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BEST PRACTICES IN TRANSFORMING RESEARCH INTO INNOVATION: CREATIVE APPROACHES TO THE BAYH-DOLE ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

TUESDAY, JUNE 19, 2012

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BEST PRACTICES IN TRANSFORMING RESEARCH INTO INNOVATION; CREATIVE APPROACHES TO THE BAYH-DOYLE ACT

TUESDAY, JUNE 19, 2012

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:01 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Judy Biggert [Vice Chairwoman of the Subcommittee] presiding.

RALPH M. HALL, TEXAS
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Subcommittee on Technology and Innovation Hearing

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Witnesses

Dr. Todd T. Sherer, President, The Association of University Technology Managers

Ms. Catherine Innes, Director, Office of Technology Development, University of North Carolina at Chapel Hill

Mr. Ken Nisbet, Executive Director, University of Michigan Technology Transfer

Mr. Robert Rosenbaum, President and Executive Director, Maryland Technology Development Corporation

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

HEARING CHARTER

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

I. Purpose

On Tuesday, June 19th, the Committee on Science, Space, and Technology Subcommittee on Technology and Innovation will hold a hearing to learn about different approaches universities and nonprofits are taking to transfer the results of federally-funded research.

II. Witnesses

Dr. Todd T. Sherer, President, The Association of University Technology Managers

Ms. Catherine Innes, Director, Office of Technology Development, University of North Carolina at Chapel Hill

Mr. Ken Nisbet, Executive Director, University of Michigan Technology Transfer

Mr. Robert Rosenbaum, President and Executive Director, Maryland Technology Development Corporation

III. Background

In fiscal year 2012, the Federal government funded more than $135 billion in research and development activities. Colleges and universities conduct the majority of basic research in the United States, and cumulatively receive more than half of their total research funding from federal agencies.[1] Because of the large amount of funding expended by the federal government on basic research by nonprofits, efforts to improve the transfer of federally-funded research are of interest to both the federal government and stakeholders across the nation.

[1] Congressional Research Service, January 2012, Federal Support for Academic Research http://www.crs.gov/pages/Reports.aspx?PRODCODE=R41895&Source=search

The Amendments to the Patent and Trademark Act of 1980 (P.L. 96-517), commonly known as the Bayh-Dole Act, were designed to improve collaboration between commercial concerns and nonprofit organizations, including universities, in addition to promoting the utilization of inventions arising from federally supported research and development. In order to encourage the two sectors to work together to generate new goods, processes, and services for the marketplace, the Act gave U.S. universities, small businesses, and nonprofits intellectual property control of their inventions and other intellectual property that resulted from such funding,. This alignment of ownership and control was a major change from the previous system where the Federal government retained title and right to license for inventions. Prior to the passage of the Bayh-Dole Act, there was limited incentive to commercialize early stage, high-risk technologies. The U.S. government had licensed fewer than 5 percent of 28,000 accumulated patents.[2] Bayh-Dole changed the incentive structure for nonprofits and small businesses to patent and license inventions. In 1980, 390 patents were awarded to universities;[3] by 2009, the number increased to 3,088.[4]

Bayh-Dole is generally considered a success by most stakeholders. In 2003, the President's Council of Advisers on Science and Technology prepared a report examining how to improve technology transfer, *Technology Transfer of Federally Funded R&D*, which found that the model of allowing universities to retain intellectual property rights to the results of federally-funded research and development"...has not only dramatically improved the Nation's ability to move ideas from research and development into commerce, but also helped enhance the return on this substantial taxpayer investment"[5]. Furthermore, the 2010 National Research Council report, *Managing University Intellectual Property in the Public Interest* found that, "[t]he system put in place by the Bayh-Dole Act, that is, university ownership of inventions from publicly funded research and latitude in exercising associated intellectual property rights subject to certain conditions and limitations, is unquestionably more effective than its predecessor system—government ownership subject to waiver in circumstances that varied from agency to agency—in making research advances available to the public."[6]

In October 2011, President Obama released a Presidential Memorandum to agencies titled *Accelerating Technology Transfer and Commercialization of Federal Research in Support of High Growth Businesses.* The memorandum required agencies that conducted intramural research to improve their technology transfer results by "establish[ing] goals and measure performance, streamlin[ing] administrative processes, and facilitate[ing] local and regional

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[2] Wendy H. Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, Congressional Research Service, March 16, 2012, at 5.

[3] National Science Board, Science and Engineering Indicators—1993 (Washington, National Science Foundation, 1993), 430.

[4] National Science Board, Science and Engineering Indicators, 2012 (Washington, National Science Foundation, 2010), Appendix table 5-48, available at http://www.nsf.gov/statistics/seind12/append/c5/at05-48.pdf.

[5] The President's Council of Advisors on Science and Technology, Report on Technology Transfer of Federally Funded R&D (2003), *available at* http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-03-techtransfer.pdf

[6] National Research Council, *Managing University Intellectual Property in the Public Interest* (2010), *available at* http://www.nap.edu/openbook.php?record_id=13001&page=2.

partnerships in order to accelerate technology transfer and support private sector commercialization."[7] The Department of Commerce's National Advisory Council on Innovation and Entrepreneurship has also partnered with research university leaders to find ways to improve technology transfer of federally-funded research.[8]

Many universities have hired professional technology managers and created technology transfer offices to work with faculty and to address patents and establish guidelines to cover industry-university relationships, with education and publication remaining academic priorities.[9]

Due in part to Bayh-Dole, academia has become a major source of innovation and new business creation. In 2010, the Association of University Technology Managers' survey identified 657 new products marketed because of academic R&D. The survey also found that more than 650 new companies were founded to commercialize university research with over five thousand new licenses or options granted mostly to small businesses.[10] A recent report found that "without accounting for product substitution effects...over the period 1996 to 2007, university licensing agreements based on product sales contributed at least $47 billion and as much as $187 billion to the U.S. GDP."[11] However, university technology managers report that the major reason for patent licensing is commercialization (or product creation), not profit, particularly since the cost of a patent is so high.[12]

There have been concerns that accelerating technology transfer at primarily research institutions may promote industry-research collaboration and result in business-dictated research. However, there are safeguards, such as university's limitations on outside research, mandated expeditious publication obligations for some federally-funded research and development, and conflict of interest provisions, which are able to insulate research from outside direction by the business community.[13]

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[7] Presidential Memorandum , Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses (Oct. 28, 2011), *available at* http://www.whitehouse.gov/the-press-office/2011/10/28/presidential-memorandum-accelerating-technology-transfer-and-commerciali

[8] April 2011 letter to Secretary Gary Locke; http://www.aau.edu/policy/letters_statements_testimony.aspx?id=11960

[9] Technology Transfer: Administration of the Bayh-Dole Act by Research Universities.

[10] Association of University Technology Managers, AUTM U.S. Licensing Activity Survey Highlights: FY2010, available at http://www.autm.net/AM/Template.cfm?Section=FY_2010_Licensing_Survey&Template=/CM/ContentDisplay.cfm&ContentID=6874.

[11] David Roessner, Jennifer Bond, Sumiye Okubo, and Mark Planting, The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-2007, Final Report to the Biotechnology Industry Organization, September 3, 2009, 32, available at http://www.bio.org/ip/techtransfer/BIO_final_report_9_3_09_rev_2.pdf.

[12] Ann M. Thayer, "University Technology Moves to Market via Patenting, Licensing,: Chemical and Engineering News, August 24, 1992, 17-18.

[13] *See* Wendy H. Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, Congressional Research Service, March 16, 2012.

IV. Institutional Efforts to Improve Technology Transfer

Universities, nonprofits, and other interested stakeholders are attempting to improve the transfer of technology through a number of methods. Some of the areas of focus include:

- **Reducing the barriers to commercialization** to ensure that technologies developed in academic and nonprofit settings make it to the public through activities such as reducing legal fees, minimizing licensing negotiations, restructuring organizational units, and building industry relationships;

- Universities and nonprofits are working with both students and faculty on **promoting entrepreneurship**. Cross-discipline and cross-college programs have helped to connect individuals and share expertise and innovative ideas;

- Increasing **collaboration** between industry and innovator through federal agency research components, collaborative models, and commercialization potential in grant proposals;

- Linking technology transfer to **economic development** through regional and local partnerships; and

- **Sharing of best practices** between institutions with different levels of technology transfer capacity and experience.

V. Issues for Examination

How has university technology transfer evolved since the passage of Bayh-Dole?

What are universities across the country doing today to expeditiously transfer the results of federally-funded research? Are there any model technology transfer activities being replicated across the Nation?

How have university-industry partnerships impacted technology transfer?

What are the most innovative practices stakeholders are using to develop ideas that have commercial opportunities or societal impact?

How is the successful transfer of technology measured?

Mrs. BIGGERT. The Subcommittee on Technology and Innovation will come to order.

Good morning, everyone. I would like to welcome everyone to today's hearing on the transfer of innovations that come from research funded by the Federal Government. The Federal Government invests more than $135 billion each year in research and development activities, and a portion of that funding supports the majority of basic research conducted by universities. The transfer of knowledge from universities into the marketplace can have profound economic and social impacts, so we are always looking for more ways to encourage this process. I am glad that our Chairman decided to hold this important hearing so that our Subcommittee can learn about the innovation—innovative approaches that institutions across the Nation are taking to accelerate the transfer of federally funded research.

In fact, tech transfer has been a priority for me. To further this goal in the energy sphere, I drafted the *Energy Technology Transfer Act*, which was signed into law in 2008. This legislation created jobs by accelerating breakthrough energy technologies out of the national labs and into the marketplace. It was based on best practices developed by agricultural extension programs at the USDA.

For American universities, however, tech transfer is governed by the *Bayh-Dole Act*. December 2010 marked the 30th anniversary of the enactment of the *Bayh-Dole Act*, which permitted universities to retain the intellectual property rights to inventions developed with federal funding.

The Act was passed during bleak economic conditions, not too unlike those that we are facing now. The United States was enduring an economic recession, declining productivity, and competition from Germany and Japan. All of this sounds familiar. The purpose of Bayh-Dole was simple: facilitate and support universities and small businesses in the commercialization of their inventions, allowing society to benefit and increasing U.S. global competitiveness. Promoting university-based innovation and technology transfer was seen as a way to combat the forces then working against the United States. Thirty years later, Bayh-Dole still elevates these efforts.

The collective efforts encouraged under the *Bayh-Dole Act* have brought about the commercialization of many new technological advances that impact the lives of millions of people across the Nation.

Prior to the enactment of Bayh-Dole, less than five percent of U.S. Government patents were commercially licensed. In 1980, 390 patents were awarded to universities; by 2009, the number increased to over 3,000. In my home State of Illinois, the University of Illinois at Urbana-Champaign holds nearly 400 patents and has created 61 companies.

I look forward to hearing from our witnesses about how university technology transfer has evolved since the passage of Bayh-Dole, and the innovative activities and partnerships institutions are trying today to get more results to the public. We thank each of you for being here and look forward to your testimony.

Let me just say that, unfortunately, Chairman Quayle was unable to attend today's hearing, but I am glad to be here to hear

about the innovative approaches to technology transfer you are all here to discuss.

I now recognize the gentlelady from Maryland, Ms. Edwards, for her opening statement.

[The prepared statement of Mrs. Biggert follows:]

PREPARED STATEMENT OF SUBCOMMITTEE VICE CHAIRWOMAN JUDY BIGGERT

Good morning. I would like to welcome everyone to today's hearing on the transfer of innovations that come from research funded by the Federal Government. The Federal Government invests more than $135 billion each year in research and development activities, and a portion of that funding supports the majority of basic research conducted by universities. The transfer of knowledge from universities into the marketplace can have profound economic and societal impacts, so we are always loooking for more ways to encourage this process. I am glad our Chair decided to hold this important hearing so that our Subcommittee can learn about the innovative approaches that institutions across the Nation are taking to accelerate the transfer of federally funded research.

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I look forward to hearing from our witnesses about how university technology transfer has evolved since the passage of Bayh-Dole and the innovative activities and partnerships institutions are trying today to get more research results to the public. We thank each of you for being here and look forward to your testimony.

Ms. EDWARDS. Thank you, Madam Chair. And thank you to the Chairman also for calling this hearing on university technology transfer. And I want to thank our witnesses for joining us here today to share your perspective on how we can get more promising research out of the university labs and right into the marketplace.

I am pleased that we are taking a serious look at this issue. I am convinced there are a number of ways that we can strengthen and improve technology transfer in this country. There are far too many good ideas out there in our universities, good ideas that have been developed through tax—federal taxpayer support, but they languish. And as we continue to look for ways to strengthen our economy and secure our global competitiveness, I think it would be wise to focus on technology transfer.

I am excited to hear from our witnesses today about some innovative approaches to technology transfer and to discuss the ways

that the Federal Government can facilitate these approaches. I am particularly interested in hearing Mr. Rosenbaum's testimony today about our experience in Maryland.

The truth is there are various elements that contribute to efficient and effective technology transfer. First, you have to be able to identify research with commercial potential. This is not an easy task. It can be a significant challenge since researchers are not necessarily equipped to recognize commercial potential and industry has limited exposure to all the research coming out of universities.

At the same time, research may have commercial relevance in a space not initially envisioned by the researcher or recognized by industry. Finding better ways to identify ideas with commercial potential is a challenge but one that is critical to the entire technology transfer process.

Once you have identified an idea or concept with commercial potential, you have to demonstrate its technical feasibility. This is often accomplished through some sort of proof-of-concept research and development of a prototype. Unfortunately, there are limited financial resources for this sort of research and development. I am pleased that the Economic Development Administration has started funding these sorts of activities through its i6 Challenges, which are generally focused on accelerating technology commercialization. And I am also pleased that EDA announced an i6 Challenge just last week specifically on the development or expansion of proof-of-concept centers.

Once the technical feasibility of an idea or concept is proven, we have to get that technology out of the lab and into the hands of a private sector entity that can commercialize it. In some cases, this is accomplished by the researcher leaving academia to start his or her own business, but it is often achieved by the university licensing that technology to an outside company or entrepreneur. Unfortunately, we frequently hear from industry that licensing university-developed technology is far from easy or straightforward and that often bureaucratic red tape and unnecessary time delays frustrate and, in some cases, deter industry altogether.

Our economy can't afford to let good ideas die in university labs. We need to figure out a way to do this more seamlessly, and I am eager to hear from our witnesses today about innovative ways of speeding up this process and making it more efficient.

And finally, once the technology makes its way out of the lab, it needs to be commercialized. This may include large-scale demonstrations and the development of functional prototypes, putting together business plans and management teams, and carrying out market validation activities. Certainly, these are private sector functions. However, when it comes to technology that has been developed with federal taxpayer resources, I believe the Federal Government may have an important role to play in facilitating the commercialization of these technologies. Our responsibility should be to ensure that federal taxpayers get the biggest bang for our buck and that technologies developed with federal resources make it across the finish line and into the marketplace.

There are, unfortunately, limited resources for commercialization assistance for federally funded technologies. I hope today we can discuss whether there are appropriate leverage points for the Fed-

eral Government when it comes to commercializing these sorts of technologies. I hope our witnesses will challenge us to think more broadly.

Mr. Chairman, I want to—or Madam Chair, I want to thank you again for holding this hearing, and I look forward to hearing from our witnesses. And I hope we will be following up this hearing with a separate hearing focused on technology transfer from federal labs. I am pretty confident that there are a number of Members on both sides of the aisle that are interested in taking a critical look at these efforts and ways that they can be strengthened and improved. And with that, I yield the balance of my time.

[The prepared statement of Ms. Edwards follows:]

PREPARED STATEMENT OF SUBCOMMITTEE RANKING MEMBER DONNA F. EDWARDS

Mr. Chairman, thank you for calling this hearing on university technology transfer. And thank you to our witnesses for joining us here today to share your perspective on how to get more promising research out of university labs and into the marketplace.

I am very pleased that we are taking a serious look at this issue. I am convinced that there are a number of ways that we can strengthen and improve technology transfer in this country. There are far too many good ideas out there in our universities—good ideas that have been developed through federal taxpayer support—that languish. And, as we continue to look for ways to strengthen our economy and secure our global competitiveness, I think it would be wise to focus on technology transfer. I am excited to hear from our witnesses today about some innovative approaches to technology transfer and discuss ways that the Federal Government can help facilitate these approaches.

The truth is that there are various elements that contribute to efficient and effective technology transfer.

First, you have to be able to identify research with commercial potential. This can be a significant challenge since researchers are not necessarily equipped to recognize commercial potential, and industry has limited exposure to all of the research coming out of universities. At the same time, research may have commercial relevance in a space not initially envisioned by the researcher or recognized by industry. Finding better ways to identify ideas with commercial potential is certainly a challenge, but one that is critical to the entire technology transfer process.

Once you've identified an idea or concept with commercial potential, you have to demonstrate its technical feasibility. This is often accomplished through some sort of proof of concept research and the development of a prototype. Unfortunately, there are limited financial resources for this sort of research and development. I am very pleased that the Economic Development Administration has started funding these sorts of activities through its i6 challenges, whic are generally focused on accelerating technology commercialization, and am particularly pleased that the EDA announced an i6 challenge just last week specifically on the development or expansion of proof of concept centers.

Once the technical feasibility of an idea or concept is proven, we have to get that technology out of the lab and into the hands of a private sector entity that can commercialize it. In some cases, this is accomplished by the researcher leaving academia to start his or her own business. But it is also often acheived by the university licensing that technology to an outside company or entrepreneur. Unfortunately, we have frequently heard from industry that licensing university-developed technology is far from easy or straightforward and that, often, bureaucratic red tape and unnecessary time delays frustrate and—in some cases—deter industry altogether. Our economy can't afford to let good ideas die in university labs. We need to figure out ways to do this more seamlessly, and I am eager to hear from some of our witnesses today about innovative ways of speeding up this process and making it more efficient.

