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FULL COMMITTEE HEARING ON THE IMPORTANCE OF TECHNOLOGY IN AN ECONOMIC RECOVERY

HEARING

BEFORE THE

COMMITTEE ON SMALL BUSINESS
UNITED STATES
HOUSE OF REPRESENTATIVES

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FULL COMMITTEE HEARING ON THE IMPORTANCE OF TECHNOLOGY IN AN ECONOMIC RECOVERY

Wednesday, April 22, 2009

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Committee met, pursuant to call, at 1:09 p.m., in Room 2360, Rayburn House Office Building, Hon. Nydia M. Velázquez [Chair of the Committee] Presiding.

Present: Representatives Velázquez, Moore, Dahlkemper, Ellsworth, Sestak, Bright, Graves, Luetkemeyer, and Thompson.

Chairwoman VELÁZQUEZ. I call this hearing of the Small Business Committee to order.

As Americans, we take great pride in our ability to innovate. Let's not forget, it was our engineers who created the Model T; our scientists who sent the first man to the moon; and our tech entrepreneurs who created the world's favorite new distraction. Yes, we can all thank Mark Zuckerberg for Facebook.com.

From cyberspace to the health care sector, this country has an impressive track record of innovation. While the economy may be suffering, that pioneering spirit is still alive and well. This is largely thanks to our nation's entrepreneurs. If we have learned anything from the economic crisis, it is that the policies of the past do not work.

We need to change the way that America does business, beginning with an increased focus on small firms. Those are the companies bringing fresh ideas to the table and new products to market. In fact, entrepreneurs produce 13 times more patents per employee than big businesses. Much of that innovation is powered by research and development grants, the largest of which is the Small Business Innovation Research, or SBIR, program.

In today's hearing, we are going to take a look at that initiative. We will examine its role in spurring innovation and discuss obstacles preventing SBIR from reaching its full potential.

Since first established in 1982, SBIR has helped launch tens of thousands of successful research projects. Every year, the program makes a $2.2 billion investment in small firms, an infusion that gets 1,500 new companies off the ground. It also serves as a driving force behind our most inventive businesses. As a result of SBIR, we have seen breakthroughs in everything from antivirus software to wireless technology for BlackBerrys. But the program doesn't just spark new ideas; it helps generate jobs, too.

High growth start-ups, the kind that receive SBIR grants, are prolific job creators. In fact, the employment growth rate for these businesses is nearly four times of that of bigger firms. Meanwhile, 40 percent of all high-tech workers, from engineers to computer programmers, are employed by these kinds of companies.

The only thing more impressive than the jobs created through SBIR are the products that come out of it. Year after year, SBIR-backed businesses account for a quarter of U.S. R&D winners. And yet it is clear that the initiative has not reached its full potential. The majority of products developed through the program never make it to market. There are a number of reasons for this, not least of all being a lack of capital.

Innovation is a resource-intensive process. It takes time and money to carry a new product from the laboratory to the marketplace. As a result, entrepreneurs often struggle to bridge the gap. SBIR-backed firms should have access to all of the tools they need, including venture capital. At a time when capital is increasingly hard to come by, it doesn't make sense to limit funding options for small businesses. It should be up to entrepreneurs themselves, not Washington bureaucrats, to decide how these firms are financed.

Last Congress, the House passed a bill to modernize and extend SBIR. Unfortunately, that legislation never made it out of the Senate. With people losing their jobs and businesses closing their doors, programs like SBIR need to be running at full capacity, especially considering the role that entrepreneurs play in economic recovery. These are the businesses willing to take risks and help rebuild our economy. With the necessary tools, they can lay the groundwork for a better, more innovative way of doing business.

I am pleased our witnesses can join us today, and I thank them in advance for their testimony.

With that, I yield to ranking member graves for his opening statement.

[The statement of Chairwoman Velázquez is included in the appendix at page 39.]

Mr. GRAVES. Thank you, Madam Chair.

I appreciate everyone taking the time to be with us here today about the Small Business Innovation Research, or SBIR, program. We have quite a few witnesses here that we will be hearing from, and I am going to give some brief remarks right now.

Today's hearing represents the beginning of the committee's work to review and reauthorization the SBIR program. Today we will focus on how the SBIR reauthorization can be better structured and its role as a vehicle of early stage development of innovative technologies. This program is an example of a highly successful Federal initiative designed to encourage economic growth and innovation within the small business community. Government assistance and funding can be critical to the start-up and development stages of small businesses. Not only does it spur growth in individual companies, the program stresses the importance of expanding and diversifying research opportunities to small businesses.

Created in 1982, the SBIR program offers competition-based awards to stimulate technological innovation among firms while providing government agencies new, cost-effective technical and scientific solutions to meet their diverse needs.

