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THE ROLE OF SMALL BUSINESS IN INNOVATION AND JOB CREATION: THE SBIR AND STTR PROGRAMS

HEARING

BEFORE THE

SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

THURSDAY, MARCH 31, 2011

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CONTENTS

Hearing Date

	Page
Witness List	2
Hearing Charter	3

Opening Statements

Statement by Representative Benjamin Quayle, Chairman, Subcommittee on Technology and Innovation, Committee on Science, Space, and Technology, U.S. House of Representatives	6
Written Statement	7
Statement by Representative David Wu, Ranking Minority Member, Subcommittee on Technology and Innovation, Committee on Science, Space, and Technology, U.S. House of Representatives	8
Written Statement	9

Witnesses:

Dr. Sally Rockey, Deputy Director for Extramural Research, National Institutes of Health	
Oral Statement	10
Written Statement	13
Dr. Donald Siegel, Dean and Professor, School of Business, University at Albany, State University of New York	
Oral Statement	16
Written Statement	18
Mr. Mark Crowell, Executive Director and Associate Vice President, Innovation Partnerships and Commercialization, University of Virginia	
Oral Statement	24
Written Statement	26
Mr. Doug Limbaugh, Chief Executive Officer, Kutta Technologies	
Oral Statement	30
Written Statement	31
Ms. Laura McKinney, President and Chief Executive Officer, Galois, Inc.	
Oral Statement	35
Written Statement	37

Appendix I: Answers to Post-Hearing Questions

Dr. Sally Rockey, Deputy Director for Extramural Research, National Institutes of Health	60
Dr. Donald Siegel, Dean and Professor, School of Business, University at Albany, State University of New York	68
Mr. Mark Crowell, Executive Director and Associate Vice President, Innovation Partnerships and Commercialization, University of Virginia	70
Mr. Doug Limbaugh, Chief Executive Officer, Kutta Technologies	74
Ms. Laura McKinney, President and Chief Executive Officer, Galois, Inc.	84

Page

Appendix II: Additional Material for the Record

Material Submitted by Representative David Wu, Ranking Minority Member, Subcommittee on Technology and Innovation, Committee on Science, Space, and Technology, U.S. House of Representatives 92

Material Submitted by Representative John P. Sarbanes, Subcommittee on Technology and Innovation, Committee on Science, Space, and Technology, U.S. House of Representatives 96

THE ROLE OF SMALL BUSINESS IN INNOVATION AND JOB CREATION: THE SBIR AND STTR PROGRAMS

THURSDAY, MARCH 31, 2011

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

The Subcommittee met, pursuant to call, at 2:03 p.m., in Room 2318 of the Rayburn House Office Building, Hon. Benjamin Quayle [Chairman of the Subcommittee] presiding.

RALPH M. HALL, TEXAS
CHAIRMAN

EDDIE BERNICE JOHNSON, TEXAS
RANKING MEMBER

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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Technology and Innovation Subcommittee

The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs

Thursday, March 31, 2011
2:00 p.m.-4:00 p.m.
2318 Rayburn House Office Building

Witnesses

Dr. Sally Rockey
Deputy Director for Extramural Research, National Institutes of Health

Dr. Donald Siegel
Dean and Professor, School of Business, University at Albany, State University of New York

Mr. W. Mark Crowell
Executive Director and Associate Vice President for Innovation Partnerships and Commercialization, University of Virginia

Mr. Doug Limbaugh
Chief Executive Officer, Kutta Technologies

Ms. Laura McKinney
President and Chief Executive Officer, Galois, Inc.

HEARING CHARTER

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

The Role of Small Business in Innovation and Job Creation:
The SBIR and STTR Programs

THURSDAY, MARCH 31, 2011
2:00 P.M.—4:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

1. Purpose

On Thursday, March 31, the Subcommittee on Technology and Innovation of the Committee on Science, Space, and Technology will hold a hearing to examine the role of the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) Programs in promoting innovation. Witnesses will discuss their experience with the SBIR and STTR Programs and will provide advice on areas of potential improvement as the Committee considers reauthorization of these programs.

2. Witnesses

Dr. Sally Rockey is the Deputy Director for Extramural Research at the National Institutes of Health.

Dr. Donald Siegel is Dean and Professor at the School of Business, University at Albany, State University of New York, and a Member of the research team for the Committee for Capitalizing on Science, Technology, and Innovation, National Research Council of the National Academies.

Mr. Mark Crowell is the Executive Director and Associate Vice President for Innovation Partnerships and Commercialization at the University of Virginia.

Mr. Doug Limbaugh is the Chief Executive Officer of Kutta Technologies.

Ms. Laura McKinney is the President and Chief Executive Officer of Galois, Inc.

3. Brief Overview

The hearing will examine the effectiveness of the SBIR and STTR Programs in promoting small business innovation and job creation. Witnesses will describe whether the programs are achieving their defined objectives, whether the current structure and size of the programs are appropriate, and whether eligibility requirements should be adjusted.

4. Issues for Examination

The Committee will examine several aspects of the SBIR and STTR programs including: whether the SBIR and STTR Programs are effectively promoting innovation and job creation; whether firms that are majority-owned by venture capital operating companies should be eligible to apply for program funding; whether the current extramural research set aside of 2.5 percent for SBIR programs is adequate; whether the current guidelines on award sizes is appropriate and to what extent agencies should have flexibility in determining award sizes; whether there is significant geographic concentration among award recipients and, if so, what accounts for this concentration; whether there is evidence to suggest that a significant number of companies receive multiple SBIR awards with unusually low commercialization rates; and whether the management and coordination of the program across the federal government needs to be improved.

5. GAO and NRC Reviews of the SBIR and STTR Programs

The GAO has conducted multiple studies of the SBIR and STTR programs since their inception assessing: rates of commercialization; effectiveness of SBIR and STTR activity in meeting agency R&D needs; small business participation in gov-

ernment R&D; geographical concentration of award funding; and ability of agencies to effectively evaluate the SBIR and STTR programs.

In June 2005, the GAO submitted congressional testimony, which found that the SBIR program has helped "enhance the role of small businesses in federal R&D." [1] However, an October 2006 GAO study found that "agencies need to strengthen [their] efforts to improve the completeness, consistency, and accuracy of awards data" to better assess the effectiveness of the program in achieving its defined objectives. [2]

As part of the 2000 reauthorization of the SBIR program, Congress directed the National Research Council (NRC) of the National Academies to conduct a comprehensive evaluation the SBIR program. The NRC report, published in 2008, found the SBIR program to be "sound in concept and effective in practice" while also recognizing areas of potential improvement. The NRC found that the "SBIR program is making significant progress in achieving the congressional goals for the program," though it also noted that more regular evaluations are needed, since "insufficient data collection, analytic capability and reporting requirements, together with the decentralized character of the program mean there is limited ability to make connections between program outcomes and program management and practices." [3]

As part of its assessment, the NRC conducted surveys of SBIR and STTR award recipients. The Phase II Survey found that "34 percent of NIH projects surveyed generated at least one patent, and just over half of NIH respondents published at least one peer-reviewed article." [4]

According to the NRC Firm Survey, over 20 percent of companies indicated that they were founded entirely or partly because of an SBIR award. On average, companies that responded to the survey reported adding 29.9 full-time equivalent employees since receipt of their SBIR award. Comprehensive data on commercialization rates is inconsistent across federal agencies, but respondents to the survey "indicate that just under half of the projects do reach the marketplace." [5]

6. Background

SBIR

Congress passed the Small Business Innovation Development Act (P.L. 97–219) in 1982 to increase participation of small high-technology businesses in federally funded research and development activity. The Act established the SBIR program within the major federal research and development (R&D) agencies. Research has suggested that small businesses are both highly innovative and engines of significant job creation. [6]

The original objectives of the SBIR program include:

- Stimulation of technological innovation in the small business sector;
- Increased use of the small business sector to meet the government's R&D needs;
- Additional involvement of minority and disadvantaged individuals in the process;
- Expanded commercialization of the results of federally funded R&D.
- The 1992 SBIR reauthorization placed greater emphasis on the objective of commercialization of SBIR projects.

Current law requires that every federal department with an extramural R&D budget of $100 million or more establish and operate an SBIR program. Eleven federal departments have SBIR programs, including the Departments of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, and Transportation; the Environmental Protection Agency, the National Aeronautics and Space Administration; and the National Science Foundation. Under the program, each qualifying federal department is mandated to set aside 2.5 per-

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[1] U.S. General Accountability Office, Observations on the Small Business Innovation Research Program, GAO–05–861T, Washington, DC: U.S. General Accountability Office, 2005.

[2] U.S. General Accountability Office, Small Business Innovation Research: Agencies Need to Strengthen Efforts to Improve the Completeness, Consistency, and Accuracy of Awards Data, GAO–07–38, Washington, DC: U.S. General Accountability Office, 2006.

[3] National Research Council of the National Academies *An Assessment of the SBIR Program*, Washington, DC, The National Academies Press, 2008.

[4] Ibid.

[5] Ibid.

[6] J. O. Flender and R. S. Morse, *The Role of New Technical Enterprise in the U.S. Economy*, Cambridge, MA: MIT Development Foundation, 1975, and David L. Birch, "Who Creates Jobs?" *The Public Interest*, 65:3–14, 1981.

cent (doubled from 1.25 percent in the 1992 reauthorization) of its applicable extramural R&D budget to support mission-related work conducted by small companies.

Agency SBIR efforts are broken down into three phases. In the first phase, awards up to $150,000 for six months (increased from $100,000 as of March 30, 2010 under a Small Business Administration (SBA) Policy Directive[7]) are provided to evaluate a concept's scientific or technical merit and feasibility. The project must be of interest to and coincide with the mission of the supporting organization. Projects that demonstrate potential after the initial endeavor may compete for Phase II awards of up to $1,000,000 lasting one to two years (increased from $750,000 under a March 30, 2010 SBA Policy Directive[8]) to perform the principal R&D. Phase III funding, directed at the commercialization of the product or process, is expected to be generated in the private sector. Federal dollars may be used if the government perceives that the final technology or technique will meet public needs, though this funding must come from outside the SBIR Program.

The SBA created broad policy and guidelines under which individual departments operate SBIR programs. The agency monitors and reports to Congress on the conduct of the separate departmental activities.

Criteria for eligibility in the SBIR program include companies that are independently owned and operated; not dominant in the field of research proposed; for profit; the employer of 500 or fewer people; the primary employer of the principal investigator; and at least 51 percent owned by one or more U.S. citizens or lawfully admitted permanent resident aliens. Subsidiaries of SBIR-eligible companies are also eligible to participate as long as the parent company meets all SBIR requirements.

The SBIR program has been reauthorized several times since its creation and was scheduled to terminate on September 30, 2008. While the program has not been specifically reauthorized since then, it has been extended by several bills, most recently by P.L. 112–1, which extends the program through May 31, 2011.

STTR

The Small Business Technology Transfer Program (STTR), created by P.L. 102–564 and reauthorized several times through fiscal year 2009, is a small business program that provides federal R&D funding for research proposals that are developed and executed cooperatively between a small firm and a scientist in a nonprofit research organization, and fall under the mission requirements of the federal funding agency.

Up to $100,000 in Phase I financing is available for one year; Phase II awards of up to $750,000 may be made for two years. Federal departments with annual extramural research budgets over $1 billion must set aside of 0.3 percent for STTR programs. Currently, the Departments of Energy, Defense, and Health and Human Services, NASA, and NSF participate in the STTR program.

STTR-eligible small business partners must be American-owned and independently operated, be for-profit, and must have no more than 500 employees. Nonprofit research institution partners must be located in the U.S., and must meet one of three definitions: a nonprofit college or university; a domestic nonprofit research organization; or a federally funded R&D center (FFRDC).

While the STTR Program has not been reauthorized since fiscal year 2009, it has been extended by several bills, most recently by P.L. 112–1, which extends the program through May 31, 2011.

7. 110th and 111th Congressional Hearings

The House Committee on Science, Space, and Technology held two hearings in the 110th Congress and one hearing in the 111th Congress to examine SBIR and STTR programs and to analyze the success of the programs in meeting their defined objectives.

8. SBIR/STTR Discussion Draft Reauthorization

For purposes of discussion, draft legislation to reauthorize the SBIR and STTR programs has been supplied to witnesses and Members of the Subcommittee prior to the hearing. Among other things, the draft would reauthorize both programs for three years; increase Phase I and Phase II award sizes for both programs; allow for greater participation of venture-capital backed firms in the SBIR program; and enhance data collection for the programs.

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[7] Federal Register, Vol. 75, No. 60, Tuesday, March 30, 2010, 15756

[8] Federal Register, Vol. 75, No. 60, Tuesday, March 30, 2010, 15756

Chairman QUAYLE. The Subcommittee on Technology and Innovation will come to order. Good afternoon, everybody. Welcome to today's hearing entitled, "The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs." In front of you are packets containing the written testimony, biographies, and truth-in-testimony disclosures for today's witnesses. I would now like to recognize myself for five minutes for an opening statement.

Good afternoon. I would like to welcome you again to today's hearing where we will be examining the Small Business Innovation Research and Small Business Technology Transfer Programs.

The SBIR Program was signed into law by President Reagan in 1982, to help spur innovation and increase small business participation on federal research and development activity. Since its inception, this competitive grant program has awarded over $23 billion in SBIR awards for more than 100,000 projects across the Nation and has helped spawn familiar companies such as Qualcomm, Sonicare, and Symantec.

SBIR and STTR award winners have also created equipment critical to agencies such as parts for the Mars Rover for NASA or a unique cockpit airbag system to protect Army helicopter pilots at the Department of Defense. In Tempe, Arizona, Kinetic Muscle has created innovative therapy robots for patients suffering from stroke or traumatic brain injury.

These systems are being adapted for use at home, lowering their cost, and allowing patients to receive the intensive, repetitive therapy that is often needed for meaningful recovery.

In my own district, Kutta Technologies has created a unique subterranean communication device for the coalmining industry. As this week marks the one-year anniversary of the Upper Big Branch Mine disaster in West Virginia where we lost 29 miners, we are cognizant of how such technologies can make a difference to so many people.

Today 11 federal agencies provide funding to small businesses through SBIR, and five agencies provide funding through STTR. Grant recipients have contributed to the country's scientific and technical knowledge, generating thousands of patents and a wealth of peer-reviewed articles.

These small businesses have expanded innovation, helped grow our economy by creating thousands of jobs, and are assisting participating federal agencies to fulfill their mission. SBIR and STTR are unique in that they are examples of federal programs that have largely been successful and have received bipartisan support since their creation.

The National Research Council's review of SBIR found the program to be, "sound in concept and effective in practice" but also identified ways the program can be improved. For instance, our ability to effectively evaluate the programs is hampered by insufficient data collection and a lack of common measurement criteria among participating federal agencies.

Improving these assessment tools is crucial to ensure the Federal Government is getting the greatest return on its investment. This is particularly necessary in today's budget environment.

It is also important to examine if the current funding set-asides for the programs are appropriate and whether the eligibility cri-

teria for these programs should be expanded to allow majority-owned venture capital companies to compete for awards.

Finally, I want to address the issue of how we measure commercialization. It is vital for SBIR and SBIR–STTR awards to result in commercial technologies, but we must be mindful that some of these efforts are going to fail, and some companies will have to go back to the drawing board. If all projects are certain to succeed, then there is not sufficient justification for strong government involvement.

While we look for ways to improve commercialization success, these programs must continue to support the innovators and entrepreneurs engaged in high-risk research and development.

We have an excellent panel of witnesses before us who will discuss their experience with SBIR and STTR—I did that twice already—STTR Programs and provide advice on areas of potential improvements as the committee considers their reauthorization. We will hear perspectives from private small businesses, a federal agency, a university representative, and from a member of the National Research Council committee which conducted the most comprehensive review of the SBIR Program to date.

I would like to extend my appreciation to each of our witnesses for taking the time and effort to appear before us today. Thanks again to our witnesses for their participation, and we look forward to hearing from you.

[The prepared statement of Mr. Quayle follows:]

PREPARED STATEMENT OF CHAIRMAN BENJAMIN QUAYLE

Good afternoon. I'd like to welcome everyone to today's hearing, where we will be examining the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) Programs.

The SBIR program was signed into law by President Reagan in 1982 to help spur innovation and increase small business participation in federal research and development activity. Since its inception, this competitive grant program has awarded over $23 billion in SBIR awards for more than 100,000 projects across the nation, and has helped spawn familiar companies such as Qualcomm, Sonicare, and Symantec. SBIR and STTR award winners have also created equipment critical to agency missions, such as parts for the Mars Rover for NASA, or a unique cockpit airbag system to protect Army helicopter pilots at the Department of Defense.

In Tempe, Arizona, Kinetic Muscles has developed innovative therapy robots for patients suffering from stroke, or traumatic brain injury. These systems are being adapted for use at home, lowering their cost, and allowing patients to receive the intensive repetitive therapy that is often needed for meaningful recovery. In my own district, Kutta Technologies has created a unique subterranean communication device for the coal mining industry. As this week marks the one year anniversary of the Upper Big Branch Mine disaster in West Virginia where we lost 29 miners, we are cognizant of how such technologies can make a difference to so many people.

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The National Research Council's review of SBIR found the program to be "sound in concept and effective in practice," but also identified ways it could be improved. For instance, our ability to effectively evaluate the programs is hampered by insufficient data collection and a lack of common measurement criteria among participating federal agencies. Improving these assessment tools is crucial to ensure the federal government is getting the greatest return for its investment. This is particularly necessary in today's budget environment.

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We have an excellent panel of witnesses before us who will discuss their experience with the SBIR and STTR Programs, and provide advice on areas of potential improvement as the Committee considers their reauthorization. We will hear perspectives from private small businesses, a federal agency, a university representative, and from a member of a National Research Council committee, which conducted the most comprehensive review of the SBIR program to date. I'd like to extend my appreciation to each of our witnesses for taking the time and effort to appear before us today.

Thanks again to our witnesses for their participation and we look forward to hearing your testimony. With that, I now recognize the gentleman from Oregon, Mr. Wu, for his opening statement.

Chairman QUAYLE. With that I now recognize the ranking member, the gentleman from Oregon, Mr. Wu, for his opening statement.

Mr. WU. Thank you very much, Mr. Chairman, and I just want to note that the alphabet soup of federal acronyms is something that trips the tongue up frequently and does so to me also.

And thank you very much for calling this very, very important hearing. I also want to thank the witnesses, some of whom have traveled a long distance to contribute to our discussion of this very important legislation, and I look forward to your testimony.

As many of you know, a comprehensive reauthorization of the SBIR program is and has been my top priority. We got very close to getting it done in the last Congress. The Senate put together a compromise bill that reflected agreement between key players, which had eluded previous reauthorization efforts.

Unfortunately, while that bipartisan bill passed the Senate by unanimous consent in the waning days of the last Congress, we were unable to get it over the finish line. In fact, it came down to the last day of the lame duck session.

Now, as ranking member of this subcommittee, I remain as committed as ever to a long-term comprehensive reauthorization of this very important legislation, and I look forward to working with Chairman Quayle, who has taken the reins of this very important subcommittee, and with our colleagues on the Small Business Committee in the coming months to make that a reality. And I do hope that we get this done quickly, because this bill, I think, will be the first important jobs legislation done by this Congress, and it is important to get it done early in this Congress for the good of the American people.

This is because our economy is continuing a long, incremental–but slow–recovery, and I think that it is absolutely vital to make this particular contribution. Small businesses are on the innovation frontline, developing new technologies that will lead to new products and services in the market, and more importantly, create high-wage, private sector jobs and spur economic growth.

I truly believe that small businesses are the key to getting our economy back on track and maintaining the technological leadership of the United States in the future. The impact of a thriving small business sector cannot be overstated and must not be overlooked, and that is why it is so important that we find bipartisan consensus in this reauthorization.

While the SBIR program is crucial to encouraging technological innovation by small businesses, it also plays an equally important role in meeting federal research and development needs, particularly in the national security sphere.

Small businesses, represented by the two before us today, have been integral in driving research and development in areas that federal agencies cannot or do not perform, and thus, developing technologies that are directly responsive to national needs.

We now have a public discussion draft of an SBIR reauthorization bill which closely mirrors the bill we passed in the last Congress, both the House and the Senate. It represents the common ground that I believe exists on this issue.

I am eager to work with you, Chairman Quayle, in a bipartisan manner to get the bill ready for introduction, through the Committees of jurisdiction, and to the Floor of the House as quickly as possible.

It is no secret that our constituents are looking to us for non-partisan jobs legislation. I think SBIR is our first and best foot forward. We should do everything we can to ensure that we don't find ourselves in the same avoidable stalemate with the Senate we reached at the end of last year. I would like to believe we learned a lesson that endless waiting and jockeying benefits no one, least of all small business owners across America, and those looking for work, and that we can get our economy back on track to prosperity.

Thank you, again, Mr. Chairman, for holding this hearing, and I look forward, again, to the witnesses' testimony. Thank you.

[The prepared statement of Mr. Wu follows:]

PREPARED STATEMENT OF RANKING MINORITY MEMBER DAVID WU

Thank you, Chairman Quayle, for calling this hearing. And thank you to our witnesses for being here today. I look forward to your testimony and to what I hope will be a fruitful discussion about the role of the SBIR and STTR programs in promoting innovation.

As many of you may know, a comprehensive reauthorization of the SBIR program was one of my top priorities while I was chair of this subcommittee. We got very close to getting it done at the end of last year.

The Senate put together a compromise bill that reflected agreement between key players that had eluded previous reauthorization efforts. Unfortunately, while that bipartisan bill passed the Senate by unanimous consent, we were unable to get it over the finish line here in the House in the waning days of the 111th Congress.

As ranking member on this subcommittee, I remain as committed as ever to a long-term, comprehensive reauthorization of this important program. I look forward to working with Chairman Quayle-who has taken the reins of this important subcommittee with skill and seriousness-and our colleagues on the Small Business Committee in the coming months to make that a reality.

As our economy continues its long and incremental road to recovery, I believe it is vitally important that we do all that we can to support small businesses throughout the United States.

Small businesses are on the innovation frontline - developing new technologies that will lead to new products in the market, create high-paying jobs, and spur economic growth. I truly believe that small businesses are key to getting our economy back on track and maintaining the technological leadership of the U.S. in the future. The impact of a thriving small business sector cannot be overstated and must not

be overlooked, and that is why it is so important that we find bipartisan consensus to reauthorize the SBIR program.

While the SBIR program is critical to encouraging technological innovation by small businesses, it also plays an equally important role in meeting federal research and development needs, particularly in the national security sphere. Small businesses, represented by the two before us today, have been integral in driving research and development in areas that federal agencies cannot or do not, and thus developing technologies that are directly responsive to agency needs.

Earlier this week, a discussion draft of a comprehensive reauthorization bill was released. My initial impression is positive. In many respects, it is very similar to the House bill we passed in the last Congress, and it appears to represent the common ground that I believe exists on this issue.

I am eager to work with you, Chairman Quayle, in a bipartisan manner to get the bill ready for introduction, through the Committees of jurisdiction, and to the floor of the House as quickly as possible.

It's no secret that our constituents are looking to us for bipartisan jobs legislation. I think SBIR is our first and best foot forward. We should do everything we can to ensure that we don't find ourselves in the same avoidable stalemate with the Senate we reached last year. I'd like to believe we learned a lesson that endless waiting and jockeying benefits no one, least of small business owners across America that can get our economy on track to prosperity.

Thank you again Mr. Chairman for holding this hearing. And thank you again to the witnesses for being here. I look forward to your testimony.

Mr. WU. I yield back the balance of my time.

Chairman QUAYLE. Thank you, Mr. Wu. 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 would like to introduce our witnesses, and then we will proceed to hear from each of them in order. Our first witness is Dr. Sally Rockey. Dr. Rockey is the deputy director of Extramural Research at the National Institutes of Health. Next we will hear from Dr. Don Siegel. Dr. Siegel is dean and professor at the School of Business at the University of Albany, State University of New York. Dr. Siegel served as a member of the research team for the National Research Council's review of the SBIR Program and will be sharing the NRC's perspective.

Then we will hear from Mr. Mark Crowell. Crowell.

Mr. CROWELL. Crowell.

Chairman QUAYLE. Crowell. Sorry about that. Mr. Crowell serves as executive director and associate vice president for Innovation Partnerships and Commercialization at the University of Virginia. We are also privileged to hear from two businesses, two business leaders whose companies have benefited from the SBIR Program. First we will hear from Mr. Doug Limbaugh, who is the chief executive officer at Kutta Technologies based in Phoenix, Arizona, my home town. Finally we will hear from Ms. Laura McKinney, who is president and CEO of Galois, Incorporated.

Thanks again to our witnesses for being here this morning. Now, as our witnesses should know, spoken testimony is limited to five minutes each. After all witnesses have spoken, members of the committee will have five minutes each to ask questions.

I now recognize our first witness, Dr. Sally Rockey, deputy director of—for Extramural Research at the National Institutes of Health, to present her testimony.

STATEMENT OF DR. SALLY ROCKEY, DEPUTY DIRECTOR FOR EXTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH

Ms. ROCKEY. Good afternoon.

Chairman QUAYLE. Your mic, please.

Ms. ROCKEY. Good afternoon, and thank you for having me today. It is really an opportunity for me to talk to you about the National Institutes of Health's Small Business Innovation Research and Small Business Technology Transfer Programs and the role they play in stimulating innovation and our economy.

Among the 11 federal agencies that participate in the SBIR Program, the NIH is one of the largest funders of this program, and we, of course, as you know, are the largest Federal supporter of biomedical research. And the SBIR/STTR Programs play a very critical component that feeds the innovation pipeline resulting in today's medical advances.

The NIH SBIR/STTR Programs are ideally suited for creating research opportunities for U.S. small businesses to stimulate technological innovation. Part of a complex innovation system, these programs provide dedicated funding for small businesses to conduct early stage research and development to explore the feasibility of innovative ideas that may eventually result in products or services that lead to better health for everyone.

Our program is one of the means by which the NIH Institutes and Centers accomplish their research and development goals, and a key feature of the SBIR/STTR Program is that it is focused on commercialization of the research results, and that is very key. Thus our program serves to supplement much of the more basic and applied research that NIH also supports.

The NIH SBIR/STTR Program supports projects in areas such as drug discovery, medical devices, which is a large component of our program, biosensors, nanotechnologies, imaging, bioengineering, behavior research, health services, and technologies to reduce health disparities.

Investigator-initiated ideas are the cornerstone of how NIH usually supports research in our research portfolio, and the SBIR Program is also in this mix. So, thus, we solicit applications on specific projects and topics, but we encourage small businesses to propose their own innovative ideas where—that are relevant to the mission of the NIH, so that those closest to the technology highway can drive the innovation.

The NIH in accordance with the current statute must set aside 2.5 percent of its extramural research and development budget for SBIR and .3 percent for STTR. As you know, it is a two-phase program. The first phase is a feasibility project, and the second phase is a much longer continued research phase.

The overall set-aside for NIH activities in 2010 was $690 million, including $616 million for SBIR and $74 million for STTR. It supported almost 700 phase one awards and 250 phase two awards to small businesses. Applications go through a very rigorous peer-review process, very much like all of our NIH applications that—and our funding decisions are based on the rating that it gets through the technical review, when it aligns with areas of high program relevance, program desire to balance among research areas, available funds, and of course, in the case of SBIR, its commercial potential.

The number of applications and new firms participating in the program was on a downward trend between 2004 and 2009, however, the number of applications has increased dramatically in

2010, as did applications to other NIH Programs. Thus, the award phase, the award success rate of the SBIR Program in 2010 for the first time in almost six years was actually lower than our other NIH Programs.

Since its inception in 1982, we have invested more than $5 billion at NIH over 19,000 projects to over 5,000 small businesses. You are going to hear more from the NRC about their study, but, of course, this is—the program is seen as a source of economic vitality and is especially important as a source of new employment.

In looking at job growth for SBIR awardees since the receipt of their award, the NRC found that the employment gain in the long term was about, almost 30 full-time equivalent jobs. That was in the long term and for these businesses during the project they were able to hire 2.7 full-time equivalents and retain 2.2. That was just during the course of that particular project, so that does have much of an impact on the economy.

NIH is continually focusing on ways to address the needs of a diverse small business community, different industry sectors—because we deal with many—and diverse product outcomes. NIH attributes the success where we have seen it about 50 percent, we calculate about 50 percent of our awards result in commercialization, and the effectiveness of this program is attributed to a number of factors, one of which is the very flexible approach that we have to the program, which adapts, helps us adapt to changing science and research.

Some of the examples of this flexibility include the ability to propose research projects as I mentioned from the small businesses themselves that have the most potential, the ability for the applicant to resubmit an unfunded application so if they are not funded the first time, they can come back in, the ability to fund phase one and phase two awards at budgets that may exceed the established guidelines when the science proposed warrants such a deviation to produce a successful outcome. And I will point out that the SBIR median award size for 2010 was $199,000 for phase one and $1.1 million for phase two.

