IMPROVING TECHNOLOGY TRANSFER AT UNIVERSITIES, RESEARCH INSTITUTES, AND NATIONAL LABORATORIES

HEARING

BEFORE THE

SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

WEDNESDAY, JULY 24, 2013

Serial No. 113–43

Printed for the use of the Committee on Science, Space, and Technology

Available via the World Wide Web: http://science.house.gov

U.S. GOVERNMENT PRINTING OFFICE
82–222PDF WASHINGTON : 2013

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HON. LAMAR S. SMITH, Texas, *Chair*

DANA ROHRABACHER, California
RALPH M. HALL, Texas
F. JAMES SENSENBRENNER, JR., Wisconsin
FRANK D. LUCAS, Oklahoma
RANDY NEUGEBAUER, Texas
MICHAEL T. McCAUL, Texas
PAUL C. BROUN, Georgia
STEVEN M. PALAZZO, Mississippi
MO BROOKS, Alabama
RANDY HULTGREN, Illinois
LARRY BUCSHON, Indiana
STEVE STOCKMAN, Texas
BILL POSEY, Florida
CYNTHIA LUMMIS, Wyoming
DAVID SCHWEIKERT, Arizona
THOMAS MASSIE, Kentucky
KEVIN CRAMER, North Dakota
JIM BRIDENSTINE, Oklahoma
RANDY WEBER, Texas
CHRIS STEWART, Utah
VACANCY

EDDIE BERNICE JOHNSON, Texas
ZOE LOFGREN, California
DANIEL LIPINSKI, Illinois
DONNA F. EDWARDS, Maryland
FREDERICA S. WILSON, Florida
SUZANNE BONAMICI, Oregon
ERIC SWALWELL, California
DAN MAFFEI, New York
ALAN GRAYSON, Florida
JOSEPH KENNEDY III, Massachusetts
SCOTT PETERS, California
DEREK KILMER, Washington
AMI BERA, California
ELIZABETH ESTY, Connecticut
MARC VEASEY, Texas
JULIA BROWNLEY, California
MARK TAKANO, California
ROBIN KELLY, Illinois

SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

HON. LARRY BUCSHON, Indiana, *Chair*

STEVEN M. PALAZZO, Mississippi
MO BROOKS, Alabama
RANDY HULTGREN, Illinois
STEVE STOCKMAN, Texas
CYNTHIA LUMMIS, Wyoming
DAVID SCHWEIKERT, Arizona
THOMAS MASSIE, Kentucky
JIM BRIDENSTINE, Oklahoma
LAMAR S. SMITH, Texas

DANIEL LIPINSKI, Illinois
FEDERICA WILSON, Florida
ZOE LOFGREN, California
SCOTT PETERS, California
AMI BERA, California
DEREK KILMER, Washington
ELIZABETH ESTY, Connecticut
ROBIN KELLY, Illinois
EDDIE BERNICE JOHNSON, Texas

CONTENTS

Wednesday, July 24, 2013

IMPROVING TECHNOLOGY TRANSFER AT UNIVERSITIES, RESEARCH INSTITUTES, AND NATIONAL LABORATORIES

WEDNESDAY, JULY 24, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Subcommittee met, pursuant to call, at 3:08 p.m., in Room 2318 of the Rayburn House Office Building, Hon. Larry Bucshon [Chairman of the Subcommittee] presiding.

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6301
(202) 225–6371
www.science.house.gov

Subcommittee on Research and Technology Hearing

Improving Technology Transfer at Universities, Research Institutes and National Laboratories

Wednesday, July 24, 2013
2:00 p.m. – 4:00 p.m.
2318 Rayburn House Office Building

Witnesses

Dr. Brian Wamhoff, Vice President of Research & Development and Co-founder, HemoShear, LLC

Dr. Elizabeth Hart-Wells, Assistant Vice President for Research and Associate Director of the Burton D. Morgan Center for Entrepreneurship, Purdue University

Dr. Erik Lium, Assistant Vice Chancellor, Office of Innovation, Technology & Alliances, University of California, San Francisco

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

Improving Technology Transfer at Universities, Research Institutes and National Laboratories

Wednesday, July 24, 2013
2:00 p.m. – 4:00 p.m.
2318 Rayburn House Office Building

Purpose

On Wednesday, July 24, the Subcommittee on Research and Technology will hold a legislative hearing on innovative approaches to technology transfer at universities, research institutes, and national laboratories, and on potential improvements to the Small Business Technology Transfer (STTR) program. The hearing will focus specifically on a discussion draft of legislation, titled the "Innovative Approaches to Technology Transfer Act of 2013." The legislation would dedicate a portion of STTR funding to establish a program that awards grants for innovative technology transfer programs at universities, research institutes, and national laboratories with the goal of improving technology transfer.

Witnesses

- **Dr. Brian Wamhoff**, Vice President of Research & Development and Co-founder, HemoShear, LLC
- **Dr. Elizabeth Hart-Wells**, Assistant Vice President for Research and Associate Director of the Burton D. Morgan Center for Entrepreneurship, Purdue University
- **Dr. Erik Lium**, Assistant Vice Chancellor, Office of Innovation, Technology & Alliances, University of California, San Francisco

Background

In fiscal year 2012, the Federal Government funded more than $131 billion in research and development (R&D) 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 nonprofit institutions like universities, research institutes, and national laboratories, efforts to improve the transfer of federally-funded research are of interest to both the Federal Government and stakeholders across the nation.

Several researchers at policy think tanks, including the Brookings Institution, Heritage Foundation, Center for American Progress, and the Information Technology and Innovation Foundation, have called for improvements to technology transfer and return on investment of

[1] Christine M. Matthews, *Federal Support for Academic Research*, Congressional Research Service, October 18, 2012, http://www.crs.gov/pages/Reports.aspx?PRODCODE=R41895&Source=search

federally funded R&D at research universities, nonprofit research institutes, and national laboratories[2].

Bayh-Dole Act

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 technologies 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. Bayh-Dole changed the incentive structure for nonprofits and small businesses to patents and licenses of inventions. In 1980, 390 patents were awarded to universities;[3] by 2009, the number increased to 3,088.[4]

Small Business Technology Transfer Program

The Small Business Technology Transfer Program (STTR), created by P.L. 102-564 and most recently reauthorized in the National Defense Authorization Act for Fiscal Year 2012 (P.L. 112-81), is a small business program that provides federal research and development funding for proposals that are developed and executed cooperatively between a small firm and a researcher in a nonprofit research organization.

Federal agencies and departments with annual extramural research budgets of more than $1 billion are required to operate STTR programs. The Departments of Energy, Defense, and Health and Human Services, the National Aeronautics and Space Administration, and the National Science Foundation participate in the STTR program. Under the National Defense Authorization Act for Fiscal Year 2012, the formula funding for STTR is 0.35 percent of all extramural research for Fiscal Years 2012 and 2013, will increase to 0.4 percent for Fiscal Years 2014 and 2015, and will increase again to 0.45 percent for Fiscal Years 2016 and 2017.

Under the reauthorization, up to $150,000 in Phase I funding may be awarded to partnerships between small businesses and researchers to evaluate a concept's scientific or technical merit and feasibility; Phase II awards of up to $1,000,000 may be awarded for the performance of the principal R&D. The reauthorization provides a degree of flexibility on award amounts for participating agencies. In fiscal year 2012, federal agencies and departments participating in the STTR program provided 635 awards totaling more than $215 million.

---

[2] S. Ezell and R. Atkinson, *25 Recommendations for the 2013 America COMPETES Act Reauthorization*, ITIF, April 2013; D. West, *Improving University Technology Transfer and Commercialization*, Brookings Institution, December 2012; M. Stepp, S. Pool, J. Spencer, and N. Loris, *Turning the Page: Reimagining the National Labs in the 21st Century Innovation Economy*, ITIF, Center for American Progress, Heritage Foundation, June 2013.

[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.

Hearings and Legislation

In March, 2011, the Committee held a hearing on reauthorization of the Small Business Innovation Research (SBIR) and STTR programs. Mr. Mark Crowell, Executive Director and Associate Vice President for Innovation Partnerships and Commercialization at the University of Virginia, recommended dedicating a portion of STTR funds for early stage proof of concept work at research institutions, after an evaluation by panels of experts in translational and proof of concept research.[5]

The Committee approved H.R. 1425, the *Creating Jobs Through Small Business Innovation Act of 2011* to reauthorize the SBIR and STTR programs on May 4, 2011. As part of the markup of H.R. 1425, the Committee agreed to an amendment offered by Rep. Dan Lipinski (IL) to pilot a proof-of-concept grant program through the National Institutes of Health (NIH). Several key portions of H.R. 1425, including the proof-of-concept grant program, were incorporated into P.L. 112-81.

Discussion Draft of *Innovative Approaches to Technology Transfer Act of 2013*

The discussion draft of legislation provided to the witnesses would direct federal agencies and departments that participate in the STTR program to establish a grant program to fund proposals, through a competitive, merit-based process, that help facilitate and accelerate the transfer of federally funded research and technology into the marketplace.

In determining which proposals are awarded grants, participating federal agencies and departments shall consider whether the proposals demonstrate proven strategies that could achieve greater impact with grant funding, or whether the proposals outline new approaches that have the potential to increase or accelerate technology transfer outcomes and can be adopted by other qualifying institutions.

The draft legislation authorizes each participating federal agency and department to expend up to 0.05 percent of its extramural research budget on the STTR program in fiscal years 2014 and 2015, and up to 0.1 percent of its extramural research budget on the program in fiscal years 2016 and 2017.

The draft legislation also requires participating federal agencies and departments to develop a plan for program evaluation and appropriate data collection to assess the effectiveness of the program. In addition, the legislation requires the Small Business Administrator to include, on a publicly-available database required under the Small Business Act, information on the evaluation plan, recipients of program funding, and information on the use of program funding by recipients.

[5] W.M. Crowell, Testimony before the House Science, Space, and Technology Subcommittee on Technology and Innovation hearing on "The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs," March 31, 2011.

Issues for Examination

Witnesses have been asked to provide comments and recommendations on the discussion draft of the *Innovative Approaches to Technology Transfer Act of 2013* in their testimony. In addition, Dr. Wamhoff has been asked to describe how proof of concept funding helped to launch his business. University witnesses have been asked to describe innovative approaches to technology transfer at their respective universities.

The hearing will examine whether the proposed legislation can improve the STTR program and general technology transfer outcomes at research institutions.

Chairman BUCSHON. The Subcommittee on Research and Technology will come to order.

Good afternoon. Welcome to today's hearing entitled, "Improving Technology Transfer at Universities, Research Institutes, and National Laboratories." In front of you are packets containing the written testimony, biographies, and truth in testimony disclosures for today's witnesses.

I now recognize myself for five minutes for an opening statement.

Today's hearing is being held to review innovative approaches to technology transfer at universities, research institutes, and national laboratories, and to examine a discussion draft of legislation titled, "The Innovative Approaches to Technology Transfer Act of 2013."

In 2012, the Federal Government funded more than $131 billion in research and development activities. More than half of all basic research conducted at our Nation's colleges and universities is funded by the Federal Government.

According to the Association of University Technology Managers, technology transfer is the process by which universities and research institutes transfer scientific findings from one organization to another for the purpose of further development or commercialization.

The Bayh-Dole Act, passed in 1980, changed the incentive structure for universities and research institutes to work with commercial entities, including small businesses, to license and patent technologies. The Small Business Technology Transfer or STTR Program was created to provide Federal R&D funding for proposals that are developed and executed jointly between small business and a researcher in a nonprofit research organization. My own State of Indiana has seen 99 STTR awards totaling more than $26 million. Both Bayh-Dole and the STTR Program have helped to create jobs and translate new technologies into the marketplace.

However, while the rate of technology transfer at our Nation's universities, research institutes, and national laboratories has increased since the passage of the Bayh-Dole Act and the creation of the STTR Program, I believe we can do even better.

The draft legislation, which is being developed under the leadership of my colleague from New York, Mr. Collins, will create a program to incentivize research institutions to implement innovative approaches to technology transfer to achieve better outcomes. The legislation would dedicate a portion of STTR Program funding to provide grants to research institutions to help facilitate and accelerate the transfer of federally funded research and technology into the marketplace.

We will be hearing today from the co-founder of a growing biotechnology business based in Charlottesville, Virginia, that was developed out of federally funded R&D, with the assistance of private foundation technology transfer grant funding. We will also hear from the Assistant Vice President for Research and Associate Director of the Burton D. Morgan Center for Entrepreneurship at Purdue University in my home State of Indiana and from the Assistant Vice Chancellor for the Office of Innovation, Technology, and Alliances at the University of California, San Francisco. Our witnesses have first-hand experience in technology transfer and

can provide insight into how the proposed grant program could help facilitate better technology transfer outcomes.

I am looking forward to hearing from our witnesses on their thoughts about the proposed legislation, including any recommendations they have for improvements.

I would like to thank all of our witnesses for being here today, and we look forward to your testimony.

[The prepared statement of Mr. Bucshon follows:]

PREPARED STATEMENT OF SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY CHAIRMAN LARRY BUCSHON

Good afternoon, I'd like to welcome everyone to today's hearing, which is being held to review innovative approaches to technology transfer at universities, research institutes and National Laboratories, and to examine a discussion draft of legislation, titled the "Innovative Approaches to Technology Transfer Act of 2013."

In 2012, the Federal Government funded more than $131 billion in research and development activities. More than half of all basic research conducted at our nation's colleges and universities is funded by the Federal Government.

According to the Association of University Technology Managers, technology transfer is the process by which universities and research institutes transfer scientific findings from one organization to another for the purpose of further development or commercialization.