The development of this program is not only critical to the unique needs of each of the participating Federal agencies but also to our national economy. Small businesses invigorate the U.S. economy by introducing new products and cheaper ways of doing business, sometimes with substantial economic benefits. They play a key role in introducing products to the markets, often responding quickly to new market opportunities. Some of the greatest technological innovations came about from small business owners tinkering in their labs and workshops.

The SBIR program provides those innovators with an opportunity to grow their ideas into practice, provide jobs, and improve our economy.

I remain hopeful that legislation drafted by the committee will maintain the integrity of the program while not limiting participation. We must work to find an appropriate solution that funds the best science while wisely investing taxpayer dollars.

The SBIR program's track record speaks for itself. I am eager to hear the testimony this afternoon.

I look forward to working with you, Madam Chairwoman.

Chairwoman VELÁZQUEZ. Thank you.

I welcome the witnesses of our first panel.

Chairwoman VELÁZQUEZ. Our first witness is Mr. Edsel Brown.

Mr. Brown is the assistant administrator for the Office of Technology in the Small Business Administration. The Office of Technology promotes the Federal Government's high technology programs designed to improve the competitive capability of small research and development businesses.

Welcome, sir. You have 5 minutes.

STATEMENT OF EDSEL M. BROWN, JR., ESQ.

Mr. BROWN. Madam Chairwoman, Ranking Member Graves, and distinguished members of the committee, thank you for inviting me here today to discuss the Small Business Innovation Research program. I am Edsel Brown, assistant director, Office of Technology of the Small Business Administration. My office has responsibility for innovation policy and programs at SBA and for oversight of the SBIR program.

The SBIR program, established in 1982, was designed to strengthen the role of innovative small business concerns and federally funded research and development, and to utilize Federal research and development as a base for technological innovation to meet agency needs and to contribute to the growth and strength of the nation's economy.

This competitive award program attempts to promote innovation and commercialization from small companies by restricting a portion of 11 Federal agencies' external R&D spending to small business.

A National Academy of Science review of SBIR concluded that the program is sound in concept and effective in practice, meets its major congressional objectives, and is a driver of innovation and commercialization for small business. Since its inception, the program has awarded more than $24 billion to small firms.

The program is structured in three phases. Phase I awards provide up to $100,000 to evaluate the feasibility and the scientific

and technical merit of an idea. Phase II awards are funded up to $750,000 for 2 years for the further development of ideas initiated in Phase I. In Phase III, the awardee firm must either secure private sector investment to bring the innovation to market or obtain follow-on contracts with Federal agencies to meet specific agency technology needs.

SBA and the SBIR participating agencies recognize the importance of assessing the SBIR programs' outcomes and achievements. The recent National Academy of Science study provided a first step toward assessing the program. The recent National Academy of Science study found that SBIR is increasing innovation, encouraging participation by small companies in Federal R&D, providing support for small firms own by minorities and women, and resolving research questions for mission agencies in a cost-effective manner.

The study's findings highlight the SBIR program's contribution to job growth. SBIR awardees generate approximately 26 more jobs after SBIR funding.

Commercialization: Nearly 50 percent of SBIR Phase II awardees bring their innovations to the marketplace.

And small business reach: From 1992 to 2005, nearly 15,000 SBIR awards were made to small business.

An example of a success story is ArmorWorks, LLC. ArmorWorks has developed a high-performance, low-cost composite armor system for the U.S. Marine Corps new expeditionary fighting vehicle. ArmorWorks developed their composite armor system in response to a Navy requirement for a lightweight armor component that could be affordably produced and assembled.

Since 2004, ArmorWorks has won contracts from the Army and Marine Corps to provide armor technology. The technology is presently being used to provide extra armor for protective vests worn by marines and soldiers serving in Iraq and Afghanistan.

Again, this story is just one of many. The story clearly illustrates the SBIR program at its best, assisting small companies to leverage their resources and providing the country with cutting edge technology and innovation.

Another measure of success by the SBIR program is that it is being replicated elsewhere. Countries from across Europe, Asia and Latin America are establishing innovation programs based on the successful SBIR model.

Thank you for the opportunity to appear before you today. I will be happy to answer any questions you have.

[The statement of Mr. Brown is included in the appendix at page 43.]

Chairwoman VELÁZQUEZ. Thank you, Mr. Brown.

Our next witness is Mr. Michael Caccuitto. Mr. Caccuitto is the assistant director of the Office of Small Business Programs, SBIR and STTR Program Administration for the Department of Defense. The Office of Small Business Programs is responsible for developing policies to guide the Department of Defense efforts to meet small business procurement goals and objectives.

Welcome.

STATEMENT OF MICHAEL CACCUITTO

Mr. CACCUITTO. Thank you, Chairwoman Velázquez, Ranking Member Graves and members of the Small Business Committee.