In addition, we have developed programs to help companies address funding gaps between phase one and phase two and help them negotiate the period between discovery and commercialization. For example, we have what is called the Phase One, Phase Two Fast Track and the Phase Two Competing Renewal Award Program that accelerate research.

In particular, Phase Two B, Competing Renewal allows existing SBIR phase two awardees to receive a second additional increment of funding to continue the project while navigating the regulatory process, which is highly complex and time consuming.

Additionally, we manage a suite of technical assistance programs, namely the Niche Assessment Program and the Commercialization Assistance Program, and if we have time, I can explain to you more about them.

For many———

Chairman QUAYLE. Dr. Rockey, if you could wrap it up in 30 seconds or less so we can get as many people done before we get called to votes, that would be really appreciated. Thank you.

Ms. ROCKEY. Okay. I just want to mention about venture capital. For many biomedical technology companies, while this is an important source, it is impossible to really take product to market with the amount of funds that are provided by the SBIR Program. Therefore, venture capital can be very important, and the NRC studies of SBIR noted that the synergies between this funding and venture capital are useful, and therefore, even small businesses benefiting from venture capital funding may seek SBIR funding as a means to exploring this idea. So we are interested in the idea that venture capital can be included.

So I thank you very much, and I will be happy to answer any questions.

[The prepared statement of Dr. Rockey follows:]

PREPARED STATEMENT OF DR. SALLY ROCKEY, DEPUTY DIRECTOR, EXTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good afternoon, Chairman Quayle and members of the Subcommittee. My name is Dr. Sally Rockey. I am the Deputy Director for Extramural Research at the National Institutes of Health (NIH), an agency of the Department of Health and Human Services. Thank you for the opportunity to discuss the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, and the role they play in stimulating innovation and our economy. Among the 11 Federal agencies that participate in the SBIR program, the NIH is one of the largest funders of this program, and the largest Federal supporter of biomedical research. The SBIR/STTR program is a critical component that feeds the innovation pipeline resulting in today's medical advances.

Importance of the SBIR/STTR Program at NIH: Igniting Imaginations and Spurring New Discoveries

The NIH SBIR/STTR programs are ideally suited for creating research opportunities for U.S. small businesses to stimulate technological innovation. Part of a complex innovation system, these programs provide dedicated funding for U.S. small businesses to conduct early-stage research and development (R&D) to explore the feasibility of innovative ideas that may eventually result in products or services that will lead to better health for everyone. The NIH SBIR/STTR programs are one means by which NIH Institutes and Centers (ICs) accomplish their R&D objectives. A key feature that sets SBIR/STTR apart from other NIH programs is a focus on commercialization of the results of research. Thus, the programs serve to supplement the more basic and applied research programs of NIH.

Types of Research NIH Supports Under SBIR/STTR

Examples of the types of research that NIH supports through the SBIR/STTR programs include, but are not limited to: drug discovery, medical devices, biosensors, nanotechnologies, proteomics, imaging, bioengineering, behavioral research, health services, and other technologies that reduce health disparities. Investigator-initiated ideas are the cornerstone of the NIH research portfolio, including projects supported by the SBIR program. Thus, while we solicit projects on specific topics, we primarily encourage small businesses to propose their own innovative research ideas that are relevant to our mission as a way to have those closest to the technology highway drive innovation.

NIH SBIR/STTR Program Overview

The NIH, in accordance with statute, must set aside 2.5 percent of its extramural research and development budget for SBIR program and 0.3 percent for the STTR program. The overall set-aside for NIH SBIR and STTR activities in FY 2010 was $690 million, including $616 million for SBIR and $74 million for STTR that supported 681 new Phase I and 246 new Phase II SBIR projects to small businesses working in many different technology areas across the country. Once all applications go through a rigorous and competitive two-tiered peer review process, funding decisions are based on several factors: 1) ratings from the scientific and technical evaluation process; 2) areas of high program relevance; 3) program balance among areas of research; 4) available funds; and 5) the commercial potential.

The number of SBIR applications and new firms participating in the program was on a downward trend between fiscal years 2004 through 2009. However, the number of applications increased in FY 2010, as did applications for most NIH grants, likely due to the resubmission of applications that were submitted for the American Recovery and Reinvestment Act funds but not initially funded. As a result, the award success rate in FY 2010 for SBIR programs was lower than for the NIH research line for the first time in five years. The FY 2010 combined success rate-the percentage of reviewed grant applications that receive funding-for the SBIR and STTR programs was at 17 percent, which was below the success rate of 20.6 percent overall for NIH Research Project Grants (RPGs).

Overall, the SBIR/STTR programs have complemented NIH's mission to advance science while reducing the burden of illness on public health.

Employment Effects on NIH SBIR Awardees

Since the program's inception in 1982, the NIH has invested more than $5 billion in more than 19,000 projects to over 5,000 small businesses. Past studies of the SBIR program conducted by the NIH[1] and the National Research Council (NRC)[2] have shown that small businesses are seen as sources of economic vitality and are especially important as a source of new employment. In looking at job growth of SBIR awardee firms since the receipt of their award, the NRC found the mean employment gain was 29.9 full time employees (FTEs) from before obtaining the SBIR grant. In addition, respondents estimated as a result of their SBIR projects their companies were, on average, able to hire 2.7 FTEs, and to retain 2.2 FTEs that might not otherwise have been retained. Although the employee size limit for firms receiving an SBIR award is 500, the median size of companies receiving NIH SBIR awards is actually relatively small: 10 employees. Sixty percent were found to have 15 or fewer employees at the time of the NRC survey. This data suggest that the SBIR program is associated with positive employment effects on small business job creation and growth.

Program Flexibility Is Key: One Size Does Not Fit All

NIH is continually focused on ways to address the needs of a diverse small business community, different industry sectors, and diverse product outcomes. NIH attributes the success and effectiveness of its program to several factors, the most significant of which is a flexible and proactive approach that adapts to the changing nature of biomedical and behavioral research while maintaining a highly competitive and effective program.

Examples of program flexibility include the ability to propose research projects in fields that have the most biological potential; the ability for an applicant to resubmit an unfunded application; and the ability to fund Phase I and Phase II awards at budgets that may exceed the established guidelines when the science proposed warrants such a deviation to produce successful outcomes. The SBIR median award size in FY 2010 was $199,000 for Phase I and $1,120,000 for Phase II projects. For STTR, the median award size was $178,000 for Phase I and $1,112,000 for Phase II.

In addition, we have developed programs to help companies address funding gaps between Phase I and Phase II and programs to help them negotiate the period between discovery and commercialization. For example, the Phase I/Phase II Fast-Track and Phase II B Competing Renewal award programs are aimed at accelerating research projects with great potential to produce products and launching them forward into the next R&D stage of development. In particular, the Phase II B competing renewal allows existing SBIR phase II awardees to receive additional funds to continue the project while navigating the regulatory process which often can be a complex and time-consuming process. Additionally, we manage a suite of technical assistance programs, namely the Niche Assessment Program and the Commercialization Assistance Program (CAP), that provide a market opportunity analysis and tailored business mentoring to address very specific needs of selected SBIR companies. Thus we help companies grow into sustainable businesses. Additionally, we have developed a Performance Outcomes Data and Systems (PODS) tool for internal use by NIH program staff, which integrates all data about SBIR and STTR awards, success stories, and tracking data of companies that graduated from our CAP program all into one searchable platform.

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[1] National Institutes of Health, National Survey to Evaluate the NIH SBIR Program: Final Report, July 2003

[2] National Research Council Phase II Survey, An Assessment of the SBIR Program At the National Institutes of Health, 2009

For many biomedical technology companies, the SBIR program is an important source of seed funding for unproven, early-stage ideas that dilutes the risk other investors are not initially willing to bet on. However, a venture capital, angel investor, foundation, or other financing strategy is ultimately the only way that innovative products will enter the marketplace. Research and development in public health and biotechnology is characterized by high and intense capital needs to turn an idea into a product (e.g., it takes an average of $1.2 billion to bring a drug to the market). This usually requires long development times (i.e., 5–12 years), compliance with strict regulations, exceptionally high "burn rates" of capital, and a real need for investment by venture capital companies, some of which are or are not majority-owned by individuals. Often, the necessity for multiple rounds of venture financing to fund the extensive and essential clinical research is the only plausible way to commercialize a product. Individual firms or the SBIR program, alone, are not available to provide the average $8 million per deal currently characterizing venture funding agreements as found by the NRC study of 2009 that evaluated the NIH SBIR program. It is important to keep in mind that while venture capital sources are extremely scarce following the recession, it is nevertheless an option a company should be able to pursue as it fits their business strategy without the fear of being excluded from our programs.

The NRC's study of the SBIR program noted that the synergies between SBIR funding and venture capital are useful, and their study underscored the notion that the innovation process often does not follow a linear path. So, even small businesses benefiting from venture funding may well seek SBIR funding as a means of exploring a new idea, or for example, a new drug candidate. Keeping the pipeline full of new ideas is important, because in today's high-risk biomedical research environment, especially in areas such as drug development, drug discovery, and therapeutics, the reality is that fewer than one percent of the innovative, promising projects reach the marketplace.

Simply stated, one size does not fit all.

Flexibility is critical at a time when science is changing rapidly, becoming more complex, and more interdisciplinary.

Throughout the SBIR program's history, small businesses including those companies with venture capital funding have applied for and received SBIR funding in areas that help to advance our mission. The NRC's study found no evidence that participation of companies with multiple venture capital ownership was harmful to the program or that other small businesses have ever been crowded out by the participation of small businesses that are majority-owned by venture capital companies.

Program Accomplishments: Bringing Ideas To Life

The SBIR program seeks to support the most scientifically promising projects for which private funds are not traditionally available.

The examples noted below demonstrate that tangible scientific benefits can result from a small investment in early-stage ideas with viable, commercial potential.

- Martek Global Services, a Maryland company that studied the effects of DHA, an omega-3 fatty acid important for healthy eye, brain, and heart development, grew into a global leader by developing *Life'sDHA*™, a supplement contained in infant formulas, products for pregnant and nursing women, and food and beverage products sold worldwide. The company was recently acquired for $1.1 billion by a Dutch company and this year was inducted into the Small Business Administration's SBIR Hall of Fame.
- The *Sonicare Power Toothbrush* is a widely used and dentist recommended consumer home care oral hygiene device effective in reversing gingivitis that has to date grossed over $1.5 billion in sales. NIH funding allowed the company to create a $300 million business and over 500 new jobs.

Examples such as these demonstrate the value of investing in early-stage ideas and underscores why the NIH SBIR/STTR programs are important to our mission and to the entire innovation process.

Conclusion

In conclusion, I want to reemphasize the NIH's commitment to supporting small businesses, maintaining the integrity of SBIR/STTR programs, and ensuring that technology development will help improve the health and extend the lives of all people. We are looking to small businesses, primarily through these programs, to stimulate technological innovation, help us face new challenges, and to produce not only new knowledge, but also tangible benefits that touch the lives of every individual. We are hopeful that our continuing outreach efforts and actions to modernize the

SBIR/STTR programs will be helpful in that regard. Finally, we continue to believe strongly that flexibility within the SBIR program is essential to achieving greater successes in these programs. We look forward to the reauthorization of this critical program. This concludes my statement. I will be pleased to answer any questions you may have.

Chairman QUAYLE. Great. Thanks, Dr. Rockey, and the chair now recognizes Dr. Don Siegel, dean and professor at the School of Business at Albany.

STATEMENT OF DR. DONALD SIEGEL, DEAN AND PROFESSOR, SCHOOL OF BUSINESS, UNIVERSITY AT ALBANY, STATE UNIVERSITY OF NEW YORK

Mr. SIEGEL. Thank you. I am a professor, so I have to have Power Point slides. I am also an academic economist, and Ronald Reagan once said that an economist is someone who upon observing that something works in practice wonders whether it works in theory.

And like many economists I was inspired by the late Milton Friedman, and I know that sounds a little strange to use his name because I am going to be advocating government intervention, but as you can see on the next slide Friedman said there were four ways to spend money. He said you can spend your own money on yourself, which you do very wisely, you can spend your own money on others you know personally. Now, a visit to the department store on the day after Christmas tells you that that isn't always done wisely.

You can spend other people's money on yourself, which you do quite lavishly when you are on an expense account, and then he would laugh and say, well, then there is a fourth category, and that is when you spend other people's money on people you don't know, and he would laugh and say that is what government does.

Now, the lesson that I learned from that adage is that it is important to evaluate and assess government programs. We need accountability, and I ask you to think about different realms of public policy. Let's think about education, social policy, technology, and now entrepreneurship programs.

In education and social programs we have rigorous evaluation. Indeed, evaluation is built into the design of most programs. Unfortunately, when it comes to science and technology and now more recently entrepreneurship programs, there is very limited evaluation, and I think that is disappointing. Since we know that innovation and entrepreneurship are key sources of economic growth, we need to learn more about how these programs are impacting the economy.

Now, I am going to assume that you know, like an economist, I am going to make some assumptions and assume that you know about the program. What you may not know is that it took Congress 20 years to actually ask the NRC to evaluate the program, which NRC did.

Now, here is some important points about evaluating programs. Let us say technology programs. It is very important not just to collect statistical data but to have qualitative work, field research, interviews, case studies. This is a very, very complex program. You need to have multiple indicators of success, research success, commercialization, job creation, and so on.

The timeframe of analysis is critical. You have to be able to analyze the program over time, not just at one point in time but over time. You have to have multiple indicators, and those indicators will vary depending on the unit of observation. From an evaluation standpoint it is important to do a very rigorous econometric analysis and also to have a control group, which we do in science but is a little hard to do in this realm.

Now, I am very pleased to report that the NRC SBIR evaluation has all of these elements and more. It was a very rigorously-done study, consisting of basically surveys of projects, of firms, surveys that were designed in consultation with program managers, with users of the program, with even people who were skeptical about the program.

And so this is what led to the study and the key findings of the study are that the program is effective. It is meeting its Congressional objectives, stimulating technological innovation, encouraging participation by minorities and women. We could do a better job on that. I will get back to that in a few minutes. Providing support for small innovative companies and resolving some of the research questions that agencies want answered.

What does success mean? Job and new firm creation, enabling federal agencies to advance their missions, creation of new products, intellectual property that firms can commercialize to make money, and limited success in financial markets. Forty-seven percent of SBIR projects reach the marketplace, which is a very remarkable stylized fact.

The committee found that SBIR's flexibility is a key strength in meeting the missions of multiple diverse agencies. The only area where significant improvement is required is increasing the participation and success of women and minorities.

So what does the committee recommend? That the program should be continued, flexibility should be preserved, innovation and experimentation across agencies should be encouraged, award sizes should be increased. It is important to reduce the cycle time between the application of a grant and the award, to get the technologies out the door and in the marketplace. Increasing, as I said before, the success of women and minorities, and increasing management funding for SBIR, which is a very important aspect of the program.

However, in my view the most important recommendation of the committee is that it is important to conduct, as I said before, rigorous, regular evaluations of the program. It is vital that the program be analyzed over time, that we not just have a snapshot of it but that we have a so-called longitudinal or dynamic analysis of changes in the program over time.

That is why the committee is now doing a second study, analyzing the important problem of helping companies get over the so-called Valley of Death, to help them reach the marketplace, how to increase participation by women and minorities, how to leverage university-industry partnerships, which are very important in this program, how to streamline the application process, and more importantly learning from some of the interesting state-level programs that have been designed to stimulate both innovation and entrepreneurship.

I close on a personal note. Academic studies of SBIR, many of which have been based on NRC data, clearly indicate that involvement with universities enhances the probability of successful commercialization. No matter how you measure that. We need to understand that connection.

We also need to understand the connection between SBIR and our national labs, which are huge players in science and technology. The national labs, for example, in California are bigger than the University of California.

We also need to know what the role is of property-based institutions like incubators, accelerators, and science and technology parks where there has been substantial public investment, but, again, very little analysis or evaluation.

Again, I think the most important point is that I think it is important to continue support for the NRC's efforts to scrutinize this program. There is no one else that can do it, and I thank you for your time.

[The prepared statement of Dr. Siegel follows:]

PREPARED STATEMENT OF DR. DONALD S. SIEGEL, DEAN AND PROFESSOR, SCHOOL OF BUSINESS, UNIVERSITY AT ALBANY, SUNY

My name is Donald Siegel and I am Dean of the School of Business at the University at Albany, SUNY. I also serve as President of the Technology Transfer Society, a non-profit organization dedicated to identifying and disseminating best practices in technology commercialization. The Society hosts an annual conference, linking academics, practitioners, and policymakers, and also publishes the *Journal of Technology Transfer*, the only academic journal devoted to the public policy and managerial implications of technology commercialization. I am a co-editor of this journal.

For the past 15 years, I have studied technology transfer to existing firms and start-up companies, resulting from research activity at universities, federal laboratories, incubators, and science/technology parks. I was trained as academic economist, which means that I am not very practical. President Reagan once said that an economist is someone, who upon observing that something works in *practice*, wonders whether it works in *theory*. Therefore, in the remainder of my testimony, I will provide both theoretical and empirical support for this worthy program.

In 2003, I was asked to join a team of researchers commissioned by the National Research Council to conduct a Congressionally-mandated evaluation of the Small Business Innovation Research Program (henceforth, SBIR) across federal agencies. At first, I was quite skeptical. Like many economists, I was greatly influenced by the late Milton Friedman. I mention this because of Friedman's famous adage regarding the four ways to spend money. First, you can spend your own money on yourself, in which case, the funds are spent quite wisely. Next, you can use your own money to purchase goods or services for others whom you know, such as buying someone a Christmas gift. In this instance, your ability to spend astutely is limited by your ability to match the recipient's preferences. A quick visit to a department store on the day after Christmas illustrates the difficulties of successfully completing that mission. A third method of expenditure occurs when we spend other people's money on ourselves, which transpires when we are on an expense account. In this case, we have little incentive to economize, since others are footing the bill. The final case is spending other people's money on other people (people we do not know personally). According to Friedman, this is exactly what politicians do and thus, he was highly skeptical regarding the ability of government to spend its funds wisely. The lesson I learned from this adage is that government programs should be rigorously evaluated, since they may not always be meeting their objectives (e.g., spending the taxpayers money wisely).

Despite my inherent skepticism regarding the effectiveness of government programs, I was buoyed by the fact that the NRC had convened a group of scholars who could actually conduct the type of systematic evaluation that was warranted for this particular government program. This was quite a challenging assignment for us, but one that is extremely vital for accountability to the taxpayers. Please note that a fundamental rationale for government intervention in the marketplace is the existence of a "market failure." The SBIR Program, in theory, addresses two types of market failures: (1) innovation market failure (for early-stage technologies)

and (2) market failure with respect to the provision of financial capital for new enterprises seeking to commercialize early-stage technologies. Based on comprehensive evidence collected by the NRC team, I am convinced that SBIR is alleviating these market failures and additional study will help us further understand how to make this program even more effective.

SBIR and the Phase 1 NRC SBIR Study

First, let me provide some specific information about the program. SBIR is designed to provide financial assistance to firms during the initial stages of their development. It was established in 1982 as a "set-aside" program. In its current version, SBIR requires eleven federal R&D funding agencies with extramural research programs to allocate 2.5 percent of their extramural research budgets to fund through a peer-review process R&D in small (less than 500 employees) firms and organizations.

SBIR awards consist of three phases. Phase I awards fund the firm to undertake proof of concept; that is, to research the feasibility and technical merit of a proposed research project. A Phase I award lasts for six months (maximum $150,000). Phase II awards extend the proof of concept to a technological product/process that has a commercial application (maximum $1,000,000). A Phase II Award is granted to only the most promising of the Phase I projects based on scientific/technical promise, the expected value to the funding agency, the firm's research capability, and the commercial potential of the resulting innovation. The duration of the award is a maximum of 24 months and generally does not exceed $750,000. Approximately 40 percent of the Phase I Awards continue on to Phase II. Phase III involves private funding to the firm for the commercial application of a technology; no financial award from SBIR is made in Phase III.

The first phase of the NRC study assessed the SBIR program at five federal agencies, the Department of Defense (DoD), the National Institutes of Health (NIH), the National Aeronautics and Space Administration (NASA), the Department of Energy (DoE), and the National Science Foundation (NSF). These five agencies constitute approximately 96 percent of SBIR program expenditures. Specifically, the NRC committee was charged by Congress with evaluating whether the Program was advancing four key societal objectives: (a) stimulating technological innovation; (b) increasing commercialization of innovation in the private sector; (c) using small business to meet federal research and development needs; and (d) fostering and encouraging participation by minority and disadvantaged persons in technological innovation. The committee was also asked to assess the effectiveness of managerial practices, with respect to agency SBIR programs. That is, the committee attempted to determine whether there are "best practices" in certain agency SBIR programs that could be adopted by other agencies.

To accomplish these objectives, the committee employed sophisticated quantitative/statistical and qualitative analyses. It is important to note that the use of qualitative methods is highly warranted, given the complex nature of the program and the inability to capture all of its nuances with purely statistical data. A large and diverse team of expert researchers conducted extensive NRC-commissioned surveys and case studies. In addition, agencies were asked to provide program data and documents. The committee also conducted extensive interviews with program managers, program participants, agency "users" of the program, as well as program stakeholders. I am confident that the NRC study is, by far, the most comprehensive assessment of SBIR ever or more generally, of any technology-based program designed to stimulate entrepreneurship.

Key Findings/Recommendations of the Phase 1 NRC SBIR Study

The NRC committee concluded that the program was indeed advancing the goals of stimulating technological innovation, increasing commercialization of innovation in the private sector, using small business to meet federal agency R&D needs, and stimulating participation by minority and disadvantaged persons in technological innovation. Table 1 summarizes the goals, proxies for achieving those goals, and key outcome indicators the committee used to assess whether the SBIR was accomplishing these objectives.

As shown in Table 1, the evidence clearly indicates that the program has been successful in achieving these goals. Success has occurred along several dimensions: job and new firm creation, enabling government agencies to advance their missions (e.g., the development of simulation software for Navy Seals, which has saved lives and costly equipment), creation of new products and various forms of intellectual property, and success in financial markets. The only area where significant improvement is needed is increasing participation by minorities and disadvantaged people

in the technological innovation. This is especially true for minority participation, which has actually decreased over time.

The NRC Committee issued a series of recommendations. First and foremost, the SBIR program should be preserved because it is effective. Given that program flexibility (across federal agencies) is a strength, such flexibility should be preserved. The committee commended SBA, which oversees the eleven SBIR programs, for its flexibility in exercising its oversight responsibilities. There was also a strong desire to encourage innovation and experimentation across agencies, while preserving the basic program structure (i.e., the three phase approach of the SBIR program). Another key recommendation was to readjust (increase) award sizes, which have not been increased since 1995.

There were also several recommendations relating to improvements in program processes (i.e., managing the program). The most important of these recommendations is the need to shorten the cycle time from application to award (which will ultimately, accelerate technology commercialization). It is important to note that processing periods for awards vary substantially by agency, which has a significant effect on recipient companies. Agencies should closely monitor and report on cycle times for each element of the SBIR program: topic development and publication, solicitation, application review, contracting, Phase II application and selection, and Phase III contracting. Agencies should also specifically report on initiatives to shorten the decision cycle. The committee also stressed to need to increase participation and success by women and minorities in the SBIR program. They identified a set of tactics to accomplish that strategic goal, in including improve data collection and analysis of factors that may account for the lower success rates of woman- and minority-owned firms, as compared with other firms, in receiving Phase I awards. Finally, the NRC team also stressed the importance of increasing management funding for SBIR, e.g., by increasing the set-aside to provide for program management and evaluation.

From my perspective (given my concern regarding accountability and evaluation of government programs), by far the most important committee recommendation was emphasizing the need to *conduct regular, rigorous systematic evaluations of the program.* This will require direct annual reports to Congress by program managers on the state of the SBIR program at their agency. The program should be evaluated internally, i.e., within each agency and agencies should be encouraged to develop interoperable standards for data collection and dissemination. Most importantly, there is also a strong need for comprehensive, periodic external evaluations of the program by a non-partisan organization, such as NRC.

Objectives of Current NRC SBIR Study

The NRC is currently engaged in a second phase of the SBIR study, which is highly critical, given that it will enable us to generate a second "snapshot" of the program (through extensive surveys and case studies). Evaluation must always be an ongoing process and analyzing changes in the SBIR program over time will allow the NRC team to develop better recommendations for improving the program. In sum, a second phase of the SBIR study provides will facilitate a "longitudinal" analysis, rather than a simple "cross-sectional" analysis, which is both more rigorous and more relevant.

Building on the previous study, the NRC committee is currently assessing several important research questions: (1) how the program can be modified to enhance the probability of successful commercialization programs, including the use of "gap funding mechanisms" to address the "valley of death" problem, (2) identifying strategies to encourage participation by minorities and women-led firms in SBIR; (3) how to use existing university-industry partnerships to leverage SBIR; (4) new approaches to streamlining the application and grant/contract awarding processes; and (5) what we can learn from innovative state-level technology commercialization programs and how those can be leveraged at the federal level.

Although these are all important research questions, my own research underscores the importance of identifying best practices in university-industry partnering and synergies with SBIR programs. As noted in Siegel and Phan (2005), universities have recently devoted more attention to the entrepreneurial dimension of technology transfer. This has induced the creation of numerous university-based spinouts and connections to local start-up companies founded by academic entrepreneurs or their students. This is important since two recent academic studies (Link and Ruhm (2009); Siegel and Wessner (2011)), based on data collected during the Phase I NRC study clearly demonstrate that a university connection to an SBIR project substantially increases the likelihood of successful commercialization. Note that in this context (see Siegel and Wessner (2011), "success" in the marketplace resulting from SBIR projects includes numerous performance/commercialization indicators, such as:

- Sales to date of products, processes, and services from the project
- Expected future sales
- New employees hired as a result of the SBIR project
- Patents
- Copyrights
- Trademarks
- Domestic/international licensing agreements

Need for Additional NRC Studies of SBIR

Innovation and entrepreneurship are important determinants of economic growth. The SBIR Program was established because there was a strong bi-partisan consensus that, in the absence of government intervention, there is under-investment in early-stage research with commercial promise in a free market economy. The NRC study clearly demonstrates that the SBIR Program is effectively addressing this problem and significantly improving the performance of small, technology-based firms.

The quality of the analysis and usefulness of the recommendations provided by the NRC team raises an important issue relating to government accountability. Let's consider three types of government programs: social programs, educational initiatives, and technology programs. Typically, educational and social programs are rigorously evaluated. Indeed, it is quite common for evaluation to be built into the design of an educational or social program. Analysis of these programs has yielded important insights for policymakers, resulting in such important changes as welfare reform, which had broad bi-partisan support.

However, despite wide-spread agreement that innovation and entrepreneurship constitute sources of our global competitive advantage, technology programs are almost never carefully evaluated. I have always found that rather strange. Given the connection inherent in SBIR between innovation and entrepreneurship, it is the most important government program in this realm. Thus, I believe that SBIR needs to be carefully scrutinized on an on-going basis, under the auspices of the NRC. If we are serious about evaluation and accountability, we will continue to support the NRC's efforts to scrutinize this important program.