The Bayh-Dole Act, passed in 1980, changed the incentive structure for universities and research institutes to work with commercial entities, including small businesses, to license and patent technologies. The Small Business Technology Transfer or STTR program was created to provide federal R&D funding for proposals that are developed and executed jointly between a small business and a researcher in a nonprofit research organization. My own state of Indiana has seen 99 STTR awards totaling more than $26 million. Both Bayh-Dole and the STTR program have helped to create jobs and translate new technologies into the marketplace.

However, while the rate of technology transfer at our nation's universities, research institutes and national laboratories has increased since the passage of the Bayh-Dole Act and the creation of the STTR program, I believe we can do even better.

The draft legislation, which is being developed under the leadership of my colleague from New York, Mr. Collins, will create a program to incentivize research institutions to implement innovative approaches to technology transfer to achieve better outcomes. The legislation would dedicate a portion of STTR program funding to provide grants to research institutions to help facilitate and accelerate the transfer of federally funded research and technology into the marketplace.

We will be hearing today from the co-founder of a growing biotechnology business based in Charlottesville, Virginia that was developed out of federally funded R&D, with the assistance of private foundation technology transfer grant funding. We will also hear from the Assistant Vice President for Research and Associate Director of the Burton D. Morgan Center for Entrepreneurship at Purdue University in my home state of Indiana. And from the Assistant Vice Chancellor for the Office of Innovation, Technology, and Alliances at the University of California, San Francisco. Our witnesses have first-hand experience in technology transfer and can provide insight into how the proposed grant program could help facilitate better technology transfer outcomes.

I'm looking forward to hearing from our witnesses on their thoughts about the proposed legislation, including any recommendations they have for improvements.We thank our witnesses for being here today and we look forward to your testimony.

Chairman BUCSHON. I will now recognize the Ranking Member, the gentleman from Illinois, Mr. Lipinski, for an opening statement.

Mr. LIPINSKI. Thank you, Mr. Chairman. Thank you for holding this hearing, and thank each of our witnesses for being here to share your thoughts on this topic and the draft legislation we are considering today.

Today concerned Americans continue to ask the question, "What is the future of American jobs?" A big part of our future competitiveness depends on our ability to move new and emerging technologies out of the lab and into the mainstream of commerce.

Accelerating technology transfer from our universities and national labs is one of my highest priorities since I have come to Congress. I believe the potential for job creation emanating from research being performed at these institutions is immense. We must capitalize on these opportunities and get the best possible return in our investments in research through the creation of new projects, new companies, and new American jobs.

Let me make one point clear. Our competitors have noticed how well our innovation system works and many are trying to imitate it. Countries like China and members of the European Union are now investing heavily in their own R&D programs. Combined business and government spending in R&D in China, for instance, has been increasing by almost 20 percent a year over the past decade, and China has already overtaken Japan as the number two publishers of scientific articles. They are determined to move up the value chain into higher-tech, higher-paying jobs. We need sustained investments and smart policies if we want to remain the world leader in science and technology.

However, the path from the lab to a successful business is anything but straightforward. It depends on an integrated network of private companies, scientists and engineers, universities, venture capitalists, startups, and entrepreneurs. It also depends on the entrepreneurial environment, timing, and luck.

Some universities have had more success in technology transfer than others. Some scientists are better prepared or more inclined to be entrepreneurial, and some parts of the country have cultivated networks of entrepreneurials and venture capitalists who have vast experience turning ideas into products that can transform our everyday lives.

This draft legislation attempts to increase the successful transition to thriving startup by supporting innovative approaches to technology transfer. The draft bill language is similar to an amendment I sponsored two years ago to the *Creating Jobs Through Small Business Innovation Act of 2011.* My amendment was incorporated into SBIR/STTR Reauthorization with bipartisan support and allowed for a Proof of Concept Pilot Program at the National Institutes of Health. That amendment, similar to the legislation being discussed today, did not spend any new money.

Instead, it allowed NIH to use money from their STTR fund to set up a grant program to support translational research and entrepreneurial education activities at universities across the Nation.

At a time when we struggle with job creation in a fast-changing global economy, we need to be looking more closely at how best we can help our universities and national labs, filled with the world's best researchers, be even better economic engines that power America's future. When technologies have been developed with Federal taxpayer resources, we should explore whether there is a role for the government to play in aiding potential commercialization. Most venture capitalists are unwilling to take on the risk in

the early-stages of the innovation ecosystem, and in fact, their investments are moving farther and farther downstream.

I believe this legislation has the potential to improve our return on investment and research, and I am interested in our witnesses' recommendations on a draft bill.

In particular, I am interested in hearing their comments on using funds from the STTR Program to support technology transfer activities, as well as their thoughts on the reporting obligations of the draft bill and whether this information is readily available or would be overly burdensome to collect. I know that alleviating bureaucratic burdens on universities has rightfully been the focus of this Subcommittee.

I also hope the witnesses will provide us with some information on best practices, model programs, or policies that can improve the technology transfer process, and appropriate role of the Federal Government in supporting such efforts.

The draft legislation as written gives agencies discretion on what types of programs to fund with these grants. I would like to understand the most useful places for the Federal Government to be involved and the major gaps or barriers that our resources can help overcome.

I look forward to working to advance legislation on this important topic. We need to do all we can to help turn American discoveries into American jobs, and as I said, I very much like this—the draft legislation we have out there, maybe because I believe Mr. Collins is a mechanical engineer, the most brilliant people that there are, but I think that we have—there is a lot that we can learn from the witnesses today about how best to take the draft legislation and put it into a final bill.

But I appreciate the opportunity to hear from our witnesses today.

Thank you.

[The prepared statement of Mr. Lipinski follows:]

PREPARED STATEMENT OF SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY
RANKING MINORITY MEMBER DANIEL LIPINSKI

Mr. Chairman, thank you for holding this hearing and thank you to our witnesses for being here to share your thoughts on the topic and the draft legislation we are considering today.

Today, concerned Americans continue to ask, "What is the future of American jobs?" A big part of our future competitiveness depends on our ability to move new and emerging technologies out of the lab and into the mainstream of commerce. Accelerating technology transfer from our universities and national labs has been one of my highest priorities since coming to Congress. I believe the potential for job creation emanating from research being performed at these institutions is immense. We must capitalize on these opportunities and get the best possible return on our investments in research through the creation of new products, new companies, and new American jobs.

Let me make one point clear: Our competitors have noticed how well our innovation system works, and many are trying to imitate it. Countries like China and members of the European Union are now investing heavily in their own R&D programs. Combined business and government spending on R&D in China, for instance, has been increasing by almost 20% a year over the past decade, and China has already overtaken Japan as the number two publisher of scientific articles. They are determined to move up the value chain into higher tech, higher paying jobs. We need sustained investments and smart policies if we want to remain the world leader in science and technology.

However, the path from the lab to a successful business is anything but straightforward. It depends on an integrated network of private companies, scientists and engineers, universities, venture capitalists, startups, and entrepreneurs. It also depends on the entrepreneurial environment, timing, and luck.

Some universities have had more success in technology transfer than others. Some scientists are better prepared or more inclined to be entrepreneurial. And some parts of the country have cultivated networks of entrepreneurs and venture capitalists who have vast experience turning ideas into products that can transform our everyday lives.

The draft legislation attempts to increase the successful transition to thriving startup by supporting "innovative approaches to technology transfer." In fact, the draft bill language is similar to an amendment I sponsored two years ago to the Creating Jobs Through Small Business Innovation Act of 2011. My amendment was incorporated into the SBIR/STTR reauthorization with bipartisan support and allowed for a Proof of Concept Pilot Program at the National Institutes of Health. That amendment, similar to the legislation being discussed today, did not spend any new money. Instead, it allowed NIH to use money from their STTR fund to set up a grant program to support translational research and entrepreneurial education activities at universities across the nation.

At a time when we struggle with job creation and a fast-changing global economy, we need to be looking more closely at how we can best help our universities and national labs—filled with the world's best researchers—be even better economic engines that power America's future.

When technologies have been developed with Federal taxpayer resources, we should explore whether there is a role for the government to play in aiding potential commercialization. Most venture capitalists are unwilling to take on the risk in the early-stages of the innovation ecosystem, and in fact their investments are moving farther and farther downstream.

I believe this legislation has the potential to improve our return on investment in research, and I am interested in our witnesses' recommendations on the draft bill. In particular, I am interested in hearing their comments on using funds from the STTR program to support technology transfer activities, as well as their thoughts on the reporting obligations in the draft bill and whether this information is readily available or would be overly burdensome to collect. I know that alleviating bureaucratic burdens on universities has rightfully been a focus of this Subcommittee.

I also hope the witnesses will provide us with some information on best practices, model programs, or policies that can improve the technology transfer process, and the appropriate role of the federal government in supporting such efforts.

The draft legislation, as written, gives agencies discretion on what types of programs to fund with these grants. I'd like to understand the most useful places for the federal government to be involved and the major gaps or barriers federal resources can help overcome. I look forward to working with you to advance legislation on this important topic. We need to do all we can to help turn American discoveries into American jobs.

Thank you Mr. Chairman. I yield back the balance of my time.

Chairman BUCSHON. Thank you very much.

I am now going to recognize the Ranking Member of the full Committee, Ms. Johnson, for an opening statement.

Ms. JOHNSON. Thank you very much, Mr. Chairman, and thank you for calling the hearing today on this draft legislation, Innovative Approaches to Technology Transfer Act of 2013. I am glad that this Subcommittee is taking a serious look at the issue of facilitating the creation of successful, profitable, and sustainable small businesses from the discoveries of our research and development enterprise.

The topic today is so critical to our Nation's economic and national security. As we continue our efforts to keep our economy on the path of recovery, it is more important than ever that we recommit ourselves to innovation in the United States. As the President remarked two years ago in his State of the Union Address, we need to out-innovate, out-educate, and out-build the rest of the world.

Our universities and Federal labs are the foundation that America's future will be built upon.

We have world-class scientists and engineers engaged in cutting-edge research that can change the world. We must examine how to translate and transition this research out of the lab into the marketplace. Our innovation model has been the gold standard for many years, and nations around the world have been adopting it.

However, we are all very aware that our competitors are multiplying their investments in not only R&D and STEM education but also in commercialization activities. The United States cannot afford to be left behind. The ideas from our researchers and entrepreneurs with the most commercial potential deserve our best efforts.

In contemplating the next steps for advancing technology transfer, our ultimate goal is to promote the creation of innovation ecosystems that sustain long-term and mutually-beneficial collaborations. Many of today's most beneficial technologies do not emerge out of the straight-line process but rather they involve the interactions of a network of various public and private-sector elements. While we understand that university culture and business culture are separate and unique entities, we need to learn more about innovative approaches and collaborations that can accelerate technology transfer of federally funded research.

I believe there is not a clear and distinct line in the innovation process at which the public role ends and the private role begins. The next development or discovery is built on a shifting platform where the line between research, development, and a final product in the marketplace are blurred. The feedback is critical and cannot continue without consistent support of the people and the institutions that make up the innovation ecosystems.

The Federal Government has a great stake in the Nation getting a return on the investments we make, and we need to know what we can do that would be helpful to the academic community and startups in improving technology transfer.

The draft legislation we are considering this afternoon has the potential to improve technology transfer, and I hope that the final version can reflect good ideas from both sides of the aisle.

I would like to add my thanks to the witnesses for being here today and for providing us with their recommendations on how to make this bill better. I am looking forward to working with my colleagues to move legislation that addresses this important issue.

Thank you, Mr. Chairman. I yield back the balance of my time.

[The prepared statement of Ms. Johnson follows:]

PREPARED STATEMENT OF COMMITTEE ON SCIENCE, SPACE AND TECHNOLOGY
RANKING MEMBER EDDIE BERNICE JOHNSON

Thank you Mr. Chairman for calling this hearing today on the draft legislation, Innovative Approaches to Technology Transfer Act of 2013. I am glad that this Subcommittee is taking a serious look at the issue of facilitating the creation of successful, profitable, and sustainable small businesses from the discoveries of our research and development enterprise.

The topic today is so critical to our nation's economic and national security. As we continue our efforts to keep our economy on the path to recovery, it is more important than ever that we recommit ourselves to innovation in the United States.

As the President remarked two years ago in his State of the Union address, "we need to out-innovate, out-educate, and out-build the rest of the world."

Our universities and federal labs are the foundation that America's future will be built on. We have world class scientists and engineers engaged in cutting-edge research that can change the world. We must examine how to translate and transition this research out of the lab and into the marketplace.

Our innovation model has been the gold standard for many years, and nations around the world have been adopting it.

However, we are all very aware that our competitors are multiplying their investments in not only R&D and STEM education, but also in commercialization activities. The United States cannot afford to be left behind. The ideas from our researchers and entrepreneurs with the most commercial potential deserve our best efforts.

In contemplating the next steps for advancing technology transfer, our ultimate goal is to promote the creation of innovation ecosystems that sustain long-term and mutually beneficial collaborations.

Many of today's most beneficial technologies did not emerge out of a straight-line process, but rather they involved the interactions of a network of various public and private sector elements.

While we understand that university culture and business culture are separate and unique entities, we need to learn more about innovative approaches and collaborations that can accelerate technology transfer of federally funded research.

I believe there is not a clear and distinct line in the innovation process at which the public role ends and the private role begins.

The next development or discovery is built on a shifting platform where the lines between research, development, and a final product in the marketplace are blurred.

This feedback is critical and cannot continue without consistent support for the people and the institutions that make up the innovation ecosystem.

The federal government has a great stake in the nation getting a return on the investments we make, and we need to know what we can do that would be helpful to the academic community and start-ups in improving technology transfer. The draft legislation we are considering this afternoon has the potential to improve technology transfer, and I hope that the final version can reflect good ideas from both sides of the aisle.

I'd like to add my thanks to the witnesses for being here today and for providing us with their recommendations on how to make the bill better.

I am looking forward working with my colleagues to move legislation that addresses this important issue.

Thank you Mr. Chairman, I yield back the balance of my time.

Chairman BUCSHON. Thank you very much.