And, finally, once the technology makes its way out of the lab, it needs to be commercialized. This may include large-scale demonstrations and the development of functional prototypes, putting together business plans and management teams, and carrying out market validation activities. Certainly, these are private sector functions. However, when it comes to technologies that have been developed with federal

taxpayer resources, I believe that the Federal Government may have an important role to play in facilitating the commercialization of those technologies.

Our responsibility should be to ensure that federal taxpayers get the biggest bang for their buck and that technologies developed with federal resources make it across the finish line and into the marketplace. There are, unfortunately, limited resources for commercialization assistance for federally funded technologies. I hope today that we can discuss whether there are appropriate leverage points for the Federal Government when it comes to commercializing these sorts of technologies.

Mr. Chairman, thank you again for holding this hearing. I look forward to hearing from our witnesses on this important topic. I also hope that we will be following up this hearing with a separate hearing focused on technology transfer from federal labs. I am fairly confident that there are a number of Members on both sides of the aisle that are very interested in taking a critical look at these efforts and ways that they can be strengthened and improved. I yield back the balance of my time.

Mrs. BIGGERT. Thank you, Ms. Edwards.

If there are Members who wish to submit additional opening statements, your statements will be added to the record.

[The prepared statement of Mr. Quayle follows:]

PREPARED STATEMENT OF SUBCOMMITTEE CHAIRMAN BENJAMIN QUAYLE

Good morning. I would like to welcome eeryon to today's hearing.

Today we have the opportunity to survey some of the activities that universities and other organizations are undertaking to improve the transfer of federally funded research. I know there are some innovative activities regions are taking across the country, and I am looking forward to hearing about what things that have been found to work well.

Passed in 1980, the *Bayh-Dole Act* enabled universities and nonprofit organizations to retain title to their inventions that result from federally funded research programs. In 2002, the *Economist Technology Quarterly* stated that the 1980 *Bayh-Dole Act* was "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century...More than anything, this single policy measure helped reverse America's precipitous slide into industrial irrelevance." Even after 30 years under Bayh-Dole, the process of technology transfer is evolving. That's why we are here today, to understand how our Nation's universities and nonprofits can more effectively transfer federally funded technology to better society.

University research is generally long term and exploratory in nature. Even when a university works to patent a discovery, it may be many years before the intellectual property proves to be a marketable success. The are many reasons universities create new innovations, including profit, but I believe both the technology transfer process and incentives to commercialize are more complex than simply making money. Economic reward is just one of many metrics I suspect these institutions are driven by to accelerate technology transfer.I look forward to hearing from our witnesses about their experiences with technology transfer and its evolution. Thank you for your presence and willingness to testify before us today.

Mrs. BIGGERT. At this time, I would like to introduce our witnesses, and then we will proceed to hear from each of them in order.

Our first witness is Dr. Todd Sherer, President of the Association of University Technology Managers and an Associate Vice President of Research Administration at Emory University.

Next, we will hear from Ms. Catherine Innes, who is the Director of the Office of Technology Development at the University of North Carolina at Chapel Hill.

Our third witness is Mr. Ken Nisbet. Mr. Nisbet is the Executive Director of Technology Transfer at the University of Michigan.

Our final witness is Mr. Robert Rosenbaum, the President and Executive Director of the Maryland Technology Development Corporation.

Again, thank you for being our witnesses this morning. As I am sure our witnesses know, spoken testimony is limited to five min-

utes each. After all of the witnesses, Members of the Committee will have five minutes each to ask questions.

And I now recognize our first witness, Dr. Sherer, for five minutes.

STATEMENT OF DR. TODD T. SHERER, PRESIDENT, THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS

Dr. SHERER. Madam Chairwoman and Honorable Members of this Subcommittee, thank you for the opportunity to testify before you today on the important topic of transferring university technology transfer from lab to the marketplace. My name is Todd Sherer, and I am the President of the Association of University Technology Managers known as AUTM. AUTM is an international organization with more than 3,000 members, primarily university technology transfer professionals who come from over 300 universities, research institutions, and teaching hospitals.

I also head the Technology Transfer Office at Emory University, and my office is responsible for managing a portfolio of around 1,000 biomedical inventions made by Emory faculty. We work closely with our faculty inventors to evaluate early-stage technologies for commercial potential, determine the best intellectual property protection strategy, and market our technologies through a variety of channels in the hopes of finding a corporate partner. If we find an interested company, then we negotiate appropriate contractual partnerships to ensure that our inventors, our universities, and taxpayers benefit from the ultimate products. After licenses are signed, we maintain relationships throughout the life of the agreement, sometimes insisting upon return of our technology should our partners decide to abandon its development.

As a result of Emory's passion and commitment to commercializing its technology, over 90 percent of HIV-infected patients in the United States and Europe on lifesaving antiviral therapy take a drug developed by our researchers.

In the decades leading up to the 1980 *Bayh-Dole Act*, the Federal Government accumulated title to approximately 28,000 patents, of which fewer than five percent were licensed to companies for commercialization. Unless an exception was granted, the ownership of inventions was kept centrally at the federal agencies from which they were funded. The passage of the *Bayh-Dole Act* boldly changed government patent policy, providing ownership and control to any invention made with federal funds to the very universities and small businesses that made them.

Since its passage, the *Bayh-Dole Act* has proven instrumental in recognizing that federal patent policy is an integral part of U.S. competitiveness and it is the envy of nearly every country in the world, as evidenced by similar legislation in a wide variety of countries, including South Africa, India, China, Japan, South Korea, and Taiwan. Its beauty is that it aligns ownership and control of patent rights to create incentives for universities, researchers, and companies to develop and invest in patenting and licensing their new technologies. Without local pride of ownership and control created by the Act, many of these discoveries would still be lan-

guishing on the shelf and their revenues would be returned to fund even more research.

According to an article published in the journal *Nature*, "an invention made by an academic in the United States has a better chance of going to market than it does in other nations." Since the *Bayh-Dole Act* was passed, more than 5,000 new companies have formed around university research, the majority of which are located in close proximity to the university.

In fiscal year 2010, university research helped create on average 1.7 new companies a day. University technology transfer creates billions of dollars of direct benefits to the U.S. economy every year. In fiscal year 2010, universities helped create 657 new products.

According to the former President of NASDAQ, an estimated 30 percent of its value is rooted in university-based federally funded research results.

Technology transfer is not perfect. After all, we work at the riskiest of all stages in the innovation pathway where funding and resources are hardest to find. The odds of any particular technology making it to market are astronomical, so figuring out what works has not been easy and has taken time.

Despite the challenges of working at the discovery phase, the academic community and federal agencies continue to find better ways to manage innovations. Technology transfer offices are constantly adapting to changes in the economy, learning the best practices from each other, and understanding the marketplace. Technology transfer offices have expanded their service to help faculty create new companies. They are creating accelerators, finding gap funding, encouraging entrepreneurship by faculty and students, and rewarding that entrepreneurship. While TTOs focus on negotiating licenses, that is just the means to an end. The end is to get technologies out the door and into the market for the benefit of the public.

Not all technology transfer offices have the same level of experience but they have more resources to turn to than ever before. Universities from across the country are already working with smaller tech transfer offices to help them improve their technology transfer function.

AUTM will continue its commitment to providing training and education for technology transfer professionals for years to come. We will provide networking events for our members to share best practices and technology transfer as we all expect new practices to continue to emerge just as they always have. Our members must continue to strive to find new ways to reduce the barriers to getting our technology from lab to market. We believe that continued support for research at NIH, NSF, and other agencies such as the newly formed NCATS is the best way that the Federal Government can encourage even more commercialization of American technologies.

AUTM, as well as other organizations, believe that the U.S. technology transfer system will continue to be the catalyst for innovation in the U.S. economy for many decades to come.

Thank you.

[The prepared statement of Dr. Sherer follows:]

Statement of
Todd T. Sherer, PhD, CLP
President, Association of University Technology Managers
Associate Vice President Research Administration, Executive Director, Office of Technology Transfer,
Emory University
Before the
U.S. House of Representatives
Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation
June 19, 2012

Mr. Chairman and honorable Members of the Subcommittee, thank you for the opportunity to testify before you today on the important topic of transferring university technology from the lab to the marketplace.

My name is Todd Sherer, and I am the Associate Vice President for Research Administration and Executive Director of the Office of Technology Transfer for Emory University in Atlanta Georgia. I am also President of the Association of University Technology Managers (AUTM). AUTM is a nonprofit organization dedicated to promoting, supporting and enhancing the global academic technology transfer profession. AUTM is an international organization with more than 3,000 members, primarily managers of intellectual property, who come from over 300 universities, research institutions and teaching hospitals as well as numerous businesses and government organizations.

My office at Emory is responsible for managing a portfolio of around 1,000 biomedical inventions made by Emory faculty. Put simply, my professional colleagues and I shepherd them from the lab bench to the hands of commercial partners who then take them through capital-intensive development programs and complicated regulatory processes to get them into the hands of patients. While it may sound simple, in actuality, what we do is quite complex. We evaluate early stage technologies for commercial potential, determine the best intellectual property protection strategy, and market our technologies through a variety of channels in hopes of finding a corporate partner. We then negotiate often complicated agreements to ensure that our inventors, our universities and the taxpayer benefit from the ultimate products. Often we create or assist in the creation of entirely new companies to commercialize our technologies – many of them creating jobs in our own region and state. After licenses are signed, we maintain relationships throughout the life of the agreement, sometimes insisting upon the return of our technology should our partner decide to abandon our technology. Most importantly, we work as a team with our inventors to help make the world a better place by getting academic technologies out of the laboratory and into the economy.

As a result of our activities, over 90 percent of HIV patients in the U.S. on life-saving antiviral therapy take a drug developed at Emory. In addition, more than 4 million patients each year benefit from cardiac imaging innovations made at Emory, including our faculty inventor who underwent cardiac by-pass surgery.

Prior to the Bayh-Dole Act

In the decades leading up to the 1980 Bayh-Dole Act, the federal government accumulated title to approximately 28,000 patents of which fewer than 5 percent were licensed to companies for commercialization. Several factors influenced the lack of commercialization: lack of incentives for universities and faculty to engage in the very inventions they had made, patent policies that

varied by federal agency and a lack of clarity of ownership of patents developed under federal funding.

The Bayh-Dole Act boldly changed government patent policy, providing ownership and control to any invention made with federal funds to the very universities and small businesses that made them. The Act also established a federal patent policy that was uniformly applied to all of its agencies. Since its passage over 30 years ago, the Bayh-Dole Act has proven instrumental in recognizing that federal patent policy is an integral part of U.S. competitiveness and is the envy of nearly every other country in the world as evidenced by similar legislation in a wide variety of countries including South Africa, India, China, Japan, South Korea and Taiwan. The Bay-Dole Act has served the United States well for more than 30 years. Its beauty is that it creates market incentives for universities, researchers and companies to develop and invest in patenting and licensing new technologies or treatments for diseases. Without the local pride of ownership and control created by the Act, many of these discoveries would still be languishing on the shelf and no revenues would be returned to fund even more research.

After Passage of the Bayh-Dole Act

Universities responded to the passage of the Bayh-Dole Act by creating technology transfer offices (TTOs) to manage the inventions of their faculty. Only 23 universities had TTOs before Bayh-Dole; today, all major research institutions have a technology transfer operation. The level of basic technology transfer activity—invention disclosures, patent applications, patent issuances, and licensing— has increased steadily, too. AUTM has conducted an annual licensing activity survey since 1991. **Attachment 1** shows how key measures of activity have increased since the inception of the survey.

According to an article published in the journal *Nature*, "An invention by an academic in the United States has a better chance of going to market than it does in other nations." *University Entrepreneurship and Professor Privilege*, a working paper released by the Research Institute of Industrial Economics in Stockholm on April 12, 2012, also finds that U.S. technology-transfer offices have more market-analysis skills, invest more in commercialization and often license to solid businesses, boosting the chances of success.[1]

Since the Bayh-Dole Act was passed, more than 5,000 new companies have formed around university research; the majority of which are located in close proximity to the university. In fiscal year 2010, university research helped create on average 1.7 new companies a day. University technology transfer creates billions of dollars of direct benefits to the U.S. economy every year. In fiscal year 2010, universities helped create 657 new products.[2]

And, since the passage of Bayh-Dole, university innovations have helped create whole new industries, like biotechnology, where the U.S. enjoys a leadership role. The bioscience sector represents an employment impact of 8 million jobs, and 76 percent of biotech companies have a license from a university. At least 50 percent of current biotech companies got their start as a result of a university license. According to a 2009 study by the Biotechnology Industry Organization, 279,000 jobs were created through university licenses in the United States

[1] Nature, vol 485, p. 27, May 10, 2012

[2] AUTM Licensing Activity Survey FY2010, pg. 13

between 1996 and 2007 and as much as $187 billion was contributed to the gross domestic product. [3]

According to the former President of the NASDAQ Stock Market, an estimated 30 percent of its value is rooted in university-based, federally funded research results, which might never have been commercialized had it not been for the Bayh-Dole Act.

Significant benefits for public health and wellbeing are derived from technologies developed under the Bayh-Dole Act, such as:

- HIV medications
- Synthetic penicillin
- Hepatitis B vaccine
- HPV vaccine
- Cisplatin and carboplatin (cancer therapeutics)
- Human growth hormones
- Treatments for Crohn's disease
- Avian Flu vaccine

These breakthroughs occur not only in the field of biotechnology and life sciences, but in all fields ranging from electronics to agriculture. A few examples from AUTM's Better World Report series (http://www.betterworldproject.net/) are available in **Attachment 2**.

Making Technology Transfer Stronger for the Future

The academic community and federal agencies continue to find new ways to innovate and to manage innovations. Technology transfer offices are constantly adapting to changes in the economy, learning best practices from each other and understanding the marketplace. TTOs have adapted to address how to help ideas become companies—bridging the valley of death—and to do so they've had to get creative. They are creating accelerators, finding gap funding, encouraging entrepreneurship by faculty and students and rewarding that entrepreneurship. They're finding new ways to advance their technologies. While TTOs focus on negotiating licenses, that is just the means to an end. The end is to get technologies out the door and into public usage for the benefit of taxpayers.

Technology transfer offices are using innovative online partnering tools such as the AUTM Global Technology Portal (GTP). Launched by AUTM in 2012, the GTP is a website that provides a "one stop shop" for industry to identify academic innovations available for licensing thereby helping facilitate licensing agreements and investments or partnership agreements with university startups. In addition to cutting edge technology transfer activities such as the GTP and other web portals, technology transfer offices are using showcases, partnering meetings, translational research funds (gap and seed). They're also training colleagues by providing entrepreneurship assistance and providing education for professors on commercialization.

The old saying that technology transfer is a "contact sport" is still valid, but technology transfer professionals are making use of every marketing channel they have access too—including social networking sites such as Twitter, LinkedIn and Facebook.

Specific examples of innovative university programs can be found in **Attachment 3**.

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[3] The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-2007, Final Report to the Biotechnology Industry Organization, Pg. 8

Many universities across the country are working with smaller technology transfer offices to help them improve their technology transfer function. They are doing this through job shadowing, and networking events to share best practices, as well as with formal arrangements to assist with technology transfer services like the one recently announced between Notre Dame and Purdue.

These projects reflect growing interest by universities toward a more active role in bringing new technology to market.[4] As you can see, universities are not resting on their laurels as we continue to innovate and find better ways to transfer our technology from the lab to the marketplace.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants were recently reauthorized for six years, and that's great news for emerging companies in the early development stages of research—often university startups. AUTM and our sister organizations, such as the Association of Public and Land Grant Universities, and the Biotechnology Industry Organization, have advocated for reauthorization for years, knowing that the six month or even month-to-month extensions provided in the past did not give companies the ability to plan effectively. Now they can. In addition, allowing startups funded through venture capital to compete for SBIR/STTR grants will increase the number of new innovations available to the public, and making innovations available to the public is at the very heart of what we do.

AUTM will continue its commitment to providing training and education for technology transfer professionals for years to come. We will provide networking events for our members to share best practices in technology transfer as we all expect new practices to continue to emerge, as they always have. Our members must continue to strive to find new ways to reduce the barriers to getting our technology from the lab to the market. We believe that continued support for research at NIH, NSF and other agencies, such as the newly formed NCATS, is the best way that the federal government can encourage even more commercialization of American technologies – after all, it is the level of research funding that drives the level of innovation at our universities. I, AUTM, as well as other organizations, believe that the U.S. technology transfer system will continue to be a catalyst for innovation in the U.S. economy for many decades to come.

Attachment 1

Statement of

Todd T. Sherer, PhD, CLP

President, Association of University Technology Managers

Associate Vice President Research Administration, Executive Director, Office of Technology Transfer,

Emory University

Before the

U.S. House of Representatives

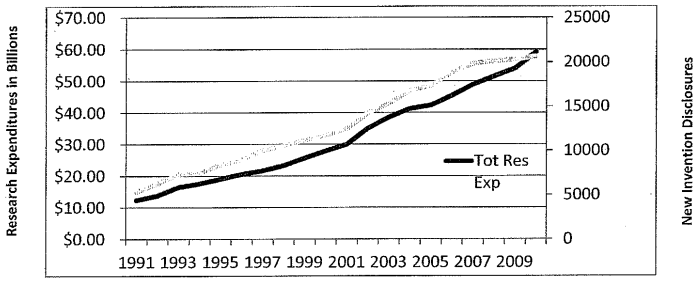
Committee on Science, Space, and Technology

Subcommittee on Technology and Innovation

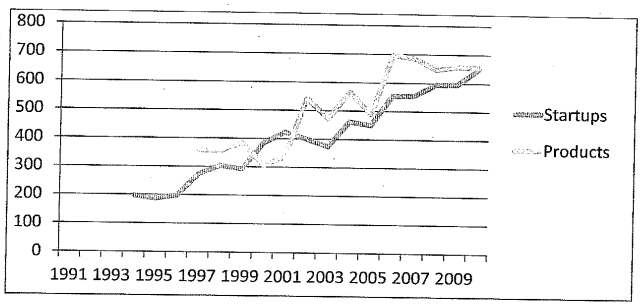
June 19, 2012

AUTM has conducted an annual licensing activity survey since 1991. Each year, the survey reveals how activity has increased since the inception of the survey.