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Table 1
NRC Assessment of SBIR Program

Goal of SBIR Program	Proxy for Achieving Goal	Key Outcome Indicators/Findings
Stimulating Technological Innovation	Generation of New Knowledge	Increases in Patents, Licenses, New Products and Processes, Creation of New Firms, Data, Models, Algorithms, and Research Equipment
Stimulating Technological Innovation	Stimulating Technology Transfer/Commercialization From Universities to Firms	Over a Third of Firms Reported University Involvement in Their SBIR Project; More Than Two-Thirds of These Companies Reported That At Least One Founder Was Previously An Academic; 27% Of Projects Used Faculty as Contractors
Increasing Private Sector Commercialization of Innovations	Facilitator of Commercialization For Small Firms.	New Firm Creation-Over 20 % of Companies Were Founded Entirely or Partly Because of a Prospective SBIR Award
Increasing Private Sector Commercialization of Innovations	The Decision to Initiate Research	Companies Reported That Over Two-Thirds of SBIR Projects Would Not Have Taken Place Without SBIR Funding
Increasing Private Sector Commercialization of Innovations	Providing Alternative Development Paths	Companies Often Use SBIR to Fund Alternate Development Strategies
Increasing Private Sector Commercialization of Innovations	Reaching the Market	Just Under Half of SBIR Projects Reach the Market (Highly Impressive, Given The Embryonic Nature of These Technologies and The Market Risk!)
Increasing Private Sector Commercialization of Innovations	A Small Percentage of Projects Account for Most Successes	As Expected, A Small Percentage of Projects Account For Significant Growth in Sales and Employment

Table 1 (cont.)
NRC Assessment of SBIR Program

Increasing Private Sector Commercialization of Innovations	SBIR is an Input, not a Panacea	While SBIR Stimulates Small Business Commercialization Of Research, Most Major Commercialization Successes Require Substantial Post-SBIR Research and Funding From a Variety of Sources
Using Small Businesses to Meet Federal Research and Development Needs	Flexible Adaptation to Agency Mission	The SBIR Program Has Been Adapted Effectively by the Management of the Individual Departments, Services, and Agencies. SBIR Flexibility in Program Management and Modes of Operation is a Key Strength
Using Small Businesses to Meet Federal Research and Development Needs	Meeting Agency Procurement Needs	SBIR Helps to Meet the Procurement Needs of Diverse Federal Agencies (e.g., at the Department of Defense, the Navy has achieved significant success in improving the insertion of SBIR-funded technologies into the acquisition process.
Providing Widely Distributed Support for Innovation Activity	Large Number of Firms	Between 1992 and 2005, Approximately 15,000 Firms Received At Least One Phase II award
Providing Widely Distributed Support for Innovation Activity	Many New Participants	Each Year, Over One Third of The Firms Awarded SBIR Funds Participate in the Program For the First Time
Fostering Participation by Minority and Disadvantaged Persons in Technological Innovation	Mixed Record	Agencies Do Not Have a Uniformly Positive Record, In Terms of Collecting Data and Monitoring Funding Flows for Research by Woman- and Minority-Owned Firms
Fostering Participation by Minority and Disadvantaged Persons in Technological Innovation	Mixed Record	While Support for Woman-Owned Businesses is Increasing, Support for Minority-Owned Firms Has Not Increased

Chairman QUAYLE. Thank you, Dr. Siegel, and as you heard from all the bells and whistles we have been called to vote, so I hope that you guys will have the patience to stick around, but this subcommittee will recess until 10 minutes after the last vote.

[Recess.]

Chairman QUAYLE. The chair now recognizes—but first thanks for your patience. Sorry about that interruption, but the chair now recognizes Mr. Mark Crowell, Executive Director and Associate Vice President for Innovation Partnerships and Commercialization at University of Virginia for five minutes.

STATEMENT OF MR. MARK CROWELL, EXECUTIVE DIRECTOR AND ASSOCIATE VICE PRESIDENT FOR INNOVATION PARTNERSHIPS AND COMMERCIALIZATION, UNIVERSITY OF VIRGINIA

Mr. CROWELL. Thank you very much, Chairman Quayle and Ranking Member Wu. Thank you for the opportunity to testify before the subcommittee on this very important topic. My written testimony contains many hopefully useful details about the research environment at the University of Virginia and about our engagement with SBIR and STTR-funded projects. In the interest of time, however, I want to immediately launch into answering the questions that you posed to me in your letter inviting me to testify today.

The first question you asked me to address was to provide my views on the role of the university in the SBIR and STTR Programs and how it relates to university technology transfer. As a 24-year veteran directing technology transfer offices, including, Mr. Chairman, at Duke and at UNC, I would say that—I know you are a Duke alum. I would say that our friends in the venture capital industry remain important partners in our innovation and commercialization efforts.

But at the same time I recognize that their reality involves shorter return horizons, higher levels of risk avoidance, and the need to invest higher dollar amounts to accelerate innovations toward the market, therefore, placing most venture capitalists much further downstream than where university deals tend to be.

The availability of SBIR and STTR funding to help de-risk such start-up companies in preparation for downstream venture capital investment is more important than ever to those of us who are charged with creating start-up companies around university inventions.

I would like to for a second provide a quick example of how SBIR and STTR funding has helped to accelerate the amazing growth, opportunity, and potential societal benefit around research developed at UVA. Adenosine Therapeutics was founded in 1999, based on research in UVA's School of Medicine. The company's development pipeline including—included promising compounds for treating cancer, diabetes, CNS diseases, and other afflictions.

In less than nine years—rocket speed in the drug development world—Adenosine was acquired by a larger company, Clinical Data. Its battle-tested CEO remained in Charlottesville and is now a serial entrepreneur, being the CEO of a new UVA start-up that just landed $4.1 million in venture capital. The company maintains

a significant presence in Charlottesville, even as this growth has occurred, and several of their promising compounds are nearing market approval.

We are serious at UVA about starting more companies like Adenosine to commercialize our research, and we need tools like SBIR and STTR to continue to be successful.

The second question you asked me to address focuses on my views of the current percentage of funding allocated to the SBIR and STTR Programs and whether venture capital-backed small companies should be eligible to participate in the programs. At the University of Virginia we strongly support current funding for the SBIR and STTR Programs.

That being said, we also believe that there is no compelling justification or need to increase the percentage of the set-aside amounts. A closed review of success rates within phase one SBIR and STTR grants will reveal that the funding success for these grants is equal to and in many cases higher than success rates for equally—for other equally important grants for basic research.

Any increase in the current SBIR and STTR set-aside would come at the expense of other peer-reviewed basic and applied research, the seed corn for the innovation pipeline. So we would caution against increasing the set-aside percentages.

We also support the eligibility of companies backed with significant venture capital investments to apply for funding under the SBIR and STTR Programs. Companies which have secured substantial venture backing by definition would have undergone significant due diligence evaluation by investors and could be assumed to be on a more certain path to success. Depriving such promising companies an opportunity to compete for sources of co-investment of de-risking capital seems contrary to public—to commonsense and public policy. So we recommend removing any restrictions on the ability of such companies to apply.

The final question I was asked to address concerns what recommendations I would make to improve these programs. The maximum per award funding amounts allowed under phase one and phase two awards should be increased to reflect renewed importance of this initiative, as well as to reflect the effects of inflation over the years.

In our view, phase one awards should be at least $150,000. Phase two should be $a million. We also would recommend incorporating sufficient flexibility in determining the precise award amount so that SBIR and STTR Program officers would have the freedom to increase each award up to 20 percent of the published cap on exceptional circumstances and high-impact opportunity are deemed to be represented in a particular funding award.

In another area, restrictions related to conflict of interest should be examined, and where feasible, flexibility should be added to make it easier for researchers with disclosed and manageable conflicts of interest to participate in SBIR and STTR-backed companies.

Further, we would encourage that additional flexibility would be built into the SBIR and STTR Programs by developing a way to enable agencies to use a portion of these funds to directly support additional proof of concept work. Europe has recently launched just

such a program, and I think it is important that we here in the U.S. find a way to fill this existing funding gap in the innovation pipeline relating to a lack of proof of concept funds.

UVA is one university which has recently demonstrated tremendous success and impact in doing so through the Coulter Translational Partnership with audited results indicating tremendous success and return on investment of these very proven concept funds that I am advocating.

Before closing I would like to point out that my written testimony contains other suggestions for improvements in these programs, including a modest suggestion for setting aside some funds for more rigorous and consistent evaluation and assessment of the type that Dr. Siegel has just recommended.

I would like to thank the subcommittee, especially the chair and the ranking member, for your support of these programs, particularly during these tough budgetary times. We understand that funding is greatly constrained, and I hope you will agree that innovation and commercialization of university research serve the public good while promoting the creation of new products, new companies, and new jobs.

SBIR and STTR funding has proven to be tremendously effective in fueling these activities, and we at the University of Virginia and throughout the university community are highly indebted for your support. Thank you.

[The prepared statement of Mr. Crowell follows:]

PREPARED STATEMENT OF W. MARK CROWELL, EXECUTIVE DIRECTOR AND ASSOCIATE VICE PRESIDENT, INNOVATION PARTNERSHIPS AND COMMERCIALIZATION, UNIVERSITY OF VIRGINIA, CHARLOTTESVILLE

Chairman Quayle and Ranking Member Wu, thank you for the opportunity to testify before the House Science, Space and Technology Committee's Subcommittee on Technology and Innovation on the important topic of the SBIR and STTR programs—and their role in facilitating the formation and growth of small businesses which, in turn, create jobs and help grow the innovation economy.

My name is Mark Crowell, and I am the Executive Director and Associate Vice President for Innovation Partnerships and Commercialization at the University of Virginia. Founded by Thomas Jefferson in 1819, the University of Virginia is committed to its founder's ideal of developing leaders who are well-prepared to help shape the future of the nation through our initiatives in education, discovery and innovation advancement. In fiscal year 2010 the University received research awards totaling over $375.34 million from all sources (federal and state agencies, industry and private foundations). Of this amount, $276.47 million, or 73 percent, came from federal grants and contracts. I should also point out that the University of Virginia has been a partner on approximately 32 SBIR or STTR awards since the program's inception; over the last five years, we have partnered on about eighteen (18) awards for a total of more than $5.7 million. The program is becoming increasingly important to us in our efforts to translate innovations and discoveries developed at our institution into new businesses and products.

The first question you asked me to address was to provide my views on the role of the university in the SBIR and STTR programs—and how it relates to technology transfer. I have been a director of technology transfer since 1987—at Duke University, at North Carolina State University, at the University of North Carolina at Chapel Hill, at the Scripps Research Institute, and now at U.Va. In the decade prior to September 11, 2001, it seemed that if the university had a patent application on file, a preliminary business plan, and an interested faculty inventor, it was possible to land a reasonable Series A round of venture funding. Today, our friends in the venture capital industry remain important partners in our innovation and commercialization efforts, but anyone involved in innovation-based business development knows that shorter term return horizons, higher levels of risk-avoidance, and the need to invest at higher levels to accelerate innovations toward the market have moved most venture capitalists much further downstream than where most univer-

sity deals tend to be. The availability of SBIR and STTR funding to help launch and grow companies, to facilitate important collaborations between such start-ups and universities, and to de-risk such start-up companies in preparation for the downstream venture capital investors is more important than ever in universities' efforts to launch, grow and sustain new ventures to commercialize their research discoveries and to connect their innovation pipeline in ways which help to create wealth and generate new jobs.

Perhaps a brief word about how universities benefit from SBIR and STTR funding would be helpful before proceeding. It is important to note that universities may not apply for SBIR or STTR funding; applicants must be companies. SBIR applicants may partner or subcontract less than one-third of the work to a university or other entity; STTR requires applicant companies to team with a not-for-profit research institution, and partnering and commercialization arrangements must be worked out in advance. Up to 60% of the work can be subcontracted, and the principal investigator can be from the partnering research institution. Under both programs, and especially under STTR, universities are able to participate in a very meaningful and strategic way as the small company develops its research and development strategy for commercializing their technology.

I'd like to provide examples of how SBIR and STTR funding has helped to accelerate amazing growth, opportunity, and potential societal benefit around research developed at U.Va. Adenosine Therapeutics was founded in 1999 based on research emanating from U.Va.'s School of Medicine. The company's development pipeline included promising compounds for treating cancer, diabetes, CNS diseases, arthritis, and COPD. In less than nine years—rocket speed in the drug development world—Adenosine was acquired by a larger, public company, Clinical Data, Inc. The Company maintains a significant presence in Charlottesville even as this growth has occurred. Several of Adenosine's promising compounds are now in various stages of FDA testing and pre-market approval, including a potential best-in-class coronary vasodilator for cardiac stress testing. Adenosine was the recipient of numerous SBIR/STTR awards beginning in 2000 through 2007. We have no doubt that this funding significantly accelerated the development of the technologies, the growth of the company, the value to the company's investors, and the pace of introducing to the market potential life-saving and life-enhancing treatments.

Another example is Directed Vapor Technologies International, Inc. (DVTI). The company was formed in 2000 to capitalize on U.Va. patents associated with the creation of a new coating method, Directed Vapor Deposition (DVD), a novel physical vapor deposition tool for applying coatings to high performance materials (such as turbine engines, batteries, and liquid crystal displays) which allow them to be made faster, cheaper, and with less waste. This new small business operates a 6,000 sq. ft. manufacturing facility in Albemarle County, VA, and maintains its relationship with the University and the region, often hiring interns, recent graduates and alumni. Development of the technologies behind DVTI was supported by grants from the National Science Foundation and the Department of Defense, including numerous SBIR/STTR awards.

For Adenosine, DVTI, and other high growth potential companies we are prepared to launch, support, and nurture, SBIR and STTR funding is extremely important to U.Va.'s efforts to help launch start-up companies. Like many universities across the country, the University of Virginia takes seriously its role in translating research results into products, companies, and jobs. The SBIR and STTR programs are key weapons in our arsenal. And as venture capital moves further down-field, and as companies large and small increasingly look to universities to be their source of innovation, it is more important than ever that we continue to have access to tools like SBIR and STTR funding. The President referred to the innovation imperative as our Sputnik moment; the Congress and our governors are focusing more and more on innovation-based economic development and job creation; and universities like U.Va. are ready to answer the call. But, we need help to bridge the valley of death, and SBIR and STTR funding has been and remains a critical resource for us.

A second question you asked me to address focuses on my views of the current percentage of funding allocated to the SBIR and STTR programs; and whether venture-capital backed small companies should be eligible to participate in the programs. At the University of Virginia, we strongly support funding for the current SBIR and STTR programs. That being said, we also believe there is no compelling justification or need for increasing the percentage set aside amounts. A close review of success rates within the Phase 1 SBIR and STTR grants will reveal that the funding success rates for these grants is equal to, and in many cases—such as with NIH funding—higher than the success rates for other equally important grants for basic research. Any increase in the current SBIR and STTR set-aside would come

at the expense of other peer-reviewed basic and applied research—the seed corn for the innovation pipeline.

We are particularly concerned about shifting funding away from basic research and into the SBIR and STTR programs at a time when we are likely to see flat, if not declining funding for basic scientific research programs as the Congress looks to address the growing budget deficit. While basic research is an essential piece of the innovation process, the long-term horizon of most scientific research performed at universities is viewed by industry as too risky for significant private sector investment. This is why the continued federal support for basic scientific research is vital. As the Congressional Joint Economic Committee has stated, "Despite its value to society as a whole, basic research is underfunded by private firms precisely because it is performed with no specific commercial applications in mind."

We also support the eligibility of companies backed with significant venture capital investments to apply for funding under the SBIR and STTR programs. Companies which have secured substantial venture backing, by definition, will have undergone significant due diligence evaluation by investors and could be assumed to be on a more certain path to success. In today's financial climate, sharing risk and leveraging investments are a market reality for even the most promising start-up companies. Depriving promising companies an opportunity to compete for sources of co-investment or de-risking capital seems contrary to common sense and public policy, and we recommend removing any restrictions on the ability of such companies to apply. Further, companies which traditionally have the need for much greater amounts of funding—such as biopharmaceutical companies—are particularly disadvantaged if there is a disconnect between SBIR/STTR-backed companies and venture capital backed companies.

In fact, a publication by BIO, the Biotechnology Industry Association, states that almost 33% of companies that brought biotherapies to market between 1982 and 2005 had SBIR funding. In this era of intense focus on innovation-based economic development, it would be wise to remove or revise this restriction so that more fast-growth, job-creating companies can benefit from SBIR and STTR funding.

The final question I was asked to address concerns what recommendation I would make to improve the SBIR and STTR programs. We note that the Association of American Universities (AAU), which represents 61 leading U.S. research universities including U.Va., along with other organizations, has recommended more rigorous evaluations of the SBIR and STTR programs. We support this recommendation and therefore support the recommendation made by the National Research Council to increase the amount of the current set aside percentage by .03 to .05 percent of total program funding, with the increase to be directed for program assessment and management. This could be a critical component in continuing to improve and to fine tune the program for future growth and impact given the renewed emphasis on innovation and economic development in the national discussion.

Maximum per award funding amounts allowed under SBIR/STTR Phase I and Phase II awards should be increased as well to reflect renewed importance on this initiative, as well as to reflect the effects of inflation over the years. Phase I awards should be at least $150,000, and Phase II should be $1 million. We also would recommend incorporating sufficient flexibility in determining the precise award amounts so that SBIR/STTR program officers would have the freedom to increase each award up to 20% of the published cap when exceptional circumstances and high impact opportunity are deemed to be represented in a particular funding award.

Restrictions related to conflict of interest should be examined and, where feasible, flexibility should be added that make it easier for researchers with disclosed and manageable conflict of interest to participate in SBIR/STTR-backed start-up companies. Consistent with efforts to encourage, recognize and reward faculty interest in research commercialization, onerous conflict of interest policies which discourage faculty from working with industry or developing innovative technologies should be examined. U.Va. and other universities have policies which focus on identifying and avoiding completely unacceptable and unmanageable conflicts, but which allow other conflicts to exist under appropriate management and monitoring committees and related mechanisms, especially where the potential benefit to society or to the institution from the proposed activity is deemed to be significant and consistent with other institutional priorities. Many institutions have in fact published policies and manuals for managing conflict of interest in the application and performance of SBIR and STTR projects; federal agencies administering SBIR and STTR initiatives should identify, incorporate and disseminate what they consider to be best practices in managing conflicts of interest in SBIR/STTR-based projects.

Finally, we would encourage that additional flexibility be built into the SBIR and STTR programs. In particular, I would like to recommend that the STTR program

be modified in a way that would enable agencies to use a certain proportion of these funds to directly support additional proof-of-concept work at universities. Specifically, we would encourage the Committee to consider allowing agencies to use a portion of STTR funds to support new demonstration projects that would support proof-of-concept grants to universities and their faculty members. Europe has recently launched just such a program, and I think it is important that we here in the U.S. also find a way to fill this existing funding gap in the innovation pipeline relating to a lack of proof-of-concept funds. Using a proportion of the STTR set aside as the mechanism by which to address this matter seems totally appropriate, especially if there were a decision made to increase the percentage STTR set aside.

It is important to note that the flexibility we are seeking is aimed mainly at allowing agencies such as the NIH and NSF to devote a proportion of their STTR funds for even earlier stage proof-of-concept research or prototype development research, the type of research that is best conducted in the settings where discoveries and innovations perceived to have commercial application are first developed, as opposed to later stage product development or for more applied pre-commercial research. Such funding should be allocated only after rigorous evaluation by carefully assembled panels of local experts in translational and proof-of-concept research—this is key to scaling success to the national level. Among the criteria for awards under this initiative should be the demonstrated willingness and capability of a university in engaging project management boards comprised of industry, start-up, venture capital, technical, financial, and business/market experts. Additionally, successful applicants for this funding should be required to prove their willingness and agility in managing translational projects stressing market-relevant milestones, in conducting rigorous oversight and management of such projects, and in their willingness to withdraw funding from projects failing to reach essential milestones so that funding can be re-allocated to projects with more potential. U.Va. is one university which has recently demonstrated tremendous success and impact in undertaking such proof-of-concept research, with audited results indicating tremendous success in return on investment of such funds.

We attribute U.Va.'s success in proof-of-concept research to the now nationally well-known Coulter process, involving a very diverse review board, in-person final review sessions, milestone-driven projects, quarterly reporting that is simple yet effective in re-directing projects, the "will to kill" projects or re-direct funds if insurmountable obstacles occur, and excellent networking to the venture capital and private sector. The Coulter program projects have generated a 5–1 overall return on investment (ROI) in new follow-on funding, and 42–1 ROI for the top ten percent of portfolio projects. The key differentiators of this process as we employ it at U.Va. versus most prior proof-of-concept funding mechanisms is the in person diligence on the involved people and ideas, dedicated project manager, the diverse composition of the board, the urgency of quarterly reviews and re-direction of projects, and will to re-direct funds as results emerge.

In closing, I would like to make a brief point about the patent reform legislation recently passed by the Senate (S. 23) and currently under consideration in the House. While not directly related to SBIR and STTR funding, patent reform is also critically important to universities seeking to translate their inventions into new products, new businesses, and new jobs. We strongly support the recently passed S. 23, but we are concerned about two provisions of the draft bill under consideration by the House Judiciary Committee: (1) greatly expanded prior user rights and (2) a lowered threshold for the initiation of inter partes review. Just as we believe that the SBIR and STTR programs are essential programs for helping universities facilitate the launch and growth of small companies, we also strongly believe that a predictable patent system which minimizes uncertainty for companies and investors is critical. The expanded prior user rights in the proposed House legislation would disadvantage universities, even with its university carve-out, and would create unpredictable, uneven, and anti-innovation impacts. As just one example—university researchers often publish their research results before filing for patents. While the grace period in S. 23 and prior House patent reform bills would protect inventors from others patenting their inventions, expanded prior user rights would have the opposite effect—i.e., competitors might be incentivized to perfect a competing trade secret product that would then be immune from infringement of the eventual valid university patent. We therefore respectfully urge this Subcommittee to work with the House Judiciary Committee on this currently pending patent reform legislation—and especially on the prior user rights provision it contains—as a way of continuing to improve federal policy promoting the successful launch and growth of innovation-based start-up companies.

I would like to thank the Subcommittee, and especially the Chair and the Ranking Member, for your support of the SBIR and STTR programs in these tough budg-

etary times. While we understand that funding is greatly constrained, I hope that you agree that innovation and commercialization serve the public good while promoting the creation of new products, new companies, and new jobs. SBIR and STTR funding have proven to be tremendously effective in fueling these activities, and we at the University of Virginia, and throughout the university community, are highly indebted for your continued support of these programs.

Thank you again for the invitation to testify.

Chairman QUAYLE. Thank you, Mr. Crowell.

The chair now recognizes Mr. Doug Limbaugh, CEO of Kutta Technologies, for 5 minutes.

STATEMENT OF MR. DOUG LIMBAUGH, CHIEF EXECUTIVE OFFICER, KUTTA TECHNOLOGIES

Mr. LIMBAUGH. Thank you, Chairman Quayle, Ranking—Congressman Wu, and all other committee members for having me here to testify in regards to the SBIR reauthorization. I am the CEO and co-owner of Kutta Technologies. We have been in business since 2001. My business partner and I, Matthew Savoca, started in a 10 by 10 corner of my house back in 2001. We rapidly grew to about 12 employees, so imagine 12 employees in your house. Imagine customers calling and wanting to come to town and visit you at the same time that didn't know you were that small, and imagine your parents deciding they wanted to pay you a visit also.

We turned that into a positive with my mom cooking food for everybody and talking to them and telling them—and your parents like to brag about you, telling them all about me and some stories that I didn't want them to hear.

But I digress, but I want to get back on track, because we have been in business—we didn't start doing SBIRs until 2003. Since then we have won 13 phase one grants, 11 phase two grants, for a total of $8.5 million in funding.

Additionally, we have received over—just about $20 million in DOD sales and commercialization. That will also continue to—that number will continue to grow as some of our products become inserted into DOD program records in the future.

One also thing that I want to emphasize, we employ over 24 engineers and scientists within our company. Not a big number but all those engineers and scientists when you look at the average wage is over $100,000 a year. We provide full healthcare benefits, 401K, and profit sharing, and we never have a shortage of people knocking on our doors wanting to come to work for our small business because we do such cool things. And that is as a result of our SBIR-based technology.

Also, we achieved one of our strategic goals this year of winning a Tibbetts Award for excellence in the SBIR Program. That gave me an opportunity to talk to a lot of other small businesses in the community and also will be part of my recommendations to the panel what I learned from those meetings and also from firsthand experience.

I also just want to talk briefly about some of the game-changing technologies that we have created at Kutta. Mainly we have invented a new, revolutionary new way to control UAVs, and our technology will be inserted into a DOD program of record at the end of this year or the beginning of next year, and it will totally

change the way the Army and the Armed Forces use UAVs on the battlefield. It will revolutionize it, it will also provide better, more accurate, and timely information to soldiers on the battlefield and also reduce, we believe, a number of deaths and wounded in action due to improvised explosive devices.

We also as Chairman Quayle expressed in his opening testimony, we also have invented a revolutionary new way for coalmining communications. After the Sago incident happened in 2006, the MSHA, Mine Safety Health Administration, did a demonstration and looked at ten different technologies. By far we had the best technology that was created out of a $70,000 phase one grant.

At that time they didn't realize the communications that we could provide in the mining industry were even possible. Now today we are getting over 6 miles of non-line-of-sight communication in a coalmine with our technologies. It is being sold to the biggest U.S. coal companies here in the United States, and we are exporting that to India, China, and around the world.

My main recommendations for the SBIR panel are obviously shortening the time to award. Everybody has that. Everybody suffers from the fact that it takes so long to get notified and then also get the contract for the phase one. I would say that it is more important to shorten the time of award for a phase two because you already have the work, and sometimes just waiting a long time to get that phase two award can be very detrimental to a small business just starting out that doesn't have cash flow, doesn't have the expertise or the assets in order to acquire short-term loans or lines of credit from the business.

Other main recommendation is within the DOD a more-centralized contracting process. There is a lot of folks in the DOD and the contracting departments that don't understand SBIRs, see them as a tax on their organization, and would just like to get rid of them altogether.

The other big thing that I want to emphasize before my time is up is be very careful about allowing venture capitalism, and this may be where I differ from other panel members. I think that venture capitalism could also be very detrimental to the small business and intent of the SBIR Program as it started in the sense that what would—the way I look at it and the way many of my colleagues in the business look at it, especially within the DOD, is, what would prevent a large prime contractor from setting up a VC shell company and basically gobbling up all the SBIRs, just loading them up and then transition to the technology?

I also think that you will end up spending more money, the DOD especially will end up spending more money on technology created out of the SBIR than if it wasn't funded by VCs.

Thank you.

[The prepared statement of Mr. Limbaugh follows:]

PREPARED STATEMENT OF MR. DOUG LIMBAUGH, CHIEF EXECUTIVE OFFICER, KUTTA TECHNOLOGIES, INC.

Thank you for selecting me to provide a written statement on behalf of Kutta Technologies, Inc. regarding the SBIR Program. The following written statement provides a summary of Kutta's history and how the SBIR program significantly changed our small business for the better. The second part of this testimony summarizes how Kutta's SBIR innovations have contributed to the nation, our

warfighters, coal miners, and first responders. The last part of the statement identifies several items in particular that can make a great program even better.

In June of 2001, my business partner Matthew Savoca and I quit our engineering jobs at Honeywell to start Kutta—an aviation engineering consulting business. We both put $5,000 into the company to buy used computers, monitors, printers, chairs, etc., and two very cheap four-legged plastic desks—the kind that barely have enough strength to hold the old desktop monitors of that day. We did not start in the garage. Instead we moved into a small 10 foot by 10 foot bedroom in my house. I did not charge the company rent because we could not afford it. Within a couple of weeks we landed our first consulting job. Things were going well, but we all know what happened on September 11, 2001. Needless to say our nation went through a rough patch and so did the aviation business. Also, outsourcing engineering services overseas by large American companies started to become a fad and slow the rapid growth of our consulting company. As many small entrepreneurs do in the United States every day, we learned from these tough lessons, adapted and overcame adversity. We determined that we needed more diversification in our company. We decided to become a product-based business. We wanted to control our own destiny and we wanted to create innovative technology that would make an impact in America and around the world—we turned to the SBIR program. Since 2001, we grew our two person company to nearly 45 employees. Because of the success we were having in the SBIR program, we decided to sell the consulting business to focus on our SBIR products. Since 2003, Kutta has won 13 Phase I grants and 11 Phase II grants for a total of $8.5M in funding. Additionally, we have received $19.4M in DoD sales and product commercialization of these SBIRs. We currently provide direct employment to 24 engineers and scientists with an average yearly salary in excess of $100K a year, with full health-care benefits, 401(k), and profit sharing. In 2011 we achieved one of our strategic goals of winning a prestigious Small Business Association (SBA) Achievement award, the SBIR Tibbetts Award, for excellence in achieving the mission and goals of the SBIR program.

However, achieving this level of success was not without its challenges. After several unsuccessful attempts at writing a winning SBIR proposal, we became aware of a state program from the Arizona Department of Commerce called the AZ FAST program. The program allowed us to hire a grant writing specialist who helped us write better proposals and win SBIRs. In June of 2003, we won our first SBIR Phase I grant from the U.S. Army. The SBIR started as a Phase I in 2003, subsequently transitioned to Phase II, and is now in Phase III. This one SBIR alone has generated over $4 million dollars in commercial sales and over $8 million in Department of Defense (DoD) sales. It will have even more of an economic impact when it becomes inserted into a DoD Program of Record (POR) in the near future.

Besides the significant economic impact, the technology will revolutionize the way the U.S. Army utilizes unmanned aerial drones. With our new Bi-Directional Remote Viewing Terminal (BDRVT) technology, front-line warfighters will be able to safely take control of an unmanned aerial system (UAS) and task the UAS to survey roads and borders for potential ambushes and Improvised Explosive Devices (IEDs), track enemy combatants while they flee a scene, and provide over watch capabilities to ground troops—all with a few simple inputs on a touchscreen panel. All of this will be demonstrated in the Army's manned unmanned system integration concept (MUSIC) demonstration in September of this year. It is not hard to envision this simple and easy-to-use device being used not only by our nation, but also by allied nations and along our borders—another commercialization avenue that we are exploring.