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

At this time I am going to introduce our witnesses. Our first witness is Dr. Brian Wamhoff, Vice President of Research and Development and Co-Founder of HemoShear, LLC. Dr. Wamhoff has expertise in small and large animal models of vascular disease, molecular biology, cell-based systems, toxicology, and interventional vascular device development. Dr. Wamhoff obtained a B.S. in biology with a minor in business administration from Rhodes College and received his Ph.D. in medical physiology from the University of Missouri in 2001.

Our second witness is Dr. Elizabeth Hart-Wells, Assistant Vice President for Research and Associate Director of the Burton D. Morgan Center for Entrepreneurship at Purdue University. Dr. Hart-Wells is responsible for managing the commercialization of Purdue's intellectual property assets, which includes responsibility of evaluating innovations, developing commercialization strategies, memorializing commercialization agreements, promoting discovery with delivery, forming startup companies, and overseeing compliance with Federal technology regulations. I don't know how she has time to do all that, but she does. She earned a doctorate in chem-

istry from Rice University where she was a Turner outstanding graduate student in organic chemistry and a Harry B. Weiser Research Scholar, and Robert A. Welch Foundation Fellow. She earned a Bachelor's Degree in chemistry from Indiana University. She is a member of the American Chemical Society, the American Association for the Advancement of Science, and the U.S. Patent Bar.

Our third witness is Dr. Erik Lium, Assistant Vice Chancellor, Office of Innovation, Technology, and Alliances at the University of California at San Francisco. He has held prior positions at UCSF of Vice Chancellor of Research, Director of the Industry Contracts Division, and Interim Director of the Contracts and Grants Division of the Office of Sponsored Research, and Director of Business Development for the Diabetes Center and Immune Tolerance Network. He served as a post-doctoral research scientist at UCSF, earned a Ph.D. from the Integrated Program in Cellular, Molecular, and Biophysical Studies at Columbia University and a B.S. in biology from Gonzaga.

Thanks again to our witnesses for being here this afternoon. As the witnesses should know, spoken testimony is limited to five minutes after which the Members of the Committee will have five minutes each to ask questions.

I now recognize Dr. Wamhoff for five minutes to present his testimony.

TESTIMONY OF DR. BRIAN R. WAMHOFF,
VICE PRESIDENT OF RESEARCH & DEVELOPMENT,
CO-FOUNDER, HEMOSHEAR, LLC

Dr. WAMHOFF. Thank you. Dear Mr. Chairman and distinguished Members of this very important Committee, as an entrepreneur and scientific executive of a startup company, I can state categorically that the American economy and its 300 plus million consumers of healthcare products and services have benefited profoundly from Federal programs that fund early-stage research in the medical sciences, particularly the SBIR mechanism. Thank you.

I have been invited to address three questions. I want to tell you a story first.

By way of background, I was an Associate Professor at the University of Virginia's Department of Medicine in the Cardiovascular Division from 2006, until 2012. Through collaboration with Dr. Brett Blackman, who, Mr. Collins is also a mechanical engineer, in the Department of Biomedical Engineering, we developed a technology at the university that became the foundation of a very successful biotechnology research company, HemoShear. We co-founded the company in 2008.

I now serve as Vice President of Research and Development, and Brett serves as Chief Scientific Officer. We are literally changing the decades-old global drug discovery and development paradigm. The old methods are inefficient, time-consuming, and more than 92 percent of drugs that go into humans today fail. They either fail because they don't work, or they fail because they are not safe. We see it every week in the news.

The adverse financial impact of these failures, in combination with patent expirations, has driven consolidation of the industry in

recent years. Our technology, which is developed out of the University of Virginia, through mechanisms that we are talking about today, has enabled the industry to transform its drug discovery paradigm while significantly improving its return on investment capital. This is because HemoShear can measure and predict the response of a drug before it ever enters the human body.

HemoShear is a successful American company. We are creating high-value, STEM-related jobs right here in Central Virginia, while positioning itself to become a world leader in drug development. The SBIR mechanism has been critical in this process.

So how has proof-of-concept funding been used to launch HemoShear? The development of the technology at the University of Virginia was funded by two seed grants, rather than the traditional NIH funding mechanism that my lab and Brett's lab was being driven by. The two funding mechanisms were the University of Virginia Heart Board Partners' Fund and the University of Virginia Wallace H. Coulter Foundation RoPE Fund.

Without these seed funding mechanisms, it is doubtful that HemoShear would exist as it does today and very doubtful that I would be sitting here right now. Equally important to funding the critical R&D to launch this technology was the exposure that we were getting to very successful board members from both organizations, the endless advice, hands-on help towards translating an academic technology to a business model for commercialization, going from academia to a commercial endeavor. It is a huge gap.

It is important to note that at the time this was not common at the University of Virginia, and by example of that success this mechanism has become a core of the university's technology transfer ecosystem and philosophy.

Now, at HemoShear we have also been privileged to secure funding through the NIH Small Business Innovation Research Program, the SBIR mechanism. It has been instrumental in the technological growth of HemoShear, allowing us to further advance our technologies for drug development in cardiovascular disease, diabetes, liver toxicity, and cancer. We have proven that the SBIR mechanism provides a great return on investment for the U.S. taxpayer.

Thank you for continuing to support that program.

What are my thoughts on today's issue? I feel that it would be beneficial to dedicate a portion of the STTR Program to proof-of-concept and other technology transfer programs at universities, research institutions, and national laboratories. Having run a large NIH-funded academic laboratory and co-founded a rapidly-growing biotechnology company, I have lived in both worlds. It is very challenging, and the investigator often finds himself, herself in conflict. The old adage that it is hard to have two bosses couldn't be any more real in that scenario, and often your bosses are diametrically opposed; bosses from the commercial side and bosses from the academic side.

As I stated in question one, if it were not for the exposure to the board members of the Heart Board and the Coulter Foundation it is highly unlikely that we would have had the foresight or wherewithal to commercialize a very important technology for human health. The failure to commercialize academic research is not for the lack of entrepreneurial faculty wanting to do so. There are

many. Rather, it is due in part to the lack of institutional support to assist faculty in these endeavors and sometimes creating barriers. Filling this gap is going to be the greatest need for technology transfers in universities.

My last thoughts or recommendations regarding the draft of this proposal, I have read the draft and fully support the award criteria. As it relates to the proposed funding mechanism, I think it is really important to establish hands-on oversight committees or boards to monitor the accountability of the funded institutions. An excellent model for this is the Wallace H. Coulter Foundation and how they monitor initial investments in translational research at U.S. academic institutions. These investments ultimately led to larger endowments for the research institution but also spun out many companies at the University of Virginia, including HemoShear.

With that I thank you for your time on this very important matter.

[The prepared statement of Dr. Wamhoff follows:]

HEMOSHEAR
THINK HUMAN.

HEMOSHEAR, LLC
1115 5th STREET, S.W.
CHARLOTTESVILLE, VA 22902

Wednesday, July 24, 2013

Testimony of Dr. Brian R. Wamhoff, PhD, before the U.S. House of Representatives, Subcommittee on Research and Technology, in the matter of "Improving Technology Transfer at Universities, Research Institutes and National Laboratories."

Dear Mr. Chairman and distinguished members of this important Committee; as an entrepreneur and scientific executive of a start-up company, I can state categorically that the American economy and its 300+million consumers of health care products and services have benefited profoundly from federal programs that fund early stage research in the medical sciences. Thank you.

I have been invited to address three questions in my testimony today:

1. To explain how proof of concept funding was used to help launch HemoShear as a business;
2. To provide my thoughts on whether it would be beneficial to dedicate a portion of Small Business Technology Transfer program to proof-of-concept and other technology transfer programs at universities, research institutions and national laboratories; and
3. To provide my thoughts and recommendations regarding the draft "Innovative Approaches to Technology Transfer Act of 2013".

By way of background, I was an Associate Professor at the University of Virginia's Department of Medicine, Cardiovascular Division, from 2006-2012. Through collaboration with Dr. Brett Blackman, PhD, Department of Biomedical Engineering, we developed a technology at the University of Virginia that became the foundation of a very successful biotechnology research company, HemoShear, LLC, which we co-founded in 2008. I now serve at Vice President of Research & Development and Dr. Blackman serves as Chief Scientific Officer at HemoShear. HemoShear is changing the decades-old global drug discovery and development paradigm. The old methods are inefficient, time-consuming, and costly because more than 92% of drugs that pass pre-clinical animal studies fail in human trials, either due to safety issues or lack of efficacy. The adverse financial impact of these failures, in combination with widely publicized patent expirations, has driven consolidation of the pharmaceutical and biotechnology industries in recent years. HemoShear's unique laboratory technology enables the pharmaceutical industry to transform its drug discovery paradigm while significantly improving its return on invested capital because HemoShear can measure and predict the response of human biology to new drug candidates. HemoShear is a successful American company that is creating high-value STEM-related jobs in central Virginia, while positioning itself to become a world leader in drug development.

1. *How proof of concept funding was used to help launch HemoShear as a business.*

The development of the technology at the University of Virginia was funded by two "seed" grants, rather than the traditional NIH funding mechanisms, such as the NIH RO1 mechanism. The two funding mechanisms were the University of Virginia Heart Board Partners' Fund and

the University of Virginia Wallace H. Coulter Foundation RoPE Fund. Without these seed funding mechanisms, it is doubtful that HemoShear would exist as it does today. Equally important to funding critical R&D proof-of-concept studies, we were given exposure to very successful board members of these organizations and endless advice and hands-on help towards translating an "academic" technology to a business model for commercialization. It is important to note, that at the time, this was not common at the University and by example of success, it is becoming a core of the University's technology transfer ecosystem and philosophy.

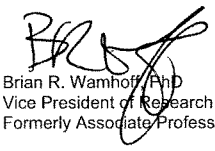
At HemoShear, we have also been privileged to secure funding through the NIH Small Business Innovation Research program. The SBIR mechanism has been instrumental in the technological growth of HemoShear, allowing us to further advance our technologies for drug development in cardiovascular disease, diabetes, liver toxicity and cancer. We have proven that the SBIR mechanism provides a great return on investment for the U.S. taxpayer. Thank you for continuing to support the SBIR program.

2. *Thoughts on whether it would be beneficial to dedicate a portion of Small Business Technology Transfer program to proof-of-concept and other technology transfer programs at universities, research institutions and national laboratories.*

I feel that it would be beneficial to dedicate a portion of the STTR program to proof-of-concept and other technology transfer programs at universities, research institutions and national laboratories. Having run an NIH-funded academic laboratory and co-founded a rapidly growing biotechnology research company, I have lived in both worlds. It is very challenging and the investigator often finds himself/herself in conflict. As I stated in Question 1, if it were not for the exposure to the board members of the Heart Board and the Coulter Foundation, it is highly unlikely that we would have had the foresight or wherewithal to commercialize a very important technology for human health. The failure to commercialize academic research is not for the lack of entrepreneurial faculty wanting to do so, there are many. Rather, it is due in part to the lack of institutional support to assist faculty in these endeavors and sometimes, creating unintended barriers of entry. Filling this gap is perhaps the greatest need in technology transfer for universities. When successful, the return on investment for U.S. taxpayers, who pay for NIH-funded academic research, will be new technologies for saving lives, improving human health, and speeding new drugs to market.

3. *Thoughts and recommendations regarding the draft "Innovative Approaches to Technology Transfer Act of 2013".*

I have read the draft and fully support the award criteria, method of program evaluation, data collection and dissemination. As I stated in Question 2 above, establishing mechanisms within universities to engage faculty and remove barriers for translating academic discoveries to commercialization is paramount to commercial success. Additionally, as it relates to this proposed funding mechanism, establishing "hands-on" oversight committees or boards to monitor accountability of the funded institution(s) is imperative. An excellent model for this is the Wallace H. Coulter Foundation and how they monitored initial investments in translational research at U.S. academic institutions that ultimately lead to larger Coulter Partnership Endowments for the successful institutions.



Brian R. Wamhoff, PhD
Vice President of Research & Development, HemoShear, LLC
Formerly Associate Professor, Department of Medicine, University of Virginia

HEMOSHEAR
THINK HUMAN.

HEMOSHEAR, LLC
1115 5th STREET, S.W.
CHARLOTTESVILLE, VA 22902

Dr. Brian R. Wamhoff is co-founder of HemoShear and co-inventor of its patented technology. HemoShear creates human relevant systems to accurately replicate the biology of organ systems and diseases for use throughout drug discovery and development. Working in strategic partnerships with pharmaceutical, biotechnology and medical device companies, HemoShear generates meaningful human response data to increase confidence in decision-making, reduce risk of costly failures and identify efficacious therapies. Our science leads to new medicines and improves human health. Dr. Wamhoff has expertise in small and large animal models of vascular disease, molecular biology, cell-based systems, toxicology and interventional vascular device development. During his tenure as Associate Professor at the University of Virginia, he obtained funding from the National Institutes of Health, the pharmaceutical industry, the American Heart Association, and other organizations to study fundamental mechanisms that regulate vascular disease. Dr. Wamhoff has authored more than 55 peer-reviewed manuscripts, as well as several book chapters and commentaries. Dr. Wamhoff has also received multiple awards for his successes, including the 2004 American Physiological Society Cardiovascular Young Investigator Award, the 2008 Atherosclerosis, Thrombosis, and Vascular Biology Irvine H. Page Award, the 2010 American Physiological Society New Investigator Award for Cardiovascular Research, the 2011 Rhodes College Distinguished Alumni Award, his alma mater and recently, he was a 2012 Center for Innovative Technology GAP 50 Entrepreneur Award recipient. Dr. Wamhoff obtained a BS in Biology with a minor in Business Administration from Rhodes College in 1996 and received his PhD in Medical Physiology from the University of Missouri in 2001.

Chairman BUCSHON. Thank you. Now I will recognize Dr. Hart-Wells for five minutes to present her testimony.