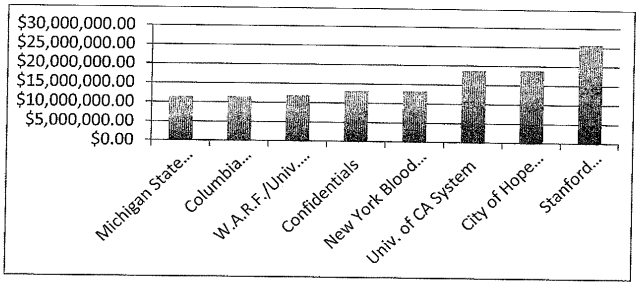
Federal Research Drives Innovation



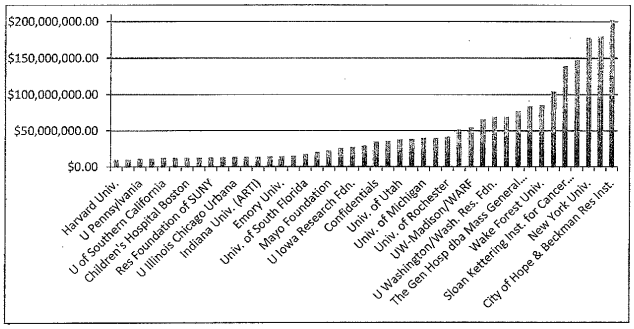
Results of Investment — Startups and New Products



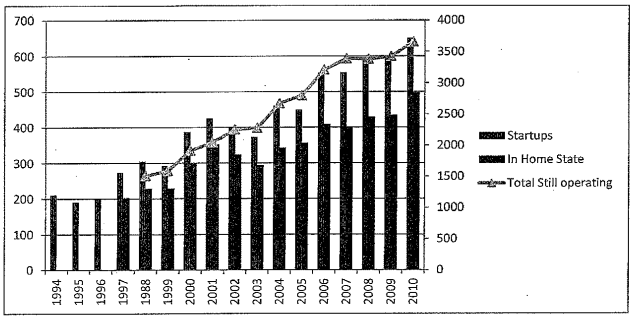
Results of Investment
1991-Universities reporting more than $10 million in license income



Results of Investment
2010- Universities reporting more than $10 million in license income



Economic Development: Startups



Attachment 2

Statement of

Todd T. Sherer, PhD, CLP

President, Association of University Technology Managers

Associate Vice President Research Administration, Executive Director, Office of Technology Transfer,

Emory University

Before the

U.S. House of Representatives

Committee on Science, Space, and Technology

Subcommittee on Technology and Innovation

June 19, 2012

Technology transfer breakthroughs occur not only in the field of biotechnology and life sciences, but in all fields ranging from electronics to agriculture. There are hundreds of examples in AUTM's Better World Report series (http://www.betterworldproject.net/). Here is just a sampling:

Arizona
Lighting strike detection technology that is now deployed in over 40 countries
University of Arizona

Chemical-free technology to help control crop diseases is licensed to companies in the Midwest
University of Arizona

California
Topical gel treatment for AIDS-related Kaposi's sarcoma
Salk Institute for Biological Studies

Electrodes that enable three-dimensional imaging with atomic force microscopy
Stanford University

Novel IV catheters that eliminate risks of potentially dangerous needlesticks
City of Hope

Florida
First blood test to diagnose brain injuries
University of Florida

Georgia
Once-a-Day HIV Medication
Emory University

Indiana
Altered yeast strains for expanded biofuel supplies
Indiana University

Maryland
Shigellosis Vaccine
University of Maryland

Nebraska
Drought tolerant grass
University of Nebraska-Lincoln

New Organo-metallic reagents for the synthesis of drugs
University of Nebraska-Lincoln

Pennsylvania
Artificial Lung
University of Pittsburgh

Vermont
Sustainable water filtration technology that reduces phosphorous, suspended solids and pathogens from water supplies
University of Vermont

Wisconsin
Brainport to help the blind "see"
University of Wisconsin

Attachment 3

Statement of

Todd T. Sherer, PhD, CLP

President, Association of University Technology Managers

Associate Vice President Research Administration, Executive Director, Office of Technology Transfer,

Emory University

Before the

U.S. House of Representatives

Committee on Science, Space, and Technology

Subcommittee on Technology and Innovation

June 19, 2012

Examples of Innovative University Programs

The University of California, San Diego is launching a Center for Novel Therapeutics (CNT) to promote interaction between private company researchers and their university counterparts based at nearby clinical facilities. The CNT will bridge the gap between academic discovery and development of new therapeutics.

The University of Florida will open its Clinical and Translational Research Building in Gainesville, Florida in February 2013. The building will house the university's Institute on Aging, the Clinical and Translational Science Institute, and an Ambulatory Clinical Research Center.[1]

The Ohio State University and Ohio University launched a new venture fund designed to finance early stages of biopharma and other innovative technology ventures from the two schools as well as other Ohio-based academic institutions.

Emory University created an in-house patent counsel as opposed to using more expensive outside law firms. This approach has not only saved the university money, but increased the number of patent filings by better aligning patent and license strategies. Emory's faculty inventors love this new service.

[1] Academia Increasingly Going Beyond Basic Research by Setting Up Translational Med Centers, Genetic Engineering & Biotechnology News, May 30, 2012

Mrs. BIGGERT. Thank you, Dr. Sherer.

Ms. Innes, you are recognized for five minutes.

STATEMENT OF MS. CATHERINE INNES, DIRECTOR, OFFICE OF TECHNOLOGY DEVELOPMENT, UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

Ms. INNES. Thank you. Good morning, Chairwoman Biggert, Ranking Member Edwards, and Members of the Subcommittee. Thank you for the opportunity to appear before you today to provide testimony on the challenging, unpredictable, and oftentimes rewarding process of moving good ideas from university labs to the marketplace. My name is Catherine Innes, and I am the Director of the Office of Technology Development at the University of North Carolina at Chapel Hill. I am responsible for patenting and commercializing promising new inventions arising from our research endeavors. My testimony today focuses on the implementation and success of the Carolina Express License Agreement, which is a one-size-fits-all approach to licensing technologies to UNC startup companies.

In early 2009, UNC began internal discussions among faculty and research administrators on what could be done to stimulate and increase the volume of new companies starting around UNC technologies and how the process could be streamlined. We wanted to start more companies and help them become sustainable. However, we were constrained by limited financial resources and unable to invest in these ventures. Instead, we focused on finding ways to make the license process faster, easier, and more transparent so that startups could more readily get up and running.

UNC formed a committee comprised of serial entrepreneur faculty members, licensing staff, general counsel, and a local venture capitalist to consider what we might do. They reviewed the terms of previous startups and determined the historical range of financial terms and equity positions, both at the time of license and at the point of a liquidity event. Our data indicated that all of our past deals had been actually very similar and that by the time an equity was liquid, the university's share was less than one percent. The committee arrived, then, at a set of financial terms that the stakeholders agreed would be fair to all parties and would not need to be renegotiated for the company to attract financing. Minimizing the need to renegotiate was an important objective as the negotiation process can be both time-consuming and costly for all involved.

A significant factor in the successful launch of this program was the buy-in from three local law firms that worked with the majority of our startup companies. They agreed to forfeit the fees they would normally receive to negotiate individual deals with the university and recommend their client sign the express license. While in part altruistic, the firms all expect their businesses will grow in the long run as we increase the rate at which we are starting new companies.

Another key feature of the express license is that it is optional. If a company wants a different deal, they are free to negotiate that deal with the university as usual. To qualify for the express license, the company must have a UNC faculty, student, or staff

member as one of the founders and the company must submit a business plan for review and approval by the university.

The financial terms of the license agreement are modest but, we believe, fair for the stage of development of the technologies being licensed. One of the most unique features of the agreement is that in lieu of taking equity, the university receives a cash payout of .75 percent of the value of the company at a liquidity event. Typically, universities take equity in their startup companies, but we felt the cash payoff when the company goes public or is acquired is much less burdensome than dealing with a stock issuance and we end up at the same overall value point.

The full text of the Carolina express license and related program documents can be found on my office's Website, and I have provided that URL in my written testimony.

As with any new and different approach, there are supporters and critics. Our motto was unique when first implemented because it offered the same set of terms to all startups regardless of technology. Many licensing professionals felt that the financial terms should vary by technology or should offer a greater return to the university. These are relevant points and questions each institution should ask in considering the implementation of a standard licensing program.

We have found the program to be very effective and it serves our objective of starting more companies. In the 2–1/2 years since inception, UNC has launched 19 startup companies around intellectual property. All but three used the Carolina express license. We have more than doubled the number of new companies forming each year. At this time, all these companies are still in existence, although most are struggling with fundraising.

We have learned through this process that most of our companies cannot repay the university for patent expenses on time, and thus we must carry these costs for them for much longer than anticipated. This is straining our internal resources, but we believe starting companies is important and we continue to explore new ways to support this effort. Many of our companies have gotten started by winning SBIR grants and we very much value this program.

In summary, I strongly believe that a standard licensing program can work for universities, particularly for licenses to startups. For a one-size-fits-all program to be successful, the university must be willing to settle for a fair deal rather than the most lucrative deal. It is also important to establish criteria for when the standard agreements can be used, and perhaps more importantly, when they cannot.

Finally, to implement a standard agreement that is intended to work for many deals, it is essential for the university to gain the support and buy-in of those negotiating on behalf of the other side of the deal because just floating a standard that one party thinks is workable will not likely get much traction.

Thank you again, Madam Chairwoman and Subcommittee Members, for the opportunity to appear before you today. I stand ready to answer any questions you may have.

[The prepared statement of Ms. Innes follows:]

Testimony of Catherine Innes
Director, Office of Technology Development
The University of North Carolina at Chapel Hill

Presented before the
U.S. House of Representatives
Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation:
Creative Approaches to the Bayh-Dole Act

June 19, 2012

Good morning Chairman Quayle, Ranking Member Edwards, and Members of the Subcommittee. Thank you for the opportunity to appear before you today to provide testimony on the challenging, unpredictable, and oftentimes, rewarding process of moving good ideas from university labs to the marketplace. My name is Catherine Innes and I am the Director of the Office of Technology Development at the University of North Carolina at Chapel Hill. I am responsible for patenting and commercializing promising new inventions arising from our research endeavors. I know the committee is aware that the Bayh-Dole Act encourages universities to license their innovations to small businesses and the Act spurred many universities into developing programs and processes to form and support startup companies. My testimony today focuses on the implementation and success of the Carolina Express License Agreement, which is a 'one-size-fits-all' approach to licensing technologies to UNC startup companies.

Personal Background

I have more than 20 years experience in academic technology transfer at three leading US public institutions: the University of California, the University of Washington and currently, the University of North Carolina at Chapel Hill. I have licensed hundreds of technologies and been involved in licensing transactions with over 100 startup companies.

Genesis of the Carolina Express License Agreement

UNC began very modest technology transfer and commercialization activities shortly after the passage of the Bayh-Dole Act in 1980 but did not actively pursue commercialization and startup formation until the mid '90s. In the boom years that followed, some 20 companies formed, but the rate of new company formation slowed considerably between the years of 2000 and 2008.

In early 2009, UNC began internal discussions among faculty and research administrators on what could be done to stimulate and increase the volume of new companies starting around

UNC technologies and how the process could be streamlined. New company formation plays an important role in regional economic development; but even more importantly, forming a company around an embryonic technology may be the only way to move it forward into commercial applications. Many innovations arising from university research are simply too nascent and pose too many technical risks to be licensable to larger firms until more data on efficacy can be obtained. This is especially true for small molecules, biological therapeutics and other life science technologies which represent nearly 80% of our innovation portfolio. To advance inventions from UNC we need to foster a robust startup pipeline.

Historically, the licensing office at UNC, the Office of Technology Development, was responsive and supportive of startups, but deals tended to become bogged down because faculty founders were unfamiliar with the licensing process and the legal obligations surrounding intellectual property. It was also costly for new companies to pay their business attorneys to negotiate a license with the University and thus the negotiations often dragged on while necessary funds were secured to continue the process.

At Carolina, we wanted to start more companies and help them become sustainable, but we were constrained by limited financial resources and were unable to invest in these ventures. Instead, we focused on finding ways to make the license process faster, easier and more transparent so that the money a company did have could go toward getting the company up and running.

As a first step, a committee comprised of serial entrepreneur faculty members, licensing staff, general counsel and a local venture capitalist reviewed the terms of all of Carolina's previous startups to determine the range of historical royalty, equity, milestone and annual fees, at both the onset of the deal and after the deal had been renegotiated to accommodate institutional investment in the company. The committee concluded that all of our past deals had been very similar by the point of company liquidity and that the University really never had a large equity stake after multiple rounds of dilutive funding.

The committee arrived at a set of financial terms that the stakeholders agreed would be fair to all parties and would not need to be renegotiated for the company to attract financing. The financial return to the University was on the low side, but within our historic norms for early stage life science deals. The next step was to find a way to embed the agreed upon financial terms into a complete contract that all parties would agree to sign. While straightforward in principle, it can take months to negotiate terms to everyone's satisfaction.

We arrived at the final contract after only a few rounds of negotiation. What made the process work so smoothly is that three local law firms that serve as business counsel for most startups in the area agreed to work with us to develop the license. It is important to recognize that by eliminating the need to negotiate a license for each new startup these firms were forfeiting significant revenue they would have otherwise been paid. Their rationale was altruistic in part, but they also recognized that by fostering a larger and more vibrant startup community would generate long term gains that could greatly exceed any short term losses.

Features of the Agreement

The Carolina Express License is an *option* for all startups with a UNC faculty, student or staff founder if we approve of the company's management team and business plan. The same financial terms are offered to all, regardless of the technology, and the financial terms in this agreement represent the best deal available from the University.

Key license provisions include:

- No upfront license fees;
- Six month delay in obligation to begin repayment of patent costs;
- Optional payment plan to spread patent cost reimbursement over four years;
- A 1% royalty on products requiring Food and Drug Administration approval based upon human clinical trials;
- A 2% royalty on all other products;
- A cash payout to UNC equal to 0.75 percent of the company's fair market value at the time of a merger, stock sale, asset sale or initial public offering; and
- Provisions to make products available on a humanitarian basis in developing countries.

The agreement does *not* include provisions granting UNC equity in the company or milestone fees. The committee found that while most universities' start-up deals have equity provisions in lieu of cash upfront fees, it is difficult for the University to manage equity and by the time a liquidation event occurs, the University typically only holds a small amount of equity in the company. One venture capital firm analyzed historical transactions and found that on average, a university has .6% equity in their startup companies at a liquidity event. UNC arrived at the payout value and royalty terms through an analysis of our previous transactions.

The first version of the Carolina Express License provided a one year deferment for repayment of incurred patent costs. We anticipated that the companies would be able to raise sufficient funds during the first year to repay outstanding patent costs by the first anniversary of the license, but this objective proved to be overly ambitious. Many companies have had to request an extended payment schedule, which the University has granted. In the current version of the Carolina Express License companies are required to begin monthly payments towards patent costs after six months. If they are unable to pay outstanding costs in full by the end of the first year, the University will offer an extended repayment schedule in exchange for increased payout percentage.

The full text of the Carolina Express License is available on our website at http://otd.unc.edu/starting_a_company.php#CaroExLic

Implementation, Supporters and Critics

Our model was unique when first implemented because it offered the same set of terms to all startups. Many licensing professionals felt that their deals were too dissimilar to offer the same

financial terms to all or that the university should receive greater returns from its licenses. These are relevant points and questions each institution should ask in considering the implementation of a standard licensing program. The value of standard licenses is they can be put in place quickly with minimal negotiation. However, for multiple parties to agree to use the standard terms the university will likely have to offer favorable financial terms and pose no unreasonable restrictions or liabilities. If the objective is to maximize financial returns to the university a standard license is not going to be helpful.

Many licensing professionals are surprised to learn that the startup companies are willing to accept a license agreement without negotiation. The important element in our case is that the agreement is non-negotiable because it has already been negotiated. By working with the local law firms that represent nearly all of our emerging startup companies we were able to reach agreement on a set of terms that each law firm would recommend to its clients without hesitation. Without the law firms' willingness to partner with UNC on this endeavor we likely would not have been able to arrive at a standard agreement. In areas where startup companies use dozens of law firms to represent them rather than two or three, it might be very difficult to find a set of terms that all firms would accept.

It is also essential to consider whether or not you have a set of transactions that are inherently similar. UNC is predominantly licensing very early stage life science technologies and the Express License royalty terms reflect those of our past deals in this sector. We have used this license for non-life science technologies and were willing to accept that our returns for these may be lower than if we negotiated a license for each specific deal. In recent years, a number of universities and institutions around the country that have implemented standard licensing programs and several, including the NIH, that have implemented programs similar to the Carolina Express License.

Results to date

In the two and a half years since program inception, UNC has launched 19 startup companies around intellectual property; all but three used the Carolina Express License. The vast majority, 79%, of these companies have formed around life science technologies.

Prior to implementation of the Express License, we were starting 3 companies per year, on average. For the past two and a half years we have started 7-8 companies per year, more than doubling our historical average. At this time, all 16 Carolina Express companies are still in existence, though most are struggling with fundraising. One of our companies has attracted institutional seed funding and several others have received loans from the regional small business development entities, or leveraged the SBIR and STTR programs.