This technology would not have become a reality if the U.S. Army's Aviation Applied Technology (AATD) did not have the vision for the product. With a Phase I and Phase II SBIR from AATD, we worked diligently to shape the vision and build a prototype to show that it was possible. It then took the Program Management Unmanned Aerial Systems (PM UAS) division of the Army to recognize the innovation and provide the funding to insert it into the UAS war fighting machines. This SBIR did not fall into the "valley of death" (the struggle to bring a product to market after a SBIR Phase II)—the new, highly-competitive, Commercialization Pilot Program (CPP) prevented that. MILCOM Venture Partners and the PM SBIR office within the DoD provided the bridge funding to move the product from a Phase II prototype into a mainstream product and reduce the risk of further procurement by PM UAS. That is, the CPP provided the infusion of funding to refine the product and reduce the risk for acquisition into the Army's supply chain. This was a winning program for everyone. The Warfighter receives a new innovation, the taxpayers save money by selecting Kutta instead of a large prime contractor, Kutta employs engineers, and our employees thrive on creating the innovation—not to mention the fact that it allows the Army to break the stove-piped and proprietary nature of many military

systems. This is a success that we share with our nation, the taxpayers, and our Army sponsors; for without them we would not be here today.

Furthermore, our enemy's tactics and creativity are unencumbered by the fair and formal procurement found in America, and our enemy's tactics can be very disruptive. Our enemies are becoming more adept at utilizing commercial off the shelf (COTS) technologies (e.g. cell phones to explode IEDs) and our defense budgets are shrinking. It is a known fact that small, entrepreneurial companies can innovate much faster than the large business. The DoD budgets may shrink, but our nation will still need ways to quickly adapt to our enemy's ever changing tactics. Therefore, to counter the fast-moving and evolving tactics of our enemies, I believe the DoD needs the SBIR program more than ever to out-innovate our enemies in a cost efficient manner.

I am also compelled to discuss another success story that has even much more far ranging impacts throughout the world than Kutta's UAS controller technology. As many of you may recall on January 2, 2006, an underground coal blast occurred in Sago, West Virginia. After the blast, 13 miners survived for nearly two days. Eventually, all of the miners except one survivor, Randal McCloy, were overcome by poisonous methane gas. The outcome of the MSHA investigation showed that those miners could have survived if they had a two-way communication device and if rescuers had known where the miners were located. The U.S. queried the DoD for technology that could fill this capability gap in the mining industry. To our knowledge, we were the only company in the United States working to solve a similar subterranean communication problem for the Army. We had also just completed a successful SBIR Phase I grant and were patiently waiting to receive our Phase II award—a wait of about 6 months. We were between the Phase I and Phase II contract stages, and we had no funding. However, the Mine Safety Health Administration (MSHA) wanted to conduct an independent survey of underground communication technology. They selected Kutta and nearly 10 other technologies for their evaluation. We were confident that our technology would work, and luckily we had enough of our own funds to refine our Phase I prototype three weeks prior to the scheduled MSHA evaluation. The results of MSHA's independent test showed that our $70,000 SBIR Phase I prototype exceeded everyone's expectations. We demonstrated wireless two-way, non line-of-sight (i.e. around corners), voice communication over two-miles in the underground mine. This was over six times further than any other wireless communication technology tested and the signal could have traveled further. In fact, our production quality radios today can provide wireless, non-line of sight, two-way communication in a mine at over six miles. After these tests, MSHA realized that post-accident communication and tracking was possible. These results prompted a call from the late Congressman George Norwood. Congressman Norwood was acting as the Chairman of the House and Education Labor Committee at the time and was excited about our technology. Subsequently, Congress passed the MINER Act and President Bush signed it into law. The MINER Act appropriated $10 million dollars to the National Institute of Occupational Safety and Health (NIOSH) to foster research into underground mine post-accident technologies (e.g. communications, tracking, rescue chambers, etc.). Kutta worked with NIOSH to receive $2.1 Million in funding to transition the SBIR Phase I prototype into a prototype for coal mines. The Army provided SBIR Phase II Plus funding of $500K for a total of $2.6 Million in funding. Although the NIOSH and Army collaboration was successful, it still only produced a prototype system for the miners. Kutta, using its own funds, spent nearly $2 Million additional dollars to bring the product to market. To this day, we are the only MSHA approved post-accident communication device available to the mining industry. Furthermore, it is the most economical two-way wireless communication device available to the mining industry. We have received orders from the largest underground coal companies in the U.S. and are currently exporting our technology worldwide.

Moreover, last year we discovered that this technology could be used by first responders to solve challenging situations where communications is not available in high-rise buildings and subterranean environments—a large problem experienced by first responders in the 9/11 disaster. We demonstrated wireless interoperable communications to the Fire Department of New York in a subway tunnel and in a high-rise building. FDNY was astonished by the capabilities of the system. However, neither FDNY nor Kutta have enough funds to modify the mining product for the first responders, although we are both trying to find a way. Furthermore, we demonstrated the capability to Border Patrol to communicate within border tunnels and to map the tunnels on the surface. The Border Patrol agents liked the technology, but they too do not have the budget to purchase the system. Lastly, the U.S. Army's 911th Technical Rescue crew received two demonstrations of our technology and they were amazed with its ease of use and its capabilities. They have been working

for nearly six months through their procurement process to purchase two of our systems. I mention these struggles to illustrate how difficult it is to bring a new product to market. Marketing and selling products takes just as much time and money as does building the prototype (Phase II Objective).

I believe it in the best interest of all SBIR-based companies, as well as those in Congress and the President, to review Mr. Glover's report on the SBIR program as recorded in his February 11th testimony. This report not only provides the quantitative justification for the SBIR program, it makes a strong case for increasing the funding for the program. When you listen to the President's State of the Union address about small business innovators, when you look at the state of unemployment in our nation, and you consider the fact that small business in the biggest employer and the largest catalyst for new innovations, the SBIR program is the program that is too valuable to fail. Why wouldn't taxpayers want a Government program that has a positive Return on Investment (ROI) and not a negative?

Obviously the SBIR program, as fathered by Roland Tibbetts, is a resounding success for our country. I firmly believe that without the SBIR program, innovation in this country would be stifled, fewer jobs would be created, and our taxpayers would be paying much more to acquire state-of-the-art military capabilities. However, just as it is good business to continuously improve a product, so to should our government look to improve the SBIR program. The following are specific suggestions for consideration that I offer from first-hand experience within the program.

Recommendation 1: Reduce the time for award notification (win or lose) to less than 60 days for a Phase I and a Phase II SBIR.

Rationale: A company can make better business decisions regarding resource allocation if they know if they won or lost as opposed to waiting for months on end to find out the result. Waiting puts a financial toll on the company and an emotional toll on those employees that put their hearts and souls into writing the proposals. Giving the companies a "yes" or "no" as soon as possible allows them to make more informed decisions sooner rather than later.

Recommendation 2: Allow the Phase I to be recognized as a grant.

Rationale: Allowing the Phase I to be recognized as a grant would simplify contracting and prevent lengthy negotiations regarding IP and Statements of Work. It will reduce the overhead of the contracting agency and speed the flow of money to a small business.

Recommendation 3: Reduce the time for contract negotiation and award to 45 days from receiving award notification of a Phase II.

Rationale: Funding for a small startup company working under an SBIR grant is vital. Small startups have a harder time acquiring a short term line of credit or a loan from a bank. Furthermore, a Phase I grant might be the only source of income to the startup company. If the company has to wait 4 to 6 months to receive funding for the next phase, it could be highly detrimental to them. From a business perspective, time to market can be critical. Allowing the small company to build a prototype and start its marketing efforts earlier could also increase commercialization success.

Recommendation 4: Within the DoD, create a more centralized contracting process that allows funding to be provided to the small companies in a more expedited manner.

Rationale: Although the SBIR program has been around since 1982, the program does not garner much affinity to those in DoD contracting departments. Many times the SBIR program is seen as a tax to them and requires them to administer a contract that they know little about or have had little training on how to handle. Having a centralized contracting team at PM SBIR to administer contracts or provide guidance to contracting officers would streamline the award process.

Recommendation 5: Educate contract representatives and encourage other government organizations to utilize the sole source SBIR Phase III processes to provide contract vehicles for small business.

Rationale: Establishing a contract with an acquisition authority in the DoD is very difficult. Therefore, commercialization with the acquisition arm of the DoD is stifled. This problem is compounded by the fact that the contracting officers in the acquisition offices are not familiar with SBIR contracts since SBIRs are mostly administered by the Research and Development of the DoD. Contract officers in acquisition inherently shy away from SBIRs because of lack of understanding and they sometimes wrongly question that a SBIR Phase III satisfies the Federal Acquisition Regulations (FARs) for competition. That leaves the contracting officers with few options: one, to not acquire the technology; two, to rebid or open the technology for other offers', which cost the government time and money; and three, find an existing contract mechanism to role the technology into. When option number three is invoked, the small business has to typically deal with a large prime contractor. Typically, these prime contractors already have an established relationship with the ac-

quisition authorities and an existing contract vehicle is in place and the technology can be acquired. On the surface that may sound good and in some cases it works out great. However, this places a small company in a very precarious situation. That is, negotiating intellectual property, payable terms, and complex DoD contracts with multi-billion dollar companies with terms that are always more favorable to the large firms than the small one. It also introduces mark ups and overhead which cost the government more money.

Recommendation 6: Consider establishing a competitive SBIR Phase III program for SBIR Phase II winners that focuses on marketing only (not technical development).

Rationale: Most SBIR funding and the newly added Commercialization Pilot Program are still focused on technology enhancements and technology maturation. It would be useful if a competitive SBIR process was started by the Department of Commerce. The program should be open to all SBIR Phase II winners across the SBIR landscape. However, the proposal should be structured more like a sales and marketing proposal for the product—not a technically oriented proposal. Providing funds to market and advertise a SBIR-generated product would increase commercialization.

Recommendation 7: Within the DoD, be very careful in allowing Venture Capital based companies into the system.

Rationale: VC funding for primarily DoD-based SBIR companies would encourage small business to concentrate more on commercial benefits and may not be in direct alignment with DoD goals. Furthermore, large conglomerate VC firms are entrenched with the government and may work the system to have SBIR's written to focus on their company's strength rather than the innovation needed for the warfighter. It also makes it very difficult for small, startup companies to compete with VC-funded companies, and appears to defeat the intent of the SBIR program.

Recommendation 8: Raise the total allocation to SBIR R & D budget

Rationale: The SBIR program creates jobs and does so more efficiently than universities. It also creates new products—products that can be sold nationally and internationally. New products create new jobs across the workforce spectrum (e.g. accounting, shipping, manufacturing, marketing, engineering, travel, etc.). It's a no-brainer. If you want new jobs, the SBIR program will deliver. It always has and it always will because it is aligned with America's core economic principles of fair competition and free markets.

Based on our experience and based on the quantitative statistics related to the SBIR program, the program is a tremendous government success and it returns more tax revenue than is used to fund it. It also creates sustainable, high-paying jobs in critical areas of technology that make America more competitive throughout the world. A reauthorization of the SBIR program is absolutely vital for our nation to remain competitive, to provide jobs for highly-educated engineers and scientists, to invent new technologies rapidly and efficiently, and to reduce our trade deficit. I firmly support the SBIR program for all its benefits. And, if you really want to prime a job creation engine, I implore you to find a way to re-authorize the SBIR and to re-authorize it with additional funding.

Chairman QUAYLE. Thank you, Mr. Limbaugh.

The chair now recognizes our final witness, Ms. McKinney, who is the president and CEO of Galois, Incorporated. I will recognize you for 5 minutes.

STATEMENT OF MS. LAURA MCKINNEY, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GALOIS, INC.

Ms. MCKINNEY. Good afternoon, Chairman Quayle, Ranking Member Wu, and Members of the Committee. It is an honor to appear to you today to testify about the role that the SBIR Program has played in Galois' business and its effectiveness in promoting innovation.

Let me begin by thanking the Members of the Committee for promoting policies that assist the growth and innovative contributions of small businesses in this country. You are to be commended for your support to programs such as SBIR.

My testimony is based solely on what Galois knows directly. Our experiences may be unique or may generalize. We acknowledge the

excellent work of the National Research Council and others who bring a broader viewpoint about what might best apply in the larger context and community.

Galois is a 10-year-old small business located in Portland, Oregon. Our mission is creating trustworthiness in critical systems. We transform computer science research into practice to address urgent problems with safety and security software.

You can think of Galois as a vital part of the supply chain that takes relatively new research technology up the hill through feasibility proof and operational demonstration stages. Galois' roots were in a 1990s Air Force research project undertaken by the Oregon Graduate Institute, a technical research-focused graduate school. This project and the visionary leadership of the Air Force program managers provided a model for many of the elements necessary to achieve technology transition.

However, despite the emphasis on transition, superior technology, and a viable implementation, the results failed to reach deployment and bring operational value. There was one critical link missing that prevented the ultimate deployment of this system; a commercially-motivated entity to bring the mature prototype into use. Despite significant interest and commitment, the effort was simply outside the mission of OGI as an educational research institute. It was a source of significant frustration to many team members that this valuable technology was essentially abandoned.

When an opportunity arose several years later with a similarly-structured research effort with the intelligence community, Dr. John Launchbury, the founder and CEO, used the lessons learned under the project with Galois, and we founded the company based on a mission with technology transition as a focus. The results of that intelligence community project are in operational use today.

Galois' revenues are generated through collaborative research projects, transition support, and licensing of technologies to product companies. Approximately 17 percent of current Galois revenues are from SBIR, making the SBIR Program a modest but highly-leveraged part of our business.

For Oregon with its geographic challenges, the SBIR Program enhances access to U.S. government agencies with operational needs, leading to results and further funding both within and outside of the SBIR Program. The frequent release of new SBIR topics from government agencies enables Galois to survey areas of work that would serve critical emerging needs.

The SBIR Program enables research transition across government agencies. Results generated under the sponsorship of one government agency are applied to problems elsewhere. The SBIR Program encourages quality operational research which is distinct in pace and focus from the kind of research done within labs and at universities.

There is a dynamic ebb and flow of small companies which have to respond rapidly to emerging needs and emerging techniques. To compete a company has to excel on the quality and relevance of its ideas. In areas such as cyber security, Galois brings global research leverage to national problems. Galois has grown transition and commercialization skills through interactions with the Navy TAP,

the National Research Council, and the DHS Commercialization Office.

Galois is recommending the following improvements with the view to making an excellent program stronger. We believe in the current approach to success metrics, particularly that failure is one expected outcome. This makes it possible to try riskier approaches that bring more significant value.

Second, that phase three is measured by a monetary investment which helps ensure that SBIRs overall are yielding value. However, there is an alternative way to bring substantial value to the Nation; through open-source technology as exemplified by goggled android mobile phone platform. Consequently, Galois recommends an augmentation of the phase three success metrics to include evaluation of open source transition.

In addition, Galois endorses and supports increasing the phase one award size in tandem with the economy, providing approaches for accelerating the pace and transition between the phases, increasing support for the technical points of contact, linking programs of record more closely with the SBIR Program, and providing incentives for prime contractors to evaluate and use SBIR-developed technologies.

Galois believes the SBIR Program is successful both for fostering the innovation and jobs engine of small businesses and for nurturing breakthrough technologies to the benefit of the government and wider economy.

Thank you, again, for the opportunity to appear before this committee, and I look forward to answering your questions.

[The prepared statement of Ms. McKinney follows:]

PREPARED STATEMENT OF MS. LAURA MCKINNEY, PRESIDENT AND CEO, GALOIS, INC.

Good afternoon Chairman Quayle, Ranking Member Wu, and Members of the Committee. It is an honor to appear before you today to testify about the role that the Small Business Innovation Research (SBIR) program has played in Galois' business, and its effectiveness in promoting innovation.

My name is Laura McKinney, and I serve as CEO of Galois, Inc., and as a member of Galois' Board of Directors.

Let me begin by thanking the Members of this Committee for your work in promoting policies that assist the growth of small businesses in this country. Small businesses are known to be a significant engine of innovation, and your role in promoting policies that have fostered innovation and created jobs in the U.S. is to be commended. The SBIR program is one such example.

For this testimony, the subcommittee requested the following information:

1) Description of Galois' awards and experience with the SBIR program.

2) Discussion of how Galois' SBIR-funded work has impacted our community and/or the nation.

3) Recommendations for improvements to the program.

We have addressed all three of the questions in the following testimony. I am able to speak from the perspective of Galois' specific experiences with the SBIR and STTR programs. It is my desire to share our story with as much depth and fidelity as possible, recognizing that it will naturally have its parochial limits. When we give recommendations, we do so based solely on what we know directly, and in recognition that our experiences may either be unique or may generalize. We acknowledge the excellent work of the National Research Council and others who bring a broader viewpoint to sort out what might best apply in the larger context and community.

Overview

Galois is a 10-year-old small business located in Portland, Oregon. Galois' mission is creating trustworthiness in critical systems. Our approach is to transform computer science research into practice to address urgent problems with safety and se-

curity software. Think of Galois as a vital part of the supply chain that takes relatively new research technology up the hill through feasibility proof and operational demonstration stages.

Galois employs over 30 people, most as employees and some under contract. We are a mix of researchers with world-recognized expertise paired with highly-skilled engineers whose practical experience converts research ideas into viable implementations. Among the 24 permanent technical staff, almost 60% hold a Ph.D., another 25% hold an MS, and five are former university professors. All are specialists in computer science, with emphasis on formal methods and high assurance techniques in software. Galois draws its expertise from a global community, with degrees represented from many first rank U.S. universities as well as overseas schools such as Oxford, Cambridge, and UNSW in Sydney.

The primary problem domains we address include those motivated by needs in cybersecurity, such as high assurance architectures, cross-domain information exchange, cryptography, and secure embedded devices. Galois' customers include the intelligence community, Navy, NASA, Army, Air Force, DARPA, DOE, Raytheon, and General Dynamics, plus other companies in the industrial and commercial sectors. Some of Galois' partnerships and relationships include Rogue River Research (Ashland Oregon), Portland State University, Oregon State University, defense contractors such as DRS, commercial entities in the cybersecurity domain such as OK Labs, and small businesses such as Dornerworks.

Galois' revenues are generated through collaborative research projects, transition support, and licensing of technologies to product companies. Approximately 17% of current Galois revenues are through SBIR Phase-I and Phase-II contracts and grants, making the SBIR program a modest but highly leveraged part of our business.

In particular, the SBIR program is a critical enabler that allows Galois to bring maturing research results developed under long-term initiatives to bear on immediate needs. We combine emerging software techniques and tools with inventions to meet specific operational requirements. Often we partner with both academia and solution providers to make this possible. Thus a primary contribution for Galois is magnifying the investment in research results funded under one government agency to a broader government and commercial community.

The technology transition gap between universities and industry

Galois, Inc., had its roots in an Air Force research project undertaken in the 90s by the Oregon Graduate Institute. This project, and the visionary leadership of the Air Force management in guiding its progress, provided a model for many of the elements necessary to achieve technology transition. However, despite all the emphasis on transition, superior technology, and a viable implementation, the results failed to reach deployment and bring operational value. Ultimately Galois was founded in response to the technology transition lessons learned under this effort.

This background is worth examining in some detail, as it demonstrates the critical role that companies like Galois can play, as they inhabit the R&D space between Universities and large industrial and commercial concerns.

As background, the Oregon Graduate Institute was a research-focused, graduate school that flourished due to the excellence of the researchers and their ability to provide compelling research results. The Oregon Legislature chartered OGI in 1963 to provide graduate-level training and expertise to the state's rapidly expanding high-tech industry. *"During the 1990s the school awarded over one thousand graduate degrees, offered hundreds of continuing education seminars and workshops, and secured more than $100 million in largely federally-funded research. In 2001, OGI merged with Oregon Health Sciences University."* (Quoted from the OGI web site).

One of the projects in the 90s was a multi-year, multi-million dollar grant to improve the production and reliability of message passing systems within the U.S. Air Force. The Air Force sponsors were committed to seeing that the research resulted in tangible and direct benefits. To enable the academic group to better meet the expectations of an operationally-focused customer, they assigned an advisor in addition to the program management oversight.

The project ultimately delivered a mature prototype message-passing system. In a controlled software engineering experiment against an existing operational solution, the system was proven to significantly improve both the productivity of the engineers that code the messages and reduce the number of errors encountered. Potential value to the Air Force included increased capability to produce new message formats, with lower failures, in response to changing mission needs.

The researchers and the Air Force advisor worked together to add rigorous project management, to complement researchers with highly-skilled engineers, to educate the team about the Air Force mission and current solutions, and to structure the

project with a tangible demonstration of value as its goal. This research community learned new approaches in terms of scope, rigor and perspective.

However, there was one critical link that was missing that prevented the ultimate deployment of this system, and that was a commercially-motivated entity to take this mature prototype and bring it into use. Despite significant interest and commitment to do so, the effort was simply outside of the mission of OGI as an educational research institute. It was a source of significant frustration to many team members that this valuable technology was essentially abandoned.

Galois' inception

In 1999, Dr. John Launchbury, an OGI professor, was approached by a research group within the intelligence community to address a critical problem in the specification of cryptographic algorithms. Some of the elements of this work drew on the research results from the prior Air Force project and elsewhere.

Significantly, both the OGI professor and the government realized that in order for this initiative to be successful, the research and development needed to be done within an entity that could nurture the system through to actual use. John Launchbury took the lessons learned from OGI and founded Galois, which has since grown steadily and strongly, winning multiple Oregon business awards and honors, including John Launchbury's selection as finalist for Entrepreneur of the Year in 2002 by the Portland Business Journal.

Cryptographic specification became the first project for Galois as well the inspiration for Galois' name, which is in honor of Evariste Galois, a 17th century French mathematician who invented the theory underlying cryptography before dying in a politically-motivated duel at the age of 21. The result of the ensuing ten-year Galois partnership with the intelligence community is the Cryptol language and tools, which are in operational and commercial use today.

For Cryptol, Galois was able to complete the transition by itself from research through to operational deployment and support because its target user group was small and sophisticated. However, Galois leadership understood early on that larger operational deployments of emerging technology would need to be done by partners who had both the operational expertise, scope of capability and mission knowledge to make it happen. Galois believes that its mission imperative, unlike academia, is to locate, assess and work with such partners until the technology has been fully transitioned.

In the early to mid 2000s, building on its base of technical skills, Galois grew by extending its research initiatives to problem areas outside of cryptography. Galois was leveraging the excellence of its researchers and its independence from the academic mission to bring a new technology transition offering to research agencies in the government.

Galois participated in a research project under the Navy PMW 160 office to improve cross-domain information exchange. This project produced specific technologies that could be used in a significant number of different devices in both safety and security domains. However, challenges exist to deployment within these areas, chief of which is the amount of up-front investment required to bring a solution into use. Deployment of such devices is gated by various government certification processes such as TSABI and SABI, which can take from 12–24 months to complete. As a consequence, the existing solutions are aging and require substantial government investment to remain viable, even as they fall behind in meeting mission need.

Galois recognized that any deployment partner would need to see a large market potential prior to engaging in such an effort. As a result, Galois started nurturing partnerships in earnest at this point, readying the field for deployment opportunities.

Galois' history with SBIR

While working with the Navy, Galois became aware of the SBIR program, and had submitted and won an early Phase-I grant with the Air Force. During the period between the win and receiving the contract, the technical point of contact changed. Galois was naive about the structure of the SBIR program, and failed to respond to this shift in technical leadership with a change in the research initiative. As a consequence, we were not responsive to the new needs of the program office and were not awarded the Phase-II. This was an education to Galois about the differences between interacting with research agencies on long-term contracts and the pace and intent of the SBIR program.

However, Galois saw the potential for the SBIR program to motivate the investment necessary to bring capabilities to market by linking the technology to specific operational needs. Galois had also written several SBIR Phase-I proposals that aug-

mented the Trusted Services Engine (TSE), a cross-domain information sharing device, which had been previously developed with Navy funding. One of these, *Cross-Domain Document-Based Collaboration in a Multi-Level Secure Environment*, resulted in Phase-II funding through the Navy, Phase-III funding through the intelligence community, transition of technology to a venture-backed startup and multiple operational deployment opportunities that are still in motion.

Because Galois is so aligned with the structure and intent of the SBIR program, we have increased our participation and written and won an increasing number of Phase-I grants and contracts, and have been moving some of those into Phase-II efforts. All of these involve taking research results from our longer-term initiatives, combining them with specific innovations that are responsive to operational needs, and producing new capabilities that are mature enough to see deployment in the short term.

Galois perspective on technology transition

Galois defines successful technology transition as the realization of significant new capability within existing problem domains through the application of revolutionary techniques that change the state of the practice. Technology transition is hard. It can take many, many years for a revolutionary technology to move from research into successful deployment. Based on our experience, Galois believes the following:

Expect the unexpected in technology transition. It is extremely difficult to predict when and where the ultimate value of technology invention will be realized. Technologies may require long-term nurturing until the conditions are ripe.

Relevance and value comes from being strongly connected with the mission and needs of operational entities. Innovation happens where technology evolution meets operational challenge.

Technology transition comes incrementally, and is built through a series of contributions by an entire eco-system of collaborators. It is exactly the breadth and diversity of the customers and the funding mechanisms that enable a healthy system. The missions of academia, technology transition agents such as Galois, and operational solution providers are different, complementary and essential to ultimate success. The variety of government funding approaches are also essential and valuable: funding from fundamental research through university grants, through bespoke applied research including SBIR initiatives, together with maturation and readiness investment, all contribute to eventual success.

Impact of the SBIR Program

The SBIR program has had a significant impact on many dimensions of Galois' business. The following describes these, with evidence drawn from some of our SBIR contracts. We also draw general lessons from other relevant engagements that we are not at liberty to discuss in this forum.

Impact: SBIRs at Galois have enabled Oregon access to broader U.S. government business

One major benefit of the SBIR program to Portland and to Oregon is the enhanced access to relationships with U.S. government agencies, particularly those with operational needs. These relationships lead both to valuable results and further funding opportunities within and outside of the SBIR program.

It has been our experience that building a good government-focused research program requires ready access to people within relevant agencies. These relationships provide deep insights into the emerging problems as well as experience about how to navigate the government bid and procurement process. Despite valuable potential, without these government relationships, businesses will stumble by failing to be truly responsive to needs or by missteps in bids and procurement. Most often, they are just 'late to the table' and miss opportunities.

Oregon is challenged geographically, both in distance and time zone, in identifying and cultivating close connections with agencies. Oregon does not have a rich community of former government workers from which to draw knowledge and experience.

The Congressional Record of the Senate, vol. 148, no. 120, from Sept 20, 2002, records Senator Wyden as alluding to the same challenge:

"Technology workers and managers from my home State of Oregon have inspired me with their technical skills and their passion to put their talents to work serving America. The Portland area is home to one of the Nation's largest concentration of

cybersecurity vendors in the country. Portland now boasts a remarkable cluster of small and large companies actively working to make America's portion of cyberspace a safer place."

He then went on to mention Galois (called Galois Connections in 2002) directly:

"Galois Connections designs and develops high confidence software for critical and demanding applications. Its clientele includes the National Security Agency."

And then indirectly:

"It is essential to eliminate the road-blocks American innovators face. A 20-person company in Beaverton, OR shouldn't have to devote precious resources to hiring lobbyists, making multiple trips to see different people in different agencies, and pursuing expensive and, frankly, frequently obsolete certifications."

The SBIR program is very helpful in this regard. It offers a level playing field. Successful Phase-I work can be the springboard for relationships that lead to future work outside of the SBIR umbrella. Further, the contracting process is straightforward and cognizant of the limitations of small business. Galois has been able to increase its breadth and diversity through SBIR participation.

For example, in November of 2009 Galois was awarded a Phase-I SBIR to provide *Active Defense against Code Injection Attacks* by Air Force Research Laboratory (AFRL), as part of their Software Protection Initiative (SPI). That single Phase-I award gave us the opportunity to build relationships with the broader cyber defense community, and a better understanding of the pressing problems they face in trying to secure cyberspace. This exposure has been instrumental in our success in building solutions that speak to the needs of both government and private industry. As a result, our initial Phase-I engagement has turned into multiple opportunities to develop, and eventually field, critical national security capabilities, such as run≥time monitoring solutions that make UAVs more reliable and robust against software-based attacks. And we are particularly excited about the fact that these opportunities have a strong commercial component to them; we're actively involved with adoption partners to make the technology transition for these solutions a success, with benefits to both government agencies and private firms.

Impact: Galois SBIRs have provided technology and market opportunities for new ventures

In 2005, Galois won the aforementioned SBIR Phase-I award, *Cross-Domain Document-Based Collaboration in a Multi-Level Secure Environment*. The Navy had recognized the need for online collaboration, including with the multiplicity of coalition partners, and called for research on the topic. Inspired by the success of Wikipedia (which was only a few years old at the time), Galois saw the potential for wiki technology to act as a vehicle for collaborative data sharing. The insight was notable. Fully a year later, in April 2006, the Office of the Director of National Intelligence (ODNI) Intelligence Community Enterprise Services (ICES) announced Intellipedia, which is an online system for collaborative data sharing within the intelligence community (IC). Intellipedia consists of three wikis running on JWICS, SIPRNet, and Intelink-U, containing data at classification levels from Top Secret (TS) to Sensitive But Unclassified (SBU).