TESTIMONY OF DR. ELIZABETH HART–WELLS, ASSISTANT VICE PRESIDENT FOR RESEARCH, ASSOCIATE DIRECTOR OF THE BURTON D. MORGAN CENTER FOR ENTREPRENEURSHIP, PURDUE UNIVERSITY

Dr. HART-WELLS. Thank you. I wish to thank the Committee, Chairman Bucshon, Ranking Member Lipinski, and the entire Subcommittee for the opportunity to participate in today's hearing. It is an honor to be provided this opportunity to discuss the draft legislation.

As mentioned, I am Elizabeth Hart-Wells, and I am the Assistant Vice President for Research at Purdue University and Associate Director of the Burton D. Morgan Center for Entrepreneurship. Further, in my spare time, I lead a team of dedicated Housiers to manage the Office of Technology Commercialization that is housed within the Purdue Research Foundation. To quantify the scope of our operation is submitted in the written testimony, so I won't comment on that in my oral.

Founded in 1869, West Lafayette, Indiana, Purdue University serves the people of the State of Indiana, the Nation, and the world through education, research, and engagement. Purdue educates over 75,000 students statewide each year and is home to a very robust research enterprise of over $650 million in research expenditures, primarily originating from the U.S. taxpayers through such programs as the SBIR and STTR.

The Committee is both aware and respectful of the critical role the American research enterprise plays in our Nation's competitiveness. Universities engage in fundamental research to grow our knowledge base, to advance understanding, and to encourage thinking without constraint or restraint in our next generations. Inherent to exploration in uncharted areas of inquiry, however, is discovery. Discovery can and should lead to delivery, however, gaps in the path that connects discovery to delivery do exist.

In my reading of its current draft of legislation, it is the filling of this gap that is the subject of the proposed draft.

Specifically, the Committee requested comment on innovative practices employed by Purdue University to develop federally funded research projects. The Purdue Trask Innovation Fund and the Emerging Innovations Fund are two of such programs. While there are details in the written testimony and I look forward to discussing those relevant aspects of the programs as the Committee wishes, I will highlight one output data of those proof-of-concept fund that we call the Trask Innovation Fund.

First I will say at the outset this fund is entirely funded with private dollars and not taxpayer dollars. Purdue, in 1973, identified this need of a gap between research results and commercial exploitation of those results and set out to fill that gap themselves. And as a result in the last five years 48 Purdue technologies have been competitively awarded development funding, and of those, 35 percent of those technologies were sponsored by the U.S. taxpayers.

Over the roughly 35 year history of the Trask Venture Fund support of filling the gap, federally funded Purdue technologies that were supplemented with these awards experienced about a 40 percent increased licensing rate than those federally funded Purdue technologies that were not supplemented with those awards.

In addition and with brevity I would like to highlight a few other innovative practices that Purdue University has undertaken in the last several months.

The Office of Technology Commercialization has unveiled new procedures and policy implementations to accelerate technology transfer out of the university, whether Purdue University owns the technology or not. Students who create inventions in the performance of their coursework, such as a design project in an engineering course, own their inventions. Purdue inventors who have contributed Purdue-owned intellectual property may elect an, "as is," license contract to establish a new venture based on those inventions to which she or he contributed.

Of particular pertinence to this authorizing body, Purdue now offers recipients of SBIR and STTR grants aimed at developing a Purdue technology, a cash-free first option to license the Purdue technology. This express first option allows these recipients to competitively leverage Purdue technology, provides a mechanism to support the commercialization of taxpayer-funded technologies, and supports speed and transparency of the licensing of the same.

Accordingly, it should be of no surprise that Purdue University strongly supports and encourages the Committee's sincere consideration of the draft legislation. It would strengthen and promote partnerships between universities and small businesses to achieve the STTR's stated goals. Proposed legislation superimposes on its predecessor and emphasizes the benefits to the Nation of technology innovation and the proficiency of small businesses to translate federally funded research results into new products and services.

The proposed legislation offers synergy to these relationships between the university and small businesses towards translation and commercialization. So maybe one plus one can indeed equal three.

I am going to defer the rest of my comments until the Q&A, and in close I just wish to express my grateful thanks to the Committee for the opportunity to participate today and for your leadership, commitment, and partnership on this important topic of technology transfer.

Thank you.

[The prepared statement of Dr. Hart-Wells follows:]

REMARKS BEFORE THE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY OF THE U.S. HOUSE OF REPRESENTATIVES , 24 July 2013

Foremost, I wish to thank the Committee for the opportunity to participate in today's hearing. It is an honor to be provided an opportunity to discuss the proposed legislation provisionally referred to as 'Improving the Transfer of Federally Funded Research and Technology Act of 2013".

I am Elizabeth Hart-Wells and I am assistant vice-president for research at Purdue University and associate director of the Burton D. Morgan Center for Entrepreneurship. With respect to intellectual property, I have worn a few relevant hats. I am an inventor on a patented technology resulting from my graduate research at Rice University, from which I earned by doctorate in chemistry. As a chemist, I have worked within a university spin-out, that was located in The Woodlands, Texas, as well as a large industrial chemical company principally based in the MidWest. At the National Academy of Sciences, and part of the Committee on Science, Engineering and Public Policy, I participated in science policy research initiatives in STEM education. I am also familiar with the hallowed halls of the U.S. House of Representatives, having been fortunate enough to earn a congressional fellowship sponsored by the American Chemical Society to participate in the American Association for the Advancement of Science's Science and Technology Policy Fellowships program. I am a registered patent practitioner with the United States Patent & Trademark Office and was with the law firm of Fulbright & Jaworski LLP, where I cut my teeth on patent prosecution, primarily working with universities and small businesses in the chemical and medical art fields.

Over the last decade of my career, I have been responsible for the management of university-generated intellectual property within the walls of academic research institutes, including the management of intellectual property for the Middle Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases, a multi-party consortium of research institutes supported by the National Institute of Allergy and Infectious Diseases, led by the Center for Vaccine Development, University of Maryland School of Medicine. This brings me to today. With a team of dedicated Hoosiers and Boilermakers, I manage the Office of Technology Commercialization at the Purdue Research Foundation, one of the most comprehensive technology transfer programs among leading research universities in the United States. Services provided by our office support the economic development initiatives of Purdue University and execute on the university's mission as a public land-grant university. Over the last five years, our Office of Technology Commercialization has received and reviewed north of 1400 new invention and copyright disclosures, obtained nearly 500 issued Letters patents worldwide, granted commercial rights vis-a-via over 400 licenses and options to license, which translates to over 600 Purdue technologies, to the private sector.

REMARKS BEFORE THE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY OF THE U.S. HOUSE OF REPRESENTATIVES , 24 July 2013

Founded in 1869 in West Lafayette, Indiana, as a land-grant university, Purdue serves the people of Indiana, the nation, and the world through education, research and engagement. Purdue educates over 75,000 students statewide each year and is home to a robust research enterprise of over $650 million in research expenditures. Academically, Purdue's role as a major research institution is supported by top-ranking disciplines in pharmacy, business, engineering, and agriculture. It's also a place where those who seek an education come to make their ideas real — especially when those transformative discoveries lead to scientific, technological, social, or humanitarian impact.

The Committee is both aware and respectful of the critical role the American research enterprise plays in our Nation's competitiveness. Universities engage in fundamental research to grow our knowledge base, to advance understanding, and to encourage free-thinking in our next generations. Inherent to exploration of uncharted areas of inquiry is discovery. Discovery can and should lead to delivery; however, gaps in the path that connects discovery to delivery exist.

In my reading of its current draft, it is the filling of this gap that is, provincially defined, the subject of the proposed legislation.

Like many research universities, Purdue University is dedicated to linking the university's assets to entrepreneurship activities and societal economic growth. Innovation and collaboration at Purdue connect its students, faculty, and staff to a network of state, national, and global partners. These activities catalyze economic growth not only in Indiana, but in the nation and around the world.

An exemplar of such is the cross-discipline Certificate in Entrepreneurship and Innovation Program which affords interested Purdue undergraduate students - whether a future civil engineer, or math teacher, or crop farmer - an opportunity to earn an academic credential in entrepreneurship complementary to their major. The campus-wide certificate program deepens students' understanding of areas pertinent to entrepreneurship that will improve their chances of success in creating new business ventures. The competitive advantage a U.S.-education in STEM wrapped in an understanding of entrepreneurship and innovation offers great potential to positively affect our nation's competitiveness.

Specifically, the Committee requested comment on innovative practices employed by Purdue University to develop federally funded research projects. It is my hope that the Committee finds the Purdue Trask Fund and, particularly, the innovative programs its supports, which I will detail below, as responsive.

I. Verne A. and Ramoth H. Trask Venture Fund

In 1973, the estate of Verne and Ramoth Trask of Indianapolis, Indiana, both dedicated and generous Purdue University alumni, was bequeathed to Purdue University and the Purdue Research Foundation. A year prior, Mrs. Trask wrote, "…I gather that Purdue has funds and procedures for funding research, and has procedures and policies for contracting with private industry to use research results…I gather also that there is a gap between the research activities and these commercial exploitation activities where development funds would be welcome and useful. I also gather that there are some research results which may be worth developing for the welfare of Purdue and the general public but which do not attract commercial sponsors. It is my idea that a Trask endowment fund might be used to **fill this gap** and to fund development of such ideas." (emphasis added). The Trask's gift established one of the first university-affiliated gap funding mechanisms dedicated specifically to university technology commercialization, and set Purdue on course to make a tangible effort to filling the gaps that connect discovery to delivery.

The gift was substantial - perhaps not by today's university giving standards but certainly given the era - and its impact in supporting initiatives that translate and develop research results into products and services for the benefit of the public is 'priceless'. Today, that visionary Trask Fund seeds proof-of-concept awards that assist Purdue researchers in furthering the commercial potential of Purdue technologies.

Two specific programs created to execute in on Mrs. Trask's idea of filling the gap are directed to (i) developing technologies within the university, to advance development and increase attractiveness for partnering with industry and probability of technology transfer; and (ii) to developing technologies within new ventures, to advance development and, by consequence, increase the new venture's competitiveness and technological and economic impact.

A. Trask Innovation Fund

Technology development awards are made through the Trask Innovation Fund (TIF). The competitively-awarded funds are made to eligible Purdue technologies and inventors of up to $50,000 to support a translational or development project that aims to prove the concept of the Purdue technology – hence, Purdue's proof-of-concept program. Awards are determined under the advisement of the TIF Advisory Council, a public-private amalgam critical to informed deployment of the TIF funds that meet the proof-of-concept objective. Advisory Council members include representatives from the local and national business communities, as well as Purdue University, including the Office of the Vice President for Research, Purdue Faculty, and Purdue Research Foundation. Successful projects may seek up to three phases of funding, but the projects must be completed within a six-month period.

Importantly, the TIF does not support basic research projects but rather demonstrative development with a commercially relevant endpoint. Examples of types of development work include reducing an invention to practice, providing critical commercial relevant data such as a comparison to an industrial 'gold' standard, or developing working prototypes. All projects must make the technology more commercially marketable. Effectively, the results aim to inform a decision by the Purdue Office of Technology Commercialization to proceed, or not, with continued investments – whether indirect or direct. Any royalty income derived from a subsequent license to the TIF-supported technology must be used to repay the TIF award back into the Trask Venture Fund, in full but without administrative fees.

Important to sustainability, repayment is a requisite of the Trask Venture Fund, the four-decade implementation of which served up a solvency that has insulated Purdue's technology commercialization efforts from the ebbs and flows of the acute financial climate and ensured its lack of dependence on future third-party contributions.

In the last 5 years, 48 Purdue technologies have been competitively awarded development funding, and of those 35% have resulted from sponsorship by the U.S. taxpayers. Over the time of the Trask Venture Fund proof-of-concept awards, roughly thirty-five years, federally funded Purdue technologies that were supplemented with such awards had about a 40% increased licensing rate than those federally funded Purdue technologies that were not supplemented with such proof-of-concept awards.

Purdue continues to explore new ways to leverage this funding for targeted industrial partnerships, in exchange for contributions by the industrial partner, such as matching funds, in-kind product development or business advisement services. Further, also being explored is a fellowship award associated with one or more of the students involved in performing the proof-of-concept work that bears the name of the industrial partner. This fall, the TIF will pilot this next generation of proof-of-concept funding in the area of agriculture with the Agricultural Alumni Seed Improvement Association, Inc., a non-profit organization located in Romney, Indiana that develops and releases high performance popcorn hybrids, many of which contain Purdue genetics.

B. Emerging Innovations Fund

The Purdue Emerging Innovations Fund (EIF) is an evergreen fund that is seeded annually by the Trask Venture Fund. New ventures eligible for the seed funding through the EIF are either developing a Purdue technology or have a principal place of business in the Purdue Technology Centers located throughout the State of Indiana. The EIF funds are awarded to the new venture to support technology translation and development as well as corporate development.

Synergistic to education, the EIF serves as an experiential learning opportunity for Purdue graduate and undergraduate students. Purdue students receive 3-course credit hours through the Krannert School of Management to undertake diligence reviews of the EIF applicants, perform an in-depth business analysis and present findings to the EIF Economic Advisory Board which includes a recommendation for funding, or not. Students from any discipline meeting minimum requirements may apply and if selected, throughout the semester, inure the benefit of interactions with the entrepreneurs and theEconomic Advisory Board, who are each active investors, financial advisors, bankers or venture capitalist.

Funding decisions are made in consultation with the Economic Advisory Board, and transacted as convertible debt. Amounts invested may be up to $150,000 and are performance-based.

After three years in earnest of enabling investments, the Emerging Innovations Fund has invested into six new ventures, four of whom have received more than $2 million in follow-on dilutive or non-dilutive funding and account for 13 new jobs in the State of Indiana. Purdue will track these value-inflections for the next several years to establish a multiplier on its overall investments. At that time will the data be sufficient to draw material conclusions.