Summary

We have learned through this process that most of our companies are having trouble finding sufficient funding to support payment for patent costs so the University must carry expenses

for three or four years rather than the one year we originally anticipated. This is straining our internal resources, but we believe starting companies is important and we must continue to find new ways to support this effort.

UNC has invested in a program called Carolina KickStart to improve the probability of successfully commercializing the intellectual property developed at UNC faculty by assisting faculty in the business planning process, building liaisons with industry, identifying stage-appropriate funding, educating faculty about the commercialization process, and incubating companies spinning out of UNC. Carolina KickStart is part of the NC Translational and Clinical Sciences (NC TraCS) Institute, the academic home of the NIH Clinical and Translational Science Awards (CTSA) at UNC.

In addition, UNC has launched the Innovate@Carolina Campaign to implement the next generation of cross-campus entrepreneurship initiatives. The $125 million campaign seeks to make Carolina a world leader in launching university-born ideas for the good of society. Key initiatives of the campaign include: seed funding for the most promising innovations on campus; entrepreneurs-in-residence to mentor and counsel students and faculty involved in entrepreneurial ventures; Innovation Professorships; a student Innovation Hub; an Innovation Scholars Program; and the expansion of the Carolina KickStart program among other initiatives.

I strongly believe that a standard licensing program can work for universities, particularly for licenses to university startups. For these programs to be successful, the university must be willing to settle for a fair deal rather than the most lucrative deal and establish criteria for when the standards can be used and when they cannot. It is essential for the university to gain the support and buy-in of those negotiating on behalf of the startups as they must be willing to forfeit payment for negotiating multiple deals with the university for the benefit of the program and the opportunity for a greater volume of business in the future.

Thank you, again, Mr. Chairman and Subcommittee Members for the opportunity to appear before you today. I stand ready to answer any questions you may have.

Mrs. BIGGERT. Thank you, Ms. Innes.

Mr. Nisbet, you are recognized for five minutes.

STATEMENT OF MR. KEN NISBET,
EXECUTIVE DIRECTOR,
UNIVERSITY OF MICHIGAN TECHNOLOGY TRANSFER

Mr. NISBET. Thank you, Madam Chair, for the opportunity to speak to you today on the important topic of technology transfer and the importance to the American public. I am Ken Nisbet, Executive Director of Tech Transfer at the University of Michigan.

The University of Michigan has a well-deserved reputation for excellence and the breadth and depth of its research of activities with over $1.2 billion of research expenditures annually. While having a robust pipeline of research discoveries is an ingredient for tech transfer success, it is only one component of many. A critical factor is support from university leadership to provide the resources and encouragement for tech transfer and entrepreneurship. Our President, Mary Sue Coleman, our Executive Officers, our Deans, and others regularly communicate the importance of our tech transfer activities with our faculty, our students, our staff, and alumni.

Each year, our faculty report to our office over 300 new discoveries that form a diverse portfolio of technologies and market applications. We enter into over 100 different agreements with our industry partners and annually and spin out an average of one new start up every five weeks, most of which stay in Michigan. We also strive to measure what is even more important—the impact of our technologies and our activities on our communities, our people, and our Nation.

There are a lot of good ideas to enhance tech transfer, but it is important to tailor these initiatives to account for the advantages and the challenges of a particular region. I want to highlight three particular efforts that we believe are making a big difference at the University of Michigan.

The first involves changes in investments we have made within our office and our university to improve our operational effectiveness. The second is using early stage development funding to reduce the technical and market risk of our early stage innovations. The third is enhancing our access to talent to speed the deployment of our technologies and the formation of our startups.

Over the last 10 years, we have revamped our office culture by attracting and training tech transfer professionals with technical and market skills and an appreciation for creativity, risk-taking, and customer service. We have simplified our work documents and processes to make working with others more rapid, effective, and friendly. We have standardized agreements for some situations—for example, software and research tool licensing—but we find it important given the wide diversity of technology opportunities and business models to be flexible and nimble for the value propositions required by our partners.

We have established a full-service venture creation capability with our office called the Venture Center to more effectively form great startups for entrepreneurs and our investors and to make it easier to do business with the university. We have changed univer-

sity policies and practices to motivate our faculty to engage with industry and to participate in commercialization activities.

We have formed broader industry research agreements with innovation partners such as Procter & Gamble, Dow, and Ford, and we have addressed industry needs for predictability and flexibility with a new program, the Michigan Research Advantage, that provides up-front license terms for future inventions that may be derived from industry-sponsored research.

We have expanded the funding resources available for our early stage technologies and new startup opportunities. Our university has several translational funds that allow technical validation for emerging discoveries. One example is the Coulter Translational Fund for promising biomedical innovations created via a matched endowment from the Coulter Foundation.

Complementing our translational funds, the university is reinvesting our tech transfer revenues into an internal gap fund that is generously matched with funds from the State of Michigan to address market validation and commercial readiness issues. And recently, we established a program called MINTS—Michigan Invests in New Technology Startups—in which the university, alongside a qualified venture firm, is investing endowment funds in promising U of M startups.

Having access to high-quality talent is a key ingredient for success, and we focused our efforts to create several effective talent initiatives. We have recruited and trained graduate students and post-docs to provide technology assessments and market analysis to enable our licensing professionals to make quicker decisions and find more potential partners. We have also pioneered a program to embed within tech transfer a team of seasoned entrepreneurs, our Mentors-in-Residence, to assist our efforts. The result has been improved venture creation capabilities and a stream of high-quality, sustainable startups that are creating jobs and providing superior investment returns.

And seeing the positive impact of our U of M talent programs over the last five years, we recently proposed and received State funding for a Tech Transfer Talent Network. With six other Michigan universities, we are sharing and creating talent tools, resources, and activities tailored to their regions to accelerate tech transfer success for their institutions.

In conclusion, at the University of Michigan, we are firmly committed to continual improvement of our tech transfer capability and sharing of our findings to maximize the impact of research discoveries on our economy and our quality of life. As U of M President Coleman has said, "universities bring ideas to life but it is technology transfer that gives them wings and lets them fly."

Thank you for this opportunity. I am happy to answer any questions.

[The prepared statement of Mr. Nisbet follows:]

STATEMENT OF

MR. KEN NISBET

EXECUTIVE DIRECTOR OF TECHNOLOGY TRANSFER

UNIVERSITY OF MICHIGAN

BEFORE THE

TECHNOLOGY AND INNOVATION SUBCOMMITTEE

HOUSE SCIENCE AND TECHNOLOGY COMMITTEE

ON

"BEST PRACTICES IN TRANSFORMING RESEARCH INTO INNOVATION: CREATIVE APPROACHES TO THE BAYH-DOLE ACT"

TUESDAY, JUNE 19, 2012

Thank you, Mr. Chairman, for the opportunity to speak to you today about the important topic of technology transfer and its value to the American public. I am Ken Nisbet, Executive Director of Technology Transfer at the University of Michigan. Our office helps to transform university research discoveries into valuable technologies for existing businesses and as the basis for creating new start-up ventures, both of which can generate jobs and economic benefits for the University, our communities and our nation.

The University of Michigan has a well-deserved reputation for excellence in the breadth and depth of our research activities, with over $1.2 billion of annual expenditures. While having a robust pipeline of research discoveries is an ingredient for tech transfer success, it is only one component of many. A critical factor is support from University leadership to provide the resources and encouragement for tech transfer and entrepreneurship. Our President, Mary Sue Coleman, our Executive Officers, our Deans and others regularly communicate the importance of our tech transfer activities to faculty, students, staff and alumni.

Tech transfer is hard work requiring professionals with an unusual combination of skills and qualifications. Each year our faculty report to our office more than 300 new discoveries that form a diverse portfolio of technologies and market applications. We enter into over 100 different agreements with our industry partners annually and spin out an average of one new start-up every five weeks, most of which stay in Michigan. We also strive to measure what is even more

important – the impact of our technologies and our activities on our communities, our people and our nation.

Examples of Michigan technologies making an impact on society include FluMist®, a nasally-administered flu vaccine that is an alternative to a flu shot, the IntraLase® FS bladeless technology for LASIK corrective eye surgery, Arbor Networks, a University start-up that is providing network access security to data centers and businesses around the world and ARTISTRY® anti-wrinkle firming serum, a recently introduced cosmetic from Amway Corporation that uses a patented U-M technology.

There are a lot of great ideas to enhance tech transfer, but it is important to tailor these initiatives to account for the advantages and challenges of a specific region. I want to highlight three particular efforts that we believe are making a big difference at the University of Michigan. The first involves changes and investments we have made within our office and our university to improve our operational effectiveness. The second is using early-stage development funding to further develop and reduce the technical and market risk of our early stage innovations. And the third is enhancing our access to talent to more fully understand market needs and speed the deployment of our technologies and formation of our start-ups.

Over the last ten years, we have revamped our office culture by attracting and training tech transfer professionals with technical and market skills and an appreciation for creativity, risk-taking and customer service. We've simplified our

work documents and processes, to make working with others more rapid, effective and friendly. We have standardized agreements where it makes sense (for example, in software and research tool licensing), but we find it important, given the wide diversity of technology opportunities and business models, to be flexible and nimble for the value propositions required by our partners.

We've established a full service venture creation capability within our office, called the Venture Center, to more effectively form great start-ups for our entrepreneurs and investors, and to make it easier to do business with the University. We have changed University policies and practices to motivate our faculty to engage with industry and participate in commercialization activities, and to encourage our students to bring their own innovations to campus without fear of losing ownership of their inventions. And we encourage outreach and service internally, for example providing mentoring to student entrepreneurs, within our region and beyond, which enhances our market understanding, cultivates more partnerships and markets our resources and capabilities.

We've formed broader industry research agreements with innovation partners such as Procter & Gamble, Dow, and Ford. And we have addressed industry needs for predictability and flexibility with a new program, the Michigan Research Advantage, that provides up-front license terms for future inventions that may be derived from industry-sponsored research.

We have expanded the funding resources available for our early-stage technologies and new start-up opportunities. Our University has several translational funds that allow technical validation for emerging discoveries. One example is the Coulter Translational Fund for promising biomedical projects, created via a matched endowment from the Coulter Foundation. Complementing our translational funds, the University is reinvesting tech transfer revenues into an internal "Gap" fund that is generously matched with funds from the state of Michigan to address market validation and commercial-readiness issues. And recently, we established a program called MINTS (Michigan Invests in New Technology Start-ups) in which the University, alongside a qualified venture firm, is investing endowment funds in promising U-M start-ups. We have worked hard to establish partnerships for other funding resources, such as a Pre-Seed Fund administered by Ann Arbor SPARK, our local economic development partner. Our State has helped to broaden our early stage venture resources with Venture Michigan, a fund of funds and other programs administered by another partner, the Michigan Venture Capital Association. We have established effective relationships with local and national venture funding partners, understanding their investment needs and resources and providing them tailored funding opportunities to make a "yes" more probable.

Having access to high-quality talent is also a key ingredient for success, and we have focused our efforts to create several effective talent initiatives. We've recruited and trained graduate students and post-docs to provide technology

assessments and market analysis to enable our licensing professionals to make quicker decisions and to find more potential partners. We also pioneered a program to "embed" within tech transfer a team of seasoned entrepreneurs, our "Mentors-in-Residence," to assist our efforts. The result has been improved venture creation capabilities, and a stream of high quality, sustainable startups that are creating jobs and providing superior investment returns. And seeing the positive impact of our U-M talent programs over the last 5 years, we recently proposed and received state funding for a Tech Transfer Talent Network. With six other Michigan universities, we are sharing and creating talent tools, resources and activities -- tailored to their regions -- to accelerate tech transfer success for their institutions.

In conclusion, at the University of Michigan we are firmly committed to continual improvement of our tech transfer operational capabilities and sharing of our findings to maximize the impact of research discoveries on our economy and our quality of life. As U-M President Coleman has said: "Universities bring ideas to life. But it is technology transfer that gives them wings and lets them fly."

Thank you for this opportunity. I am happy to answer any questions you may have.

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Mrs. BIGGERT. Thank you, Mr. Nisbet.

Mr. Rosenbaum, you are recognized for five minutes.

STATEMENT OF MR. ROBERT ROSENBAUM, PRESIDENT AND EXECUTIVE DIRECTOR, MARYLAND TECHNOLOGY DEVELOPMENT CORPORATION

Mr. ROSENBAUM. Thank you, Madam Chairwoman, Members of the Committee, for the opportunity to speak with you today. We have heard today so far from three folks with primarily academic focus. I bring a little bit different focus, never been employed by a university, always been in the private sector, and now am with a quasi-public entity. I am Rob Rosenbaum, President of the Maryland Technology Development Corporation, proud to be representing the State that was recently named number one for entrepreneurship in the country by the U.S. Chamber of Commerce and the home for many billions of dollars of federal research money, both in our universities and federal labs.

As an intermediary organization, we look at ourselves first and foremost as partners to the tech transfer offices. There are a lot of elements that go into getting a business or technology into a business. Tech transfer is one of the steps. Intermediaries provide many other skills and opportunities that don't exist within the university offices and often don't exist within the entrepreneurs that are trying to commercialize these technologies. So it is intermediaries; it is we folks that can get in there and help them and teach them and train them on the things that they need to do.

The other important difference for intermediaries versus other constituents and stakeholders in the process is that we are specifically and directly incentivized to do tech transfer, to create jobs, to create economic development. We are not there to create income for the universities, we are not there to put our names on patents, and we are not there to take the fame for successful IPO. We are there to create jobs and that is our primary role.

One of the things that we help do is deal with the difficulties of university culture. And I think it is fair to say that universities have a very distinct culture in and of themselves, and the researchers within those universities have a particular headset in and of themselves. Primarily speaking and historically speaking—although it is changing—researchers within universities are very risk-averse. They enjoy doing research, they enjoy the comforts of their labs, they enjoy creating basic knowledge, and they have been incentivized to do this over the years.

Universities are slowly changing their culture and changing the incentives to get researchers to be a little bit more risk-taking. Programs such as sabbaticals to take job creation and job company formation to reality, programs that include tenure as—include commercialization as part of tenure tracks are all important. Also, the university culture is one of fairly complex and byzantine rules and regulations. Intermediaries help the entrepreneurs who have never even known the existence of tech transfer offices to understand what is going on, to help them understand what an express license is versus trying to negotiate their own. So we play an important role in that respect.

We incentivize behavior. We believe in incentivizing behavior and we believe that the federal policies can do such things. We believe that activities such as job credits for job creation and commercialization on the commercial side, on the private sector side, would leverage public dollars with private dollars in order to introduce and exaggerate the activity of private sector organizations. We believe that there is an opportunity for grant set-asides for commercial enterprises to do tech transfer. SBIR programs are there to promote commercial activities, but they are not targeted at tech transfer. They could be targeted at tech transfer.

Some of the samples and examples of these successes in Maryland and one of the programs that I think is known to the Committee Members is the Maryland Innovation Initiative, which is a new program that aggregates five research universities with a unique process of mining technologies and utilizing an intermediary to bring those technologies to the public and to bring the entrepreneurs together with those technologies.

We have also had experience in forming foundations that can be an aggregator for private sector dollars to be brought to universities or federal labs in order to promote private-sector involvement and commercialization of technologies. We have many, many more examples, and we have created hundreds of companies and thousands of jobs and would be happy to answer any further questions you have on our specific successes or any other subjects.

Thank you.

[The prepared statement of Mr. Rosenbaum follows:]

TESTIMONY OF ROBERT A. ROSENBAUM
President & Executive Director, Maryland Technology Development Corporation

Commmittee on Science, Space and Technology
Subcommittee on Technology and Innovation
June 19, 2012

Mr. Chairman, members of the Committee, thank you for the opportunity to appear before you to discuss *Best Practices in Transforming Research into Innovation: Creative Approaches to Bayh-Dole Act.*

Background

As an innovation economy with massive future potential, Maryland ranks highly. Nationally, Maryland ranks **1st** in federal research and development dollars invested per capita and **1st** in Ph.D. scientists and engineers per capita. According to the Milken Institute, Maryland is in the **top two** for science and technology and we occupy the **top slot** for human capital investments. The U.S. Chamber of Commerce also puts Maryland in the **top five** for growth and Education Weekly has ranked Maryland's public schools **1st** for four years running. And finally, most recently in another report released by the U.S. Chamber of Commerce, Maryland was ranked **1st** in entrepreneurship and innovation. However, there is a clear gap between the significant potential suggested by these rankings and the current level of entrepreneurial activity across the State.

The 2010 Annual Survey of the Association of University Technology Managers (AUTM) reported the following data for Maryland institutions:

Total Maryland Invention Disclosures in FY 2010	768
National Ranking for Invention Disclosures per Research Expenditures	**45th**

The national rankings for start-up company formation suggest similarly low rankings, given Maryland's expenditures and assets:

National Ranking for Start-up Companies Formed per Research Expenditure	**40th**
National Ranking for Start-up Companies Formed per Invention Disclosure	**37th**

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National Ranking for University Start-ups Formed in Maryland	**38th**
National Ranking for License Agreements Completed per Disclosure	**30th**

The Maryland Innovation Initiative

The purpose of the *Maryland Innovation Initiative* (MI2) is to: promote the commercialization of research conducted in participating universities; encourage qualifying universities to partner on commercialization proposals, strategies, and funding sources, including with federal laboratories located in Maryland; and facilitate technology transfer from university labs to start-up companies.

MI2 is the first of its kind partnership between the State and Maryland's five academic research institutions designed to accelerate commercialization of technology, including, but not limited to, medical devices, imaging, informatics and cyber-security. Proof of concept and prototyping grants will be awarded to innovators and innovations best positioned to quickly create products that will meet needs present in the commercial marketplace. By supplying the right expertise and incentives, a relatively modest investment by the program can facilitate the transfer new technologies from the lab to the market within two years.