Galois' approach was to layer wiki technology on top of the Trusted Services Engine (TSE). Through successful Phase-I and Phase-II efforts, the cross-domain wiki technology was developed and demonstrated to multiple audiences within the DoD and IC, receiving Phase-III development funding from sources outside the SBIR program. Additionally, multiple conversations took place between Galois and Intellipedia staff, where each side shared ideas and insights.

In 2007, Galois connected with a Boston startup, KnowledgeBanking Systems (KSys). KSys were developing an enterprise information solution based on shared wikis, and were challenged by how to control when and when not to allow information to be shared. In a supply chain, companies need to have access to information about where their products or components will be used, and also need information from their suppliers, but they should not have access to information from their competing companies, not even to know who they are. KSys licensed the wiki technology from Galois, and worked with both government and industry to ensure that the solution they were building would be appropriate for their needs. KSys was about to close a major round of funding when the capital markets closed down with the banking crisis of 2008.

Impact: SBIR projects expose companies like Galois to real and current needs

One benefit of the frequent release of new SBIR topics from government agencies is that we as a private corporation are able to see what areas of work would serve critical, timely needs. The constant input that we receive through the SBIR program allows us to guide our research direction in order to not only answer the needs that we hear via SBIR solicitations in the present, but anticipate the needs that will arise in the near future.

Our current set of SBIR projects reflects this. For example, recent trends in mobile phone technology have pushed commercial products such as Android-based phones into security-critical environments. One of our DARPA-funded SBIR Phase-I projects (*FUSE: Inter-Application Security for Android*) leverages our existing research capabilities in program security analysis, and targets it specifically towards the Android mobile platform. Another example is the rise of scientific collaboration over large distances that heavily utilize Internet-based tools to share data and computing resources. We have successfully executed a Phase-I project and started a Phase-II project with the Department of Energy (*Grid 2.0: Collaboration and Sharing on the Grid*) to apply our expertise in building high assurance authentication and identity management software to this specific problem in computational science.

In both cases, the SBIR program has allowed us to take our broad research capabilities and apply them to specific application areas that answer timely, critical national needs.

Impact: SBIR support programs have built Galois commercialization capability

Galois has benefited from participation in several SBIR support resources, and especially from those that focus on transition and commercialization.

Prime among these is the Navy's Transition Assistance Program, or TAP, which gave Galois substantial new and useful understanding and capability in commercialization. The program is voluntary for Navy Phase-II winners, and requires a commitment in time and money from the company to participate. Over a year's time and under advisor guidance, Galois learned or improved capabilities in how to evaluate a particular market, assess a venture partner, write a business plan, produce marketing collateral that is informative to defense industry primes, and present at an industry-focused conference. Each of these skills has been reused and deepened since that experience. Of particular note, the Dawnbreaker advisor provided baseline criteria for examining venture opportunities, which Galois applied immediately to the KSys opportunity. This information facilitated the development of that commercialization effort.

Beyond the Navy TAP, there are several other national SBIR conferences held annually. These provide coaching on proposal writing, on the SBIR process itself, on building a good commercialization plan, among other things. These conferences also provide the opportunity to meet with prime contractors, and learn from fellow SBIR entrepreneurs.

Galois discovered a couple years ago, during web trawling, the excellent National Research Council in-depth studies of the SBIR program. The NRC findings and recommendations have transformed our understanding of the SBIR program, how the various agencies differ in their approaches to it, how to improve our chances of success of winning Phase-Is and IIs (particularly with regards to commercialization).

Another great example is the DHS' Commercialization Office, led by the nation's first Chief Commercialization Officer, Thomas Celluci. That office augments DHS' SBIR program by helping DHS SBIR TPOCs provide detailed operational requirements and a conservative market potential (across all DHS procurement), supporting the commercialization process, actively courting the private sector, and establishing public-private partnerships. Small businesses gain insights into how commercialization plans are assessed, which milestones and metrics will apply during execution, and into the needs of large government programs e.g., through CONOPS (Concept of Operations).

We have found, time and again, however, that there is no substitute for an engaged TPOC who is able to help the small business navigate the challenges of the SBIR program itself, and of the potential for application within the government.

Impact: SBIRs have enabled research developed for one agency to spread in impact to other agencies

One of the primary benefits of the SBIR program is its unique ability to promote research transition across government agencies. Through participants such as Galois, emerging research results generated under the sponsorship of one government agency have the potential to have immediate application across the government.

For example, the *Cross-Domain RSS Processor and Router* SBIR Phase-I from the Navy led to technology discussions and demonstrations with the intelligence community. Furthermore, the key ideas developed in the project became the core of the SBIR Phase-I*Grid 2.0: Collaboration and Sharing on the Grid* project with the Department of Energy and the Open Science Grid. Grid 2.0, now in Phase-II, is an effort to increase secure collaboration capabilities for scientists who require a lot of computational and storage resources. Its goal is to remove technical barriers to secure collaboration, including developing means of trusting digital identities among a global set of scientists from different institutions.

Impact: Galois SBIR work has brought global cybersecurity research capabilities to bear on national needs

The SBIR program fosters a dynamic ebb and flow of small companies, which have to respond rapidly to emerging needs, and even more, to emerging techniques. Phase-I SBIR proposals often have 30–50 competitors.

To compete, a company like Galois has to excel on the quality and relevance of its ideas. Unsurprisingly, therefore, within its technical domain, Galois has been motivated to draw together researchers with an international reputation.

The Association for Computing Machinery, the world's largest educational and scientific computing society, confers the designation "ACM Fellow" to a select number of ACM members whose accomplishments have distinguished themselves by outstanding technical and professional achievements in information technology. This year, Dr. John Launchbury, the founder and chief scientist of Galois, received this very high technical honor.

Beyond Dr. Launchbury, we have internationally recognized leaders in the fields of formal methods and their application to security issues (Dr. John Matthews, Dr. Joe Hurd, Dr. Joe Hendrix, Dr. Levent Erk"), in safety critical embedded systems (Dr. Lee Pike), in scientific computing and high performance computing (Dr. Matthew Sottile), and in all aspects of functional programming language design and implementation (Dr. Don Stewart, Isaac Potoczny-Jones, Dr. Iavor Diatchki, Dr. Andy Adams-Moran). Our researchers serve on editorial boards, program committees, academic steering committees, and give several invited talks per year.

This is just a small selection of the Galois researchers. The quality and international reputation of the staff make it possible for Galois researchers to bring the world's expertise to bear on research problems that influence SBIR work directly benefiting the U.S. government and, more broadly, other entities within the U.S. economy.

Additionally, the strength of our reputation within our technical domain allows us to attract notable speakers to our weekly public seminar series. These seminars draw participants from the many other companies in the Portland software community, as well as having a strong online following.

Recommendations

Galois has benefited substantially from its participation in the SBIR program, which we believe is valuable, structurally sound and strong. That said, we do have some thoughts about possible adjustments to meet emerging challenges. Most of these recommendations are targeted at incremental changes that we believe are in response to changing external conditions.

Recommendation: Augment success metrics for Phase-III to include open source

Galois recommends that Phase-III success metrics should be augmented to include evaluation for open source release of capabilities.

Galois strongly believes in the current SBIR approach to success metrics. We deeply appreciate that the SBIR success metrics are applied with failure as one expected outcome. This makes it possible for Galois and others to try riskier approaches that may bring more significant value, rather than focusing on "sure bets." Galois also strongly endorses the Phase-III monetary metric as critical and sound for ensuring that SBIR investments overall are yielding value.

However, since the advent of the SBIR program in the 80s, there has been a new vector introduced that brings substantial value to the nation: open source software.

Open source software has made tangible changes in the way computer vendors do business over the last decade. In previous decades, major computer vendors commonly used proprietary system software on their products. While many of these proprietary systems still exist, many vendors have moved to offering open source, Linux-based solutions as either the preferred option or as an officially supported one. This is true of high performance computing platforms, for example, which are in use in many areas of the government for scientific and defense applications.

The move to open source is driven by the economic benefits that vendors gain from open platforms: contributions by the community at large can have tangible impacts on their specific products and user community with minimal investment as a consumer of these technologies. Open source has also had a strong impact on the security of software systems for users everywhere. The open source Firefox web browser is a clear example of this, where the transparency, open design, and rapid response to security flaws has made it a strong alternative to proprietary web browsers that have historically been less secure or less transparent about the quality of their security. Similarly, the Android mobile platform is a very visible example of an open source technology changing the business world. The smart phone market has been revolutionized by the presence of an open platform upon which vendors can build products that integrate with a broad third-party application developer community.

Open source challenges traditional paths towards commercialization of software, but the trends as accepted by both consumers and large computing businesses are clearly turned in a direction that favors open source development. For some of our SBIR customers, the most cost-effective and sensible method for providing a capability is not through transition to a commercial venture, but rather through an open source release that then indirectly enables business growth in providing additional functionality. This is particularly true of infrastructure improvements, that are best leveraged when widely available.

While Galois has been writing commercialization cases for Phase-I and Phase-II SBIRs that outline this strategy, we do so at odds with the SBIR metrics. This puts both our customers and ourselves at some evaluation risk, despite the fact that this is the most viable strategy. We'd like to see alignment of the metrics in support of the open source release, while ensuring that the metrics stay credible through an independent valuation of the open source release to ensure it is "for real."

Recommendation: Incrementally increase Phase-I award size to enable better assessment of results in consideration of Phase-II

Galois recommends increasing the Phase-I award size in tandem with inflation or other economic measures to ensure that it remains sufficient for proposers to accomplish tangible results sufficient to make assessments about Phase-II.

At the 2010 Phase-I levels, Galois was often faced with a difficult choice. Should we submit a proposal that had a riskier profile, knowing that we might not have sufficient runway to test some ideas? Or should we wait, losing this chance to bring results? Upon selection, we also faced hard choices about how to allocate the activities between testing and maturing the technology versus communicating those results to the client.

Since the relative value of the Phase-I award level has dropped significantly since the inception of the SBIR program, we'd like to see it restored to its original intended level. Increasing the Phase-I award in this way will enable better evaluation and decisions for investment of Phase-II dollars.

Recommendation: Accelerate Phase-I to Phase-II to meet the pace of software technology change

The pace of software technology change has increased tremendously since the SBIR program began. Consequently, Galois would like to see new approaches for accelerating the transition between the phases, including optionally shortening Phase-I performance periods and setting more aggressive evaluation timelines for Phase-II awards, at least within our problem domain areas.

In our experience, there is a gap from three to six months between Phase-I and Phase-II. During this period, non-research technologies can become obsolete, requiring rework just to achieve baseline capabilities again. Needs have remained unmet during the gaps, exacerbating operational difficulties. Additionally, commercial market opportunities expire without the potential influence from SBIR results that may have yielded substantially better value.

Recommendation: Provide more support to Technical Points of Contact in the administration and guidance in SBIRs

The Technical Point of Contact (TPOC) plays a critical role in whether SBIR research is able to realize value to the government. They interpret and assess the government needs to the SBIR performers, guide the performers during the execution of the SBIR in administrative mechanics, set priorities and standards for delivery, and build the relationship with the small company.

Galois has had widely varying experience with TPOCs. Some have been extraordinary in their commitment to the SBIR results and to enabling Galois to produce relevant results. Others have been earnest but have lacked experience in one or

more important dimensions of execution. Some TPOCs have a wealth of specific experience to share and can directly convey the needs of their agency. Others are more indirect, and take a more administrative stance in management. A rare few are openly unhappy about this accountability. And all of the TPOCs seem to be trying to fit in the SBIR work amongst multiple other priorities.

Prospects for success have been best for Galois when the investment of time and the level of commitment are high. In fact, these are often the same relationships that continue beyond the initial introduction through SBIR to enable Galois to extend and expand its contribution to larger agency needs.

Recommendation: Encourage TPOCs to provide connections with interested acquisition programs

In recent SBIR rounds, some SBIR agencies have listed Programs of Record along with some of the topic description, indicating where the need comes from or where a successful SBIR project might transition. This has been very helpful in identifying real customer need. We recommend linking Programs of Record more closely with the SBIR program, to greatly improve chances of a successful transition.

We recommend that TPOCs should be encouraged to introduce SBIR companies to Program Managers early in Phase-I, so that a SBIR project can be guided by the Acquisition Programs' needs. This will also foster a closer working relationship between TPOCs and Programs.

We recommend that Acquisition Programs should be incentivized to work with the SBIR companies working on topics that are relevant to the program. This may require a modification to how Programs of Record are assessed during execution. Programs are by nature very conservative as a response to their very strict success criteria, so have a strong incentive not to include the risky outcomes of SBIR projects within the Program, yet a successful innovation could dramatically increase the impact and effectiveness of the Program.

Recommendation: Provide incentives to prime contractors to incorporate useful SBIR advances into their offerings

Understanding advanced technology requires a prime contractor's better people to serve as ?technology acceptors'. Very typically those people are tied up on major procurements or ongoing projects, and may not be accessible or available to consider potentially valuable new technologies. Providing appropriate incentives for prime contractors to assess and utilize emerging SBIR results, particularly those deemed of interest by Programs, might accelerate the uptake of new technologies.

In conclusion

Let me underline a point I made earlier: each of these suggested improvements are offered with a view to making an excellent program stronger. In my view the SBIR program is immensely successful, both for fostering the innovation and jobs engine of small businesses, and for nurturing breakthrough technologies to the benefit of the government and wider economy.

Thank you again for the opportunity to appear before this Committee. I look forward to answering your questions.

Chairman QUAYLE. Thank you, Ms. McKinney, and thanks to all the witnesses for your testimony today, and thanks again for your patience.

I want to remind the members that the committee rules limit questioning to five minutes, and at this point I will now open the round of questioning and recognize myself for five minutes.

And my first question is to Dr. Siegel. I really like the fact that you mentioned Milton Friedman in your testimony today. I enjoy his work, and that kind of gets me to one of my big questions is we talk about expanding where VC-controlled companies can be available for SBIR grants. Now, as you stated, you know, we want the Federal Government only to be in the marketplace to distort the marketplace only when there has been a market failure.

Now, is it accurate to say that there is no market failure for certain companies when they do have VC funding because they have been able to go to the private marketplace for that rather than

some smaller businesses who haven't been able to get that VC funding?

Mr. SIEGEL. I would say that Friedman would say that the ability of a firm to attract venture capital funding is an indicator that it is an efficient company. You know, there is an equity aspect to this program, and there is an efficiency aspect to it, and what venture capitalists do very effectively is help sort capital investment and target those capital investments that will generate the highest returns to them. Okay.

But in this context we are talking about technology-based programs. These also generate—I don't care about the returns to venture capitalists. I care about the returns to society. So there is—it is efficient, and in fact, I teach entrepreneurship, and when I teach the students, I tell them that your ability to attract venture capital funding is a major indicator of success, number one. Number two, in certain sectors it is required to reach the marketplace. You really need that additional investment.

And it is a very, very small pool of investment. I think there is a myth that this is a large, broad market. It is a very small, narrow sectorally-focused in many ways market, and I think it is a very, very efficient institution, and we shouldn't try to—and it is private. So you like that. Right?

Chairman QUAYLE. Exactly. That is what I was saying is——

Mr. SIEGEL. Yeah.

Chairman QUAYLE. ——if they have been able to in the early rounds of financing been able to get VC backing, do we then allow and expand? I understand the arguments for the fact that VC-backed or owned companies probably will have greater commercialization in effect because, you know, like you said, the VCs already have gone through the companies.

But don't shake your head. I haven't finished yet. So but then do we allow the Federal Government then to provide those fundings in the later phases that you are talking about, or is that actually distorting the market when the Federal Government shouldn't be involved in that?

Mr. SIEGEL. I don't think it is distorting the market, and I think these are going to be the homeruns frankly. These are going to be the companies that are going to have the largest impact on the economy, and that is why—that is what we need to look at in the long run is what is the economic impact in terms of job creation and that—you want to be leveraging the public investment by involving them and, you know, again, then they reach the private capital market. You know, they go public.

Chairman QUAYLE. Uh-huh.

Mr. SIEGEL. I mean, that is an indicator of success. That is what we want.

Chairman QUAYLE. Okay.

Mr. SIEGEL. From a societal standpoint. Not from greed. You know, I am all in favor of greed, believe me, but from thinking about it from a societal standpoint.

Chairman QUAYLE. Okay. Okay. Thank you. Then Dr. Rockey, I want to talk to you about there has been a lot of talk within your testimony as well is that we need to have improved communication between, you know, program officers, venture capitalists, outside

sources so that people can get the outside sources of funding for commercialization success.

Now, the PODS Program that you guys have at NIH, integrates all the data from SBIR and STTR, awards the success stories, and basically it is one searchable platform basically. Right?

I was just wondering could PODS be a tool that is used to improve outreach and networking opportunities for small businesses and outside funding sources?

Ms. ROCKEY. Well, thanks for that question.

Chairman QUAYLE. Could you push your mike again?

Ms. ROCKEY. No one has ever accused me of not being able to talk, but that doesn't work too well here. The PODS Program right now is in a—it is in its beta form. So it is really designed to be an internal process to do exactly the things that you had suggested to help us among—at the NIH to have the program officers and others involved with the SBIR Program really understand what is happening with these businesses, where they have commercialized, what has worked for success, et cetera.

So we do feel, and we are working with SBA on this particular system because we think this is a way to have accountability for the program and also to set up as you say, these networks to be able for us to understand the networks and where there is areas of opportunities for these businesses to help them along.

And it also helps us for best practices to understand which companies have worked, which companies have found success, how have they found success, et cetera. So we have great expectations that the POD Program will help us in managing the SBIR Program overall.

Chairman QUAYLE. Okay. Thank you, and Mr. Limbaugh, along those lines with that PODS Program, I know you have dealt with the DOD——

Mr. LIMBAUGH. Uh-huh.

Chairman QUAYLE. ——in some contact. Have you seen similar programs at DOD or other agencies that you have dealt with?

Mr. LIMBAUGH. Yes, we have. We have seen similar things within the Air Force and the Army where you can go onto a web portal and search for technologies that you have been working for. I don't know how successful that has been in helping commercialized technologies. I think it is still of onus of running a small business to really go out and find a customer or your current program managers that you are dealing with.

Chairman QUAYLE. Do you think those types of programs would be able to help you and businesses like you to go out and have commercialization success?

Mr. LIMBAUGH. We do use that tool. I just would say that we haven't had a lot of success with it, but that is—I think the tool is useful.

Chairman QUAYLE. Okay. Thank you very much.

The chair now recognizes the ranking member, Mr. Wu.

Mr. WU. Thank you very much, Mr. Chairman. Before I make a unanimous consent request, I just want to say that I am going to enjoy working with you, Mr. Chairman, on this subcommittee very, very much. After all this time I am finally not the most theoretical person here, and you know, perhaps you will take it back, in addi-

tion to that economist, Adam Smith and John Maynard Keynes and, you know, we are going to have fun here.

Mr. Chairman, I ask unanimous consent to include in the hearing record a written statement from Puralytics, a small business from Oregon that is pioneering an innovative new water purification technology, and is a recipient of SBIR grants from the U.S. Army and the National Science Foundation.

Chairman QUAYLE. Without objection.

[The information appears in Appendix II:]

Mr. WU. Thank you very much. Let me start by asking of all the witnesses and this is aimed at my Congressional colleagues, the answer I hope to be useful vis-a-vis my Congressional colleagues. How important is it that we enact a long-term comprehensive reauthorization of the SBIR and the STTR programs?

And the question is how important is speed because we came this close in December, and it is either now or six months from now or maybe the next Congress. How important is speed?

Ms. ROCKEY. So I will be point out during this course of uncertainty over the past couple of years with the reauthorization, it has had an impact on our—the SBIR community because of this uncertainty, and I had mentioned to Mr. Quayle earlier that—to Chairman Quayle that during the time of reauthorization there is a lot of questions on whether or not the program would still exist.

In some ways that generated more applications because there were individuals who were afraid that the program would go away, and so they quickly submitted applications. But the program for NIH is extraordinarily vital as it does provide that later piece of the pipeline to get things to commercialization.

So for us having a program where it is stable, where we have a long-term reauthorization that has some—provided some flexibility for us is of utmost importance.

Mr. SIEGEL. Yeah. I would just echo that and say it is vital.

Mr. CROWELL. I would say it is vital that we do it and that we do it fast. As the universities are looked to, for example, more and more to help stimulate local economic development and job growth, this is a tool that is extremely effective in helping us achieve that goal.

Mr. LIMBAUGH. We are waiting on a couple phase two awards that probably would benefit from a quick reauthorization.

Ms. MCKINNEY. Likewise.

Mr. WU. Terrific. Thank you very much.

Dr. Rockey, and this is really for the benefit of Chairman Quayle's colleague from Arizona, who commendably is consistent in his opposition to earmarks, and his concern is that there are earmarks in the SBIR program, and I have defended this program on the Floor in floor debate, maintained to him that these are all peer reviewed based on merit, et cetera.

Dr. Rockey, you first. Anyone else who wants to follow on, if the chairman permits a little additional time, could you further address the peer review, merit review process and whether this is in any way a Congressionally-directed award program or not?

Ms. ROCKEY. So I would say that NIH as a whole has been free of earmarks. The SBIR Program along with other programs within NIH all go through a very extraordinarily vigorous peer review

process. The small businesses as well as the regular research programs with our academic partners. It is a two-phase program, excuse me. A two-phase peer review that looks at technical merits as well as aligning the applications with the priorities of the institutes and centers.

In the case of small business, on top of that there is an assessment of the potential for commercialization, and virtually all our applications go through this rigorous process. So the outcome of the application is based on its quality, its technical quality, its alignment with strategic goals, and as well with potential for commercialization.

Mr. SIEGEL. To the best of my knowledge there are no earmarks in the SBIR Program.

Mr. CROWELL. I will just say very quickly that the peer review in my view is one of the strengths in terms of leveraging not just VCs but quite a number of states to put up matching funds where they have no additional peer review process of their own. They trust this process so much.

Mr. LIMBAUGH. I think it is true that the SBIR and STTR is not earmarked per se, but there are a lot of small businesses within the DOD community that get earmarks for their technology, and if you are competing with a company . . .

Mr. WU. That is post-SBIR.

Mr. LIMBAUGH. Post-SBIR.

Mr. WU. Thank you.

Mr. LIMBAUGH. Yes. Post-SBIR.

Mr. WU. Important to be clear.

Mr. LIMBAUGH. Okay. Post-SBIR that really upsets, can upset the competitive balance when you are competing against another company that just got a $1, $2 million earmark.

Ms. MCKINNEY. We have not in our experience ever seen any kind of pre-selection or earmark in any of the evaluations that we have been party to or observed, and I have actually been quite impressed with the rigor and dispassion that happens in the course of the evaluating.

Mr. WU. Thank you very much, and thank you very much, Mr. Chairman.

Chairman QUAYLE. Thank you, and now the chair recognizes the gentlelady from Illinois, Mrs. Biggert.

Mrs. BIGGERT. Thank you, Mr. Chairman, and thank you for holding this excellent subcommittee hearing. I think that the witnesses have been really good, and I think it is something that we all need to address if we are going to be able to find the innovation and the creativity to create the jobs that are so important to the private sector. You are going to create them, not us.

But as a member representing a national lab and dozens of healthcare and energy spin-off companies, I know how valuable the SBIR and STTR Programs are to local job creation, and as we work to reauthorize and reform SBIR, I don't want us to take our eye off the ball in terms of positive economic affects the SBIR and STTR Programs have on our economy, and so I have a couple of questions.

In your opinion is the current 2.5 and the .3 percent set-aside from a federal agency's extramural research and development

budget an appropriate amount for SBIR and STTR Programs respectively? And what would be the effect of either an increase or a decrease in the set-aside amounts?

Dr. Rockey.

Ms. ROCKEY. So currently the Administration is reviewing the issue of the—regarding any increase to the program, and one of the nice things, though, about the SBIR, STTR Program is because it is a set-aside, as the size of the agency increases, so does the amount available for the SBIR Program.

As an example, the NIH went through a doubling from 1998, to 2003, and during that time the small businesses programs doubled as well. So, however, NIH is expected to have flat budgets for the future, and the current set-aside will compete with the scarce resources needed for all of the NIH Programs in effect.

So we have to take them into consideration. I think Mr. Wu will remember that in 2009, I testified before this same committee and answered the question by saying that the current levels are appropriate to meet the mission of the NIH and to support innovation in the small business community.

Mrs. BIGGERT. Okay. Thank you. Dr. Siegel.

Mr. SIEGEL. I would say the NRC does not have an official position on this, but some universities——

Mrs. BIGGERT. I think this is just your opinion.

Mr. SIEGEL. Yeah. Some universities might oppose that because they would view it as a zero sum gain. They would say that some—if a higher percentage of the research budget at the agency is going to this program, it would be taking away from initiatives and programs that they would be using the money for. So that would be one concern that some universities would have.

Mrs. BIGGERT. Thank you. Mr. Crowell.

Mr. CROWELL. I am glad that Dr. Siegel listened to my testimony. I think officially we do believe the overall amount of the set-aside in both programs is probably appropriate and would have a concern not just in deluding our research funding but from an innovation management point of view. The basic science is funded by the rest of the budget. This is what provides the seed corn for the innovation work later on. So that is a very real concern that we have.

That being said, to try to be a little more responsive and a little more granular, I personally—I can't say this is UVA's position, I personally would be interested at looking at the STTR percentage to see if the flexibility or the wall between the two programs might be made a little more—the barrier maybe lowered and made it earlier for—the STTR Program makes it so much easier for a university to participate in developing early stage technology with commercial potential. So if there was some way to add flexibility to change the relative balance of the set-asides to make more STTR-like procedures apply to the whole pool or a larger piece of the pool, we would be very supportive of that.

Mrs. BIGGERT. Mr. Limbaugh.

Mr. LIMBAUGH. I think increasing the amounts to SBIR companies would actually be of benefit, not only from an innovation and product development standpoint, you get more innovations, I think you will see a better increase in jobs from that funding. I think the

free market is better at taking money and actually creating jobs and creating products, creating patents and exporting technology.

So I would be in favor of increasing the award amounts or the set-aside to small business.

Ms. MCKINNEY. I think if you look at the performance within the small business community in terms of innovation and its impact and use that as a guiding point. If you really want to increase the level of innovation looking to the community that is doing that I think is the best place to go.

Mrs. BIGGERT. Just following up on that, Mr. Limbaugh, you, in your testimony you said that venture capital was not such a great idea, and would that create—it doesn't—it limits the innovation and creativity. Correct?

Mr. LIMBAUGH. It can, could possibly do that in the sense that if VCs, at least we, our company plays mostly in the Department of Defense world, and I have talked to a lot of small businesses that kind of play in that community, and we are just fearful of like the large primes setting up a shell company, shell VC company, and then basically gobbling up all the SBIRs and basically being as a conduit to get that—those research dollars into their hands as opposed to into the small business hands.

Mrs. BIGGERT. Okay. I guess my time has expired.

Mr. WU. Would the gentlelady yield for just one second based on that point?

Is the gentleman, Mr. Limbaugh, are you aware whether that has ever happened historically?

Mr. LIMBAUGH. I don't think that has ever—I don't know if it has happened historically ever. I guess what I am also thinking is that from a small business standpoint there is nothing that prevents a company nowadays that has a phase two technology and starting another company and getting VC funding to back that other company if it is such a great idea. Why not wait until, you know, the phase two or whatever for VCs, after—before they can kind of step—you spin it off or whatever to create that new technology and have venture capital play at that level.

Mrs. BIGGERT. If I might reclaim my time, which I don't have, I think that this happens more or just in a small business that creates something, and the venture capital comes in and then they decide that they can better run the company, and it has taken over and pretty soon the people that have been the creators are no longer there.

I don't—but that doesn't happen in this situation.

I yield back.

Chairman QUAYLE. The chair now recognizes the gentleman from New Mexico, Mr. Lujan, for five minutes.

Mr. LUJAN. Mr. Chairman, thank you very much, and I very much appreciate the conversation and the hearing, and again, thank you as well. Like Ms. Biggert, I also share a passion for our national labs, New Mexico having two of them, one in my district.

And as we engage in this conversation, please don't misunderstand my wanting to concentrate on the STTR program as not supporting SBIR. I think that they are good programs, and they are strong programs, but with that, I am very interested in technology transfer, and myself and a few colleagues are having a conversa-

tion. Mr. Wolfe has been willing to work together to develop a tech transfer caucus, and we are quickly understanding through the conversations that we have with our colleagues, with our constituents, with experts, small business owners, entrepreneurs, and venture capitalists, and everyone that is part of that process, that you have to include the aspect of commercialization and maturation.