Thank you for this opportunity to testify on the Small Business Innovation Research Program. I welcome the opportunity to provide a perspective on how the program is implemented and managed within the Department of Defense.

Consistent with program guidelines and mandates, the program is used principally as a tool for the Department of Defense to seed innovation in our industrial base and, in so doing, develop leading-edge technologies with the potential to enable acquisition of lower cost or new war fighter capabilities through the marketplace. Now more than ever, we need to leverage the responsiveness, efficiency, and capacity to innovate of our nation's small businesses.

By way of our brief overview of the DOD SBIR program, it is comprised of 12 military departments and defense agencies with oversight and central administration provided by my office, the Office of Small Business Programs DOD. This model of centralized administration and decentralized management and execution allows each participating component to tailor the program to meet their unique and diverse mission needs.

The largest three participants in the program are the Air Force, Navy and Army, which together constitute about three quarters of our overall DOD budget.

The DOD program is the largest among the Federal agencies. The budget for fiscal year 2008 was nearly $1.2 billion. This funding supported over 1,800 new Phase I contracts and over 1,000 new Phase II contracts.

Interest in the program is intense among small businesses. For the past 7 years, the department has received over 12,000 proposals per year. The competition remains very strong, with only the very best proposals getting funded. Historically, about one in six proposals in Phase I get funded, and about 50 percent of those move on to Phase II.

The defining characteristics of the applicant firms have remained fairly consistent over time. Contracts are awarded in every State to firms of all qualifying sizes, and to a great extent to firms that are new to the program in DOD. Additionally, about 30 percent are awarded to small businesses owned or controlled by socially or economically disadvantaged individuals, women-owned small businesses, veteran-owned small businesses, and small business concerns located in hub zones.

While it is relatively easy to identify specific SBIR funded firms, or particular technologies that have contributed to our missions, it is difficult to accurately quantify the broader impact of the SBIR program on the economy.

While in the course of administering the program the department tracks the number of employees of participating firms, we do not collect data specifically measuring job creation. However, we can estimate job creation or sustainment by calculating the employment associated with both the SBIR budget expenditure and reported commercialization, or market or Phase III activity derived from extending or logically concluding SBIR funded work. DOD has collected this type of data for the past 9 years.

Using a conservative conversion factor, the DOD SBIR funding supported the creation or sustainment of between 9,000 and 16,000 jobs per year between fiscal years 2001 and 2008. While reported commercialization in the form of follow-on sales or investment supported the creation or sustainment of between 10,000 and 37,000 jobs per year.

This estimate is believed to be conservative as many firms outgrow the program, are acquired by larger firms, or otherwise do not continue to participate, and thus report to us. Additionally, they do not account for spillover effects of knowledge generated through the program that create or effect other market activity.

On the other hand, this process of jobs creation sustainment has opportunity costs associated with it and uncertainties also, and should be therefore considered with some degree of caution and care.

I thank you for the opportunity to testify on the program today, its size, its scope, and impact to DOD. I hope my testimony provides you with an understanding of how the program works. I would be happy to answer any questions you have.

[The statement of Mr. Caccuitto is included in the appendix at page 47.]

Chairwoman VELÁZQUEZ. Thank you.

Our next witness is Ms. Jo Anne Goodnight. She is the NIH SBIR/STTR program coordinator to the Office of Extramural Research in the National Institutes of Health. The Office of Extramural Research administers grants accounting for 84 percent of the NIH's $29 billion budget, including grants to small research companies.

Welcome.

STATEMENT OF JO ANNE GOODNIGHT

Ms. GOODNIGHT. Thank you.

Good afternoon, Chairwoman Velázquez, Ranking Member Graves and committee members. Thank you for the opportunity to discuss the NIH SBIR program and the importance of technology in an economic recovery.

NIH is one of the largest funders of the SBIR program, and the largest supporter of biomedical research that focuses on extending health life and reducing the burdens of illness and disabilities.

The SBIR program is poised to fund early stage high-risk and high-quality research from which important medical advances can be developed. This fiscal year, the total SBIR and STTR set-aside is about $672 million.

NIH SBIR projects are stories of igniting imaginations and spurring new discoveries that can make a difference in people's lives. For example, several companies in New York are focused on detecting, diagnosing, or treating Lyme disease.

Altea Therapeutics, a Georgia company, developed a needle-less infusion patch called the PassPort System for painless and controlled delivery of drugs such as insulin, or vaccines, such as hepatitis B antigen, through the skin.

Three Rivers Holdings, an Arizona company, focused on assistive technology and developed better wheels for wheelchairs. The

SmartWheel optimizes wheelchair use to root out causes of chronic pain on the shoulder, hand or wrist.