The State has appropriated $5M to establish MI2. Additionally, all five of the state's academic research institutions, University of Maryland College Park (UMCP), University of Maryland Baltimore (UMB), University of Maryland Baltimore County (UMBC), Morgan State University and Johns Hopkins University (JHU) are participating in the program. The three largest universities, UMCP, UMB and JHU are investing $200k each and the two smaller universities, UMBC and Morgan State are investing $100k each. These investments by the universities are new dollars expended beyond current resources to seed research. Combined, this provides an annual budget of $5.8M for the program.

MI2 will be managed by a full-time Director. The Director will report to the participating members of the initiative, which will include one representative from each participating university, one State official, and two private sector representatives with relevant professional expertise appointed by the Senate President and House Speaker.

MI2 will use "site miners" who will:

- Be either technology transfer professionals who work in consultation with university faculty, or members of university faculty;

- Create inter-disciplinary teams of clinicians, scientists, engineers, business strategists, lawyers, and pharmacists to solve existing problems identified in the commercial marketplace; and
- Will work within the academic research facilities, and will come together as a single group periodically to enable multi-university collaborative solutions to identified market needs.

The teams created by the site miners will compete for up to 40 grants of up to $100K. The grants will be awarded on a rolling basis over the course of 12 months by the MI2 board. The board will meet as often as necessary to ensure the grants are awarded in a timely manner.

By linking innovators with experienced entrepreneurs and the technology transfer offices at these five institutions, we anticipate 10% - 20% of the funded projects will become new start-up companies, be licensed to established companies, and/or become standards of clinical care within two years of receiving funding.

In addition to creating jobs, spinning off new businesses, and spurring growth in Maryland's innovation economy, MI2 will generate broader collaboration among the State's leading private and public research institutions. The partnership will further develop the existing entrepreneurial environment within the institutions, and allow all the institutions to seek outside funding for more technology transfer and commercialization projects.

Tech Transfer Best Practices and Policies

In an effort to think about what policy changes could be made in support of university technology transfer efforts, one approach is to start with the greatest obstacles to commercializing technology and consider the policies that could minimize these obstacles. To this point, university technology commercialization faces two significant challenges, which have the potential to be affected by federal policy:

1. Invention disclosures resulting from federal (and other) funding are not sufficiently mature for commercialization and cannot be evaluated effectively for their commercial applications and potential – there is insufficient funding for translational research in universities (the "Translational Research Problem"); and

2. There is not sufficient interaction between universities and industry to foster commercialization of university technology (the "Industry Involvement Problem").

Best Practice Approach to Translational Research Problem

The Translational Research Problem (#1 above) has two main causes. First, the majority of federal funding programs supporting university research are targeted to basic research. Long standing federal policies focused on basic research have positioned the United States as the world leader in scientific discovery and helped to position the nation as a leader in higher education. While a strong policy focus supportive of basic research has served this nation well by creating a wealth of new discoveries, it has ignored the step of commercialization that is required for these discoveries to be translated into products that can benefit the public good. Second, the academic culture that values independent, basic research and a focus on publication in academic journals, which also have a bias toward basic research, stifle translational research and commercialization.

Cognizant of the power of public funding to influence behavior, over the last 8 years TEDCO developed and refined two programs to promote desired behaviors.

TechStart

The techstart program is designed to validate the commercial need for an innovation developed by researchers in the insulated environs of a research lab. The program's key feature is that before excessive dollars are spent on pilot programs or proof of concept projects a team evaluates the commercial demand for the technology. Specifically, an entrepreneur, the inventor and a representative from the tech transfer office come together to answer a strategic question. Depending upon the technology this question or analysis may be what is the commercial market size, what is the competitive landscape, a freedom to operate evaluation, are there viable distribution channels, or the answer to any other strategic issue that would indicate commercial viability.

Only with an affirmative answer to the TechStart is further money invested in the translation, or commercialization of the technology at hand. The benefits of this approach are a significant savings of capital, human resources and infrastructure assets. First, this research can be done for $10k to $15k, a small fraction of the cost of a pilot project that can cost $100k or more and second, human resources and lab facilities and equipment can be directed at other innovations that have more commercial viability instead of driving to a dead end.

University Technology Development Fund & Maryland Innovation Initiative

Only once an affirmative answer has been established via a Techstart project, or a commercial need has been identified by the site miners deployed by MI2 is it time to expend resources on proof of concept to pilot projects. While MI2 is a new program, TEDCO's University Technology Development Fund (UTDF) has been in operation for many years and has demonstrated the

efficacy of similar programs. Like MI2, UTDF is designed to provide limited dollars to a university or federal lab researcher in order to complete a proof of concept project.

UTDF resources have been limited to providing $50k per project and have only been able to complete 112 projects. Despite its small scale, UTDF's results are impressive. Of the 112 projects funded, 43 resulted in new license agreements for the developed technology and 29 new companies were formed. MI2 will scale up the successes in Maryland. Federal funds, in keeping with the intent of the presidential memorandum dated October 11, 2011 regarding *Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses* would do the same for federal research laboratories.

Best Practice Approach to Industry Involvement Problem

The Industry Involvement Problem (#2 above) is created primarily by the difference in corporate and university cultures. This is compounded by issues related to intellectual property, publication, conflict of interest, and other issues that are rooted in public policy, e.g., Bayh-Dole. The cultures at universities and those in industry are well-entrenched and would require policy changes that create strong incentives to have an impact. TEDCO, in collaboration with the University System of Maryland has developed an effective program to address this problem.

The Maryland Industrial Partnerships Program

The Maryland Industrial Partnerships Program (MIPs) primary objective is to promote collaboration between commercial enterprises and a university research lab. The basic premise of the program is that there are resources and know-how in university labs that can solve commercial problems. The economic element is a sliding scale of state matching funds to the dollars invested by the company. Depending upon the size and maturity of the company, the state will provide between 50% and 90% of the cost of the project. This effort has been highly successful resulting in 1000's of jobs, billions of dollars in revenue and at least one public company.

Other Policy Changes to Support Technology Transfer

The recent increased focus on innovation and the creation of new jobs at the federal and state levels creates an opportunity for new policies that loosen the bottleneck between university discovery and the development of new products. Fundamentally there needs to be more emphasis placed on translational research. This may come at the expense of basic research or it may come as a further compliment to basic research, either way the additional emphasis is needed.

Following are a number of thoughts for consideration in discussions about policies that address the specific problems listed above:

Translational Research Problem

- It might be useful to allocate a percentage of the federal extramural research budget for programs directed to translational research in universities. Translational research will need to be defined carefully for these programs, but applicants could be required to include a commercialization plan with a description of potential products as part of the proposal process. In addition to academic reviewers, individuals from industry should be included on review committees for these proposals, as these individuals are more likely to have an understanding of the market demand for university innovations that might arise from the proposed project.

- Traditional basic research programs should add a review criterion requiring the applicant to describe the potential commercial application of any newly discovered knowledge that could result from the proposed project. In addition, some programs should be targeted for specific public needs – even if they are for basic research. For example, an NIH funding program supporting basic research that could lead to the reduction of some aspect of healthcare costs would be more likely to generate an invention that could be commercialized. Such a program could help to focus basic research toward specific outcomes rather than just the pursuit of new knowledge. Again, these statements are not intended to suggest that all research programs should change; rather, a portion of programs should consider this approach.

Industry Involvement Problem

- The SBIR/STTR programs are great resources for entrepreneurs and small businesses, but they could be modified to foster more university commercialization. First, more people from industry, rather than just academics, should be used on review committees so proposals are evaluated with a bias toward commercial research rather than academic research. Second, setting aside a percentage of SBIR/STTR funding for companies that are commercializing technologies licensed from universities (or federal labs, to be inclusive) would foster more commercialization of university technology. Third, limiting the number of companies that can apply for SBIR funding might create more opportunity for small business, which is where most job creation occurs. To this point, policy could create a preference for micro enterprises (less than 50 employees) or give preference for companies that have only been in business for less than 5 years. The current definition of "Small Business" includes 99.7% of all companies in the U.S. This

makes it difficult for start-up companies (like the ones commercializing university technologies) to compete with larger, established companies.

- One way to force companies to interact with industry is to change the dynamic with respect to who is funding university research. For example, providing industry tax credits for sponsoring research in universities would incentivize interaction. The potential success of such a fund matching program is demonstrated by the state matching dollars in the MIPS program previously described. The tax credits could be paid for by reallocating research funds in the federal research budget. Moreover, the tax credits, which would only be a percentage of the industry-funded research, would be leveraged by industry funding and ultimately could lead to greater university research funding. A similar model could be used as an incentive for companies licensing technology – i.e., tax credits for licensing fees, much of which is returned to the university to support research in accordance with Bayh-Dole. With universities and industry working closely, more opportunities for collaboration, licensing, and commercialization would result.

- Industry often claims that it is difficult to negotiate license agreements with universities. A guidance or effort in conjunction with the Association for University Technology Managers (AUTM) and the Licensing Executives Society (LES) for standardizing licensing terms for federally funded inventions might help to address this issue and facilitate the licensing and commercialization process. There are already some efforts to accomplish licensing standardization at the University of North Carolina and at NIH. Expanding these efforts would be beneficial.

Other General Suggestions

- Programs like the NSF's *Partnerships for Innovation* should be created at other agencies to explore new models of technology transfer and commercialization. NSF's PFI was used to fund two highly successful programs in Maryland, Activate and Innovate. These programs were an experiment in entrepreneurship and tech transfer targeted at women and post-doctoral fellows respectively. Deemed very successful tech transfer programs, they also helped to foster relationships between universities and industry.

- University policy changes regarding tenure and sabbaticals could also have an impact on commercialization efforts. Currently, and simplistically, success, defined as tenure, for a university researcher is accomplished in part by the publication of a paper, the filing of a patent, or a speaking engagement at a conference. Nowhere in that success formula is commercialization. The Regents of the University System of Maryland, however,

recently modified tenure criteria to include commercialization. Likewise, universities offer sabbaticals for research but not for entrepreneurship. A sabbatical program offering a year to go start a business with the security of returning to the university if needed would go a long way to incenting the desired actions.

The initial thoughts that are described above are specifically for improving university technology transfer. While these ideas could benefit technology transfer from the federal labs, the federal labs have a unique set of challenges that could also be addressed with changes to policy. Such challenges are not specifically addressed in this document.

The ideas contained in this document are preliminary in nature and intended to foster discussion. Clearly, additional thought and discussion would improve these ideas and generate others.

Mrs. BIGGERT. I thank the witnesses for their testimony and reminding Members that Committee rules limit questioning to five minutes.

The Chair will at this point open the round of questions. And I recognize myself for five minutes.

This is a question for, I guess, whoever wants to answer. I hope you all do. In considering inventions to accelerate technology transfer, what do you set as your target metric? New businesses, products, patents, profit, citations? And then depending on the metric, how does the metric influence the intervention? Dr. Sherer, do you have any comment on that?

Dr. SHERER. Yeah, it is a great question. The way I view that and the way I articulate it to my staff in my offices that we are dealmakers, and so the important thing for us to do is to get a deal done, whether that is with a startup company or an established company because that is the beginning of how we transfer our technology. There is a lot that goes on in a relationship with a startup or an established company once the license is signed.

Mrs. BIGGERT. Okay. Ms. Innes.

Ms. INNES. Thank you. Yes, much like Dr. Sherer, we have the same philosophy. Our goal is to get technologies licensed because if we can't get a commercial partner, those good ideas are going to sit on our shelves. So our most important metric would be getting that deal done, whether it be to a university startup or to an existing firm. So we look for technologies that have a market opportunity and try to position them and find the partner. So those are our most important activities.

Mrs. BIGGERT. And Mr. Nisbet, you have had a lot of, it sounds like, companies and—companies that are well entrenched already that you have dealt with.

Mr. NISBET. Right, and our approach is similar that we do look for having agreements and not just an agreement—but a good agreement—with either an existing company or a startup. I think our measure is both to have a quantity of agreements showing that transfer of technology but also trying to measure the impact that the agreement and our technology would play in the American public. And we feel that is far more important than the revenue. If you do a successful job, the revenues will follow.

Mrs. BIGGERT. Thank you.

Mr. Rosenbaum.

Mr. ROSENBAUM. Yes, substantially different from the universities, our incentive is measured by economic development. Are we creating jobs? Are we creating revenues? Are we creating tax base? And one of the things we look at is capital that is brought into our State as a result of our activities. And we bring $43 for every dollar we spend back into the State. So that is a huge measure for us and our primary goal.

Mrs. BIGGERT. And certainly job creation is very important to us, and thank you for what you are all doing.

But should technology transfer be a priority for every university? Is it likely to be a profitable business for any but the major research institutions? Mr. Nisbet, I think you could speak to that.

Mr. NISBET. Right. That is a great question because I think that the potential of tech transfer at a particular institution is depend-

ent on a number of factors. Obviously, you have to have a stream of quality research and researchers that form the pipeline for those opportunities, but I think the ecosystem also that the institution resides in is very important. So we have worked with our sister universities in Michigan trying to adapt some of the practices we have found that have worked in the Ann Arbor area where we tried to figure out a way to kind of influence things and augment their resources to do a better job.

In the end, it is a very patient business and trying to go after it just for money is, I think, shortsighted because it takes so long. But the long-term potential of job creation and economic opportunity is very vital.

Mrs. BIGGERT. Are there any other reasons for technological transfer to be important to an institution?

Mr. NISBET. There are tremendous side benefits to tech transfer besides the engagement and the attraction and recruitment of key faculty. It also is a wonderful way for students who are finding it more and more important for them to engage in these activities. So it is a wonderful learning opportunity. It is a great attraction opportunity. It has wonderful opportunities for engagement with the industry and other partners. It is a great way to engage with industry, which brings also great learning. So there is a number of reasons besides the direct tech transfer activity itself that brings benefits back to the institution and the region.

Mrs. BIGGERT. Thank you.

You know, with the research—and I know sometimes that the labs that—you know, the funding runs out. What happens? And this—you have got a contract, whatever, and a license. What happens if—or that the research just doesn't go anywhere?

Ms. INNES. Those are very real questions. Thank you.

We do our best to help the companies. If they are small companies, we help them get on their feet. We give them payment plans. We do everything we can to keep them moving forward because, I think, as my colleagues have said, we are really trying to see these technologies advance because we want to see an impact from our research. But it is very difficult. We spend money on patents that we end up not being able to license or that companies can't pay us for and that, unfortunately, is just a cost of doing this business. We try to make more good decisions than bad and try to choose wisely and invest wisely, and I think to a large extent we do. But there are difficulties. And again as we hit them, we try to work through them. And so we are pretty flexible in our licensing terms. We want to work with a company if they have hit hard times or cannot pay to try to find a solution and maybe it is, again, a longer term to pay us back.

Mrs. BIGGERT. Thank you. My time is up.

Ms. Edwards, you are recognized for five minutes.

Ms. EDWARDS. Thank you, Madam Chair, and thank you to the witnesses.

I mean I think it has really been clear that all of us agree that the *Bayh-Dole Act* was really transformational in terms of university research and moving toward commercialization, but in recent years, a number of very provocative ideas have been thrown out about ways to modify Bayh-Dole. And some of those include allow-

ing the Federal Government to recoup some of its investment if a federally funded technology is successfully commercialized. Others include allowing researchers to choose a third party or themselves to negotiate license agreements for commercialization or establishing regional technology transfer offices. And of course there are others and so I wonder if each of you would just briefly comment on some of these concepts or others that would challenge the status quo and discuss why they are or are not good ideas. Dr. Sherer.

Dr. SHERER. Thank you, Ms. Edwards. I will speak first to the concept of potentially allowing researchers to control or make a decision about who would manage their intellectual property, a concept which is sometimes referred to as "free agency." I think that is a bad concept and the reason that I think it is is because it adds additional negotiation time to an already pretty burdensome process, because by definition you have to add at least one more negotiation to whatever negotiations are going to follow. And that is a negotiation between the home institution and the party that is going to now manage that intellectual property.

I think it is best to keep incentives aligned between the university and the faculty member at which the invention was created. And I also think that that kind of a system could potentially—we could see more of our innovation move out of state because you tend to engage the experts and the money and the people around you where you are putting the deal together. And if it is being managed out of state or across the country, I would argue that that would be where things would have a tendency to be concentrated.

Ms. EDWARDS. Thank you.

Ms. Innes.

Ms. INNES. Yes, thank you. I think a number of initiatives that would be very helpful. In particular I wanted to talk about the regional tech transfer offices. I think in areas where you have a number of smaller universities who may not have a large research base and can't really sustain an office that could be very helpful. Those are some initiatives we have talked about in North Carolina for our large university base where we have tech transfer offices in place at 6 of the larger of the 16 institutions.

I am not in favor of free agency. I just don't see that as workable. I know I would have no capacity to take on innovations from another university, from a free agency. Times are tough; finances are tight. I am going to use my resources to support the best and brightest coming out of my own institution. So I think that is just not a workable situation for us. And honestly, I think most faculty—but very few—would be skilled negotiators for themselves. I think we offer a very value-added service and we are helping protect their interest. We are helping them find a good deal and a favorable deal so I think we add value in that process.

So I think there are ways to enhance this and those would be—my focus would be helping the regional offices get created.

Ms. EDWARDS. Thank you.

Mr. Nisbet.

Mr. NISBET. I will also address that regional question. I think it is a good one, because I think one size does not fit all in terms of how you do it. Sometimes it makes sense to have something centralized within a region, but often I find that the hub-and-spoke

model of cooperation is better. We have recently had some experiences because our state government has provided some funds to encourage just that, that partnering among some of the neighboring Michigan schools and it has worked very well, in particular helping to fund—find the talent and fund the talent that helps with the evaluation of new opportunities, to help with the venture creation activities, finding and prospecting for new licensees, especially in the execution of those relationships.

