disease, we have proof of concept. What do I mean by that? With new targeted drugs, such as Gleevec that you just heard about from Dr. Lindberg, we are on the threshold, we believe, of a paradigm shift in the way we treat cancer. This