You have to look to see what needs to be done from a seed perspective and understand where these ideas come from and often times how disappointing it is when we have these great ideas that can't make it out the door from behind the wall of some of our institutions to get into the hands of entrepreneurs. And to see what we can do when our entrepreneurs have these fabulous ideas to get behind that wall and use that computing capacity, that modeling capacity, to have that breakthrough of whatever it may be, which is why I am so very passionate about CRADAs, Cooperative Research and Development Agreements, which we saw as a success in the 1990s, but saw it deteriorate over years as funding disappeared.

We are looking to see what we can do to encourage that kind of relationship. We were encouraged with the announcement just last week by Secretary Chu for the Start Up America Initiative where the idea is to make it easier to license technologies through DOE's national labs through reducing fees as well as reducing paperwork.

We need to do more. That is a good step, but we want to hear from you on what that more is.

So with that being said, as, you know, we talk about STTR and I am glad that the last question was asked pertaining to the level of funding because when we look at .3 percent associated with funding with STTR and I would be glad if someone could show me a recent study associated with the program, all that I was able to find was a 2001 GAO report which was used for the 2001 reauthorization of the program. But that report was based off of phase two projects from '95, to '97, the first three years that such awards were made.

So we haven't had a good look to see if this program is working. Same reason why I think that CRDA's have disappeared. There wasn't a good look to see the success associated with them, truly evaluating that program to take out what was bad and truly accelerate and reward what was good, respecting very much and agreeing that the best thing we can do with these dollars is see what we can do to get these ideas in the hands of small businesses, of the smartest people we have in America, and what I like to think as ingenuity as part of the human soul in this great Nation of ours.

What can we do to make that happen? And so I apologize for using so much of my time with describing that and talking about this with the passion that we all have for it, and quite honestly, Mr. Chairman, I am saddened that this hearing is not full of people. When we talk about getting the economy back on track in this great Nation of ours, unleashing the capacity in our universities and in our national labs and combining that with the ingenuity of our small businesses, we should be able to quickly accelerate what we are able to do to get the economy turning again.

And, Mr. Chairman, rather than I think engaging in questions now, I will see if there is a second round of questions and I will

wait to ask a few questions then, but I will simply add this. Not understanding the constraints of requesting unanimous consent to submit a book to the record but with that being said, I will do my best to see what approvals we need to be able to do that or at least maybe get some excerpts out of it.

I was recently engaged in a conversation with a few people around manufacturing and tech transfer, and someone that works with Dow Chemical gave me a book that their CEO, Andrew Liveris, wrote, and it is called, "Make it in America: The Case for Re-Inventing the Economy." And it also lays out the foundation that we have to reestablish our manufacturing base in this great Nation of ours which will help spur innovation as well, because I certainly believe we need to be doing more to invent things here in this country.

But we also have to do more to be able to manufacture them, so that when you have those manufacturers, people that are building it on that assembly line, and you are looking to see how you can make that product stronger and smarter, that is what we should be doing.

And although people may not think of this as high tech or tech transfer, but all these smart phones that we walk around with today, in 2008, if my numbers are correct, 1.2 billion phones were sold worldwide. Not a one was built in the United States. We see what has happened to smart phones from 2008 to 2011, and to make sure that we are pushing that ingenuity here at home is why you are so important to this debate.

So, Mr. Chairman, thank you for indulging me for going over the time, but I look forward to this questioning and developing the policy around this because this is going to be one of the key drivers of what makes this economy strong and makes America stronger than what it is today.

Chairman QUAYLE. Thank you, Mr. Lujan.

The chair now recognizes the gentleman from Maryland, Mr. Sarbanes, for 5 minutes.

Mr. SARBANES. Thank you, Mr. Chairman. This is a very important hearing. I want to echo the comments of my colleague in terms of how critical is it that we have these kinds of programs and resources and the opportunity for partnerships to support American manufacturing and not to view that as some afterthought in terms of our economic strength but really as the main event. I think you all probably appreciate that implicitly.

Before I forget, I do have a letter. I talked to your staff, Mr. Chairman, about entering this in the record, and so I would ask unanimous consent. This is a letter from executives of the U.S. Small Biotech Medical Device Association, and they have a number of members in Maryland. Maryland was actually a driving force in establishing this particular coalition of small biotech business coalition. They have a letter they would like to enter into the record. Without objection I would like to do that.

Chairman QUAYLE. Without objection.

[The information appears in Appendix II:]

Mr. SARBANES. Appreciate it.

I wanted to ask the panelists, both the businesses that are here and the other experts, to speak if you would to the—well, first of

all, to the businesses, have you ever utilized any of the federal labs through SBIR from opportunities that you have pursued? If so, why and how? If not, were there any reasons you didn't pursue that kind of partnership?

And then from others on the panel, maybe you could just speak to the opportunities through SBIR for small businesses to do that kind of partnering and what the, you know, what the process involved in that is.

And start here.

Mr. LIMBAUGH. We have not used any national labs in our research and development at Kutta. However, maybe there is a general feel within the small business community working with the national labs could be expensive, and small businesses don't have a lot of capital to work with them.

And a lot of times if you are working under a SBIR, you know, you have to disclose that you are working with a government entity. I don't know how well that would work, and I don't—I would like to see the statistics on how many small businesses team with the national labs because I know—I don't think there is probably that many.

But that is my own personal opinion.

Mr. SARBANES. Ms. McKinney, do you have a perspective on it?

Ms. MCKINNEY. So we collaborate with folks at the national labs and research initiatives. I don't think we have ever officially done it under the auspices of the SBIR Program.

However, lots of the applications that we have are of interest to that community, so we target deployments into the research in the DOE. So I would just have an experience directly under the SBIR Program with partnering with them.

Mr. SARBANES. Do any of the others on the panel have a perspective in terms of partnering with the federal labs or pursuing that as part of an SBIR initiative?

Mr. CROWELL. I will just say very quickly that as a person who has spent his career in universities, I can't think of an example where we have collaborated on SBIR project.

I will also tell you, however, that I sit on the Commercialization Advisory Board at Los Alamos and was just on a telephone call this morning with the federal laboratory consortium talking about this very issue, and we were talking about getting a group of people together to begin to develop a mechanism to expose Los Alamos and potentially other labs more aggressively to this mechanism.

Mr. SIEGEL. Yes. In my written testimony I noted that the NRC needs to study the relationship between SBIR and the federal labs because the federal labs are the last frontier of technology transfer. The universities have been studied to death, but the labs are actually in many ways bigger and more important potentially for the economy.

So I—my sense is that the labs currently do not have enough incentives to work through this program, and I think that is a major problem that maybe can be addressed through some legislation, but we certainly need to study this, and I think the NRC can do that.

Mr. SARBANES. Dr. Rockey.

Ms. ROCKEY. I would just like to mention that at NIH we had through our office of technology transfer we have what is called the

Pipeline to Partnership. This is a website that allows small businesses as well as NIH-licensed technologies to marry up, and obviously people can peruse this website and try to find places where they have, could have relationships.

NIH, of course, our intramural program is a beneficiary oftentimes of the products and services that are provided by the small businesses. We also have, and some of our institutes have targeted SBIR Programs where for the—in order to meet the mission of the particular institute such as the National Cancer Institute, they will target particular priority areas in the SBIR Program to fund small businesses to provide technologies and services that we in our NIH—and the federal labs can use as well.

Mr. SARBANES. Well, I appreciate that. I am out of time, but I just would observe it is interesting to hear you speak of it as kind of the last frontier, and I assume you all would be supportive of efforts through the reauthorization to try to enhance the partnerships that occur there between the federal labs and these SBIR business initiatives.

Thank you. Yield back.

Chairman QUAYLE. The chair now recognizes the gentleman from Illinois, Mr. Lipinski, for five minutes.

Mr. LIPINSKI. Thank you, Mr. Chairman. I thank you and Ranking Member Wu for holding this hearing today, and I also want to congratulate you on being chair of this subcommittee. We were both at Duke together, although I was a graduate student, you were an undergrad at the time, but we both shared some time there together, and I don't know if I should admit I got there before you did, and I left there after you left. But I was in grad school.

SBIR and STTR are critical programs because they are an essential link between our country's tremendous advances in basic research and creating jobs that we need, as we have heard, the last two members have asked important questions on—about that.

But generally speaking the concern that I have is that American research innovations are turning into products that are manufactured in Japan and China. So I would like to talk about how SBIR and STTR can help to solve this problem.

And I want to start with Dr. Rockey. Last year you testified that the NIH SBIR projects achieved an impressive 50 percent success rate for commercialization. And in your testimony you discussed several factors that NIH considers in reviewing SBIR applications and selecting its awardees. And commercial potential is one of those.

So I have two questions on this. First, can you just expand on how you define commercial potential and what factors you use to assess the commercial potential of a project? And second, do you look at the potential of a project to create jobs, especially manufacturing jobs here in America?

Ms. ROCKEY. Thank you very much for that question. So we do assess commercial, the potential commercialization. We look at such things as the value of the project. We look at the company itself, the markets that are potential—available for this particular idea or project, intellectual property, and what is potentially there for protection, financial plans, et cetera.

Because this is oftentimes early stage, we don't necessarily look at what the economic impact as far as jobs will be, but our desire is that with commercial and because we are a knowledge-based society here at NIH and the biomedical research, the biomedical market is so dependent on this knowledge base, that it is an economic driver, and thus, by supporting projects that will eventually lead to commercialization, we will result in helping the economy thrive.

Now, again, one thing I would remind you that, of course, these are U.S. companies, and the SBIR program, it is a requirement that they be U.S. companies. But the issue about manufacturing is a different issue, and as often more long-term issues for all of us here.

Mr. LIPINSKI. Is there any way to look, to try to make any determinations about the potential future for whether this is going to be an American-made manufactured project? Is there any way to do that?

Ms. ROCKEY. I think for the—yeah. So we have a cap program. Our CAP Program is the Commercial Assistance Program. This is a program that we provide a number of companies with up to $4,000 of technical assistance to look at markets, and in that they are encouraged to seek manufacturing opportunities in the U.S.

So we do at least try to drive them towards that. Whether or not we are ultimately successful, again, we will have to see the outcome of what the product is that they are producing, but we do try to drive them towards U.S. manufacturing.

Mr. LIPINSKI. In the remaining time I have I want to turn to Dr. Crowell. I know that top research universities in the U.S., including several in Illinois, have spun off numerous start-ups, and many of them are increasingly looking at economic development as part of their core mission.

I just want to ask, what does the University of Virginia do to create jobs locally and regionally, and how do SBIR and STTR programs help this?

Mr. CROWELL. Thank you for the question, and good to see you again after we made our UNC, Duke connection last summer, so I thought I would just keep the rivalry going here.

The University of Virginia, like many universities, is undertaking an effort to identify technology or innovation assets that have the potential for building a small company to begin to commercialize that asset base. I would say that the processes we have in place for understanding technologies that are more ready to license to an existing company are rather set. We know how to do that very well. What we have been doing is investing in our business development capacity, our ability to understand markets, to undertake some of the same types of evaluation that Dr. Rockey just mentioned. And when we think we have a platform technology capable of attracting investment and building a company, we really devote an awful lot of resources and time to help do that.

We network effectively and aggressively with local investors, with local commercial real estate providers, with state agencies, with not-for-profit foundations. We are looking to piece together through SBIR, STTR, venture capital, private foundations, state funds, sometimes local economic development funds, everything we can do to create an entrepreneurial ecosystem in which we can

plant the seed for this new company and watch it grow and help sustain that growth over time.

We realize that some may get acquired and move away. An example I gave in my testimony was one where it was acquired, it did maintain the significant presence in Charlottesville, but one of the things I would argue is that one of the most lasting effects of that was it maintained the CEO who built that company in Charlottesville, who has just become the CEO of a new company that just landed $4.5 million in venture funding.

So we are creating serial entrepreneurs within the culture where we believe the benefit from this investment, whether the companies end up moving to other states or not, but there is an awful lot of return to the region from this activity and this investment.

Mr. SIEGEL. I would like to chime in and say that entrepreneurship is flowering at universities. There are more courses and programs in entrepreneurship, and there is more student-based ventures that are emerging at universities. And even we have now alumni commercialization funds.

So I think one reason why universities have been very receptive to this is they tried the large licensing deals with pharmaceutical companies, and they are moving as somebody who studies tech transfer at universities, they are moving more in the direction of promoting entrepreneurship. That is why this program is very attractive to them, but frankly, they are also viewing it from an opportunistic standpoint. In my current job I am basically an extortionist in the sense that—don't put that in the record. But I deal with donors, and I can tell you that the donors that I deal with and the stakeholders in the community want to support entrepreneurial activity at the university, including faculty and student-based start-up companies.

So I think—and there is an economic spillover associated with that activity, and they see that benefit, but they also see the monetary benefit as I do.

Mr. LIPINSKI. Thank you. Thank you, Mr. Chairman.

Chairman QUAYLE. The chair now recognizes Mr. Lujan for one very short, very succinct, and very clear question.

Mr. LUJAN. Mr. Chairman, we have quickly learned how to ask compound questions in Congress. What I would ask is this, and Mr. Chairman, I will be submitting a question to Mr. Crowell as well to respond to the record.

Thank you very much for what you do at Los Alamos National Lab in encouraging the opening of those doors.

Specifically to those of you that have experience with engaging our national labs, do you believe that there is some positive aspect of tying tech transfer, maturation, commercialization, and job creation to the metrics for full contracted payment for those that are engaged with our national labs, both DOE and DOD, which will not add one penny to the deficit.

Mr. CROWELL. I would like to jump in and say absolutely. It gives me an opportunity, however, to say, and this was also the subject this morning with my federal lab consortium colleagues on the phone call, I would at the same time require those labs to take a close look at their policies which inhibit, dis-incentivise, or create roadblocks. I have helped Los Alamos spin a company out within

the last 9 months in the plant biotechnology area. I would say to you that if we had to go through that every time at the University of Virginia or other universities where I have worked, our success rate would be about half of what it is.

So I think there are some—there is some culture building to do, there is definitely some policies, some incentives to look at to create a road forward where they could be major players. The talent and the seed corn is there. They have too many obstacles in front of them that some—the rest of us don't have to deal with.

Mr. SIEGEL. I would say that what we also need to do is collect more data from the federal labs. One of the most interesting organizations is the one that Mark ran for a while called the Association of University Technology Managers, and they started collecting data from universities on various metrics like patenting, licensing, start-ups, and all those kinds of measures of—that lead to economic growth and development.

And we are not doing that currently. The FLC is not doing that, and I think we should, you know, try to find some institution that would, maybe NRC, that would collect those data so that we could evaluate, and once you evaluate people, once you start collecting those metrics, there is competition, and people want to, you know, do better along those dimensions. It is natural.

Mr. LUJAN. Mr. Chairman, if anyone else has a response, please submit it in writing. I want to be respectful of the time, and I yield back my time. Thank you.

Chairman QUAYLE. Without objection.

I want to thank the witnesses for their very valuable testimony and for their patience today.

The members of the subcommittee may have additional questions for the witnesses, and we will ask you to respond to those in writing. The record will remain open for two weeks for additional comments and statements from members. The witnesses are excused. Thank you all for coming, and this hearing is adjourned.

[Whereupon, at 3:58 p.m., the Subcommittee was adjourned.]

Appendix I

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses of Dr. Sally Rockey, Deputy Director for Extramural Research, National Institutes of Health

Questions for the Record
HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION
The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs
Thursday, March 31, 2011
2:00 p.m.

The Honorable Ben Quayle

1. **If a company that receives SBIR funding has a low commercialization rate, does this factor into the scoring of the company's subsequent SBIR applications? If so, in what ways?**

The NIH peer review system does not factor past commercialization rate into the technical scoring decision for subsequent SBIR applications since all new applications represent different original projects with their own inherent market risk considerations. Project applications are always peer-reviewed based on their scientific merit, and for Phase II applications, the successful completion of the Phase I project is an important review consideration. As evidenced by the National Research Council's findings, we know that approximately 40% of NIH SBIR projects reach the marketplace.[1] Therefore, the NIH process for selecting projects with the greatest potential for commercialization works well.

Importantly, for all Phase II SBIR applications, companies must provide a detailed commercialization plan along with their research plan. The commercialization plan is evaluated by the peer-review committee and the quality of the plan factors into the overall impact priority score, which ultimately serve to inform the program managers in making final funding decisions. The elements of the commercialization plan include:

a. ***Value of the SBIR/STTR Project, Expected Outcomes, and Impact.*** Describe, in layperson's terms, the proposed project, and its key technology objectives. State the product, process, or service to be developed in Phase III. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR/STTR project integrates with the overall business plan of the company.

b. ***Company.*** Give a brief description of your company including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization, and any current products/services that have significant sales. Include a short description of the origins of the company. Indicate your vision for the future, how you

[1] National Research Council of the National Academies, *An Assessment of the SBIR Program at the National Institutes of Health*, p.5 (2009).

will grow/maintain a sustainable business entity, and how you will meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity.

c. ***Market, Customer, and Competition.*** Describe the market and/or market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles you will have to overcome in order to gain market/customer acceptance of your innovation.
Describe any strategic alliances, partnerships, or licensing agreements you have in place to get FDA approval (if required) and to market and sell your product.
Briefly describe your marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years.

d. ***Intellectual Property (IP) Protection***. Describe how you are going to protect the IP that results from your innovation. Also note other actions you may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar to yours.

e. ***Finance Plan.*** Describe the necessary financing you will require to commercialize the product, process, or service, and when it will be required. Describe your plans to raise the requisite financing to launch your innovation into Phase III and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways:
• Letter of commitment of funding.
• Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist.
• Letter of support for the project and/or some in-kind commitment, e.g., to test or evaluate the innovation.
• Specific steps you are going to take to secure Phase III funding.

f. ***Production and Marketing Plan.*** Describe how the production of your product/process/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps you will take to market and sell your product/process/service. For example, explain plans for licensing, Internet sales, etc.

g. ***Revenue Stream.*** Explain how you plan to generate a revenue stream for your company should this project be a success. Examples of revenue stream generation include, but are not limited to, manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how your staffing will change to meet your revenue expectations.

2. To what extent does the NIH track data on the STTR program and award recipients? How does NIH data tracking on the SBIR program differ from that on the STTR program?

The NIH conducted two comprehensive surveys in 2002[2] and 2008[3] to evaluate commercial outcomes of its SBIR and STTR award recipients. These reports contain detailed information about how the programs stimulate technological innovation, if Federal R&D needs are satisfied, and whether the programs increased private sector commercialization. Additionally, we track SBIR Phase II companies that participate in the Commercialization Assistance Program (CAP) for eighteen months to measure both the impact of the program and specific commercialization outcomes. Comparable STTR data are not available as these awardees are presently not permitted to receive technical assistance. All these aforementioned data and success stories are housed in a recently launched NIH Performance Outcomes and Data Systems (PODS), which is presently available only to NIH program staff that manages SBIR and STTR grants.

The Honorable David Wu

1. As you are certainly aware, last year, the Small Business Administration increased the standard limit for awards to $150,000 for Phase I and $1,000,000 for Phase II. Do you believe these standard limits are appropriate, or would you recommend that they be increased further?

NIH supports the Administration's position and believes these guidelines are appropriate. Any consideration for increasing the limits on the award guidelines should only apply to NIH due to the need for more program flexibility and the intense funding needed for biotechnology. Currently, NIH has a waiver to exceed these award guidelines for Phase I and II awards when scientifically appropriate and when within the general SBIR budget. Specifically, the SBA waiver allows NIH to exceed the current SBIR/STTR budget guidelines up to $3 million for Phase II awards. A hard cap on budget requests (without the possibly of a waiver to exceed them) would affect some Phase II awards and virtually eliminate all Phase IIB competing renewals. These are typically pre-clinical and clinical applications from companies very near to commercialization and applying to FDA for drug/device approval. These expensive studies could have to scale back, possibly to the point of being unsuccessful statistically and/or clinically. This provision would also affect many targeted NIH SBIR/STTR Phase II funding opportunities. Regardless of the size of the budget limits, NIH would prefer to retain the flexibility to obtain a waiver to exceed the limit to fund awards at a level that is appropriate for the project.

2. What percentage of SBIR awards are going to woman- and minority-owned small businesses? How does the National Institutes of Health conduct outreach to woman- and minority-owned small businesses to increase their participation?

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[2] National Institutes of Health, Section on Small Business Research Funding Opportunities, *National Survey to Evaluate the NIH SBIR Program*, available at http://grants.nih.gov/grants/funding/sbir_report_2003_07.pdf (last visited May 16, 2011).

[3] National Institutes of Health, Section on Small Business Research Funding Opportunities, 2008 *National Survey to Evaluate the NIH SBIR Program*, available at http://grants.nih.gov/grants/funding/sbir_2008surveyreport.pdf (last visited May 16, 2011).

In Fiscal Year 2010, NIH awarded 11% of SBIR awards to women-owned businesses and 3% of SBIR awards to minority-owned and disadvantaged businesses.

The NIH SBIR Office participates in several national, regional, and local SBIR events, conferences, and panels each year. These functions typically attract diverse audiences and businesses and sometimes occur in areas of the country where a lot of participants are business owners who are women, disadvantaged, or minorities. Given limited travel funds, the NIH SBIR Office strategically prioritizes events it attends, and ensures participation at events targeting disadvantaged or minority-owned small businesses.

Examples include:
(1) At last year's NIH Annual SBIR/STTR Conference, NIH held a session specifically focused on issues and resources that pertain to women-owned small business concerns,
(2) NIH partnered with a local group called Springboard Enterprise that manages a commercialization assistance program for women-owned small business concerns to talk about NIH's programs, resources, and additional tips,
(3) NIH attends events geared toward women-owned small business concerns,
(4) the NIH SBIR Office presented a webinar to the Kansas Bioscience Authority and Kansas Technology Enterprise Corporation in 2010 which had a very large minority-owned business audience, and
(5) NIH attended and presented at the New Jersey Diversity Alliance Conference in 2009 whose audience was almost exclusively minority-owned businesses.
NIH posts all relevant information on our website which is accessible by all small businesses. NIH also disseminates relevant SBIR information internally (to NIH Institutes and Centers) and externally to as wide of an audience as possible. NIH Institutes and Centers may also have their own additional efforts in this area.

The Honorable Lamar Smith

1. One of the more important aspects in H.R. 1425 involves how small businesses can leverage the technical resources of our Federal Laboratories. However, one of the onerous regulations one of my constituents who runs a small business in San Antonio recently faced in working with a Department of Energy laboratory was that he needed to provide upfront funding to the lab for the first 90 days of the project. Small businesses find it difficult to come up with such a large advance payment.

Does the NIH have a similar 90-day funding requirement for collaborative projects between industry and your research institutes?

NIH does not require 90 day upfront funding to a Federally Funded Research and Development Center (FFRDC) participating in an STTR award.

The Honorable Randy Neugebauer

1. What effects do you believe would result from allowing majority-owned venture capital businesses to compete for SBIR funding? Will it result in a decrease in competitive Phase I applicants?

Particularly for new lines of research in a company's product pipeline, the SBIR/STTR program plays a distinct and important role in financing the critical early stages of the drug development process as venture capital (VC) financing is important in the later stages. VC participation in the SBIR program encourages additional VC investment by enabling small businesses to pursue new directions of innovative, high risk research under Phase I and Phase II awards. VC financing often helps a project get further along the product development pipeline and enables a small business to pursue a portfolio of projects that are high risk and high impact.
Allowing majority-owned VC small businesses to compete for SBIR funding will enrich the pool of qualified U.S. small businesses that the National Research Council found to have a greater success rate in bringing products to market. Such an outcome aligns directly with the NIH mission and will help us further meet our goals. Ultimately, the NIH peer review process will ensure only the most meritorious small business projects will be funded.

2. How heavily do small businesses rely on the SBIR and STTR award programs for research and development funding? What overlap exists, if any, with any other federal programs with similar goals and objectives?

The National Research Council's study reported that small businesses that received NIH SBIR Phase II awards rely heavily on the SBIR program for research and development (R&D) funding. Specifically, the study highlighted that over 25% of companies that received NIH SBIR Phase II awards were founded entirely or partly because of an SBIR award.[4] The study also revealed that more than 50% of SBIR funded projects would never have occurred without SBIR funding.[5] Currently, there are no formal evaluations by NIH or the National Research Council on NIH STTR awardees and their level of dependence on the STTR program. While small businesses are eligible for several other R&D funding programs at NIH, these programs do not have the same Congressional and commercialization goals as the SBIR and STTR programs. Companies are likely not as competitive for these other R&D programs as they are for the SBIR and STTR programs. NIH is not aware of overlap with other Federal programs that may have similar goals and objectives.

<u>The Honorable Ben Ray Lujan</u>

1. Do you believe that there is some positive aspect to tying a national laboratory's performance on technology transfer, technology maturation, commercialization, and job creation to the payments given to the operating contractor of each national laboratory for good performance? What metrics for technology transfer, technology maturation,

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[4] National Research Council of the National Academies, *An Assessment of the SBIR Program at the National Institutes of Health*, p.22 (2009).

[5] National Research Council of the National Academies, *An Assessment of the SBIR Program at the National Institutes of Health*, p.23 (2009).

commercialization, and job creation would you recommend?

NIH is not the appropriate recipient of this question. We recommend sending this question to the Department of Energy, the agency responsible for managing the National Laboratory System.

The Honorable Chip Cravaack

1. There has been a great deal of discussion about the role of venture capital in both the SBIR and STTR programs. What do you think will be the impact of changing the current venture capital requirements on the program? Do you believe this will lead to an increase in the quality of applicants into the program?

Particularly for new lines of research in a company's product pipeline, the SBIR/STTR program plays a distinct and important role in financing the critical early stages of the drug development process as venture capital (VC) financing is important in the later stages. VC participation in the SBIR program encourages additional VC investment by enabling small businesses to pursue new directions of innovative, high risk research under Phase I and Phase II awards. VC financing often helps a project get further along the product development pipeline and enables a small business to pursue a portfolio of projects that are high risk and high impact.

Allowing majority-owned VC small businesses to compete for SBIR funding will enrich the pool of qualified U.S. small businesses that the National Research Council (NRC) found to have a greater success rate in bringing products to market. Such an outcome aligns directly with the NIH mission and will help us further meet our goals. Ultimately, the NIH peer review process will ensure only the most meritorious small business projects will be funded.

2. I like the concept of allowing small businesses to compete for federal research dollars. After all, small business is the backbone of our economy. Can you discuss the economic impact of this program and if you feel Congress should allow a greater share of R&D funds to be targeted at small firms?

The economic impact of the program is a significant source of economic vitality and job creation. The National Research Council study on the SBIR program showed that the small business concern experienced a mean employment gain of 29.9 full-time equivalencies (FTE) since the date of the SBIR award.[6] In addition, the immediate impact of the SBIR grant allowed the business on average to hire 2.7 FTEs and to retain 2.2 FTEs.[7] The program has experienced a level of success and about 40% of the funded projects reach the marketplace.[8]

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[6] National Research Council of the National Academies, *An Assessment of the SBIR Program at the National Institutes of Health*, p.103 (2009).

[7] National Research Council of the National Academies, *An Assessment of the SBIR Program at the National Institutes of Health*, p.103 (2009).

[8] National Research Council of the National Academies, *An Assessment of the SBIR Program at the National Institutes of Health*, p.5 (2009).

NIH agrees with the Administration that the current set aside levels are appropriate. NIH believes that the current share of R&D funds allotted to the SBIR and STTR programs is sufficient to accomplish the goals of the programs. For NIH, an increase to the mandatory set asides would negatively affect NIH's mission because it would decrease funding for scientifically meritorious projects in other areas of research.

3. As Members of Congress, we all have a responsibility to ensure that tax dollars are being spent wisely. Do you believe that Congress should demand more accountability from the SBIR program in terms of its reporting and data collection requirements? If so, in what, ways?

NIH believes the current level of accountability in the SBIR program is sufficient. NIH is timely and responsive to all reporting and data collection requirements from DHHS, SBA, Congress, and other offices as required. The NIH conducted two comprehensive surveys in 2002[9] and 2008[10] to evaluate its SBIR and STTR award recipients. These reports contain detailed information about how the programs stimulate technological innovation, if Federal R&D needs are satisfied, and whether the programs increased private sector commercialization. Additionally, we track SBIR Phase II companies that participate in the Commercialization Assistance Program (CAP) for eighteen months to measure both the impact of the program and specific commercialization outcomes. Comparable STTR data are not available as these awardees are presently not permitted to receive technical assistance. All these aforementioned data and success stories are housed in a recently launched NIH Performance Outcomes and Data Systems (PODS), which is presently available only to NIH program staff that manages SBIR and STTR grants.