And I think it is important to note, though, that we have found that the strength of those regional centers, the pride in their ownership, the links to their own alumni are very important to maintain. So that is one reason why I am in favor of a hub-and-spoke model to try to have the best of both worlds.

Ms. EDWARDS. Thank you.

Mr. Rosenbaum.

Mr. ROSENBAUM. I guess, with my background, I am going to follow the money. You mentioned the Federal Government recovering some of their investment in the research and my concern with that is there are different motivations for every entity and institution and money is a huge driver. And when you redirect money, you are going to redirect incentives and you are going to redirect efforts. And while it may be beneficial to see some of that money come back to the federal labs that have done that research, I don't think in the grand scheme of things it is going to be a significant number of dollars on the federal side but I think there are going to be some significant changes in behavior on the research side, on the university side that could be adverse. So I would be very worried about making changes like that.

Ms. EDWARDS. Thank you. My time is expired. Thank you.

Mrs. BIGGERT. Thank you. The gentleman from Illinois, Mr. Hultgren, you are recognized for five minutes.

Mr. HULTGREN. Thank you, Chairwoman Biggert.

Thank you all for being here today. A couple of questions, first, Dr. Sherer, wondered with the AUTM annual licensing survey, I wondered what the biggest surprise you have found from AUTM and just wondering if you are seeing any trends that encourage you or anything that disturbs you really from the findings from AUTM, the—I guess the Association of University Technology Mangers annual licensing survey. So I wondered if you could give me any thoughts on that.

Dr. SHERER. I would be happy to. We just completed 20 years of holding and conducting the licensing survey and had a chance to look over some of the trends of that data for the last 20 years. We don't have 20 years worth of data points for every question within the licensing survey. The one result that I found most surprising was that if you look at the—and it is in my—the attachment of my materials. If you look at the rate of federal research funding over the last 20 years, you can see there has been a very steep and steady increase in federal funding and what I found amazing was how closely the number of new invention disclosures and errors that occur. Again, it is on a different scale but the shape of those lines and the increase of those lines is very similar. We have always said that the amount of federal funding drives the amount of

tech transfer that we expect to see at our universities, but I didn't expect the data to mirror each other that closely.

The other interesting thing is that everything sort of follows from it. As we get more inventions disclosures, we found more patents. As we found more patents, we get more issued patents. As we negotiate more licenses, we see more products on the market and we have—we are actually awaiting some new job data that is going to be released tomorrow at the BIO International meeting in Boston with calculations of jobs created as a result of the licensing revenue.

Mr. HULTGREN. Great, thank you.

Want to open this up to any of you that would have some thoughts on this but one of my passions is again encouraging young people to go into research and science and wonder just as we are considering ways to help faculty and students transfer more of the technology that they conduct research on wondered from your perspective are younger faculty more open to spending time on technology transfer? Have you seen that institutions have built technology transfer into their tenure award system? Or what approaches could we do to—and that have you seen, to catch future faculty at earlier stages in their careers to encourage them in this process of technology transfer?

Mr. NISBET. Yes, I think that is a great question because we are seeing efforts to try to engage both the younger faculty in particular, but also some of the students, the post-docs and the grad students who are engaged in these research activities. They are very much interested in engaging in these both for career opportunities but also for learning and for their own networking purposes.

At the University of Michigan, we would make it a point to try to reach every new faculty and to make sure that they are acquainted with our office and the advantages. We have been surprised that sometimes in recruiting trips from faculty to Michigan they are actually looking for our capabilities and it is one of the factors in their decision. That is always great. We are looking for ways to try engage students in particular in this through internships. The fellows program that I mentioned is a great way to bring in grad students and post-docs and introduce them to new opportunities and the thought process, the decision process that shows their attraction in the marketplace.

And we are now trying to experiment with an opportunity to take post-docs who often have challenging academic career decisions and if they are interested in following a commercialization path through a new company that we have licensed or into an existing company to provide some funding to give them that path to see if that might be a career decision they would like to make. So all of those things are very important for the culture of the university, for the vibrancy of the region, and for our activities in tech transfer.

Ms. INNES. I would also like to comment that we have done a number of programs as well at the university. We do factor in participation in the patenting and invention disclosure process as part of promotion and tenure decisions. I think that is very important to get our faculty engaged. And we are seeing a lot of activity towards this coming out of the departments. They are very interested

in innovation. They are very interested in seeing an impact from their research.

We have also developed a program for an entrepreneurship minor for students in the College of Arts and Sciences, and it is our most popular minor to date. We also have a program where we are teaching how to start a company through our business school and that is accessible to all faculty, students, and staff. It is in the evening and it is free so we are really trying to promote this.

As part of our new innovative Carolina fundraising campaign, we also intend to—some of the money is going towards innovation faculty so that we can really extend and consider this opportunity.

Thank you.

Mr. HULTGREN. I am going to ask one more question real quick. My time is running down, but I would love to get some quick comments on one last thing.

Many of you have talked about programs that allow business people to come alongside faculty and to assist in the commercialization process here. Wondered if you could just briefly talk about best practices that you have seen to help us do that.

Dr. SHERER. One area of the best practices is to have an entrepreneurial residence type of program where you bring a skilled industry expert into the university and let them spend x period time, maybe six months, and you work with them to meet with faculty and potentially find an opportunity that they could spin out into a company.

Ms. INNES. We also use entrepreneurs and local businesspeople to help us make tough decisions if we are deciding on whether or not a technology we should continue with that if the licensing is stagnant. We gather their expertise, help us redirect the technology, help us find some way to help the company if necessary, a very valuable resource.

Mr. NISBET. And quickly, we took the approach of a mentor-in-residence. We changed it because rather than follow one technology, we wanted them to have a portfolio of technologies like staff. It has been great with assessment, it has been great for faculty consulting, and it has really enhanced our capabilities.

Mr. ROSENBAUM. And finally, real quickly, before we fund any project that is a tech transfer or otherwise, we engage outside industry experts to help evaluate the viability of it so we are making sure there is a commercial viability before we spend the dollars.

Mr. HULTGREN. Well, thank you again. Thanks for your speedy answers there but appreciate it so much. Appreciate your being here and I yield back.

Thank you.

Mrs. BIGGERT. Thank you.

The gentlelady from Oregon, Ms. Bonamici.

Ms. BONAMICI. Thank you very much, Madam Chair.

I have the privilege of representing a district in Oregon that includes part of what is known as the "Silicon Forest." We have trees and more rain. The important work that is conducted by our high tech sector there is really exciting. Of particular importance to the State is the Oregon Nanoscience and Microtechnologies Institute, which is affectionately known as ONAMI. It is a Signature Research Center that is an academic, business, and government col-

laboration that grows research volume and commercialization in the broad area of nano- and microscale science and engineering.

Since its inception in 2003 and through last year, they have leveraged more than $185 million in federal and private, created 21 startups with $70 million in venture and capital funding. They employ 86 full-time people and support another 1,700 jobs through research grants. They have created $290 million in revenue and filed 211 invention disclosures and received 21 patents in nanoscience and microtechnology. So I can tell you from looking at this record that they have been a key player in our community.

So I would like to ask our witnesses how do you work with any external partners like ONAMI to accelerate commercialization?

Dr. SHERER. Well, I can't resist taking that question, because I hail from Oregon myself and ran the tech transfer program at the University of Oregon and Oregon Health Sciences University where I was born and raised before coming to Georgia in 2003. So I missed ONAMI and I know a number of great things have happened since I left the State.

One of the things that we do in Georgia and do quite successfully—and it is similar to what you are describing—is we work with the Georgia Research Alliance, which is money that comes out of the State and helps provide valuable risk capital for early stage projects with the goal of creating new companies that are going to build a workforce in Oregon. In order to do that, we not only sit down with experts at the Georgia Research Alliance, but through that program, we engage some of the entrepreneurs I was talking about a moment ago. And we also work closely with sister institutions throughout the State because we all compete and participate in this Venture Lab program.

Ms. BONAMICI. Thank you.

Anyone else.

Ms. INNES. Similarly, we work very closely with the biotech sector in North Carolina. We have the North Carolina Biotech Center. They are helping us with technology transfer grants, with loans to startup companies, and a number of programming to foster the innovation coming out in the large bioscience sector in our region.

Ms. BONAMICI. Terrific.

Mr. NISBET. In a similar vein, we have an organization called Ann Arbor SPARK, which is a public-private entity that is a collaboration with the university and with government and industry that actually industry was formed as a result of a recommendation from my Tech Transfer National Advisory Board that were looking for ways to enhance our tech transfer performance. And we talked about some of the ecosystem advantages that we were lacking.

We have a very close relationship. We serve on the board. They focus on things that we also focus on—business development and traction, business acceleration, talent and funding, and of course marketing of a region. So it is a very close collaboration. It also has an extension into our state government with our Michigan Economic Development Corporation. So very similar outcomes, slightly different format.

Ms. BONAMICI. Excellent.

Mr. ROSENBAUM. And I daresay TEDCO is one of those aggregators and accumulators of skills and technologies. We actu-

ally—because we are not aligned with a specific university, a specific corporation, or a specific interest or stakeholder, we can actually aggregate and do aggregate resources from around the State and are able to convene groups of folks that wouldn't otherwise be able to get together. We sit on the boards of every incubator in the State. We sit on the board of every tech council in the State. We are involved with every tech transfer office in the State both federal and university. And we very often and easily can bring a cross-section of all those constituents to the table in order to collaborate in a very unthreatening manner.

Ms. BONAMICI. Terrific.

And just as a follow-up to the earlier response about how do we inspire and involve especially the students—and know Dr. Sherer will be proud of this—the University of Oregon has a technology entrepreneurship program. It is a year-long program in which business, law, and science graduate students work together to evaluate new technologies for commercial potential and then they develop a business plan. It has led to the creation of several successful companies since its inception in 2003. So that is a good partnership of bringing groups together.

And I am almost out of time, but I wanted to ask Mr. Nisbet. You mentioned that the University of Michigan has changed policies and practices to motivate faculty to engage more with industry. Can you talk about the challenges that researchers face when engaging with industry and participating in commercialization activities?

Mr. NISBET. Yes. Often it is because of the nature of their research interests and the interest of the organization that is from industry. What we have found, actually, it wasn't so much the terms that were really important; it was the predictability and the timeliness as you mentioned. So that is why we formed this recent initiative called the Michigan Research Advantage and we—it is again optional and sometimes the industry does not want it. But what we try to do is to come up with a way of predetermining the license terms before the invention is even created, which of course is quite difficult. But we find that when we bound the opportunities and bound their cost, it would lead to a much richer relationship with industry, which leads to a lot of other advantages.

Ms. BONAMICI. Thank you very much.

I will yield back.

Mrs. BIGGERT. Okay. The gentleman from New Mexico, Mr. Luján, is recognized for five minutes.

Mr. LUJÁN. Thank you very much, Madam Chair, and appreciate you calling this hearing.

Dr. Sherer, I very much appreciate you bringing to light the correlation behind the investment into tech transfer and the number of licenses that are being yielded. Sometimes we don't have to look far to see the importance of investment to tech transfer. And I think we all certainly agree, including most of us on this Committee, about the significance of what tech transfer can yield for the United States economy. Does everyone here—is there anyone that would disagree with the statement that the future of the economy in the United States can be strengthened through more robust investments and collaboration with the Federal Government, uni-

versities, and our national labs, and the private sector in developing tech transfer?

I appreciate that because this is something that if the United States was serious about—and I will just note for the record that no one disagreed with that, Madam Chair—the seriousness behind this is what can we do to turn this up? Herein lies an opportunity where we have seen the loss of manufacturing in the United States or even on that assembly line, on the frontline the innovation yields that we reap that were highlighted in a book "Make it in America" by the former CEO of Dow Chemical—or the CEO from Dow Chemical talks about the need to be able to bring that back. But in the realm of tech transfer specifically, what are the right metrics to use in judging the success of technology transfer? Just looking at the number of patents and licenses is not anything sufficient to understand the effect on the economy. And also, wouldn't it be helpful to have longitudinal studies that would look over time at the impacts of technologies? Ask anyone. Mr. Rosenbaum.

Mr. ROSENBAUM. Yes. We actually measure our tech transfer programs, not by the number of licenses because every project we fund is a tech transfer license, but we track our companies longitudinally for job creation, total revenue tax base, and are proud to say that with the right support these young companies can beat the averages. We have 82 percent of our companies still in existence after five years, which is off the charts compared to most startup statistics in the country.

Mr. LUJÁN. Mr. Nisbet.

Mr. NISBET. I think that is a very important point that we also try to—I think that quantity is important by the way. The number of agreements, number of startups does show that the number of shots on goal, but it is also important to measure the impact of what occurs. And I think part of it is going to be to follow on job opportunities and tax rates. That is a very long-term process though and it is very difficult to measure that when your technologies go into existing companies, which is common.

Instead, what we try to do is to tell stories, show stories of the inventors, of the inventions, of the technologies, and the companies and try to show the impact on the American people. I think that is one great way to motivate people. And in the end what you are trying to do is to promote more engagement which what you want to do is have some very careful ways of marketing and reaching to all of your channels, including your alumni which are quite valuable to get them to work with the universities and to get your technologies out into the marketplace.

Dr. SHERER. I would just add that I have always felt like new products on the market are the ultimate validation of any tech transfer program because that is really what it is all about and used to think that it didn't really matter whether it was a startup or an established company because it is just a means to an end and the end is to get—the end goal is to get products on the market. But in this jobless economy, talking about jobs has become much more important.

We do know from an old BIO study that about 279,000 jobs were created between 1996 and 2007 as a result of licensing revenue and the products put on the market through universities and hospitals.

And so I would still advocate that products are a very important metric that we track and that we need to get deals done so that our partners can get products on the market.

Ms. INNES. I would emphasize that it is also—I agree with everything that we have said. It is here on the—with my colleagues. It is important to get the products on the market. Absolutely that is the number one. Licensing is a measure of how well you are reaching your contacts. But I think it is also important to recognize this is an extremely long-term process, especially if you are in early stage therapeutics and biotech. So the return on investment is likely to come 10, 15, even—years later. So it is important to recognize it is a number of things that have to come together. It is not one metric or another.

Mr. LUJÁN. Thank you. And I have some other questions I will be submitting to the record, but given the—we have heard a little bit about SBIR today. We don't talk much about STTR, a program that has been terribly neglected by the Federal Government when I would suggest the importance of what we could be doing with small businesses around small business technology transfer programs. Could STTR be reprogrammed to be able to better work with small businesses, universities, and encourage collaboration with our national labs to close that gap to have better yields associated with technology transfer? Anyone.

Mr. NISBET. I think absolutely it does and it is—and one is obviously because of the funding. As my colleague mentioned, you know, follow the funding and that does create incentives. But it is also I think that engagement. It has to be a carefully crafted opportunity that is not just finding funding for the discovery purpose itself but to try to have that partnership that whatever discoveries occur because of that have a place in the marketplace. So it has to have a market awareness and validation aspect to make sure that it is going to be successful. But I think it definitely could be a valuable part.

Mr. LUJÁN. Anyone else? Dr. Sherer.

Dr. SHERER. Yeah, I would just argue that we use the STTR a lot as in—sometimes we use SBIR just sort of loosely to meet those two programs. But we work very closely with our startup companies to help them submit SBIR as well as STTR applications.

Mr. LUJÁN. Very good. Thank you very much.

Thank you, Madam Chair—Mr. Chairman.

Chairman HALL. [Presiding] Gentleman yields back, I presume?

Mr. LUJÁN. Yes.

Chairman HALL. Chair recognizes Mr. Lipinski, the gentleman from Illinois.

Mr. LIPINSKI. Thank you, Mr. Chairman.

I think that this is one of the most important hearings going on right now up here because everyone wants to know the answer to the question where are the jobs going to come from in our country? And there are great concerns over that and I certainly think that we need to be doing more to leverage the great research universities of our nation and also make sure we do what—all that we can to get the return on investment for all of the federal dollars that go into research in our Nation.

So let me start out with—there are a lot of different questions because I think this is critically important. But I want to first talk about the National Science Foundation program called the Innovation Corps or I–Corps. And the purpose of the I–Corps—it is a new program at NSF. It is to take individuals who have received NSF funding for research before and to teach them how to be entrepreneurs, essentially how to commercially develop their ideas. Are any of you familiar with the I–Corps program? I just wanted to know—I see Mr. Nisbet nodding his head. Do you have any comments on the value of the program or suggestions to improve it? So let me start, Mr. Nisbet.

Mr. NISBET. In our case it is fairly new. We are establishing an I–Corps center in Ann Arbor for the Midwest to provide that training that is associated with the I–Corps program. The one thing I find most valuable is—it is twofold. The focus on market awareness and understanding the market needs before getting too far into the funding that typically occurs through NSF grants and others; and secondly is developing the entrepreneurial support and the mentorship to try to provide some early stage guidance to those projects. But I think it has the potential to—one, to attract more people into the whole area of trying to commercialize research but also to put it in a more focused path towards a real market need.

Mr. LIPINSKI. Well, I was hoping Mr. Nisbet was familiar with it since July 16 is one of a—that starts at—another round that starts at Michigan. Thank you.

Anyone else? Mr. Rosenbaum.

Mr. ROSENBAUM. Yes, I would just like to say that I–Corps as well as many other entrepreneurship programs around the country and most universities today are very important but they are just the first step of getting products to market. A business needs to mature and I find that a lot of the entrepreneurship programs teach folks how to start a business but don't necessarily teach them how to grow a business and manage a business. So I think that the I–Corps program is great but we are going to need some follow-on support behind it if we are going to have some long-term success. As we have said, these things don't happen in a year or two years. Sometimes they take ten years. And an entrepreneurship program talks about the first year of life.