II. Other Purdue University Innovative Practices that Support Technology Transfer and Development

In the last several months, the Office of Technology Commercialization has unveiled new procedures and policy implementations to accelerate the quantity of technologies transferring out of the university, whether owned by Purdue University or not. Purdue students who create an invention in the performance of coursework, such as a design project for an engineering course, own those inventions. Purdue inventors who have contributed Purdue-owned intellectual property may elect an 'as is' license contract to establish a new venture based on the invention to which she or he contributed. Purdue-owned intellectual property will be reviewed and assessed by the Purdue Research Foundation on a 6-month timeline, ending in a go/no go decision.

Of particular note, Purdue is now offering recipients of SBIR and STTR grants aimed at developing a Purdue technology, a cash-free first option to license the Purdue technology provided at least 30% of the total award is performed at Purdue University. This express first-option allows STTR and SBIR recipients to competitively leverage Purdue technology, provides a mechanism to support the commercialization of Purdue technologies and supports speed and transparency in the licensing of Purdue technologies. A copy of the relevant contract is provided as 'Supplemental Material Exhibit A'.

Turning to related but different and no less important initiatives in support of increasing the impact of Purdue technologies to the benefit of the community, Purdue has evolved its business advisement services inward.

Previously focused primarily as a service to Purdue Research Park tenants, business advisement and ancillary resources to support small businesses and their growth have recently been positioned inside Purdue's Burton D. Morgan Center for Entrepreneurship. Coined the Purdue Foundry, it will support the development and sustainability of new businesses that are incubating within the university research enterprise by offering grant writing support for STTR and SBIR grants, mentoring, business plan support by specialized staff, and access to the University Development Office's network.

Based on the summary of innovative practices employed at Purdue University, it is no surprise that Purdue University supports and encourages the Committee's sincere consideration of the Improving the Transfer of Federally Funded Research and Technology Act of 2013.

The proposed legislation would promote continued progress by university and small businesses in achieving the STTR's stated goals as envisioned in pilot form under Title II of The Small Business Research and Development Enhancement Act of 1992. The goals of the proposed legislation superimpose on its predecessor, as it too emphasizes, albeit subtly, the benefits to the nation of technology innovation and the ability of small businesses to translate federally funded research results into new products and services.

In this spirit, the proposed legislation currently recites a stated outcome of the proposed awards, both generally and implicit in the criteria, is the marketplace. While a necessary means, the Committee may consider coming full circle and expressly reciting the intended benefactors of the program, the public, as the proposed programs endpoint. It is undisputed that the Committee intends the American people – from whose pockets these funds flow - to benefit from its investments in research and development through partnerships between university and small businesses. Making such intent explicit in the proposed legislation would seem appropriate.

Further, research universities often view sponsors of research as benefactors of such research, contractually. Such concept introduced in an explicit manner to this proposed legislation is consistent with the practice of research universities today, for other sponsors of research and likely would make clear the foundation from which the outcomes and metrics of any funded innovative programs are measured.

The importance of the positive impact of federally funded research and development is such that the proposed legislation may better articulate the objective if technology transfer strategies were assessed on increased impact rather than scale. Talking to a university employee, 'scale' tends to take our minds to more or bigger campus buildings. While increased infrastructure may indeed be an effective technology transfer strategy that receives a proposed award, embracing impact-driven strategies of all types offer creative license to the agency and

prospective awardees to arrive at strategies that are customizable, by geographic region, socioeconomic context, industry target market, and the like.

Such creative license turns the focus to measurable metrics, which when measured will drive the outcomes of the proposed program. I wish to applaud the Committee's proposed scope of possible evaluation metrics currently included in the proposed legislation. As well-documented, informed decision-making requires robust and objective data analysis and, until recently, the area of technology transfer and commercialization has too long ignored its importance. There is a very good reason: it's difficult and likely requires longitudinal examination. Similar to the patient analysis of R&D investments for impact, data collected in determining effective technology transfer strategies also requires us to be patient analyzers.

Fortunately, material attention is being paid by several organizations to better assess the breadth and depth of technology transfer contributions to regional and national technological, economic and societal impact. To cite just one, the Association of Public and Land-Grant Universities recently published its' Commission on Innovation, Competiveness and Economic Prosperity New Metric User Guide, which was the culmination of four years of work by numerous individuals. Appropriately noted as a living document, this guide offers a good start in scoping out what activities and outcomes to monitor for accurate and objective assessment of the full breadth of impact university technology transfer provides to the nation.

While no one metric will likely ever be sufficient, a compilation of myriad data along the lines of those in the proposed legislation, in which several options are provided, is also a good start. I would caution the confidential nature of some of those options to small businesses may ultimately render them underdisclosed. Aggregation in a central database, across all awardees despite agency sponsor, in a manner that borrows from the common practice employed in clinical research to render anonymous origins of data may ensure increased quality of data and, thus, robustly informed decision-making in the future.

In closing, I wish to express my grateful thanks to the Committee for the opportunity to participate today and for your leadership, commitment, and partnership on this important topic of technology transfer of federally funded research and development.

EXHIBIT A

Purdue Express Option to License for SBIR/STTR Recipients

PURDUE
RESEARCH FOUNDATION

SBIR/STTR EXPRESS OPTION AGREEMENT

This Option Agreement **("Agreement")** is effective as of the date of the SBA Award (defined below) ("**Effective Date**") and is made by and between the PURDUE RESEARCH FOUNDATION, a statutory body corporate formed and existing under the Indiana Foundation or Holding Companies Act of 1921, with offices located at 1281 Win Hentschel Blvd., West Lafayette, Indiana ("**PRF**") and _____, a _____ corporation / limited liability company / other organization **("Optionee").**

BACKGROUND

PRF owns valuable technology generally known as "TITLE" (PRF Ref. No.: XXXXX)" ("**Invention(s)), which** is/are the subject of the patents and/or patent applications, described in Schedule A (the "**Optioned Patent(s)**").

ARTICLE 1. TERMS OF OPTION

1.1 Subject to the terms and conditions of this Agreement, PRF hereby grants to Optionee during the Term (defined below) an exclusive first right to enter into negotiation with PRF to obtain an exclusive, royalty-bearing license to the Licensed Patents [in the following fields of use: _____] (the **"Option"**). The Option (and any license resulting from the Option) is limited to PRF's presently licensable interest in the Inventions and Licensed Patents.

1.2 All rights in this Agreement are solely for the purpose of (i) developing technology described in the Optioned Patents using funding received by Optionee in collaboration with Purdue University and in performance of an award from a Phase I Small Business Innovation Research ("SBIR") or Small Business Technology Transfer ("STTR") program within an agency of the U.S. Government ("**SBA Award**"), in which the performance of at least 30% of the direct costs of the SBA Award is performed under appropriate contract between Optionee and Purdue University, in the Purdue laboratory of [PI NAME], and (ii) evaluating the Optioned Patent(s) for potential licensing to Optionee by PRF. No rights are granted to Optionee to sell, offer to sale, export, distribute or otherwise commercially exploit the Optioned Patent(s) without the express prior written permission of PRF.

1.3 (a) No cash fee is owed to PRF by Optionee during the Term; and

(b) In consideration for the rights granted hereunder, Optionee agrees to provide PRF with (i) on or before the Effective Date, a copy of the relevant grant application that led to the SBA Award and current business plan; and (ii) a detailed progress report against the statement of work in the SBA Award due at both the midpoint and conclusion of the SBA Award, including data and results generated in the performance of the statement of work.

1.4 Optionee may exercise the Option before the expiration of the Term by providing (a) a written statement of its intention and ability to develop licensed products for public use as soon as practicable, and (b) submission to PRF of a business plan reasonably acceptable to PRF inclusive of a current capitalization table of Optionee.

1.5 Upon exercise of the Option in accordance with Section 1.3 and for a reasonable period not to exceed ninety (90) days (or such longer period as the parties may agree), PRF and Optionee agree to negotiate in good faith to establish the terms of a license agreement (the **"License Agreement"**). The License Agreement shall be in PRF's standard form, and will contain terms and conditions customary to patent and technology licenses

normally granted by PRF, including without limitation: a defined licensed field; terms consistent with the provisions of U.S. law applicable to intellectual property funded in whole or in part by the U.S. Government; a reservation of the rights to practice and to grant other not-for-profit organizations the right to practice the Inventions and Optioned Patents for research, teaching and other incidental research and educational purposes; license fees that may include an ownership interest in Optionee; royalty payments; milestone payments; reimbursement of expenses including but not limited accrued patent expenses; commercially reasonable due diligence obligations for the development and commercialization of the Optioned Patents, the right of PRF to terminate the license for failure to meet specified due diligence milestones; liability limitations; warranty disclaimers consistent with an "as is" license; and indemnity and insurance provisions in favor of PRF, Purdue University and, if and as applicable, co-owners of the Optioned Patent(s).

1.6 This Agreement and the Option shall expire upon the earlier of: (a) the expiration of the SBA Award, or (b) any earlier termination of the SBA Award (the **"Term"**). However, if Optionee exercises the Option within the Term, this Agreement will expire at the end of a ninety (90) day negotiation period or upon execution of the License Agreement, whichever first occurs.

1.7 During the Term, PRF may afford Optionee a reasonable opportunity to provide input into material patent prosecution matters corresponding to the Optioned Patent(s). Notwithstanding the foregoing, at all times, PRF shall retain sole authority for decisions regarding protection of the Inventions including without limitation scope, breadth, prosecution and maintenance of the Licensed Patents.

1.8 Optionee agrees not to identify PRF or Purdue University or any employee or student or agent thereof in any solicitation relating to the Invention(s), Optioned Patent(s), or this Agreement absent the prior written consent of PRF. Nothing in this Agreement shall be construed as an endorsement by PRF or Purdue University, or its personnel, of Optionee or any of its product or services; Optionee shall refrain from representing to the contrary in any and all manners whatsoever. Optionee shall indemnify, defend and hold harmless PRF, Purdue University, and the State of Indiana and each of their respective current and future regents, directors, trustees, officers, faculty, medical and professional staff, employees, students, trainees, and agents, and their respective successors, heirs, and assigns against any claim, liability, cost, damage, deficiency, loss, expense or obligation attributable in any party directly or indirectly to a breach of the prohibition stated in this Section 1.8.

ARTICLE 2: MISCELLANEOUS

2.1 This Agreement may not be amended, nor may any right or remedy of either party be waived, unless the amendment or waiver is in writing and signed by a duly authorized representative of each party.

2.2 Notices and invoices under this Agreement shall be in writing and shall be delivered by electronic mail and certified mail return receipt requested. Notices shall be addressed to a party at the address specified on the signature page, or at such other place or places as shall from time to time be specified in a notice similarly given. All notices shall be effective upon receipt.

2.3 PRF and Optionee are not (and nothing in this Agreement may be construed to constitute them as) partners, joint venturers, agents, representatives or employees of the other, nor is there any status or relationship between them other than that of independent contractors. No party has any responsibility or liability for the actions of the other party except as specifically provided in this Agreement. No party has any right or authority to bind or obligate the other party in any manner or make any representation or warranty on the other party's behalf.

2.4 This Agreement, including without limitation the Option shall not be assigned.

2.5 This Agreement is made and construed in accordance with the laws of the State of Indiana without regard to choice of law issues. Each party consents to the jurisdiction of the Circuit Court of Tippecanoe County, Indiana for any suit against the other party relating to this Agreement, and agrees to file any such suit in that court.

2.6 This Agreement does not confer any license, right or other permission on Optionee to any research, development, rights, data, results, material, information, intellectual property not expressly and specifically stated in this Agreement. There are no contracts, understandings, conditions, warranties or representations, oral

or written, express or implied, with reference to the subject matter of this Agreement that are not merged in this Agreement.

2.7 This Agreement may be executed in any number of counterparts, each of which shall be an original, and all of which shall together constitute one agreement. This Agreement may be signed and delivered, or a signature may be transmitted or communicated, by means of facsimile or other electronic transmission (such as a Portable Document Format (PDF) copy of an original signature).

The parties have caused this Agreement to be executed by their duly authorized representatives, under seal.

[OPTIONEE]

By: _____

Name: _____

Title: _____

Date: _____

_____

_____

_____

Attn: _____

Email: _____

PURDUE RESEARCH FOUNDATION

By: _____

Name: _____

Title: _____

Date: _____

Purdue Research Foundation
Office of Technology Commercialization
1281 Win Hentschel Blvd.
West Lafayette, Indiana 47906-4182
Attn.: OTC Director
Email: otcip@prf.org

PRF Docket:

SCHEDULE A

Invention:	(PRFXXXX)	
Patent Info:	**Application Number:** **Application Title :** **Filing Date:**	
Inventors:	*Name:*	*Employer when invention was made:*

**** Third Party Funding*** ☐ *Yes* ☐ *No*

If yes, provide funding entity and contract no.:

* The U.S. Government retains certain rights in the Invention, and the Option is subject in all respects to U.S. law applicable to intellectual property funded in whole or in part by the U.S. Government.

REMARKS BEFORE THE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY OF THE U.S. HOUSE OF REPRESENTATIVES
22 JULY 2013

Short narrative biography for Elizabeth Hart-Wells, Purdue University:

Elizabeth Hart-Wells, Assistant Vice-President and Director of the Office of Technology Commercialization. Hart-Wells is responsible for managing the commercialization of Purdue's intellectual property assets which includes responsibility of evaluating innovations, developing commercialization strategies, memorializing commercialization agreements; promoting discovery with delivery; forming startup companies; and overseeing compliance with federal technology regulations. She previously managed the University of Maryland, Baltimore's Commercial Ventures and Intellectual Property Group where she oversaw the university's intellectual asset portfolio. She supervised all technology transfer activities, including asset evaluation, patent prosecution, business development, and negotiations with licensees. She also managed the intellectual property for the Middle Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases, a multi-party consortium of research institutes supported by the National Institute of Allergy and Infectious Diseases.