4. There have been several suggestions to shorten the award cycles in the program. Do you have any administrative concerns about this type of change? If so, what are these concerns?

Compared to most other NIH mechanisms, the NIH SBIR and STTR applications (over 6,000 per year) already undergo an accelerated peer-review cycle. In addition, all competitive applications (including SBIR and STTR) are required by law to undergo a second level of administrative review by an NIH Institute or Center. Shortening the award cycle would present several administrative concerns at NIH including: 1) not allowing sufficient time to assemble an outside expert peer-review panel, 2) allowing reviewers insufficient time to adequately review and rate an application, and 3) allowing insufficient time for the required second level of review. Additionally, NIH makes SBIR and STTR awards for three cycles throughout the

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[9] National Institutes of Health, Section on Small Business Research Funding Opportunities, *National Survey to Evaluate the NIH SBIR Program*, available at http://grants.nih.gov/grants/funding/sbir_report_2003_07.pdf (last visited May 16, 2011).

[10] National Institutes of Health, Section on Small Business Research Funding Opportunities, 2008 *National Survey to Evaluate the NIH SBIR Program*, available at http://grants.nih.gov/grants/funding/sbir_2008surveyreport.pdf (last visited May 16, 2011).

fiscal year, and award decisions for the first two cycles are often delayed due to an absence of an enacted Appropriations bill.

Responses by Dr. Donald Seigel, Dean and Professor, School of Business, University at Albany, State University of New York

Questions from the Honorable Benjamin Quayle

Q1. In your testimony you mention the National Research Council's recommendation regarding the importance of conducting regular, rigorous systematic evaluations of the SBIR program, and you call for the development of interoperable standards for data collection and dissemination. What do you think is the best way to develop these standards?

A1. The best way to develop these standards is to convene a group of "users" of the program, program managers at the federal agencies, and academic experts of the SBIR program. It is important to note that perspectives on the use and importance of the data will vary across these groups. For example, program managers will want to collect data that allows them to determine whether the program is advancing agency goals. "Users" will be concerned about response burden. Policy-makers and academics will use the data to address braoder issues, such as how to make the program more effective. I am confident that the NRC can provide guidance to agencies on how to develop these standards

Q2. The NRC recommends a number of different practices that agencies can employ to shorten award cycles. Are there any recommendations that can be implemented immediately to shorten these cycles now?

A2. One recommendation is to expand the National Cancer Institute's SBIR Phase II Bridge Award pilot program. This is a three-year, milestone driven grant (up to $1 million per year for three years), which requires matching funding from angel or venture capital investors or larger firms. Another attractive aspect of the Bridge program is that many reviewers are employed at venture capital firms, pharmaceutical companies, and successful small firms.

It would also be useful if agencies (e.g.) adopted the SBIR review practices of the NSF. NSF Program Officers disaggregate grant applications by technical subject matter, choose reviewers with technical and business expertise as reviewers, and then include themselves on the review committee, to manage the review process. Permitting Program Officers to participate in the review process would accelerate the review process and also make it more predictable. It would also generate more useful interaction between the applicant and the SBIR program staff.

Question from the Honorable David Wu

Q1. As you are currently aware, last year, the Small Business Administration increased the standard limit for awards to $150,000 for Phase I and $1,000,000 for Phase II. Do you believe these standard limits are appropriate, or would you recommend that they be increased further?

A1. I believe that these standard limits are appropriate ($150,000 for Phase I and $1,000,000 for Phase II).

Questions from the Honorable Randy Neugebauer

Q1. What effects do you believe would result from allowing majority-owned venture capital businesses to compete for SBIR funding? Will it result in a decrease in competitive Phase I applicants?

A1. I support allowing majority-owned venture capital businesses to compete for SBIR funding. That is because I am convinced it will enhance the overall effectiveness of the SBIR program, in terms of job creation and economic impact. It will result in only a small decrease in competitive Phase I applicants and the efficiency gains more than make up for the loss of "equity."

Q2. How heavily do small businesses rely on the SBIR and STTR award programs for research and development funding? What overlap exists, if any, with any federal programs with similar goals and objectives?

A2. Small businesses are highly reliant on these programs for R&D funding. This program is somewhat unique, so there is only a slight overlap with other federal programs with similar goals and objectives.

Questions from the Honorable Chip Cravaack

Q1. There has been a great deal of discussion about the role of venture capital in both the SBIR and STTR programs. What do you think will be the impact of changing the current venture capital requirements on the program? Do you believe this will lead to an increase in rhe quality of applicants into the program?

A1. I am opposed to any restriction, pertaining to the program, on firms in which venture capital firms have a controlling interest (i.e., the 2002 Small Business Administration policy directive). The proposed compromise (which I presume you are referring to), which eases the restrictions on the involvement of venture-backed firms is a step in the right direction and will certainly lead to an increase in the quality of applicants.

Q2. I like the concept of allowing small businesses to compete for federal research dollars. After all, small business is the backbone of our economy. Can you discuss the economic impact of this program and if you feel Congress should allow a greater share of R&D funds to be targeted at small firms?

A2. The NRC committee I served on clearly documented that the SBIR program has a strong impact on the American economy. Having said that, I do believe the current "set-aside" for SBIR is optimal. Allocating a higher share of federal R&D (from federal agencies) to small firms would penalize universities and large firms. Although it is clear that small firms create most of the new jobs, it is less clear that small firms are more efficient in R&D than large firms (the empirical evidence on the question of whether there are "economies of scale" I R&D is inconclusive).

Q3. As Members of Congress, we all have a responsibility to ensure that tax dollars are being spent wisely. Do you believe that Congress should demand more accountability from the SBIR program in terms of its reporting data collection requirements? If so, in what ways?

A3. As stated in my testimony, I strongly advocate accountability for the SBIR programs (and all government programs). The best way to ensure this is to allow the NRC to evaluate the program on a systematic basis and ensure that sufficient data are collected to allow for a rigorous evaluation.

Q4. There have been several suggestions to shorten the award cycles in the program. Do you have any administrative concerns about this type of change? If so, what are these concerns?

A4. I have no concerns about shortening award cycles. We need to accelerate the time lag between research/discovery and commercialization. We have to stay ahead of our foreign competitors.

Questions from the Honorable Ben R. Luján

Q1. Do you believe that there is some positive aspect to tying a national laboratory's performance on technology transfer, technology maturation, commercialization, and job creation to the payments given to the operating contractor of each national laboratory for good performance? What metrics for technology transfer, technology maturation, commercialization, and job creation would you recommend?

A1. I applaud your suggestion. The national laboratories are the "last frontier," with respect to technology transfer. Most academic studies of technology transfer focus on universities, yet the national labs are even more important for certain types of early-stage research. For example, there has been considerable study of the effects of the Bayh-Dole Act, with little analysis of the impact of the Stevenson-Wydler Act and the Federal Technology Transfer Act of 1986 (my recent paper is a notable exception).

The first step is to collect better data on commercialization activies at federal labs. While there is an extensive AUTM survey of university technology transfer offices, there is no corresponding survey for technology transfer offices at federal labs. The metrics I would use are those in the AUTM survey, patents, licenses, sponsored research, and start-ups. I would try to construct broader measures of economic impanct, such as job creation. NRC would be an ideal institution for spearheading the collection and analysis of such data, under the auspices of FLC.

Responses of Mr. Mark Crowell, Executive Director and Associate Vice President for Innovation Partnerships and Commercialization at the University of Virginia

Questions from the Honorable Benjamin Quayle

Q1. In your testimony, you recommended that the programs provide flexibility to allow researchers with "manageable" conflict of interests to participate. Can you provide an example of a manageable conflict of interest? To what extent do you see university conflict of interest policies as inhibiting active academic involvement in SBIR or STTR projects? How might dissemination of best practices in managing conflicts of interest improve this problem?

A1. An example of a manageable conflict of interest would be a scenario where a university inventor who co-founded a start-up company (and who thus would have founder's equity in that company) would be able to be the PI on an SBIR or STTR subcontract from the applicant company back into this university laboratory. While this is a per se conflict, I see such a scenario as exceedingly healthy and, in fact, as one of many reasons that start-up companies represent an excellent path to market for university discoveries. Many universities would allow this; some would not; and most have some degree of angst and ongoing concern about whether a scenario of this sort would represent a manageable conflict.

Another more challenging—but still manageable—conflict of interest might be a scenario where a start-up company would like to lease available space in a university facility to establish "company facilities" in order to qualify as an SBIR or STTR applicant. In some cases, the conflict of interest inherent in such a situation could inhibit the university from leasing space to such a company. Tax regulations could also inhibit the ability of universities to allow start-up companies an opportunity to lease university facilities which otherwise are available.

I believe that best practices in conflict of interest management exist for managing scenarios of the types outlined above, and that these "case studies" of manageable conflict of interest should be made available to universities participating in SBIR or STTR programs. Many conflict of interest policy statements at universities are predicated on guidelines or policy issues promulgated at by federal agencies such as NIH. A proactive statement by Congress, or issued as policy guidance by NIH or other federal agencies funding SBIR and STTR programs, indicating support for entrepreneurially focused (but still robust) conflict of interest guidelines could be a tremendous boost for institutions to more aggressively seek to manage properly disclosed conflicts of interest.

Questions from the Honorable David Wu

Q1. As you are certainly aware, last year, the Small Business Administration increased the standard limit for awards to $150,000 for Phase I and $1,000,000 for Phase II. Do you believe these standard limits are appropriate, or would you recommend they be increased further?

A1. I believe these amounts are generally appropriate but as stated in my testimony, I believe that program officers should have the freedom to increase any award up to 20% beyond the published cap when exceptional circumstances and high impact opportunity are deemed to be represented in a particular funding project.

Q2. In your testimony, you recommend that the STTR program be modified in a way that would enable agencies to use a certain proportion of these funds to directly support additional proof-of-concept work at universities, including demonstration projects that would support proof-of-concept grants to universities and their faculty members. Can you tell us more about your proposal and how it might be implemented?

A2. I highly recommend that $10 to 20 million be identified within one or more federal agencies' existing set aside amount for SBIR/STTR and made available to fund a three-to-five year pilot "proof-of-concept" initiative at multiple universities—at $1 million per year per university. Among the criteria for these awards should be the demonstrated willingness and capability of a university in engaging project management boards comprised of industry, start-up, venture capital, technical, financial, and business/market experts. The review process for such funding should be high-touch and market focused, with corporate partner input and development milestones being key components for initial and ongoing funding. Such funding should be allocated after rigorous evaluation by carefully assembled panels of experts in translational and proof-of-concept research. Among the criteria for awards

under such an initiative should be the demonstrated willingness and capability of a university in engaging project management boards comprised of industry, start-up, venture capital, technical, financial, and business/market experts. Additionally, successful applicants for this funding should be required to prove their willingness and agility in managing translational projects stressing market-relevant milestones, in conducting rigorous oversight and management of such projects, and in their willingness to withdraw funding from projects failing to reach essential milestones so that funding can be re-allocated to projects with more potential.

Questions from the Honorable Randy Neugebauer

Q1. What effects do you believe would result from allowing majority-owned venture capital businesses to compete for SBIR funding? Will it result in a decrease in competitive Phase 1 applicants?

A1. I believe that allowing majority-owned venture capital-backed businesses to compete for SBIR funding will increase the quality of applications—and the impact and return on investment of such funding. As I stated in my written testimony, venture capital-backed companies have undergone extensive due diligence and a market-based valuation; I see no reason why the federal government would not want to support such companies and to speed their ability to grow and accelerate the development of their product(s). I also see no reason or evidence to suggest that there would be a decrease in competitive Phase 1 applications; in fact, I would predict that this change would result in an increase in quality Phase 1 applicants.

Q2. How heavily do small businesses rely on the SBIR and STTR award programs for research and development funding? What overlap exists, if any, with any other federal programs with similar goals and objectives?

A2. From my perspective as a university business development officer, I would suggest that SBIR and STTR award programs are extremely important to many university start-up companies. I don't have statistics on how many of our start-ups pursue such funding, but I would suggest that it is at least 35-50% of such companies—and growing fast. It is often perfectly-placed funding for a start-up company—initial capital desperately needed to advance the innovation toward initial commercially relevant proof-of-concept milestones, enabling many companies to launch with critically important momentum rather than languishing while investment capital is raised. It also offers many small companies an opportunity to leverage the investment provided by initial investors, again, accelerating the pace of proof-of-concept work and innovation. There really isn't any overlap that I see or know of with other federal programs with similar goals or objectives.

Questions from the Honorable Chip Cravaak

Q1. There has been a great deal of discussion about the role of venture capital in both the SBIR and STTR programs. What do you think will be the impact of changing the current venture capital requirements on the program? Do you believe this will lead to an increase in the quality of applicants into the program?

A1. I fully support revising the guidelines for SBIR and STTR to allow venture capital-based companies to compete for funding—and believe this will lead to an increase in the number and quality of applicants. Please see my answer to Congressman Neugebauer's question on this subject.

Q2. I like the concept of allowing small businesses to compete for federal research dollars. After all, small business is the backbone of our economy. Can you discuss the economic impact of this program and if you feel Congress should allow a greater share of R&D funded to be targeted at small firms?

A2. I believe that SBIR and STTR have been tremendously successful and should be continued. I also strongly support revising the programs to allow a portion of the set aside funds to support commercially relevant proof-of concept research which is essential to conduct before deciding whether to form a start-up company. I would be pleased to see increased funding to support these programs, but NOT at the expense of cutting current federal funding available for basic research. As noted in my written testimony, the success rates for Phase 1 SBIR and STTR grants is equal to, and in many cases, higher than the success rates for other equally important grants for basic research. Any increase in the current SBIR and STTR set-aside would come at the expense of other peer-reviewed basic and applied research—the seed corn for the innovation pipeline—so I recommend against increasing the set aside percentages.

Q3. As Members of Congress, we all have a responsibility to ensure that tax dollars are being spent wisely. Do you believe that Congress should demand more accountability from the SBIR program in terms of its reporting and data collection requirements? If so, in what ways?

A3. I do not recommend that Congress demand more accountability than currently exists in terms of reporting and related compliance requirements. This would seem counter-intuitive, in fact, and would divert attention of both funding officers and grant recipients. However, I believe that increased accountability and quality could and should be made part of the program by incorporating more private sector expertise on review panels, and by adhering to newly refined review and monitoring criteria which ensure that market-relevant and commercially-oriented milestone selection and monitoring are a requirement of SBIR and STTR awards.

Q4. There have been several suggestions to shorten the award cycles in the program. Do you have any administrative concerns about this type of change? If so, what are these concerns?

A4. I am not familiar with such suggestions and the rationale for them—so don't have an opinion that allows me to provide a direct answer to this question. But since I am recommending for a more rigorous review process, for certain changes in review criteria, and advocating for a new demonstration "proof-of-concept" activity with SBIR/STTR, I am disinclined to recommend shorter award cycles. Such a change would seem to require more administrative oversight and bureaucratic activity—and thus it's hard to see how this change would increase the quality, quantity, and impact of SBIR and STTR projects.

Questions from the Honorable Ben R. Luján

Q1. Do you believe that there is some positive aspect of tying a national laboratory's performance on technology transfer, technology maturation, commercialization, and job creation to the payments given the operating contractor for each national laboratory for good performance? What metrics for technology transfer, technology maturation, commercialization, and job creation would you recommend?

A1. I do believe such criteria would be extremely useful and impactful—provided, however, that attention is paid to enhancing the technology transfer capacity, resources, and environment within federal laboratories. Federal labs are treasure troves of outstanding science—and I have no doubt that much potential exists to leverage far more innovation impact from the great science and tremendous investment which is made in the research at such facilities.

From my experience, however, I believe that federal labs have far more hurdles to overcome in seeking to identify, protect, and translate importance discoveries into new products, services and businesses. Their technology transfer staffs are often small and inexperienced. Their policy environment and tolerance for conflicts of interest and commitment is established in a way which makes it extremely difficult for entrepreneurial scientists and technology transfer personnel to spin off start-up companies. In fact, in some cases, it seems that entrepreneurial scientists who wish to pursue such a path with their discoveries are almost required to leave the lab because of the way in which the conflict of interest is perceived. Other practices also exist which slow transaction time and creates obstacles, real and imagined, and which disincentivize investors, entrepreneurs and business development officers from doing deals with labs or from doing multiple deals with labs.

Notwithstanding the above, there are examples of remarkable entrepreneurial activity in federal labs. I am most familiar with the technology transfer division at Los Alamos National Laboratory, which has an entrepreneur-in-residence program; an entrepreneurial leave initiative; a relationship with a venture group through from which the lab obtains start-up counseling and early stage investment possibilities; an external commercialization advisory board (on which I sit as a member); and a long history of partnering with existing companies through licensing, CRADAs and related activities. And yet even Los Alamos, with its strong initiatives and success stories, struggles with more bureaucracy and related obstacles than a typical university would have to face.

I strongly support establishing incentives and metrics tying in performance in technology transfer to laboratory evaluation and performance payments, but believe this should include a robust effort to assess policies which make success for labs in carrying out these activities much more challenging than most universities have to face.

Possible metrics could include: number of invention reports; number of transactions with business and industry; companies launched and successful in raising early institutional, SBIR, or other peer-reviewed or market-based investment, in-

cluding amount of investment capital raised; patent strength indices (measuring citations of a labs patents in patent applications from other applicants); success by the lab or its commercial partners in hitting market-relevant regulatory or commercial development milestones related to product(s) based on lab research; potentially, jobs created in start-up companies; new commercial or investment partners signing confidentiality agreements, CRADAs, options, or related agreements; and others.

Q2. In your testimony, you specifically recommend that conflict of interest restrictions be examined and steps be taken to make it easier for researchers with disclosed and manageable conflicts of interest to participate in the SBIR and STTR start-up companies. Can you talk about this further and make specific suggestions about what should be done to improve the situation for both universities and national laboratories?

A2. Conflict of interest restrictions can interfere with the ability of entrepreneurial scientists and their institutions to move aggressively toward a commercialization opportunity for a given technology—especially in the case of start-up companies. In the case of universities, scientists with a significant financial interest in a start-up company (which they likely all will have because they typically receive founder's equity) sometimes are prevented from accepting research funding from the company, from consulting with the company, or from licensing further discoveries to the company. An additional layer of obstacles often exists at federal labs, where these conflicts may be more sensitive, tolerance thresholds lower, and absolute prohibitions of certain conflicts more numerous. Institutions themselves are also often seen as having conflicts—the institution may hold equity in the company via the license agreement and may stand to receive substantial royalties if the company is successful, and thus may encounter rules or barriers which prevent it from offering space, providing initial access to critical equipment (on terms other outside parties could obtain), conducting further research, and related company support activities.

I am very sensitive to conflict of interest and have certainly witnessed behaviors which provide clear examples of why conflict of interest policies are needed. But I've also witnessed far more examples of breakthrough products, new start-up companies, and academic-industry partnerships which had the potential to change the world and to create enormous economic impact as well. Conflict of interest policies should not stand in the way of such opportunities unless there is a compelling public interest requiring such a policy—an example, in my opinion, would be a policy (which most universities with medical schools have) preventing a professor with a significant financial interest in a company development a new drug or device from conducting clinical trials of that product.

Instead, conflict policies should be predicated on a regular and full disclosure within the institution; on a disclosure outside the institution (such as in publications) when the conflict is of a certain level or type; and on the creation of conflict of interest management plans for the vast majority of such conflicts where regular oversight and monitoring can allow the activity to take place in an open and reasonably objective way. Management mechanisms which can mitigate against conflicts (real and perceived) could include a regular interview by a conflict of interest management committee to make sure that normal academic milestones are being achieved (grants, publications, student progress toward degrees, etc.); full disclosure of conflicts on an institution website and on publications; independent documentation of scientific and technical reasons for supporting a start-up company's initial need to use a university lab or specialize core facility; an independent management or pre-determined formula for holding and liquidating institutional equity in start-up companies; and others.

Finally, at many institutions, and perhaps including federal labs most of all, conflict of interest may be more of a perception than a reality. Such conflicts still require full disclosure and proper management—but they also require a robust and strategic communication strategy on the part of the institution's management. If creating spin-off companies, commercializing products, and partnering with industry on their research challenges are indeed a key component of the missions of research institutions in today's economy—and I believe they are—then acknowledging that engagement in these activities is likely to create conflicts of interest is a message which institutional leadership should address on a regular basis. Acknowledging the reality of conflicts, the success of management mechanisms, and the importance of innovation and commercialization should mitigate many problems and encourage more scientists and outside partners to interact and partner with more confidence and success.

Responses of Mr. Doug Limbaugh, Chief Executive Officer of Kutta Technologies

Questions for the Record
The Honorable Ben Quayle

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs

Thursday, March 31, 2011
2:00 p.m.

QUESTIONS FOR MR. LIMBAUGH:

1. Outside of the SBIR and STTR programs, what opportunities do you see for small businesses to secure federal research and development funding?

   To my knowledge there are not a lot of opportunities for small companies to get involved directly with federal research and development outside the SBIR and STTR programs. However, I'm sure there are small companies that provide research and development services to federal labs and large prime contractors, but these types of arrangements do not allow the small company to retain intellectual property for commercial purposes like the SBIR and STTR programs do. It also does not allow the federal government to obtain the innovative ideas that are fostered as part of a small company's entrepreneurial culture.

2. How many jobs were you able to add as a result of your SBIR awards? Have been able to retain those jobs after your SBIR award funding ended?

   All of our staff of nearly 30 employees is sustained via SBIR grants or are a result of the commercialization of SBIR technology. We anticipate a 50% growth in business employment within the next year as our SBIR-based technology is manufactured and deployed to the military and commercial marketplace. Hiring will take place in all aspect of our business to include electronics technicians, manufacturing and administrative staff, as well as more highly-paid engineers.

Questions for the Record

The Honorable David Wu

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs

Thursday, March 31, 2011
2:00 p.m.

QUESTIONS FOR MR. LIMBAUGH:

1. As you are certainly aware, last year, the Small Business Administration increased the standard limit for awards to $150,000 for Phase I and $1,000,000 for Phase II. Do you believe these standard limits are appropriate, or would you recommend that they be increased further?

   I believe the amounts of $150K and $1M are at an appropriate level for a Phase I and Phase II, respectively. However, I believe the way the additional funding for the Phase I grants is distributed in a $80K Phase I and a $70K Phase I option is not ideal. That is, a company does not receive the Phase I Option funding unless a Phase II is awarded. This process of awarding the Phase I and Phase I Option funds is not ideal for the small business, creates extra contract overhead on the part of the government, and typically adds to the time of an award for the Phase II. In essence, it really did not add much to the actual Phase I funding amount. It does not help the small company perform more research or gather additional data to write a better Phase II proposal. It also does not reduce the government risks of building a quality Phase I prototype, which is typically a goal for Phase I.

   Keeping the funding to this amount forces a small company to think out of a box and gives the government enough time to determine if the small company is performing. If the company does perform good research and is making good progress toward a marketable prototype, Program Managers should have additional incentives to provide the company with additional funds. The commercialization pilot program (CPP) is great start at this.

2. In your testimony, you propose a competitive SBIR program at the Department of Commerce that would be open to all SBIR Phase II winners and would be focused on the marketing side, rather than the technical aspects, of commercialization. Can you provide us more detail on your idea for this program and how it would operate?

   I thought of the DOC grant process because so many SBIRs fall into the Valley of Death (a funding gap between Phase II and Phase III commercialization). A rough outline of a competitive program is as follows:

a. Allow Phase II SBIR and STTR awardees to submit a 25 page Sales and Marketing proposal to DOC after the first year of a company's Phase II work.
b. The Proposal should include:
    i. A brief overview of the marketing and distribution strategy.
    ii. An estimate of the domestic and international market size (commercial and military) for the product
    iii. A detailed strategy to introduce the product domestically and **internationally**
    iv. A strategy to leverage the grant funding and any outside funding mechanisms to complete the strategy (e.g. Commercialization Pilot Program funds, bank loans, lines of credit, leverage DOC international programs, venture capital funding, angel investor, etc.)
    v. A detailed Statement of Work (SOW) for the sales and marketing plan as well as a detailed budget.
c. Winners of the competitive grant would obtain $250K - $500K for sales and marketing services based on the SOW contained in the proposal.

I believe a program such as this would increase commercialization success of SBIR/STTR technologies and allow small businesses to start exporting their innovations around the world to help with the U.S. trade deficit.

Questions for the Record
The Honorable Lamar Smith

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs

Thursday, March 31, 2011
2:00 p.m.

QUESTIONS FOR MR. LIMBAUGH:

1. One of the more important aspects in H.R. 1425 involves how small businesses can leverage the technical resources of our Federal Laboratories. However, one of the onerous regulations one of my constituents who runs a small business in San Antonio recently faced in working with a Department of Energy laboratory was that he needed to provide upfront funding to the lab for the first 90 days of the project. Small businesses find it difficult to come up with such a large advance payment.

   We have never heard of a Federal Lab requiring upfront payment. This is also counter to most business relationships in which a party performing work for another party receives payments based on achieving specific milestones, meeting specifications with respect to deliverables or performing services on a predefined timetable. Furthermore, most businesses have typical payable terms (i.e. net 30) after an invoice for services or products are received by the purchaser. Paying up front is very onerous for any business, let alone for a small business. I would be surprised if a contracting officer working for the government and issuing a SBIR or STTR contract would allow an arrangement for advanced payments unless a company has a very good reason for it.

Questions for the Record
The Honorable Randy Neugebauer

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs

Thursday, March 31, 2011
2:00 p.m.

QUESTIONS FOR MR. LIMBAUGH:

1. What effects do you believe would result from allowing majority-owned venture capital businesses to compete for SBIR funding? Will it result in a decrease in competitive Phase I applicants?

I believe allowing a majority-owned VC funded business to compete for SBIR and STTR funds is counter to the original intent of the SBIR program. The competition for the grants will become more competitive amongst the VC-funded company, but I believe it will stifle the creativity and innovation that results from today's SBIR/STTR process. That is, the small entrepreneur will find it too difficult and will become unmotivated to participate in the program. Would you want to start a small company with two or three individuals, with very little cash flow and compete against multi-million dollar, well-capitalized firms? I would be concerned and think much harder about writing a SBIR if I knew my small company had to compete against a business with millions of dollars backing it. Most small companies participate in SBIR/STTR because they see a small opportunity in a market that they can exploit or find a technology that intrigues them intellectually. VC-funded companies do not think this way. VC-owned companies are motivated by a business case, not an intellectual passion to find a creative solution to a problem. Furthermore, VC-backed companies can throw additional money at their Phase I and Phase II efforts and give the impression of outperforming or out-innovating their truly small company competition. This will also lead to the government not obtaining Government Purpose Rights to utilize the technology for U.S. Government purposes because privately-funded IP lynch pins will be thrown into the intellectual property creating even more administrative and legal overhead for the government. These types of activities will be even more prevalent within the Department of Defense SBIR and STTR programs.
In my verbal testimony before the committee I suggested that large prime-contractors would set up VC-shell companies to funnel technology into their IP pipeline. The shell companies will plant IP seeds into the SBIR and STTR that will lock the government out of the rights to core technology and eventually lead to higher prices on military goods and services that result from SBIR/STTR technologies.

Currently, there is nothing preventing a small business to spin off a separate business or license its SBIR or STTR technology to VC-funded companies. If VC companies want to participate in SBIRs or STTRs let them seek out and find the companies that are willing to set up a separate

business or license their SBIR/STTR technology. I don't really understand the reason for allowing VC-backed companies to participate in the initial stages of the program.

2. How heavily do small businesses rely on the SBIR and STTR award programs for research and development funding? What overlap exists, if any, with any other federal programs with similar goals and objectives?

SBIR and STTR funding are the sole funding source for most small companies that participate in the program. However, as a small business matures, like Kutta has done, profits from commercialization allow us to internally fund research and development. I would imagine that there is overlap between Federal Labs and the SBIR/STTR program. However, I've never seen a concerted effort from our Federal Labs to advertise its research very well. I would suggest that the Federal Labs be required to query the SBIR/STTR solicitations for potentially overlapping research efforts and contact the winners of the Phase I grants to see how Federally-funded research could assist the small company in its SBIR/STTR efforts.

Questions for the Record
The Honorable Chip Cravaack

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs

Thursday, March 31, 2011
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QUESTIONS FOR MR. LIMBAUGH:

1. There has been a great deal of discussion about the role of venture capital in both the SBIR and STTR programs. What do you think will be the impact of changing the current venture capital requirements on the program? Do you believe this will lead to an increase in the quality of applicants into the program?

   I believe that allowing venture capital-funded companies into the SB IR program will result in a system where well-funded, venture-backed companies are competing with small, start-up companies for the same funding. The end result is that the very small companies will not be able to compete with the well-funded companies. The venture-backed companies will have the resources to hire professional proposal writers and business development experts to write and win SBIRs.