Mr. LIPINSKI. Anyone else.

Move on to another issue Mr. Rosenbaum had mentioned that Maryland Innovation Initiative supports the use of funds for early stage proof-of-concept and prototyping work. I was able to get language into the SBIR reauthorization last year that grants authority to NIH for a proof-of-concept program. What—I am going to ask everyone on the panel. What are your thoughts on the early stage funding for proof-of-concept programs? Is it something that all federal agencies should be exploring? So I will start with Mr. Rosenbaum.

Mr. ROSENBAUM. Yes, proof-of-concept is important, but one of the unique elements of the Maryland Innovation Initiative and other programs that TEDCO has had is that we don't fund those proof-of-concept projects until we know there is a market availability and viability for the product. A challenge with federal lab in particular is they don't have resources to look outside at market

needs. So you will need a third party to validate a market need and then absolutely fund that proof of concept for that research. But I would hate to see proof of concept funds going to a dead-end product.

Mr. NISBET. We have had some great experiences with the Coulter Translational Fund that we have operated at the University of Michigan for about five years. We have addressed that issue of the market validation by actually closely coupling the project management resources that were involved with shepherding the inventions and the work that was going on in the lab with work—with insider tech transfer office for doing the market awareness and assessing the market needs. They also used a board of directors, a council to help steer those projects on a quarterly basis so the results we saw was much accelerated projects with better decision-making and some real market successes. We think that that early stage funding, although not very large, can go a very long way in ensuring success.

Ms. INNES. I think it is a tremendous idea to support the proof-of-concept center and proof-of-concept funding. This is an area that is really important, especially in these long-term development projects such as early stage therapeutics. We really need to get more information before you can tell if they will be able to address the market they are attempting to serve and this proof-of-concept center would be tremendous.

Dr. SHERER. I would just add that the single most common feedback we get from potential licensees is the technology is too early. So proof-of-principle, proof-of-concept funding is the gating factor to getting more technology to a go-or-no-go decision point.

The other thing I would add is that too often proof-of-principle funds provide the same level of funding for life sciences and physical sciences type of inventions, and it takes a lot more money to get a life science invention to a proof-of-concept stage.

Mr. LIPINSKI. Thank you for your testimony. I yield back.

Chairman HALL. The gentleman yields back.

I don't see anyone else that needs to testify or wants to testify but I want to thank you for your time, and thank you for timely presenting your testimony to where we could be ready to ask you the proper questions. And thank you for the time it took to travel here and you have been very generous. And with that, I would ask you that we may ask you to respond to some of the things in writing we send you, to timely do that if you can. There will be others that aren't here. The other empty chairs indicate that they have got other hearings and things that are going on now but they are interested in your testimony and they are appreciative of your testimony and may have some other questions to ask you.

Mr. LUJÁN. Mr. Chairman.

Chairman HALL. Yes, sir.

Mr. LUJÁN. Because there were not a lot of folks that came to the Committee hearing today, is it possible to get another round of questions?

Chairman HALL. I don't think so. Do you have any other questions?

Mr. LUJÁN. I do, Mr. Chairman.

Chairman HALL. All right. I will recognize you for how many minutes?

Mr. LUJÁN. You can give me two, Mr. Chairman.

Chairman HALL. I will give you five minutes.

Mr. LUJÁN. Appreciate that, sir.

Chairman HALL. I will give anybody else time if they have questions they really want to ask.

Mr. LUJÁN. I appreciate that, Chairman, and thank you for calling this hearing. As I said earlier, I hope that we are able to have a similar discussion when it comes to natural labs—national labs and the technology transfer associated with the relationships with our universities as well.

There is a program that recently was granted to one of the universities of the United States where there is a collaboration around entrepreneurship training. I appreciate the recognition of what has been done to introduce entrepreneurship into undergraduate programs but also making sure that across disciplines—engineering, medical fields—that we are including entrepreneurial studies to see what we can do there.

Mr. Chairman, we have encouraged the entity associated with the responsibilities with Epicenter that they invite Members of Congress to be able to put together an entrepreneurship training so that way we begin to be able to think outside of the box associated with policy as well.

But specifically, Dr. Sherer, I am interested in the role of the Federal Government in funding transitional research beyond basic research to bridge the valley of death and help mature promising new technologies. There already exist a number of such federal programs with ARPA–E and with DARPA. Now, we begin to see the DHS S&T directorate as well beginning to take shape to spur innovation in particular sectors. However, there is not a lot of promising technologies—or there are a lot of promising technologies that don't necessarily fit into those programs necessarily from a top-down approach. What are your thoughts associated with the importance of strengthening the Nation's economic competitiveness from a bottom-up technology transfer approach?

Dr. SHERER. There are a lot of different directions I could go with that question. One of the challenges I think with translational funding is—and I think it is what you were alluding to—is there are pockets of it and you can participate in this particular one if you happen to come out of a particular area and maybe this one over here—excuse me—if you are in engineering or something of that sort. So not every technology necessarily has a route or a path or the same path and access to translational research funding.

But the other thing that I fear we are going to abandon in these times that we are in is just the need to continue to focus on the fundamentals and invest in the fundamentals. And we need to have properly staffed tech transfer offices and we need adequately sized patent budgets. The good news is is if—again if you look at the amount of data, it hasn't started to really taper off. It is in a few categories. If federal funding goes down, it will be interesting to see if that disclosure rate goes down and then everything else falls—flows from there.

So we don't yet—so the good news is is despite what is going on in the economy, tech transfer activity has been strong even over the last two or three years. I don't know what the next two or three will look like.

Mr. LUJÁN. Appreciate that.

Mr. Rosenbaum, I am very intrigued and supportive of the Maryland Innovation Initiative, so congratulations there, in part because there are some similarities in this area between Maryland and New Mexico and having a large number of researchers yet a relatively low degree of entrepreneurial activity that we are hoping to spur up. We have two national labs. We have the Air Force Research Labs, Air Force Nuclear Weapons Center, in conjunction with Kirtland Air Force Base where work was done with Sandia to the Satellite Operations Office, three bases from a military perspective that the energy directive programs, with Boeing, things of that nature, but yet we are not seeing the promise there.

Over what time frame does the State of Maryland expect its innovation initiative start yielding a positive return on its $5 million investment? And what are the key factors in making it a success? And what is the role of the Federal Government to support that initiative?

Mr. ROSENBAUM. Thank you. The key factor is some of the uniqueness in the way it has been structured. There are five universities participating, and all five universities will have a modified version of an entrepreneur in residence. We are calling them site miners because there will be multiples from each university and they will be cross-discipline and they will be charged with collaborating amongst each other and going to each other's universities to see pieces that may be able to be put together to create a whole solution. Much of what goes on in medicine today, for instance, is as much involved in IT as it is involved in biology. So having cross pollination across the disciplines is a key success factor there.

TEDCO's history with doing proof-of-concept projects is that we get about 25 percent of our projects to turn into companies. We get about 40 percent of them end up licensing technologies and about 25 percent turn into companies. So with our $5 to $6 million budget, once we are up and fully running, we expect to be funding between 40 and 45 projects a year so we expect to be spawning 10 to 15 new companies a year out of that. And we think that that will start in year two.

Mr. LUJÁN. Mr. Chairman, I appreciate your graciousness in the recognition of more time. And with that I yield back.

Chairman HALL. The name of Luján in New Mexico is very dear to me, and that is why I give you 10 minutes and everybody else gets five. If there are no further questions, the witnesses are excused. And for any additional comments and statements that we need from Members, you can do it by writing to them.

And at this time we are adjourned.

[Whereupon, at 11:14 a.m., the Subcommittee was adjourned.]

Answers to Post-Hearing Questions

Answers to Post-Hearing Questions

Responses from Dr. Todd T. Sherer

Questions from the Honorable Judy Biggert (R-IL)

Q: How does the US' model for technology transfer compare to technology transfer in other countries? Are our universities generally more or less successful, and in what ways?

A: The U.S. model is very similar to that used in a number of countries such as Canada, Europe and Australia. The U.S. model is being emulated by other countries that hope to improve the impact of their technology transfer. Migrating to a university-owned IP model is central to these efforts. The U.S. system is widely recognized as the most successful in the world due to the sheer size of our investment in research leading to new technologies as well as the maturity of our programs and economic landscape.

Q: Do you have any recommendations for changing the Small Business Technology Transfer Program (STTR) to allow for better utilization by universities and businesses?

A: The STTR program provides a valuable funding mechanism for companies looking to develop new products. I do not have any recommendations at this time except to continue to provide this funding.

Q: What are the complexities of the technology transfer lifecycle that merit the necessity of a university technology transfer office?

A: For the purposes of brevity, I will limit my response to the complexities of the business of technology transfer and the natural cultural gap between academia and industry. To address the later first, a cultural gap naturally exists between academia—which pursues knowledge for the sake of knowledge— and industry— which pursues knowledge for the sake of achieving a profit.

Technology transfer offices bridge this cultural gap by hiring professionals with experience in science, business and law—allowing faculty inventors to remain experts in teaching and research. In addition, technology transfer offices provide services focused on triaging new inventions, marketing them to companies, negotiating license agreements, managing the related compliance activities, and managing the expenses and revenues associate with these activities. The lifecycle for a given technology can be in excess of 20 years during which time an inventor could change employment many times.

Questions from the Honorable Donna Edwards (D-MD)

Q: We often hear how important comprehensive market analysis and market validation are to successfully commercialize new technologies. I'm wondering what AUTM is doing to help facilitate these activities for university-developed technologies, particularly for university researchers who generally will not have the expertise or market contacts to carry out this sort of analysis? What more, if anything, could be done?

A: Education of technology transfer professionals is one of AUTM's pillars of service to our membership. We regularly hold training sessions on the marketing and triaging of new inventions at many of our events including our national meeting, regional meetings, focused conferences, and webinars. We also provide education and resources via our *Technology Transfer Practice Manual* and our website. In addition, many other organizations

also provide this kind of training, including the Licensing Executives Society and Technology Transfer Tactics. Universities are currently building additional capacity in their technology transfer offices to do more of this including hiring dedicated marketing/triaging personnel, engaging graduate student interns and hiring external vendors to provide these services.

Questions from the Honorable Randy Neugebauer (R-TX)

Q: Historically, federal funding has primarily focused on basic research and not on the post-applied steps towards commercialization. In the current budget environment, I know we would all like to see more funding for everything, but that is simply not the reality. If you had to choose whether to fund basic research or commercialization at a university, where do you think federal funds should go?

A: Without research funding at universities, there would be no technologies to transfer or commercialize. Under the current budget cycle, more federal dollars are being allocated to more applied/translational research then in the past. It is largely unproven how successful these programs will be and for that reason I think a balanced approach is most prudent. In areas like the drug discovery, the odds are very small that any new drug will make it through the clinical and regulatory hurdles and onto the market. Without an ongoing investment in basic research we will soon run out of new drugs to study and many diseases will continue to go untreated for years to come

Q: Besides funding, what do you think is the biggest obstacle to accelerating technology transfer?

A: Patience, proper expectations, the economy and uncertainties regarding changing regulatory and clinical requirements.

Q: Many of you are promoting programs that allow business people to come alongside faculty to assist in the commercialization process. Could you elaborate on what you have found to be the best practices in this area?

A: Many universities have created comprehensive programs to assist startup companies. In addition, there are often many other sources of this support within our local economic ecosystems. As you allude to, it is critical to provide industry insight into product development, venture capital insight in fundraising strategies, and legal insight into corporate/patent matters. Best practices are to directly, or indirectly, link faculty-startups to all of these areas as they need to cross all the plates to hit a home run.

Questions from the Honorable Ben Luján (D-NM)

Q: This regards the role of the federal government in funding translational research, beyond basic research, to bridge the valley of death and help mature promising new technologies. There already exist a number of such federal programs that support technology transfer from the top-down, such as ARPA-E, to spur innovation in particular areas such as energy security. However, there are a lot of promising technologies that don't fit within that top-down approach, but could still contribute to the Nation's economic competiveness. Should the federal government support such bottom-up technology transfer?

A: I don't have knowledge of the ARPA-E program. I can imagine that such a top-down approach could be particularly useful in certain technology areas like energy. It would need to be evaluated more closely in areas that have a history of less government support to market.

Q: How are the changes to the patent law affecting university technology transfer?

A: Universities across the country have worked closely with their legal counsel to understand the implications of the America Invents Act. My sense is that everyone is feeling prepared for the changes. What is of bigger concern are the technical amendments and our hopes that they do not materially change the way the AIA is currently expected to work.

Q: What are the right metrics to use in judging the success of technology transfer? Just looking at the number of patents and licenses is not sufficient to understand the effect on the economy. Also, wouldn't it be helpful to have longitudinal studies that look over time at the impacts of technologies?

A: I have always felt that the number of new products on the market is the ultimate validation of technology transfer and new products take time to develop and very few technologies will make it that far. For some, that will be an appropriate metric, for others it will be the impact of those products which AUTM captures in its *Better World Report* featuring short stories about university technology that is making the world a better place to live. Still others will want to see the jobs number. University technology transfer offices aren't directly responsible for any of these metrics, though our activities make them possible. We are directly in control of working with faculty to solicit new inventions, filing patents and negotiating deals. Completing the deal is the final step in transferring our technology into the hands of a corporate partner who will then develop new products for the market. Of course, the number of deals will be larger at universities with more sponsored research. Longitudinal studies are very helpful as they help emphasize the many steps and timelines required to get technologies to market and the totality of their impact once on the market.

RESPONSES TO
QUESTIONS FOR THE RECORD
THE HONORABLE JUDY BIGGERT (R-IL)
U.S. House Committee on Science, Space and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012

Submitted by Catherine Innes
Director, Office of Technology Development
University of North Carolina at Chapel Hill

1. How does the United States' model for technology transfer compare to technology transfer in other countries? Are our universities generally more or less successful, and in what ways?

The United States has the most well established technology transfer program in the world. With the passage of the Bayh-Dole Act in 1980, most research universities in the U.S. developed technology transfer offices and began the process of commercializing innovations arising from their research. Over the past 30 years, many other countries, including South Korea, Germany and France, have passed similar laws and emulated the U.S. technology transfer model and expanded upon it.

For example, the United Kingdom has implemented a number of programs to enhance academic technology transfer. The Government has contributed to early stage seed funds at universities, created entrepreneurship centers, and in 2000 began the Higher Education Innovation Fund to create business development offices at universities. This influx of funding has dramatically changed the technology commercialization landscape in the UK and resulted in business development offices at most universities and regional networking activities and proof of concept funds.

The German Government launched a Patent Marketing Agency program in 2002. These Agencies provide professional services to universities and research institutes to evaluate, protect, and market new technologies. The Agencies work with technology transfer offices to select the most promising technologies to move forward. This approach has resulted in increased patent and commercialization awareness as well as an integrated national network among the Agencies representing more than 200 scientific institutions in the country.

U.S. universities have been engaged in technology transfer for more years than our counterparts in other countries so we have seen more technologies enter the market and we have generated more revenue than our peers around the world. By these measures we are likely more successful, but over time I would expect European and Asian nations to see similar results.

The challenges in commercializing university technologies are global: inventions arising from academic research are early stage and unproven. They require significant investment to reach commercial adoption. The majority of universities in the U.S. have not achieved significant financial success from their efforts. We would do well to emulate other countries and develop a sustainable source of funding to support early stage technology development through both public and private investment.

2. Do you have any recommendations for changing the Small Business Technology Transfer Program (STTR) to allow for better utilization by universities and businesses?

Reimburse Patent Costs. It would be very helpful if STTR and SBIR funds could be used for patent cost reimbursement when the startup company is licensing technology from a university. Universities often cannot carry patent expenses for their startups and the companies may have very limited funding when filing for patents is critical. Patent costs are not an allowable expense for any of the 11 participating federal agencies except the Department of Energy. While all of the agencies do allow for a line item to be included in the SBIR/STTR budgets called a "fee", the maximum fee that can be requested is 7% of the total direct and indirect costs that are being requested. The fee can be used for business related expenses such as patent costs, but often the costs a startup must cover from this fee far exceed the total they may spend.

Reduce Wait Time for Notification of Award. One item that is difficult for applicants to endure is the long wait time for reviews for both Phase 1 and Phase 2 proposals. While it is understandable that reviewing of thousands of proposals is a monumental task, it would be helpful for companies to have a clear picture of whether or not they have been funded sooner than the six to nine months it currently takes.

Diversify Awardees. Finally, it appears that a relatively small number of companies across the country continue to win a large number of awards (the proverbial "SBIR Mills"). The agencies have taken steps toward requiring companies that have won previous awards to demonstrate that they are adequately commercializing research from previous awards, but it would help to ensure that funds are broadly disseminated.

3. In your experience with the Carolina Express License, you mention that the small number of law firms that UNC-Chapel Hill companies typically use helped ease the development of a standard agreement. Does this mean that larger cities and communities may have difficultly modeling this type of licensing agreement? What other aspects of the agreement do you feel may have worked because of the size or unique nature of where your university is located?

Being located in a relatively small region made it easier for us to implement the Carolina Express License as the number of key players we needed to bring into the process was relatively small. While it will be more complex to engage a greater number of stakeholders in a larger region, this need not be a barrier. The key factor is to engage with those representing the startup community: attorneys, venture capitalists and serial entrepreneurs, and ask them to work with the university to implement a standard program that will benefit all stakeholders. In the RTP region, there is tremendous collaboration between regional universities, state government and the business community and these factors also aided development of our standard license.