Hart-Wells served as a Congressional Fellow for the American Association for the Advancement of Science where she served on the professional legislative staff for the ranking member of the Energy and Commerce Health Subcommittee. She served as a patent agent for Fulbright & Jaworski LLP. She was a research associate for the National Academy of Sciences where she executed policy analysis of postdoctoral programs in academia, government and industry to aid the National Academies' Committee on Science Engineering and Public Policy. Hart-Wells earned a doctorate in chemistry from Rice University where she was a Turner Outstanding Graduate Student in organic chemistry, a Harry B. Weiser Research Scholar and a Robert A. Welch Foundation Fellow. She earned a bachelor's degree in chemistry from Indiana University where she was a member of the Phi Eta Sigma Honor Society, the Alpha Lambda Alpha Honor Society and the Alpha Chi Sigma Chemistry Fraternity. She is a member of the American Chemical Society, the American Association for the Advancement of Science and the U.S. Patent Bar.

Chairman BUCSHON. Thank you very much.

I now recognize Dr. Lium for five minutes to present his testimony.

TESTIMONY OF DR. ERIK LIUM,
ASSISTANT VICE CHANCELLOR,
OFFICE OF INNOVATION, TECHNOLOGY & ALLIANCES,
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Dr. LIUM. Mr. Chairman, Ranking Member Lipinski, and Members of this Subcommittee, the University of California, San Francisco is widely recognized as a leader in the health sciences and as the birthplace of biotechnology. I am here today to testify on my own behalf and would like to thank you for the opportunity to appear before you to discuss the important issue of commercializing federally funded research. I am a molecular biologist by training and as a prior co-founder of a venture-backed software company, an entrepreneur.

At UCSF I lead a team responsible for streamlining the creation of public-private research partnerships, licensing technologies for commercialization, and education of budding life science entrepreneurs.

Federal funding, the lifeblood of basic research, is essential for the development of groundbreaking discoveries. The challenge is commercializing these discoveries for public benefit, especially in capital-intensive fields such as the life sciences.

My testimony today on expanding the use of STTR funds to support innovative approaches to increase the commercialization of federally funded research is focused on three points specifically related to life science discoveries.

First, venture capital, one of the historical mainstays for advancing life science discoveries through proof-of-concept has fallen sharply as investors have shifted capital to lower-risk opportunities. Early-stage life science ventures are struggling to fund proof-of-concept, which is a critical value inflection point required to attract investment today.

Some estimates suggest that the number of venture firms investing in life sciences has fallen as much as 2/3 in the last five years. In essence, a shortage of early-stage pre-proof-of-concept funding is impeding the commercialization of federally funded research.

My second point. It is reasonable and appropriate for the Federal Government to play a role in funding proof-of-concept research at universities, research institutes, and national labs given the requirement today for proof-of-concept to attract investment. The gap between development of an intriguing, yet unproven discovery and the investment to commercialize that discovery is characterized as the Valley of Death. The virtual disappearance of pre-proof-of-concept venture financing and the lack of sufficient programs to fund proof-of-concept research make crossing the Valley virtually impossible for countless technologies.

Take, for example, a team of investigators from UCSF, the Cleveland Clinic, Vanderbilt University, and the University of Michigan, who invented an implantable artificial kidney device with the potential to improve the health and wellbeing of individuals suffering from kidney failure and to reduce the estimated $41 billion spent

annually in the U.S. on this disease. Despite receiving numerous awards based on promising results, having substantial interest from potential corporate partners, and being selected by the FDA as one of three projects for a pilot program to fast track the development of breakthrough medical devices, investors have been reluctant to provide funding without proof-of-concept in large animals.

Simply stated, a new model to attract private investments to once again fuel the commercialization of early-stage discoveries is required. The Federal Government could play a role in this model. It could help bridge the gap.

Finally, I would like to enthusiastically express support for the draft legislation to expand the use of STTR funds to support innovative approaches that increase the commercialization of federally funded research. Grant programs created under the Act could address the crucial need for proof-of-concept funding as well as the need for experiential training in commercialization.

For example, I would welcome expansion of the NSF Innovation Corps Program to additional agencies and the inclusion of phased proof-of-concept funding programs administered by universities, research institutes, and national labs to validate and advance a broader array of federally funded discoveries.

I support including requirements for the collection and analysis of programmatic data to identify best practices. Though steps should be taken to ensure that such requirements are not an impediment to participation.

Thank you, Mr. Chairman, Ranking Member Lipinski, and Members of this Subcommittee for the opportunity to discuss this important issue. I look forward to answering your questions.

[The prepared statement of Dr. Lium follows:]

WRITTEN TESTIMONY OF

Dr. Erik Lium

Assistant Vice Chancellor for Innovation, Technology & Alliances

University of California, San Francisco

BEFORE THE

Subcommittee on Research and Technology,

Committee on Science, Space and Technology

U.S. House of Representatives

HEARING ON

"*Improving Technology Transfer at Universities, Research Institutes and National Laboratories*"

July 24, 2013

Mr. Chairman, Ranking Member Lipinski, and Members of the Subcommittee, my name is Erik Lium and I currently serve as the Assistant Vice Chancellor for Innovation, Technology & Alliances at the University of California, San Francisco (UCSF). I am here to testify on my own behalf. Thank you for the opportunity to appear before you today to discuss the very important issue of translating federally funded basic research into commercial applications for public benefit.

In my current role, I am responsible for the UCSF Office of Innovation, Technology & Alliances ("ITA") which serves to streamline the creation of public-private research partnerships, the transfer of UCSF technologies to the commercial marketplace and the education of budding entrepreneurs. I am a molecular biologist by training, and as a prior co-founder of a venture capital backed enterprise software company, an entrepreneur.

UCSF is widely regarded as one of the world's leading universities in the biological and health sciences, and as the birthplace of the biotechnology industry. UCSF's mission is to advance health worldwide through innovative health sciences education, discovery and patient care. Our graduate Schools of Medicine, Pharmacy, Nursing, and Dentistry are ranked among the very best schools nationwide, our Medical Center among the nation's premier hospitals for the 12th consecutive year, and our research enterprise received over $1 billion in research funding in 2012 of which $521 million was from the National Institutes of Health (NIH). UCSF's faculty

includes five Nobel Laureates, ten recipients of the Albert Lasker Award, four recipients of the Shaw Prize in Life Sciences and Medicine, four recipients of the National Medal of Science, 44 members of the National Academy of Sciences and 89 members of the Institute of Medicine.

My comments today will be focused on three issues:

- First, early-stage life science companies are struggling. They are in desperate need of funding to reach technological proof-of-concept ("PoC"), a critical value inflection point required in today's marketplace to attract private investment funding.
- Second, it is reasonable and appropriate for the Federal Government to play a role in funding PoC research given the prerequisite in today's marketplace to substantially de-risk early-stage discoveries in order to attract investment; and,
- Third, the proposed legislation to expand the use of STTR funds to support innovative approaches to technology transfer will increase commercialization of federally funded basic research. Notably, it will enable agencies to fund programs to de-risk early-stage discoveries at universities, research institutes and national labs without the requirement for a commercial partner. We support including requirements for the collection and analysis of data on the performance of programs to identify best practices, though steps should be taken to ensure that such requirements are not an impediment to participation.

I will address these issues through my responses to the three questions the Committee has specifically posed for my testimony.

The first question I was asked to address today is, "What innovative practices does the University of California at San Francisco employ to develop federally funded research projects that have commercial opportunities?"

Federal funding is the lifeblood of basic research and enables our scientists to pursue potentially groundbreaking innovative research. The challenge is translating the fruits of this basic research into commercial applications for public benefit, a goal that is strongly supported by UCSF leadership. UCSF has established an innovation ecosystem to address this challenge, and I will describe a few noteworthy elements of this ecosystem in my testimony.

The ***UCSF Clinical & Translational Science Institute (CTSI)*** provides infrastructure, services and training to support clinical and translational research, and seeks to facilitate the rapid translation of research to improvements in patient and community health. Established in 2006, the CTSI was among the first of the now 60-member Clinical & Translational Science Awards consortium funded by the NIH. To advance early-stage discoveries, it established the Early Translational Research Program to connect researchers with industry executives, business leaders and funding resources. This innovative program provides pilot grants and tailored mentoring to advance early-stage discoveries.

The ***UCSF Office of Innovation, Technology & Alliances ("ITA")*** was created in 2011 to streamline the development of collaborative public-private research partnerships and facilitate the commercialization of UCSF discoveries. The ITA integrates business development, industry contracting, alliance management, technology transfer and entrepreneurship training, optimizing the support of UCSF researchers and discoveries, and catalyzing the connections, relationships and educational resources required to advance discoveries. UCSF has over 1,600 active inventions and 679 active patents. Thirteen UCSF drug candidates and medical devices are in clinical development and 97 commercial products were derived from basic research performed at UCSF.

UCSF has hundreds of active research partnerships with industry that often serve to advance basic federally funded research. A few noteworthy examples include the UCSF-Pfizer Center for Therapeutic Innovation, which is developing novel small and large molecule drugs, a partnership with Sanofi U.S. to support and extend highly innovative breakthrough biomedical research and the UCSF-Onyx Pharmaceuticals Oncology Innovation Alliance which seeks to develop novel treatments for cancer.

The ***Entrepreneurship Center at UCSF***, a division of the Office of Innovation, Technology & Alliances, offers pragmatic courses on essential aspects of commercialization, educational programs featuring top-tier members of the entrepreneurial ecosystem, a network of investors, entrepreneurs and service providers and experienced industry mentors to coach fledgling entrepreneurs in the creation of new ventures. The Center, headed by an experienced industry veteran, Stephanie Marrus, serves as an essential bridge between UCSF researchers and clinicians and the Silicon Valley/Bay Area entrepreneurial ecosystem. Our flagship

entrepreneurship course, now in its 13th year, employs team-based experiential learning to educate new entrepreneurs on the essential requirements for a commercially viable life science venture culminating in a presentation of their business plans to Silicon Valley venture capitalists. This course can be transformative, opening the eyes of scientists and inventors to new career paths. I would like to share two noteworthy stories form this course.

The first is about a doctoral candidate bioengineer at UCSF performing groundbreaking research on brain mapping, an essential procedure performed at the beginning of brain surgeries to map the functional areas of a patient's brain thereby enabling a surgeon to plan their path to a successful surgery while minimizing impact on healthy functional tissue. Patients are conscious during the mapping process, which traditionally relies on the surgeon manually stimulating areas of the patient's brain while requesting feedback on the effect. Brain mapping using this technique is a long and arduous process, often requiring several hours to be completed. In collaboration with a UCSF neuroscientist, this doctoral candidate has developed a mapping approach using novel software and FDA approved devices that substantially shorten the time required for the procedure, reduce pain, and that appear to be safer and more accurate.

From a nascent idea on the first day of class to a mature business concept at the final competition, this researcher attracted a team, explored all aspects of creating a venture, developed a commercialization plan, presented to investor judges and won $15,000 in funding. She is now following the path of an entrepreneur with hopes of commercializing a basic research discovery, and is preparing an application for a SBIR grant.

The second story is about a clinical urology resident who conceptualized a novel approach to address geriatric urinary incontinence. The management of incontinence represents a substantial economic burden to the U.S. health care system with annual costs estimated at $20 billion. In addition, urinary incontinence in older adults is humiliating, disabling, and causes stress and depression. Research on urinary incontinence demonstrates that an effective management strategy is frequent clearance. The physician designed a device to detect the volume of urine in an individual's bladder in real-time, and notify the individual and nursing staff when the volume is approaching a level that may cause spontaneous clearance. The urologist's venture, which seeks to commercialize an easy-to-wear sensor integrated with an intuitive mobile application, is initially seeking to serve patients within nursing homes.

An exciting addition to the UCSF Entrepreneurship Center is the NSF's Innovation Corps (I-Corps) program, an experiential educational program designed to increase the commercialization of NSF funded research. UCSF, UC Berkeley and Stanford University have partnered to create the Bay Area Node of the NSF I-Corps, and have received an NSF grant to support this highly innovative program. UCSF is leading the development of life sciences/healthcare-specific curriculum within the I-Corps framework in preparation for launching a life sciences/healthcare-specific course in late 2013.

In its first two years of existence, the I-Corps has facilitated the creation of numerous startups that are working to commercialize discoveries made through federally funded research. Based on analyses to date, ventures that have participated in this program receive SBIR funding at a rate 3-times higher than those that have not.

The final element of the UCSF innovation ecosystem highlighted in this testimony is the ***California Institute for Qualitative Biosciences (QB3)***, a three-UC campus organization that includes UCSF. QB3 maintains crucial incubator space for biotech startups, provides support for incorporating new companies, training on SBIR/STTR grant writing and has a small seed-stage fund to help entrepreneurs emerging from the University of California.

The second question I was asked to address today is, "Please provide your thoughts on whether you think it would be beneficial to dedicate a portion of Small Business Technology Transfer (STTR) program funding to proof-of-concept and other technology transfer programs at universities, research institutions and national laboratories."

It is more than beneficial; it is essential. UCSF innovations, which predominantly fall within the drug, medical device, diagnostic and research tool markets, require substantial funding in the form of risk capital for commercialization – funding that has rapidly disappeared as venture capitalists have become increasingly risk averse since 2008.

Early-stage life science ventures desperately need funding to reach technological proof-of-concept ("PoC"), a prerequisite to attract private investment. The funding environment has changed dramatically in recent years. Small innovative drug companies were once able to secure tens of millions of dollars of funding through venture capitalists or public markets to advance early-stage discoveries to human clinical trials, at which point the enterprise became an attractive

partner or target for acquisition. In recent years, venture financing for life science companies has dropped sharply as private capital has shifted to lower risk markets that deliver faster returns. Today, few investors are willing to risk investing in early-stage life science ventures. Why invest hundreds of millions of dollars in a business that often will not provide returns for a decade, if ever, when the funds can be invested in a smartphone application or social media company that may attain that value in three to five years?