   I do not believe that allowing venture-backed companies to compete in the SBIR program will result in an increase in the quality of applicants, and actually the opposite could happen. Because the venture-backed companies will have the resources to write many SBIR proposals, they may be writing proposals that do not match well with their company goals and expertise, essentially becoming "SBIR mills" and flooding the SBIR system with their proposals. This is bad for both the SBIR program and small businesses.

2. I like the concept of allowing small businesses to compete for federal research dollars. After all, small business is the backbone of our economy. Can you discuss the economic impact of this program and if you feel Congress should allow a greater share of R&D funds to be targeted at small firms?

   Small business has much lower overhead than large business and is generally able to accomplish more with less funding. I agree that large business is needed to roll out products in large quantities, but to actually develop many of those products, small business can do just as well, if not better, than large ones. Small businesses are also more adept at handling changing requirements and quickly adapting to those changes. And providing more funding for small business can help prevent the practice of awarding large businesses large contracts simply due to name recognition or inertia.

I believe if the government awarded more contracts to small business, either through the SBIR program or other means, the financial impact to the government would be significant. Currently large businesses do have requirements to provide a certain percentage of work to small businesses. While this is good for small business, it is still tenuous for the small business because the large business still ultimately controls the purse strings. Additionally, the large companies have the advantage of being the prime, which allows them to charge overhead on the small business work. If more small business were allowed to act as primes, it would greatly reduce government overhead and most likely result in higher-quality products coming to market quicker.

3. As Members of Congress, we all have a responsibility to ensure that tax dollars are being spent wisely. Do you believe that Congress should demand more accountability from the SBIR program in terms of its reporting and data collection requirements? If so, in what ways?

   As a participant in the SBIR program I am not aware of specific reporting and data collection requirements. However, as a small company we fill out many forms and have to document our commercialization revenues that result from our SBIR technology. I would say the data reporting and collection as a participant seems sufficient. If Congress levies more data collection requirements on agencies that most likely mean that small companies would be saddled with more data entry and unpaid overhead.

4. There have been several suggestions to shorten the award cycles in the program. Do you have any administrative concerns about this type of change? If so, what are these concerns?

   I think that shortening the award cycles would be a very positive change to the program. I do not have any administrative concerns if this was done.

5. In your testimony you make several recommendations. As a former Naval Officer, I am most interested in your opinions on how this program can work better at the Department of Defense. Can you please talk about your experiences with DOD and any reforms specific to DOD that you think would improve this program.

   We have had a lot of success within the DOD SBIR process. We believe it is a well run program, but it could also be improved. Recommendations within the DOD are as follows:

   1. Shorten award cycles.
   2. Establish a more centralized SBIR contracting office for SBIRs that is separately funded so that contracts people within the R & D agencies don't look at SBIRs/STTRs contracts as a tax.
   3. Encourage more collaboration between the R & D agencies and the Acquisition agents. Provide better mapping of R & D grants to actual DOD requirements and acquisition needs.
   4. Educate and encourage more Phase III participation to decrease DoD acquisition cost and break-down proprietary barriers on almost every military platform.
   5. Increase funding to the commercialization pilot program.

6. I was also interested in your work on wireless communication devices. I represent 8th District of Minnesota, which has a proud history of mining. I was happy to learn that you have developed a two-way wireless communication device for the mining industry with

the help of the SBIR Program. As I understand your written testimony, this devise was originally developed for use by the army, but ended up being utilized by the Mine Safety Health Administration. I feel this type of collaboration should be encouraged, do you have any suggestions on how to make this happen?

I also believe it is important to foster collaboration between government agencies. It seems to us like the SBIR program is actually moving away from this, not towards it, at least in the Army. It appears as though the Army has put a great deal of emphasis of late on finding an "Army need" for SBIR technology, especially in the funding of the Commercialization Pilot Program (CPP). I completely understand the need for this from the Army's perspective, but I wanted to point out that the Army is not necessarily encouraging commercialization down other paths. I would encourage the SBIR program to encourage and reward all commercialization, including non-government. Commercializing technology helps mature and improve that technology, and in the long run, it could come back around to benefit the Army. One example is our radio product. We did not find an "Army need" during our Phase 2 contract, and because of that we were not awarded a CPP contract. But we did find a need in the mining industry, and now that the technology has matured, the Army 9-11th Technical Rescue team is very interested in it, as is FDNY. If we did not have the mining commercialization, we would not have found the Army and FDNY need.

Questions for the Record
The Honorable Ben Ray Luján

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs

Thursday, March 31, 2011
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QUESTIONS FOR MR. LIMBAUGH:

1. Do you believe that there is some positive aspect to tying a national laboratory's performance on technology transfer, technology maturation, commercialization, and job creation to the payments given to the operating contractor of each national laboratory for good performance? What metrics for technology transfer, technology maturation, commercialization, and job creation would you recommend?

   I would recommend that the Federal Labs be subjected to the same reporting standards as SBIR participants are required to do so – including the number of people employed at the labs and the economic impact from commercialization of the lab's research. However, these statistics should be viewed carefully. Federal Labs do research that is classified and the U.S. might not want to commercialized the technology very strategic reasons.

Responses of Ms. Laura McKinney, President and Chief Executive Officer of Galois, Inc.

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April 30, 2011

The Honorable Ben Quayle
Chairman
Subcommittee on Technology and Innovation
Committee on Science, Space, and Technology
U.S. House of Representatives

2321 Rayburn House Office Building
Washington, DC 20515-6301

Dear Mr. Quayle:

Thank you for the opportunity to appear before you on the March 31, 2011 hearing entitled, *The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs*, as well as the additional opportunity to respond to written questions submitted for the record by the Members of the Committee, as communicated to me in your letter dated April 18, 2011.

Please find enclosed my written responses to the Members' questions.

Thank you again for the opportunity to participate, and for the work you and the members of the Committee do on behalf of innovation and job creation across the nation.

Sincerely

Laura McKinney
CEO
Galois, Inc.

Enclosures: Member Questions and Ms. McKinney's Responses

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Questions for the Record
The Honorable Ben Quayle

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
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The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs

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QUESTIONS FOR MS. MCKINNEY:

1. How many jobs were you able to add as a result of your SBIR awards? Have been able to retain those jobs alter your SBIR award funding ended?

RESPONSES FROM MS. MCKINNEY:

1. Since 2005, Galois has received approximately $4,000,000 in SBIR Phase I and Phase II funding. While Galois does not hire personnel solely for the purpose of contributing to SBIR work, these awards have provided support for more than 20 one-year equivalent employees. Galois' $2.9 million in Phase III funding has supported an additional 14 one-year equivalent employees.

   Beyond the direct funding, it is difficult to quantify the contribution of the SBIR results to Galois' overall success. However, the ideas and inventions made under SBIR contracts have had a lasting impact on Galois' growth in other venues, contributing to job growth and increased value to the company.

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Questions for the Record
The Honorable David Wu

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
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The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs

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QUESTIONS FOR MS. MCKINNEY:

1. As you are certainly aware, last year, the Small Business Administration increased the standard limit for awards to $150,000 for Phase I and $1,000,000 for Phase II. Do you believe these standard limits are appropriate, or would you recommend that they be increased further?

RESPONSES FROM MS. MCKINNEY:

1. Galois considers these increased standard limits for awards to be appropriate for providing adequate funding to satisfy Phase I and Phase II objectives. We do not recommend that they be increased further at this time, since the priorities of the program are best served through a larger number of appropriately sized awards, particularly for Phase I efforts, rather than a smaller number of more substantial ones.

   However, some agencies choose to split the Phase I funding across a base and an option. This works against the increase in funding limits: when a Phase I base award is reduced to $60,000, for example, it is much more difficult to achieve meaningful Phase I goals.

   If the SBIR program is reauthorized for a significant period of time, it would be beneficial for the program to include an economically-based periodic increase in award size to ensure that the funding amounts remain adequate in the future.

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Questions for the Record
The Honorable Lamar Smith

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The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs

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QUESTIONS FOR MS. MCKINNEY:

1. One of the more important aspects in H.R. 1425 involves how small businesses can leverage the technical resources of our Federal Laboratories. However, one of the onerous regulations one of my constituents who runs a small business in San Antonio recently faced in working with at Department of Energy laboratory was that he needed to provide upfront funding to the lab for the first 90 days of the project. Small businesses find it difficult to come up with such a large advance payment.

   In your experience as a small business owner, have you found similarly onerous regulations in your work with the Federal labs? What do you think would be a reasonable requirement for upfront funding for joint projects between small businesses and Federal labs?

RESPONSES FROM MS. MCKINNEY:

1. Galois has engaged in work involving collaborators at multiple Department of Energy laboratories. We have not encountered any funding related obstacles, nor any onerous regulations in our work with these Federal laboratories. Our work is entirely focused on computer science research, and therefore does not require access to the kind of expensive lab equipment or facilities that may require additional access funding.

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Questions for the Record
The Honorable Randy Neugebauer

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1. What effects do you believe would result from allowing majority-owned venture capital businesses to compete for SBIR funding? Will it result in a decrease in competitive Phase I applicants?
2. How heavily do small businesses rely on the SBIR and STTR award programs for research and development funding? What overlap exists, if any, with any other federal programs with similar goals and objectives?

RESPONSES FROM MS. MCKINNEY:

1. One of the unique benefits of the SBIR/STTR programs is its ability to engage small, geographically dispersed innovators to address US government research needs. The introduction of venture capital companies will compromise this aspect of the program, leaving most regions of the country at a disadvantage. Maryland, Massachusetts, Virginia, Texas and California will be big winners, while Oregon and other states will be at a disadvantage.

   The argument has been made that venture capitalists increase the efficiency of funding by pre-screening technologies and markets. We believe that this assumption ignores the reality that venture capitalists use *geography* as a primary screening factor. It is extremely difficult to engage venture interest outside of certain favored regions.

   Right now, Oregon is highly competitive, with one study placing Oregon 5th in the nation at number of SBIR/STTRs won per 1000 PhDs. Venture capital investment will shift the playing field: researchers who have venture funding will be supported to write SBIR/STTR proposals and do preliminary research whereas others must self-fund. Thus, allowing firms that have already qualified for venture funding to compete will shift the pool of proposers, decreasing the diversity of the research base.

   Additionally, reduced RDT&E budgets are exerting downward pressure on large prime contractors. This potential change in the SBIR/STTR provides an attractive mechanism for them to recapture a share of lost market. A large prime could set up a 'captured' small company through venture funding and compete directly, thereby wholly subverting the intent of the SBIR/STTR program.

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2. The SBIR and STTR programs play a critical role in research and development funding for small businesses like Galois. They are unique in their emphasis on commercialization success of the research that they fund. Non-SBIR/STTR funding often has different metrics by which projects are considered successful, and these do not always mesh well with the needs of small businesses.

   While other government funded research programs address similar areas as the SBIR/STTR programs with respect to their impact in areas of relevance to the government and nation as a whole, they provide less incentive to bring products to market with a consequential wide impact on the country and economy.

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Questions for the Record
The Honorable Chip Cravaak

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QUESTIONS FOR MS. MCKINNEY:

1. There has been a great deal of discussion about the role of venture capital in both the SBIR and STTR programs. What do you think will be the impact of changing the current venture capital requirements on the program? Do you believe this will lead to an increase in the quality of applicants into the program?
2. I like the concept of allowing small businesses to compete for federal research- dollars. After all, small business is the backbone of our economy. Can you discuss the economic impact of this program and if you feel Congress should allow a greater share of R&D funds to be targeted at small firms?
3. As Members of Congress, we all have a responsibility to ensure that tax dollars are being spent wisely. Do you believe that Congress should demand more accountability from the SBIR program in terms of its reporting and data collection requirements? If so, in what ways?
4. There have been several suggestions to shorten the award cycles in the program. Do you have any administrative concerns about this type of change? If so, what are these concerns?

RESPONSES FROM MS. MCKINNEY:

1. The one compelling reason to allow venture funded companies is in domain areas where the capitalization required significantly exceeds that which is available through SBIR/STTR. In those domains, allowing venture funded companies to compete would increase the opportunity for the requisite research to be accomplished, and will lead to a consequential increase in the quality and range of applicants into the program.

   In other domains, where the Phase I and Phase II awards limits provide sufficient capitalization, introduction of venture funded companies will skew the applicant pool towards those geographic regions favored by venture firms, thereby decreasing quality and range of applicants into the program.

   Galois recommends that, just as the definition of a small business varies by industry, the allowance of venture capitally-funded companies be guided by the varied capitalization requirements of the industry. For pharmaceutical start-ups, venture funding may well be a

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necessity. For most DoD areas it is not, and in these areas venture funding should be disallowed to preserve diversity and competitiveness.

Since the SBIR/STTR program demonstrates extraordinary effectiveness against its stated goals, we recommend caution in playing with the basic tenets of the program.

2. As is widely acknowledged, small businesses are the backbone of the economy, and a key engine of innovation. Small businesses provide many of the breakthrough ideas that fuel sustained economic growth.

   To the extent that the nation's strategy calls for increasing innovation and economic stimulation, increasing investment in this area by increasing the proportion of R&D funds targeted to small businesses will have a corresponding impact.

3. The National Research Council of the National Academies has gathered a wealth of information regarding the overall SBIR/STTR program and presented this data in a compelling and useful manner. Additionally, the metrics on individual SBIR efforts continue stimulate the right kinds of activities from small businesses.

   At some point, increasing the number of metrics simply increases the administrative overload placed on the small businesses, and the additional overhead then works against the innovation goals of the program. In our view, the SBIR program's current reporting and data collection requirements appear to be just about optimal. We recommend leaving them unchanged.

4. In our original testimony we also called for shortening the award cycle, in particular reducing the gap between Phase I and Phase II awards.

   While we are unfamiliar with the precise suggestions being floated for new administrative procedures, we have a couple of recommendations. First, predictability about when the Phase II funding will start is even more important for planning and forecasting than simply shortening the average gap between Phase I and Phase II.

   Second, we consider it to be a mistake to split Phase I into a base and option, perhaps as a way to address the funding cycle issues. This effectively reduces Phase I funding, leaving too few resources in the base to be able to conduct a convincing demonstration of a breakthrough idea.

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Questions for the Record
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RESPONSES FROM MS. MCKINNEY:

1. Galois has numerous projects with national laboratories, including those in New Mexico. National laboratories fill a hole that has emerged in industry over the last few decades. By imposing strict requirements for a rapid transition of research to products, world-renowned industrial laboratories such as AT&T Bell Labs have largely stopped pursuing long term research. Yet it was this long-term research vision that led to much of the technology that we see today in common products, such as mobile phones and the Internet.

   The national laboratories are some of the last places in the country in which active, cutting-edge long-term research can take place, to push forward our national capability in science and technology. This freedom to push the boundary of human knowledge requires a relaxation of commercial constraints that would demand rapid technology maturation and transfer.

   Galois believes that basing the payments to the operators of national laboratories on metrics that encourage short-term commercial success at the cost of long-term vision could damage this critical national science resource that is key to keeping our country at the forefront of science and technology.

Appendix II

Additional Submitted Statements for the Record

MATERIAL SUBMITTED BY REPRESENTATIVE DAVID WU, RANKING MINORITY MEMBER, SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION, COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY, U.S. HOUSE OF REPRESENTATIVES

Puralytics

Hearing Testimony
Mark D. Owen
Chairman and CEO
Puralytics

Before the House Committee on Science, Space, and Technology's
Subcommittee on Technology and Innovation
On behalf of the SBIR Program
"The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs"
March 31st, 2011

Chairman Quayle, Ranking Member Wu, and Members of the House Committee on Science, Space, and Technology:

I appreciate the opportunity to provide written testimony today before the Committee regarding the Small Business Innovation Research (SBIR) grant program, which has for several decades provided a platform by which innovative, small companies can compete and participate in federal research and development programs directed at areas of national strategic interest. Surely water quality is becoming one of the greatest of those national interests, and is in significant need of new research, new development and new thinking as our nation moves forward.

My name is Mark D. Owen, and I am the Founder, Chairman, and Chief Executive Officer of Puralytics. Puralytics is a private, early stage company started in 2007, developing an innovative new technology for purifying water using a light-activated nanotechnology coating. We entered the market over the last year with two new products which are being used for decentralized drinking water and waste water solutions both in North America and in the developing world. I'm a serial inventor and entrepreneur with more than 30 patents granted or pending, and products involving my patents have generated more than $1B in revenue. I was previously the founding CEO of Phoseon Technology, which uses UV LEDs to dry inks, coatings, and adhesives in industrial processes.

National Strategic Interest in Water Quality Research:
Water plays a critical role in the health of our people, our environment, and our business community. 60-70% of the human body is made up of water, and our personal health is driven by a constant need to consume a continuous, uninterrupted supply of clean water. As we have seen in times of national crisis following a natural disaster, the need for clean water quickly rises to a critical concern. Even developed countries like the United States and Japan have found it very difficult to supply emergency water supplies in a crisis as we saw after Hurricane Katrina and still see following the tsunami in Japan. The United States is often on the front lines of emergency response to such disasters, and the need for new technologies for providing pure water onsite is of strategic national interest to the United States.

Even outside of crisis situations, our national water quality is in need of significant innovation. We have aging infrastructure, and our municipal water systems suffer more than 200,000 mains water breaks a year and water quality excursions are becoming increasingly more frequent. While most of the technologies in our municipal systems pre-date the 1960s, most of the industrial contaminants in our water supply, over 80,000, have been introduced since that time. The EPA is now monitoring 169 "endocrine disrupting compounds" which have been widely found in growing quantities in our water supplies, many of which cannot be continuously monitored or efficiently removed by any available technology. In providing for the public health, there remains an active strategic national interest in providing for state-funded research in water quality monitoring and treatment.

We have also seen the way water is tightly interlocked with our national energy policy and protection of the environment. All of the primary methods of generating energy require consumption of significant water resources, and failures in our energy supply system have drastic effects on our environment. Whether we point to the oil spill in the Gulf, the water quality impact of natural gas fracking in the Marcellus Shale, the lowering of the aquifers in the Midwest to support biofuel production, or the radiation spills near the nuclear reactors in Japan, we see that degraded water quality and damage to the environment is often the unintended byproduct of our pursuit of more energy. They are inseparably linked in what is now referred to in the industry as the Water-Energy Nexus, further emphasizing that water treatment is of critical national interest to the United States.

Water availability and water quality are also of critical importance to the viability of our business community. Production of integrated circuits and solar power cells requires large volumes, typically thousands of gallons per minute, of water purified well beyond municipal drinking water standards to ultrapure standards. Food production requires safe water to grow, clean, and prepare. The electronics industry consumes water to cool server farms and computers. In virtually every industry, the need to purify water beyond drinking water standards for processing and the need to remove contaminants from process waste water is critical.

Clearly, the link between our national interest in health, safety, economic viability, and long-term prosperity and the quality of our water demand an ongoing interest in government funded research into these critical areas.

Critical Role of the SBIR Program:
Congress authorized the SBIR grant program in 1983 in order to stimulate and utilize the capabilities of smaller, innovative, domestic companies to address research and development of national interest. Linking the research requirements of various departments of the government to direct allocations, and allowing flexibility of the departments and agencies to define their own SBIR programs is a great strength of the program. Like the nation, the needs of water technology in the government varies significantly across departments and agencies, and Puralytics has seen research calls from NASA, the ARMY, EPA, NAVY, and NSF which were each looking at various aspects of water monitoring and treatment technologies.

Puralytics has received both an ARMY and National Science Foundation SBIR research grant. These two contracts were:

- Jan-Jun, 2009: US Army SBIR Phase I Contract W911QY-09-C-0040 for a "Greywater Recycling System for Mobile Kitchens and Sanitation Centers"
- Jan-Dec 2010: NSF SBIR Phase I & Phase IB Awards IIP-0945901 for a "Novel UV Photocatalytic Process for Removing MTBE from Water"

The timing of receipt of these grants was formative in the development of our company. Water purification technology requires 3rd party validations, and very expensive laboratory equipment is required to assess the removal of critical microbiological, organic and inorganic contaminants. Through the grants we have received, we have been able to build a set of test data and 3rd party relationships that continue to be important in driving the company forward. Additionally, these grants were received during the trough of the financial crisis, when virtually every source of financing was constrained. Our NSF grant was expanded under the Stimulus Package, enabling progress through a critical stage of our company's growth.

Recently, our technology has been awarded several industry awards, including the National Grand Prize in the Cleantech Open, the first time a water technology company has ever won this award. We were also selected by an audience of water industry executives and water legislators here in Washington, DC to be the Best Water Investment of 2010, through Global Water Intelligence's Water Investment Idol competition. We've been named Finalist in the ImagineH2O water-energy Nexus Prize, and were named a Top 50 Water Technology Company by The Artemis Project. In each of those competitions, the validation which came from a successful SBIR grant was important to our success.

Positive Aspects:
SBIR funding is an excellent opportunity for small businesses to address research objectives of national interest. Phase I funding in the $70-150k range is enough to actually test feasibility of a concept that is well-aligned with goals of both the small company and a sponsoring agency. The goal of Phase I work is to demonstrate product feasibility and wrap a business plan around the product that is strong enough to justify substantial ($500k+) further investment by the agency in Phase II. Phase II needs to actually develop the basis for a successful business over a further two years of development. Support from the sponsoring agency after each project was funded has been good in our experience, both in aligning Phase I work to the agency's needs and in preparing a Phase II proposal that will meet the Agency's expectations.

The Army provided access to a cadre of independent advisors that gave guidance on what to include in the Phase II proposal, as well as how to present the case. The message we got as grantees was that the Army needs a better solution to recycling greywater in field kitchens and they wanted us to succeed in producing that solution.

NSF has a strong education program for all Phase I grantees, with a two-day mandatory conference each year that teaches grantees what they need to do to get Phase II funding. NSF also makes clear that the primary goal of their SBIR program is to foster healthy companies that produce viable products and thereby create US jobs. This seems like it is or should be the primary goal of all SBIR funding, and the clarity of the NSF mission is refreshing.

Negative Aspects:
SBIR programs have a "one size fits all" approach that is intended to move concepts to successful products in companies that employ <500 people. As a <10 person company, we found that we were at a disadvantage in applying for NSF Phase II funding because reviewers viewed us as having insufficient resources to complete a practical Phase II development program. It is clearly a challenge for small businesses to overcome that hurdle.

Secondly, the timeline for SBIR funding is too long for a small business. Typically Phase I funding is received 6-9 months after submitting a proposal, and Phase 2 funding is spread out over a subsequent two years. For a small company, that means up to three years from submission to commercialized product. A small company may not have the luxury of waiting a year to determine whether a product is feasible,

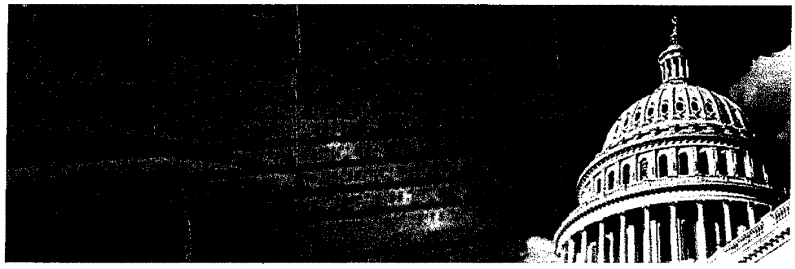
since the whole company may need to have that product in the market in a year to be viable. Streamlining this process would be a significant advantage in fostering small businesses.

Thirdly, there is not a great link between solving a research need through the SBIR program and actually becoming a solution provider to the sponsoring agency or department that originally stated that need. I think an improvement to the program would allow a phased analysis of the government's requirements and a fast tracking of technologies funded, developed and commercialized through the SBIR program.

Finally, although we have been able to successfully use the SBIR program to finance research and validate our technology on problems of significant national interest, there are other problems which prevent wide scale implementation. The EPA SBIR program is the only program linked to a testing protocol which can certify a new water purification technology for commercial use. It would be appropriate that a Phase 1 awardee be allowed to apply for Phase 2 grants in other agencies within the SBIR program.

Again, thank you for providing me with the opportunity to testify today before the Subcommittee.

MATERIAL SUBMITTED BY REPRESENTATIVE JOHN P. SARBANES, SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION, COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY, U.S. HOUSE OF REPRESENTATIVES



AN OPEN LETTER FROM EXECUTIVES OF U.S. SMALL BIOTECHNOLOGY & MEDICAL DEVICE COMPANIES REGARDING SBIR REAUTHORIZATION & INCREASING THE NIH SBIR INTERNAL ALLOCATION

March 18, 2011

Chairman Graves & Ranking Member Velazquez
House Committee on Small Business;

Chairwoman Landrieu & Ranking Member Snowe
Senate Small Business Committee;

Chairman Hall & Ranking Member Johnson
House Committee on Science, Space, & Technology;

Chairman Quayle & Ranking Member Wu
House Subcommittee on Technology & Innovation;

Dear Honorable Chairpersons & Ranking Members,

We, the undersigned leaders of small U.S. biotechnology and medical device firms write in strong support of the SBIR/STTR Reauthorization Act of 2011 (S. 493).

Today there is limited access to capital for companies developing cutting edge, early stage technologies that can cure or ameliorate disease while creating substantial numbers of new high wage jobs. The SBIR/STTR program has therefore become a primary and essential funding source for most small biotech and medical device companies throughout the country. Many important medical products now on the market were developed with funds from the SBIR/STTR program.

While we fully support this legislation we respectfully urge that the SBIR/STTR allocation at the National Institutes of Health (NIH) be increased by at least one percent for each of the next three years.

In considering our request please consider the following facts.

- For more than a decade, small business has created more than 2/3 of all new science & engineering jobs in this country and continues to sustain 38% of all science & engineering jobs nationwide. These high-paying jobs knowledge industry jobs often average $60,000+ per year.
- Small businesses receive only about 2.8% of NIH funding (4.3% of all federal R & D funding). Academic institutions are awarded over 97% of NIH's funding, and as much as 32% of all Federal R & D.
- The number of SBIR/STTR grant applications at the NIH is at an all time high while the percentage receiving funding are at an all time low. 2010 applications increased by 40% from the prior year while the number of applications that received funding plummeted to 17.0% from 24.5% in 2009.
- Small businesses apply for 38% of new patents, 12 times more than the number of applications filed by academic institutions, and at 1/35 the cost.
- Firms receiving SBIR grants now account for nearly a quarter of *R&D 100 Awards*
- The Biomedical Research Authority of the European Union awards about 15% of their research funds to small businesses, and other countries are following suit.
- The SBIR/STTR allocation was removed from the NIH stimulus funding on the eve of passage due to behind-the-scenes lobbying by the academic community.
- Small technology companies lead translational science, transferring the majority of technology breakthroughs to the public. This translates to better medicines and better diagnostic devices that lead to a healthier society.
- The SBIR/STTR program represents a path to translate discoveries made by academic, government and non-profit institutions, funded by NIH, into valuable products and new jobs, leveraging the enormous investment in basic research.

Many of us have advanced scientific degrees and have extensive experience in working in or with nonprofit biomedical research institutions. We understand both the value

and limitations of academic research with respect to developing and commercializing innovative technologies. While academic research often serves as a foundation for our work, the true costs and risks of bringing biomedical products to market are overwhelmingly borne by companies. This reality is not reflected in the current NIH funding paradigm which provides disproportionate funding to academia.

The gross funding imbalance at the NIH—a result of persistent lobbying by the university community – hinders the ability of small companies to deliver lifesaving drugs, diagnostics and devices to patients as quickly as can be done with critical, early stage government funding. Timely delivery to the market of new products by innovative companies creates job growth in fields as diverse as manufacturing and marketing. In contrast, research projects by academia are often sustained solely with perpetual government funding

We recall that the academic lobby vigorously fought the creation of the SBIR program when it originated in the early 1980s. They argued then that the NIH in particular should devote 100% of its external funds to university based research. Over the past 30 years, SBIR funded companies have delivered hundreds of successful products to market and each year are responsible for nearly one quarter of *R&D Magazine*'s list of 100 top innovations. Numerous studies by the National Academies of Sciences and others have documented the enormous success and productivity of the SBIR program which has become a global model duplicated in several other nations.

Expansion of the allocation at the NIH specifically is warranted because other agencies like DOD have an array of contract and grant programs for which companies can fairly compete. At the NIH, where funding priorities and review criteria are established by academia, companies win less than 0.1% of funds outside of the SBIR/STTR programs.

Importantly, the proposed modest increases in the SBIR/STTR allocations do not increase the Federal deficit and could be implemented without any reduction in government supported research by nonprofit entities. A mere 1% decrease in the overhead rates to all NIH grantees should permit at least a doubling of the current SBIR/STTR allocation.

In conclusion, we respectfully urge prompt reauthorization of the SBIR/STTR program with an increase in the allocation at the NIH to help us launch products that cure disease, promote human health, and create sustainable new jobs.

Sincerely,

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