RESPONSES TO
QUESTIONS FOR THE RECORD
THE HONORABLE DONNA EDWARDS (D-MD)
U.S. House Committee on Science, Space and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012

Submitted by Catherine Innes
Director, Office of Technology Development
University of North Carolina at Chapel Hill

1. We often hear how important comprehensive market analysis and market validation are to successfully commercializing new technologies. I'm wondering what the University of North Carolina at Chapel Hill is doing to help facilitate these activities for university-developed technologies, particularly for university researchers who generally will not have the expertise or market contacts to carry out this sort of analysis? What more, if anything, could be done?

Market analysis and validation are critical aspects of commercial development. Much of this activity at UNC Chapel Hill is conducted by the technology transfer office staff. We keep abreast of the state of the art and what companies are developing in our target market sectors. We obtain feedback from industry contacts and investors on the potential for our innovations. In addition, there are a number of resources available, such as consultants and market reports, that are extremely valuable and many technology transfer offices use these resources. We do not make extensive use of external resources due to budgetary constraints.

One of the biggest challenges in assessing the market viability of an invention is that our invention is unproven rather than there being a question of market need. For example, we have a number of compounds that have shown efficacy in treating bacterial infection, malaria, and epilepsy. Clearly there is a market for therapeutics for these indications; however, it will take considerable development and testing to determine if any of our compounds are efficacious in humans, cost effective, and non-toxic. In other cases we have innovations that have considerable functionality but there is no current market for it as yet, such as a development for solar fuels or use of hepatic stem cells to treat liver disease. It is hard to predict if the state of the art will evolve along the lines of our innovation and if we invest in patents, whether these will prove to be marketable when they issue several years later.

For the U.S. to maintain its leadership in the innovation economy, we must find ways to cost effectively advance promising technologies to point of adoption. We should consider developing non-profit regional proof of concept facilities offering at-cost or low cost experiments to advance early stage life science technologies. In this way universities could identify most viable technologies and accelerate commercial development. This would be particularly valuable if

structured as a public-private partnership such that the projects selected for advancement could address industry needs. Further, we need to find a way to close the development gap and offer incentives to companies licensing in early stage inventions from universities such as R&D tax credits, fast track patent review vouchers, or other.

2. In your testimony, you mention that the University of North Carolina was interested in starting more companies and helping them become sustainable, but that you had been constrained by limited financial resources and were therefore unable to invest in those ventures. I also understand that the University of North Carolina – along with over 30 other partners – submitted a proposal to the Economic Development Administration's i6 Challenge but unfortunately did not receive funding. Can you tell us some of the areas you would invest in if you had additional financial resources? What activities would have been funded had the University of North Carolina received the i6 funding?

We proposed to leverage i6 funds with existing resources to establish the ACTION Model (Accelerating Commercialization and Transfer – Innovation Opportunity Network) in North Carolina. The comprehensive model proposed to address persistent areas of critical need in North Carolina's innovation ecosystem, including a strategic build-out of the innovation culture and supporting infrastructure, talent development, and gap funding. The ACTION model as proposed initially focused on the University of North Carolina's (UNC) sixteen constituent universities, particularly those where an infusion of resources could further their impact in economically distressed areas.

Had this proposal been funded, North Carolina proposed to accelerate discovery of new innovations at UNC campuses that do not currently have a technology transfer program. The grant would have funded fellows to serve the 10 campuses in less populous regions of the state to identify promising innovations and develop the commercialization assessment resources and infrastructure for supporting new ventures. We are still seeking ways to advance technology commercialization throughout the state with other funding approaches.

RESPONSES TO
QUESTIONS FOR THE RECORD
THE HONORABLE RANDY NEUGEBAUER (R-TX)
U.S. House Committee on Science, Space and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012

Submitted by Catherine Innes
Director, Office of Technology Development
University of North Carolina at Chapel Hill

1. Historically, federal funding has primarily focused on basic research and not on the post-applied steps toward commercialization. In the current budget environment, I know we would all like to see more funding for everything, but that is simply not the reality. If you had to choose whether to fund basic research or commercialization at a university, where do you think federal funds should go?

This is very difficult question to answer. UNC, like many of its peer institutions across the country, relies heavily on federal funding to support our research initiatives and we would lose the ability to conduct important breakthrough research if federal funding were reduced. That said it would be beneficial to have additional funding opportunities to move promising innovations forward.

If I had to choose where federal funds would go I would have to say we need to continue funding basic research. While I personally would like to see more funding for applied research, it cannot be at the expense of basic research funding. Basic research is vital to the innovation economy and reduction in funding could cause irreparable harm to our innovation capacity.

2. Besides funding, what do you think is the biggest obstacle to accelerating technology transfer?

The biggest challenge is finding the market for technologies that are at an extremely early stage of development. Even with all the digital technology available today, we still have no effective way to easily connect university innovations to the companies that can advance them. There have been many good efforts at developing searchable databases for technologies from multiple sources, but in my view none has emerged as the sole 'go to' resource for universities to find licensees for their inventions. Part of the challenge is that a business model for this type of resource has not yet evolved and thus a common platform has not been established. Sourcing deals remains largely a network contact approach.

3. Many of you are promoting programs that allow business people to come alongside faculty to assist in the commercialization process. Could you elaborate on what have you found to be the best practices in this area?

One of the industry activities that we have found to be very helpful is the creation of dedicated 'technology scouts' that work with researchers and technology transfer offices at universities to identify research and inventions that are of interest to the company. In many cases research can be supported by the company and if inventions arise they can be readily licensed to the company, often on pre-established terms. This has worked well in the pharmaceutical sector and we hope to see this trend continue in other markets as well.

A new initiative in North Carolina is a partnership between the Blackstone Charitable Foundation and UNC Chapel Hill, North Carolina State University, North Carolina Central University, Duke University and the Council on Economic Development. This five-year initiative is aimed at making North Carolina's Research Triangle headquarters for America's next high-growth companies with the greatest potential to create new jobs. A $3.63 million gift will serve as the impetus to bring master entrepreneurs to the area and accelerate the rate of new company formation around new innovations.

RESPONSES TO
QUESTIONS FOR THE RECORD
THE HONORABLE BEN LUJÁN
U.S. House Committee on Science, Space and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012

Submitted by Catherine Innes
Director, Office of Technology Development
University of North Carolina at Chapel Hill

1. How are the changes to the patent law affecting university technology transfer?

The America Invents Act will make many improvements to the patent system that will benefit universities. Universities support the reduced fees under the new micro entity status and the simplified application process. Harmonization with the rest of the world should increase the opportunity for global interactions for both research and licensing. There also are protections for university inventions such as an exemption from the "prior user rights" defense to patent infringement. As we are awaiting final rules and the implementation of major provisions of the Act next year we can only speculate on the impact to universities at this point in time.

University technology transfer offices have to determine which potentially patentable inventions they should protect and which they should discard when the inventions are at a very early stage of development. Technology transfer offices try to balance the need to file patent applications prior to a researcher's publications and the risk that the innovation is not sufficiently developed to attract a licensee before incurring patent prosecution and foreign filing costs. While the new first inventor to file system is not effective until March of next year, university technology transfer offices are likely to be under increased pressure to file applications early and this will strain already tight budgets in most offices. I expect this impact to be transitional as inventors become familiar with the new system.

Universities will need to be far more diligent in educating researchers on disclosure requirements and the expanded body of prior art that will come into play in the new system. I understand that these provisions are still evolving and appreciate that universities have engaged in the process to ensure that the new law is balanced and provides a robust patent system for the United States.

2. What are the right metrics to use in judging the success of technology transfer? Just looking at the number of patents and licenses is not I think sufficient to understand the effect on the economy. Also, wouldn't it be helpful to have longitudinal studies that look over time at the impacts of technologies?

This is an extremely important question without an easy answer. I think it is important to look at the percentage of disclosed inventions that are licensed and whether those licenses result in new products and services entering the market. This type of metric can only be measured over considerable time as time to license may be up to ten years after an invention is reported and time to commercial products may be another decade beyond that. This has a great deal to do with the stage of development of the invention and market sector. But beyond licensing, we also need to look at what happens because of a license. Licensing should foster increased research and development and ultimately new business creation and new products and services on the market.

It is also very important to measure economic activity related to technology transfer efforts. The number of new companies formed is important to capture, but it is most important to track this impact over time and measure the growth in the number of employees and products emerging from these companies. My understanding is that start-ups based on university technologies have a good track record in this regard. Technology licensing often leads to increases in sponsored research funding back to the university and further technology innovation.

You have hit upon a key point in that any measure of technology transfer must be over decades rather than one or two years. Groups such as the Association of University Technology Managers (AUTM) and the Association of Public and Land Grant Universities (APLU) have been working to develop better metrics.

Nisbet - Response

QUESTIONS FOR THE RECORD
THE HONORABLE JUDY BIGGERT (R-IL)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and. Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19,2012

1. How does the United States' model for technology transfer compare to technology transfer in other countries? Are our universities generally more or less successful, and in what ways?

My informal comparison from conversations with peers in other countries indicate that the U.S. model based on Bayh-Dole is seen as being very successful. The ownership by universities drives subsequent internal investment in offices, development resources and leveraging of university relationships.

2. Do you have any recommendations for changing the Small Business Technology Transfer Program (STTR) to allow for better utilization by universities and businesses?

No.

3. In 2010, 14 Ohio universities signed an agreement with Proctor and Gamble (P&G) to simplify the legal process of negotiating joint research projects with the intent of bringing ideas to market faster. I understand that the University of Michigan has similar agreements in place with P&G, Dow Chemical, and the Ford Motor Company. How do such agreements provide predictability and flexibility for both the University and the innovation partner? Have you seen the anticipated results come to fruition?

These master agreements are helpful in cases when there is potential for significant engagements between the parties, as they provide a template to

- enhance relationships to expand partnering opportunities
- define major terms for the initial and subsequent agreements
- define expectations and priorities between the parties (useful for future inventor and business participants)
- facilitates discussions of future needs and opportunities

Yes, our researchers are very happy with the expanded project relationships and both parties feel good about our enhanced relationships.

QUESTIONS FOR THE RECORD
THE HONORABLE DONNA EDWARDS (D-MD) U.S.
House Committee on Science, Space, and Technology
Subcommittee on Technology aud Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012

1. We often hear how important comprehensive market analysis and market validation are to successfully commercializing new technologies. I'm wondering what the University of Michigan is doing to help facilitate these activities for university-developed technologies, particularly for university researchers who generally will not have the expertise or market contacts to carry out this sort of analysis? What more, if anything, could be done?

We do leverage the contacts and expertise of our faculty, which is often the best source for market partners and information. We also recruit and train our licensing staff to have these market analysis and validation skills. We invest in market research tools and databases, and also in industry conferences and engagements to obtain market intelligence. We also have created a Tech Transfer Fellows program using advanced degree students managed by a central tech transfer resource, to perform market studies to assist our license professionals in making decisions.

2. In your testimony, you mention the importance of tailoring technology transfer initiatives so that they account for the advantages and challenges of a specific region. Can you please elaborate on this comment and the how technology transfer initiatives could, or should, vary across regions? Also, in your experience, what are the key elements necessary to foster regional innovation and how can we leverage Federal research dollars to contribute to regional innovation ecosystems?

It is important to understand a region's advantages and resources, along with their challenges and lack of resources, in constructing a viable commercialization process. The "tailoring" factors include:

- availability and access to industry
- availability of early stage funding and entrepreneurs
- the amount and quality of research, and the areas of expertise
- the availability of regional commercialization resources and expertise

Some key elements for fostering innovation include

A. Talent – to
- assess technical and market potential
- model commercialization plans
- connect to market partners and expand networks
- operationalize opportunities

B. Funding (translational and gap funds, early stage private funds, growth funds)

C. Supportive culture and ecosystem

We can leverage Federal research dollars by ensuring vibrant support mechanisms are in place to support researchers and their research.

QUESTIONS FOR THE RECORD
THE HONORABLE RANDY NEUGEBAUER (R-TX)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012

1. Historically, federal funding has primarily focused on basic research and not on the post-applied steps toward commercialization. In the current budget enviromnent, I know we would all like to see more funding for everything, but that is simply not the reality. If you had to choose whether to fund basic research or commercialization at a university, where do you think federal funds should go?

Tough question. I would fund commercialization funding only if there was minimal impact on the quantity and quality of basic research funds.

2. Besides funding, what do you think is the biggest obstacle to accelerating technology transfer?

Having expertise and resources to understand market needs related to tech transfer opportunities
Having access to talent to plan and implement commercialization plans

3. Many of you are promoting programs that allow business people to come alongside faculty to assist in the commercialization process. Could you elaborate on what have you found to be the best practices in this area?

We have a Mentor-in-Residence (MiR) program in which experienced entrepreneurs are employed as half-time employees for 12-18 month rotations within our tech transfer office. They help assess our new inventions and provide guidance to our inventors and our staff in creating new ventures. They can have no financial stake in our projects, ensuring total objectivity in their work. They expand our networks by connecting us to additional talent and resources. We have seen a dramatic enhancement in our productivity with this program.

QUESTIONS FOR THE RECORD
THE HONORABLE BEN LUJAN (D-NM)
U.S. House Committee ou Science, Space, and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19,2012

1. How are the changes to the patent law affecting university technology transfer?
   We have seen no material changes.

2. What are the right metrics to use in judging the success of technology transfer? Just looking at the number of patents and licenses is not I think sufficient to understand the effect on the economy. Also, wouldn't it be helpful to have longitudinal studies that look over time at the impacts of technologies?

License agreements (to existing and start-up businesses) are our primary measure of success.
Licenses to start-ups are a special focus because of their regional economic development impact.
Impact is difficult to measure because success often requires long-term efforts. We measure business expansions and jobs created, as well as induced investment in the University (new sponsored research) and community. We find that telling stories and describing their impact is helpful: cost savings, lives saved, productivity, industries created, enhanced quality of life, etc.

Rosenbaum

QUESTIONS FOR THE RECORD
THE HONORABLE JUDY BIGGERT (R-IL)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012

1. How does the United States' model for technology transfer compare to technology transfer in other countries? Are our universities generally more or less successful, and in what ways?

Biggert Question 1: The only other country I am familiar with is Israel and to the best of my knowledge tech transfer is not intended to be a profit center. The only motive is to get technology into the commercial markets, with or without defined remuneration.

2. Do you have any recommendations for changing the Small Business Technology Transfer Program (STTR) to allow for better utilization by universities and businesses?

Not Answered.

QUESTIONS FOR THE RECORD
THE HONORABLE DONNA EDWARDS (D-MD)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012

1. Identifying ideas in a university that have commercial potential can be a challenge. The concept of using "site miners" in the Maryland Innovation Initiative has the possibility of speeding up the identification and commercialization of federally-funded university research. Can you please elaborate on how these "site miners" would operate and what makes their activities different than activities performed in a university technology transfer office?

Edwards Question 1: A white paper was written by Bryan Sivak during his tenure as Maryland's Chief Innovation Officer. Within the white paper he described the site miners as follows:
The site miners will:

- Either be technology transfer professionals who work in consultation with university faculty, or members of university faculty;
- Create inter-disciplinary teams of clinicians, scientists, engineers, business strategists, lawyers, and pharmacists to solve existing problems identified in clinical practice; and
- Will work within the academic research facilities, and will come together as a single group periodically at a location designated by the Secretary of Business and Economic Development.

The teams created by the site miners will compete for no less than 40 grants of up to $100K. The grants will be awarded on a rolling basis over the course of 12 months by the MI board. The board will meet as often as necessary to ensure the grants are awarded in a timely manner.
By linking innovators with experienced entrepreneurs and the technology transfer offices at these three institutions, we anticipate 10% of the funded projects will become new start-up companies, be licensed to established companies, and/or become standards of clinical care within two years of receiving funding.

2. We often hear how important comprehensive market analysis and market validation are to successfully commercializing new technologies. I'm wondering what TEDCO is doing to help facilitate these activities for university-developed technologies, particularly for university researchers who generally will not have the expertise or market contacts to carry out this sort of analysis? What more, if anything, could be done?

Edwards Question 2: TEDCO has a program targeted at that very problem. The TechStart program provides funding to a small team consisting of an entrepreneur, scientist and the tech transfer office to evaluate the commercial viability of the scientist's innovation. The money is used to answer a strategic

question around competition, market size, freedom to operate, or any other issue that is needed to decide if there is a viable business that can be created from the innovation.

QUESTIONS FOR THE RECORD
THE HONORABLE RANDY NEUGEBAUER (R-TX)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012

1. Historically, federal funding has primarily focused on basic research and not on the post-applied steps toward commercialization. In the current budget environment, I know we would all like to see more funding for everything, but that is simply not the reality. If you had to choose whether to fund basic research or commercialization at a university, where do you think federal funds should go?

Neugebauer Question 1: Assuming federal labs continue basic research commercialization funding for universities would be very beneficial.

2. Besides funding, what do you think is the biggest obstacle to accelerating technology transfer?

Neugebauer Question 2: University culture

3. Many of you are promoting programs that allow business people to come alongside faculty to assist in the commercialization process. Could you elaborate on what have you found to be the best practices in this area?

Not Answered.

QUESTIONS FOR THE RECORD
THE HONORABLE BEN LUJÁN (D-NM)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act

Tuesday, June 19, 2012

1) Over what time frame does the state of Maryland expect its Innovation Initiative to start yielding a positive return on its 5 million dollar investment? Also, what will be the key factors in making it successful?

Lujan Question 1: We believe company formation will start within 6 months of the first project completion. The key success factor will be the collaboration between industry and the site miners.

2) How are the changes to the patent law affecting university technology transfer?

Not Answered

3) What are the right metrics to use in judging the success of technology transfer? Just looking at the number of patents and licenses is not I think sufficient to understand the effect on the economy. Also, wouldn't it be helpful to have longitudinal studies that look over time at the impacts of technologies?

Lujan Question 3: I believe commercial impact, either jobs, revenue, or in the case of medicine, improvements in the standard of care should be considered. Longitudinal studies would definitely be beneficial.

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