Initial financings of U.S. - based biotechs are down an alarming 30% from their peak in 2007. Most funding is directed to existing companies with products in late-stage development, not to startups. According to Fenwick & West, only $2.5 billion, or 12.5% of funds raised by venture capital firms in 2012, is likely to be deployed in the life sciences, which stands in stark contrast with the $7.8 billion that was invested in 2008. The dearth of risk capital is discouraging even seasoned entrepreneurs from attempting to develop innovative medicines. In our classes at UCSF, we see a significant reduction in proposed therapeutic ventures and an increase in ventures, such as digital health, requiring limited time, limited funding and that offer substantially less regulatory risk.

The implication for the U.S. is sobering: there will be few truly innovative medicines and our leadership in innovation is at risk. Medical devices and diagnostics are similarly challenged: little funding is available. Thanks to a difficult U.S. regulatory environment, reimbursement issues and lack of risk capital, many medical technology ventures are moving offshore. Consider this story from an experienced device entrepreneur. When looking for investors to fund trials for an implantable heart device, his search took him far from Silicon Valley and Boston to Asia, courting investors in Singapore, Hong Kong, Thailand, and Malaysia. "Companies like ours with very promising technology that in years past would have been funded very richly, are struggling to find money to even stay in business." As he explained, his last company raised $50MM in 2007 for a cardiac device and "it never would have even crossed my mind to look to Asia." Since then, funding from U.S. venture capital firms for medical devices has dropped 35% to approximately $2.4 billion last year, according to the National Venture Capital Association.

We need a new model to attract private investment capital into biotechnology, medical devices and diagnostics to once again fuel the commercialization of federally funded basic research and to preserve the U.S.'s dominance in these fields.

The gap between the development of intriguing but unproven innovations, and the investment to commercialize those innovations, is characterized as "the Valley of Death." The U.S. lags behind other nations in not having a national funding program to cross this "Valley," placing us at a disadvantage.

Recognizing the need to reduce technological, regulatory and market risks for early-stage life science and healthcare ventures, UCSF is leading the development of a life sciences/healthcare-specific curriculum within the framework of the NSF Innovation Corps program, a program supported by this Committee. This program aims to empower entrepreneurial teams to effectively identify the most promising ventures by thoroughly examining key elements of each, and adapting or terminating the venture accordingly, thereby reducing the overall failure rate, improving the utilization of capital and ultimately increasing investment in these markets.

UCSF is initially offering this life sciences/healthcare-specific curriculum in October 2013 for up to 32 teams, and thereafter hopes to expand this program.

The third question I was asked to address today is, "Please provide comments and recommendations on the discussion draft of the "Innovative Approaches to Technology Transfer Act of 2013".

We enthusiastically support the proposed legislation that establishes STTR grant programs to support innovative approaches to technology transfer that increase the commercialization of discoveries made through federally funded basic research. In my role as Assistant Vice Chancellor, I routinely interact with bright and enthusiastic scientists and clinicians with early-stage discoveries with commercial potential who are struggling to secure essential PoC funding. For example, a successful senior investigator at UCSF has invented an implantable artificial kidney device in collaboration with scientists at the Cleveland Clinic, Vanderbilt University and the University of Michigan. This device has the potential to improve the health and well being of individuals suffering from kidney failure, freeing them from numerous miserable dialysis sessions per week, and reducing the estimated $41.5 billion spent on end-stage renal disease per year in the US. Despite receiving numerous awards, substantial interest from potential corporate partners and being selected by the FDA as one of just three projects for a pilot program that will

fast track the development of breakthrough medical devices, our entrepreneur has been unable to raise funds to support commercial development.

Grant programs created under the Act could address this crucial need for PoC funding. We support the development of programs that fund the creation of university-based PoC programs and the development of crucial institutional infrastructure to support entrepreneurs. Such programs should not include a requirement for company participation, thereby removing the existing incentive to prematurely create startup companies for the sole purpose of qualifying for SBIR/STTR grants, and allowing funds to be used exclusively for reaching technical PoC. New requirements, such as matching industry funds, should also not be included in order to avoid potentially costly delays, as companies often require PoC as a prerequisite for investment.

We would welcome expansion of the NSF Innovation Corps program to additional agencies and the addition of phased PoC funding. This expansion would establish a means to validate and advance the development of a broader array of discoveries while providing entrepreneurs crucial training and PoC funding.

We enthusiastically support the proposed legislation, including the requirements for the collection and analysis of data on the performance of funded programs to identify those that may warrant expansion; however, we strongly caution against including excessively burdensome and costly administrative requirements that may inadvertently reduce the effectiveness of the program by reducing participation.

I hope that my testimony has provided background, context and recommendations that can help this Committee in its laudable goal of improving technology transfer and the innovation eco-system in the United States.

Thank you Mr. Chairman, Ranking Member Lipinksi and Members of this Subcommittee for the opportunity to discuss this important issue and I look forward to answering any questions you may have.

WITNESS BIOGRAPHY

ERIK LIUM, PH.D.

Dr. Erik Lium serves as the Assistant Vice Chancellor for Innovation, Technology & Alliances at the University of California, San Francisco (UCSF). He has held prior positions at UCSF of Assistant Vice Chancellor of Research, Director of the Industry Contracts Division and Interim Director of the Contracts & Grants Division of the Office of Sponsored Research, and Director of Business Development for the Diabetes Center & Immune Tolerance Network. Dr. Lium was President of LabVelocity Inc., an information services company focused on accelerating life science R&D processes prior to its acquisition in 2004. He served as a postdoctoral research scientist in the laboratory of Nobel Laureate J. Michael Bishop, MD at UCSF, earned a Ph.D. from the Integrated Program in Cellular, Molecular and Biophysical Studies at Columbia University in the laboratory of Dr. Saul J. Silverstein. Dr. Lium holds a B.S. in Biology from Gonzaga University.

Chairman BUCSHON. Thank you very much for your testimony.

Because of the delayed start Chairman Smith will not be able to attend but he asks now that, with unanimous consent to submit his statement for the record. Without objection.

[The prepared statement appears in Appendix I]

Chairman BUCSHON. I would like to thank the witnesses for their testimony and remind Members of the Committee that questioning is limited to five minutes.

The Chair will now recognize himself for five minutes for the first round of questioning.

Dr. Hart-Wells, thanks for coming from Purdue. We appreciate that.

Dr. HART-WELLS. My pleasure.

Chairman BUCSHON. In your testimony you state that federally funded Purdue technologies that were supplemented by proof-of-concept awards had about a 40 percent increase in licensing rate compared with other federally funded programs not supplemented by proof-of-concept awards.

Can you explain what the reasons are for that, and how might the proposed grant program we are considering improve that?

Dr. HART-WELLS. Certainly. Thank you for the question.

Yes. That data is 35 to 40 years of data that, granted this Trask Venture Fund has evolved over time. Very recently in the last three to four years the program is run very similar to an early pre-proof-of-concept and proof-of-concept type with business executives and local business community representatives, as well as university leadership or an advisory council. The funding is targeted through their advisement towards answering questions that de-risk a technology for transfer to a private sector partner.

So the goal of the fund has been focused on experiments that fill the gap. That was part of the fund when it was established in '73, many moons ago, before even the Bayh-Dole legislation that created technology transfer offices in universities. And I believe based on our experience and having done the analytics of the program over the years that the targeted deployment with a goal to transfer research results for commercial products and services made the focus of the decision making in such a way that it produced the kinds of outputs that it did, which is the university to transfer out the technology. Get it into the hands of a partner like Dr. Wamhoff, HemoShear, whether you are creating a new company or you are partnering through licensing. But to get it out of the university so that it has an opportunity to be developed further into products and services that can benefit those folks that paid for it.

And that is the number that we can use and put our finger on in a reliable way to say that we were able to get going in that right direction. So I believe it is the targeted, the metrics and what you are measuring will determine how these programs perform, and I believe that was part of this program from the beginning and helped inform its outcomes.

Chairman BUCSHON. Thank you. Dr. Wamhoff, I have to ask you, what do you see as the strengths and weaknesses of the STTR Program?

Dr. WAMHOFF. I think one of the strengths is that it gives investigators critical seed money to do proof-of-concept studies, check off

a go, no-go box for a technology you are trying to commercialize. I think one of the challenges is putting a mechanism in place to let them know what is the go, no-go box on that technology. Scientists—no one loves their science more than the scientist that is developing it, and there is a lot of emotional attachment to it, and there comes a point for every technology when it is going to move out of academia, does it really have legs, and getting exposure to non-scientists, people from the industry, advisors that can help you make that decision to fail fast and move on is really important and a critical gap that needs to be filled.

Chairman BUCSHON. Thank you very much. That is all I have. I will yield now to the Ranking Member, Mr. Lipinski, for five minutes.

Mr. LIPINSKI. Thank you, Mr. Chairman. I thank everyone for their testimony.

As I noted in my opening statement the draft legislation doesn't specify the types of activity that should be supported, so I wanted to get a little bit more into that. Certainly we heard from I think all of you about proof-of-concept, the importance there, and as I said, something I support for NIH. It is just NIH because that was the opportunity we had. I certainly think that is critical. Entrepreneurial education is something I also am very supportive of. Dr. Lium mentioned I–Corps, which I have mentioned countless times in this Committee, my support for I–Corps, I think that is an entrepreneurial education program that has worked very well and should be expanded to other agencies.

What other areas, are there other areas, you know, maybe this is what we should be limiting this bill to, but are there other areas that you think may fit into this bill to help us accelerate commercialization of federally funded research?

Start with Dr. Lium. If there is nothing else, you don't have to make up something else just to answer the question. I just want to see if there were other things that you wanted to add.

Dr. LIUM. My impression is that the bill provides significant flexibility on what programs can be developed by agencies. We have already touched on a number of issues that are relevant from experiential entrepreneurial education, mentorship, and resources within the university to provide a strong infrastructure for technology transfer. I think all of those issues are very important.

Again, based on the draft legislation it appears to me that those types of programs could be developed.

Mr. LIPINSKI. Dr. Hart-Wells.

Dr. HART-WELLS. Yes. I would like to add the critical component in coincident with technology development is cultivation of business experiential learning, kind of on-the-job. There is student entrepreneurialship programs I think at all of the—a lot of universities including Purdue, but perhaps these are opportunities that the faculty researcher or staff or students who are participating in the development of the technology would also perhaps benefit from business support services.

I would agree that my reading of the draft allows that degree of freedom. I refer to a creative license, the way that I read the draft so that it can be customized to the appropriate geographic regions and what those needs are.

But I would add that one of the support mechanisms that could accelerate the translation and transfer of federally funded research results is business support services or mentoring and counseling, along those lines, just generally of how to write a business plan. These are things that are not taught to you in graduate school as you well know when you get an advanced degree.

Thank you.

Dr. WAMHOFF. I remember when I wrote my first business plan actually. I had no idea what I was doing, and I was six years into tenure. But I agree with you, Dr. Hart-Wells, that bringing the private sector into this in any way possible I think is a great idea. At the end of the day they are the consumer of this technology before it goes into the general public. They are the ones licensing it out of the university, they are the ones that are further developing it, putting more capital into it to make it available to the taxpayer, and I don't think there is enough of that. I know at Purdue you have recently changed your boards around where you have a lot of influence, advisors from the private sector. It is not just an academic setting, and having that leeway to do that I think would be really important.

Mr. LIPINSKI. Thank you. I want to quickly ask Dr. Lium, you talked about UCSF's entrepreneurial education activities. You are certainly strong in the focus on life sciences.

Are there any steps that you are taking to adapt entrepreneurial education courses like I–Corps to life sciences? Are there any other special hurdles that you face in tech transfer from the life sciences that other disciplines do not face?

Dr. LIUM. Sure. I think I will start with the hurdles of transferring life science technologies into the commercial sector first. Life science technologies have a particularly long timeframe for development. They are very high risk in general. There are technical risks, regulatory risks—will the product be approved by the FDA?—reimbursement risks. So the—and then the comments that I have made regarding proof-of-concept funding. So there are significant risks related to the investment in the life sciences that are not present in all other fields.

In regards to the Innovation Corps, the UCSF is fortunate to participate in the program. The University of California Berkeley, UCSF, and Stanford are—formed the Bay Area Innovation Corps Node. UCSF in particular is developing life-science-specific curriculum for the Innovation Corps Program in the fields of drugs, devices, diagnostics, and digital health. And I would be happy to answer any questions about that.

Mr. LIPINSKI. Thank you. I yield back.

Chairman BUCSHON. Thank you. I now recognize Mr. Collins for five minutes.

Mr. COLLINS. Thank you, Mr. Chairman. I want to thank both you and Chairman Smith for assisting me and us in putting this forth. My background, yes, I am a mechanical engineer from North Carolina State. Even though I know you have a background from Duke, we won't talk about Duke. But I also have a biotechnology company with two level three plus space labs involved in virus production and the like and also a phase 2B multiple sclerosis secondary progressive MS drug trial ongoing right now in Australia

and New Zealand. So I live the life sciences world a lot, at least before I came here.

But I agree with you on the Valley of Death and you know, the scientists who do really love their science, but when you talk to them and say, all right, now how are we going to get it to market, what is the market, how are we going to price it, and, again, what is the fail safe point, they usually give you the deer in the headlights look.

But one question I know we are going to get is we are going to take money that is already in the STTR Program, and so we want to designate a small piece of it for this new Valley of Death, proof-of-concept.

Would you speak to what you would say the return on investment to the taxpayers and taking this small piece and addressing the Valley of Death versus not doing that and having that money instead go to the traditional programs, in other words, speak to the importance of creating this and what I would hope would be a very high return on investment or your opinion on that for the taxpayers.

Start with Dr. Wamhoff.

Dr. WAMHOFF. Sure. I don't know the metrics on the success of the STTR mechanism, but I can tell you that any time you can decrease the gap in the Valley of Death, it is a good return on any investment, whether it is advice or seed funding on a go, no-go decision, you can end a $2 million venture with $100,000 of seed funding very quickly and say, you know what? This is great science, but it is not going to translate out. Take it back into the lab and do what you need to do, publish in your academic career.

So I am fully for it. I think that it is a real event that happens to a lot of academic investigators. They just get lost.

Mr. COLLINS. Thank you. Dr. Hart-Wells.

Dr. HART-WELLS. Yes. Thank you. I think the—it is—metrics in this space are always tough. This is difficult. There is a lot of good momentum in discussing and deliberating what are appropriate metrics. I would note in my written testimony at Purdue we also have a pre-seed evergreen fund for new ventures. Most of the applicants to these programs, as well as the proof-of-concept, are in the life sciences. There is some data following funds in the universities, and the biggest consumer of these funds are in the life sciences, and that is not surprising given the high risk associated with those technologies.

My belief is—and live this every day is that if universities can incubate a little longer some of these technologies and de-risk them, there are opportunities that are—that will be delivered to the private sector, in particular small businesses, which is our preference. They are statistically proven to generate more jobs. We are responsible to helping those technologies along as much as we can, and a lot of universities are doing that at their own expense, and it is only the Federal Government that can step in and have broad impact across the board. And I see that embraced in the spirit of this legislation.

So I actually see synergy and improvements in the starting point from which a small business would pick a technology, perhaps

what Dr. Wamhoff articulated wouldn't have to be the norm anymore.

Mr. COLLINS. Thank you. We are running a little out of time, so not to skip Dr. Lium, but I would like to ask each of you, right now there is a $150,000 limit on the phase 1 STTR funding. We haven't addressed a particular number here, and I wonder if you could offer a quick opinion on what you might think would be an appropriate dollar limit for this Valley of Death funding.

Dr. WAMHOFF. Oh, for the Valley of Death funding? So you are talking about pre-STTR money essentially.

Mr. COLLINS. Yes. You have got the 150,000 phase 1, the million dollar phase——

Dr. WAMHOFF. I can tell you that with the Coulter Foundation at the University of Virginia you could do a lot with 25,000, $50,000. I believe you have a specific number.

Dr. HART-WELLS. Our data suggests an average of $48,000.

Mr. COLLINS. So $50,000 would be a good number for both of you.

Dr. Lium?

Dr. LIUM. We have a small program at the University of California San Francisco that averages between 50 and $75,000. One comment that I would also make is that I believe that the award size should reflect the technology and the market and the next milestone that—or inflection point of value that one wants to achieve.

Mr. COLLINS. Good. Thank you all for your testimony. I yield back.

Chairman BUCSHON. Thank you. I now recognize Ms. Esty for five minutes.

Ms. ESTY. Thank you, and I want to thank Mr. Collins for asking several of my questions, but to follow up on that and really to sort of point out the question you asked about diversion of funds from existing programs, I believe, Dr. Lium, you mentioned how the current structure, because presumably because it does not fund the Valley of Death, ends up then with premature formation of startups, which then fail.

So could you discuss a little bit whether you think this focus on permitting grants to be used in relative, we are talking small amounts of grants, $50,000, $75,000, can you explain if you think that really would help better deployment and leverage of those resources?

Dr. LIUM. The simple answer to the question is yes. I believe that conducting proof-of-concept research within the university where the discovery was made can be done much, much less expensively than in the context of a company. Creating a company and the cost of a company and the complications of a company and the distraction that the company represents for a faculty member relative to being able to raise a small amount of proof-of-concept funding, do the research within the university, using the same individuals that likely made the invention is actually—would be a very, a significant advantage. And ultimately in the long run would be a better utilization of capital.

Ms. ESTY. I represent northwest Connecticut, so we have Farmington U–Conn Medical Center with the Jackson Labs coming in

and synergies with Yale as well and attempting to do this licensing better.

Can any of you discuss, this is a great concern in my state, things that we might be able to do as we look at this issue about aiding universities that are already very focused on this? What can we do to aid that process on the tech transfer? We have got big centers, both of them working a lot of life sciences. Are there other things we haven't flagged in this bill or related issues that we should put on their radar?

Dr. LIUM. I think many of the comments that have been made today related to having external boards and mentorship are very important in the context of licensing as well. We recently were negotiating a license with a small company and reached out to neutral parties in the field—neutral venture capitalists—to determine what the cost or what the value of the technology was to provide us some comfort in the level of—in the financial terms that we were negotiating. We were actually, by doing that kind of homework able to complete the financial negotiations within one hour.

So I think that engaging the commercial community to help in the technology transfer process is essential.

Ms. ESTY. And a final quick question. There has been some discussion, certainly looked at—at Commerce looking at regional clustering for say excellence in manufacturing. Is this something we could also be looking, at say in the life sciences? Again, that is an area where they are looking at public-private partnerships to address in part these entrepreneurial outside advice to help make that transition. We have been attempting to do this with the investing at the state level in Connecticut, but obviously the resources get quite limited, and there is criticism that we are picking winners and losers.

So can you help us, you know, how do we avoid that picking winners and losers problem but nevertheless provide the resources for these startups? The outside advice. Do you have thoughts on how we could structure that, what the Federal Government's role should be or whether that is just advisory to suggest that they do this?

Dr. LIUM. I think advice has to be tailored very specifically to the technology that one is examining at any particular time. We have a program within the Clinical Translational Science Institute at the University of California San Francisco that utilizes mentors with very specific expertise to advise faculty with early-stage technologies.

So, again, I am very supportive of these structures. That program is structured in such a way where there is a call for proposals twice a year from faculty. They are evaluated by boards of mentors, individuals are selected and mentored for a period of months, and then there is a report out at the culmination, and a number of the projects then receive a small amount of funding. I think there is an opportunity to use those types of external boards to help make these types of decisions.

Ms. ESTY. Thank you very much, and thank you, Mr. Chairman.

Chairman BUCSHON. You are welcome. I now recognize Dr. Bera for five minutes.

Mr. BERA. Thank you, Mr. Chairman, and I am not a mechanical engineer, but a physician, and I will give a shout out to the University of California system where I did my training and was on faculty.

I think this is fascinating, and, again, I am glad that we are addressing the issue of technology transfer. When you talk about this Valley of Death, you know, going through the three stages from basic research to proof-of-concept to commercialization, I know when we are in the lab, you know, in the academic center we just like to think of ideas, and we like to, you know, and the academic center is very well situated for this exchange of ideas where—which is what we are trained to do, but we are not thinking about how to take product to market.

And it has always occurred to me that if we could take the entrepreneur and actually partner them very early on, so while we are formulating our ideas and so forth, they are also thinking about and providing input into how to bring that product to market.

So, again, creating a context that allows that to happen at an early-stage as opposed to a later stage certainly is something that we should be working on, and I would be interested in hearing your thoughts on how we best go about, you know, getting that at that earlier stage.

The other question is—I was down at the University of California San Diego this past weekend meeting with Chancellor Khosla and some of his faculty, and I knew this hearing was coming up, so I actually posed to them the question of what could we do to better help technology transfer obviously at one of our major research institutions, and the answer they gave me surprised me. What he said was look at tax-exempt bonds, and I tested this with my home institution at U.C. Davis, and they talked about how the Federal Tax Reform Act really limits their ability to provide research space. They said, you know, industry is knocking on their door. They want to partner, they want to come in and, you know, work side by side in these lab spaces, but our tax code currently limits their ability, you know, because these are tax-exempt bonds, to allow the entrepreneur to come in, and I would ask you guys to comment on that and, you know, provide perspective.

Dr. Hart-Wells.

Dr. HART-WELLS. I will take that first. While I am not a tax attorney or a mechanical engineer for that matter, we run into this, and we have this conversation, actually more vigorous conversations more recently, what you are referring to is what is referred to as private use and bonded facilities. And there is a prohibition on basically for-profit activities in those spaces.

So that is actually an input in the analysis that is often not considered inside the university in the dialogue on the outside but is a critical go, no-go of whether a university can even undertake a partnership, whether it wishes to or not. It would be a very, I think appropriate in the context of all of the conversations about realizing the value of federally funded research through products and services where appropriate, to consider and take up the question of private use and its impact, positive and negative, on this whole ecosystem.

Mr. BERA. So it would be possible actually in this body to perhaps amend the Tax Reform Act to allow at an earlier stage those entrepreneurs to come into the lab, work side by side.

Dr. Lium. Yes.

Dr. LIUM. Yes. I think that would be true. We do have relationships with corporations that allow for their personnel to come onto campus and work closely with our investigators but on a limited basis. One example of a close relationship that the University of California San Francisco has is the Center for Therapeutic Innovation with Pfizer. In this particular case they have established a laboratory across the street from the campus.

We do believe very strongly that collaborative research between industry and academics is essential to translating academic inventions into the commercial sector.

I can also take, if you would like, I can also comment on your first question related to in essence, if I understood you correctly, early intervention. I think a very good model for this, again, is the National Science Foundation Innovation Corps Program. This is a program that takes teams, small teams at the very earliest stages that apply to participate. It is highly experiential. The teams go through a process of meeting with a very large number of customers and stakeholders from whatever particular market is appropriate for the technology that they have over a relatively short period of time to establish beyond proof-of-concept around the technology itself, but actually they understand what the market is, what the product should be, what they would be able to charge for it. So really getting a much, much deeper understanding. That is a short, intensive program. The goal is to help individuals or to help teams fail early and then also to identify those that have a successful concept and take those forward.

Mr. BERA. Okay. Thank you.

Chairman BUCSHON. Thank you. I now recognize Mr. Kilmer for five minutes.

Mr. KILMER. Thank you, Mr. Chair, and thank you all for your testimony. You have shared with us, I think, some interesting ideas around a number of themes; financing, mentorship, partnerships. We talked about some challenges including prohibitions on for-profit activities, and that is something we have grappled with in my state, the State of Washington, where we had to update our ethics laws as we dealt with commercialization of research.

Can you touch on, you know, as you look both in the areas where you work and other states, have you seen any other best practices that as we noodle on these issues we ought to be thinking about, we ought to be looking at? And that we ought to think about scaling up at the Federal level.

Dr. HART-WELLS. I will comment that I believe there are a number of practices undertaken across the country now as you start to see folks inside the university change over into individuals with industrial experience or experience in technology transfer. For example, Dr. Wamhoff, the Coulter, I will say the Wallace H. Coulter Foundation in my opinion is a best practice that is scalable and is embedded in a number of universities throughout the country, a small number. It is not dissimilar to how we implement our proof-of-concept awards. But the business advisement component that

has been mentioned as critical is a requirement, I believe. Business advisors who compensated for their time and knowhow and expertise, and then done so in a way that conflicts of interests and tax bonds, all these types of very critical considerations are done, with the goal in mind, which is not dissimilar to your proposed legislation.

I would offer up that program as a best practice.

Mr. KILMER. Thank you.

Dr. WAMHOFF. Yeah. I would like to echo what Libby said. The Coulter Foundation, that mechanism is extremely effective. What they were able to do with a $1 million seed grant at the University of Virginia in partialing out $25,000, $50,000, $75,000 seed grants and the number of companies that launched off of that simply because of the fact there was an oversight board of university faculty but more importantly outside members in the community as well as other industries helping academics make very critical go, no-go decisions. It is either going to work when you do this study, or it is not going to work, and at the end of the day you are going to know whether to turn left, right, or keep going forward or abandon it, and that is a mechanism that is now, I think, being implemented not just in the original nine universities, but they have now branched it out probably closer to 20 universities.

So it is in place, and it is a great structure.

Dr. LIUM. I think that we have touched on a number of themes today that are repeated in many programs across the Nation from proof-of-concept funding, fail early, experiential learning for entrepreneurship, bringing mentors, actually true commercial mentorship to the table. One thing that hasn't been mentioned is incubator space. I think it is important to have space that this type of work can be done in, particularly when it is time to create a company, have space that a small company can take a very small amount of space and move forward. Really it is about creating the ecosystem, and so if we can create an ecosystem that supports entrepreneurship and commercialization within the academic environment without actually fundamentally changing the academic mission of an institution, I think we would be very successful.

The educational issues that we face are significant. I think we have all mentioned or referred to them in terms of individuals understanding truly what does it take to take a basic discovery into the commercial marketplace. It is a very complex process. The mentorship alone can be very time consuming, but, again, these are the kind of things and ultimately what the goal is to create that entrepreneurial supportive environment that cultivates this.

Mr. KILMER. Thanks, Mr. Chair.

Chairman BUCSHON. Thank you very much.

At this point I would like to thank the witnesses for their valuable and very fascinating testimony and the Members for their questions.

The record will remain open for two weeks for additional comments and written questions from Members.

The witnesses are excused, and the hearing is adjourned.

[Whereupon, at 4:13 p.m., the Subcommittee was adjourned.]

Appendix I

Additional Material for the Record

SUBMITTED STATEMENT BY CHAIRMAN LAMAR SMITH,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

Thank you, Chairman Bucshon, for yielding me time. And I thank our newest member of the Science Committee, Chris Collins, for bringing his small business experience and leadership position on the Small Business Committee to bear in developing the discussion draft of "The Innovative Approaches to Technology Transfer Act of 2013."

The research and development conducted at our nation's universities, research institutes and national laboratories have served as the basis for many technology breakthroughs that have driven American innovation and our economic growth.

It is our job as policymakers to help create a healthy, pro-business environment that brings new inventions to the market.

Today's hearing will provide a focused discussion on how to improve technology transfer at our nation's research universities and laboratories in order to promote American competitiveness.

I look forward to hearing from our witnesses and I yield back the balance of my time.