Lickenbrock Technologies, a Missouri company, developed a 3-D imager that helps doctors monitor and treat diabetics for eye diseases.

And a Florida firm, Biopsy Sciences, developed the HydroMARK, a novel site marker used in breast biopsy ultrasound procedures.

Stories such as these come from companies all over the United States and underscore the importance of SBIR to our mission. In support of the goal to increase commercialization of federally supported R&D, NIH offers programs such as the Fast-Track and Competing Renewal award to help awardees negotiate the agonizing period between discovery and commercialization, the so-called valley of death.

In addition, NIH offers commercialization assistance programs and facilitates matchmaking through the NIH pipelined partnerships.

NIH is pleased that a recent study conducted by the National Research Council found that 40 percent of NIH SBIR-funded projects are commercialized. Further, using a dynamic monitoring system to track continued achievements over time, we have found that about 50 percent of our awardees have achieved sales. Other factors, such as FDA approvals, strategic partnerships and investments, also demonstrate program success.

Economic impacts can also result from an SBIR award. For example, job growth, the theme of today's hearing, the study found that small businesses serve as potential sources of economic vitality and can be an important source of new employment as a result of NIH's SBIR funding. Companies hired an average of 2.7 full-time employees and retained 2.2 FTEs that otherwise would not have been retained.

NIH attributes the success and effectiveness of its program to several factors. The most significant of these is flexibility in our administration of a program to address the changing nature of biomedical research and accommodate the needs of multiple industries and diverse product outcomes.

Examples include the ability of companies to propose their own project ideas, an opportunity to resubmit an unfunded application, and the ability to exceed award guidelines in justified cases. Simply stated, one size does not fit all. Flexibility is critical at a time when science is changing rapidly, becoming more complex and ever-more expensive.

Despite program flexibility and enhancements, we have observed some troubling trends. Specifically, the number of SBIR applications declined from fiscal years 2004 through 2008 by nearly 40 percent. Though the reasons are not fully understood, this disconcerting trend may be related to certain disincentives that are either rendering worthy companies ineligible or driving them away for other reasons.

For some, the award amounts or current phase structure are not sufficient incentives for applying. For others, the process is too competitive. Others may have lost eligibility or be confused about eligibility criteria.

New companies may find the process daunting or are unsure of how to match their skills with our research areas. Appropriate incentives can strengthen the role of small businesses in stimulating technological innovation during the economic recovery period.

In conclusion, I want to reemphasize the NIH commitment to supporting small businesses and maintaining the integrity of the SBIR program. We look to small businesses to stimulate technological innovation, help us face new challenges, and produce benefits for the public.

We look forward to working with Congress on ways to reinvigorate the program, incentivize America's small businesses to participate, and create an environment enabling commercialization of health-related products and services that will sustain our national economy.

This concludes my statement. I will be pleased to answer any questions you may have.

[The statement of Ms. Goodnight is included in the appendix at page 62.]

Chairwoman VELÁZQUEZ. Thank you, Ms. Goodnight.

Our next witness is Mr. Larry James. Mr. James is the acting SBIR/STTR program manager in the Department of Energy's Office of Science. The Office of Science has managed the SBIR program for the Department of Energy since the program was founded in 1982.

Welcome.

STATEMENT OF LARRY JAMES

Mr. JAMES. Thank you.

Chairwoman Velázquez, Ranking Member Graves and other members of the committee, thank you for inviting me to speak today about the Small Business Innovation Research Program at the Department of Energy.

The Office of Science manages the SBIR program for the Department and has done so since the program was formed in 1982. The SBIR program is regarded within the Department of Energy like any other program, namely, as a vehicle for which the Department accomplishes its R&D objectives. The Office of Science's long history of using merit-based review of grant applications and its thorough understanding of scientific and technical research are key elements in the Department's program.

Cooperation throughout the Department in administering the SBIR program is a key to the success of the program. The Department issues an annual combined solicitation for the SBIR and STTR programs. Proposals are awarded through a rigorous merit-based review process.

Many of the SBIR awardees have excellent skills in science and engineering research but lack experience in product development, financing business growth, raising venture capital, and marketing. Because commercialization of innovations derived from Federal R&D is critical to its mission, the Department provides funding for technical assistance, including commercialization.

The National Research Council's 2008 assessment of the SBIR program at the Department of Energy noted that the DOE SBIR program has made significant progress in stimulating technological

innovation in three important ways: one, by generating patents and publications; two, by stimulating a transfer of technology from universities to the market; and three, through indirect paths, for example, through knowledge transferred to other related projects.

In addition to the potential for commercial success, SBIR-funded innovations advance the DOE mission in critical areas.

The lithium ion battery developed by A123 Systems, for example, has an unprecedented combination of safety, power and long life compared to previous lithium ion batteries. A123 Systems and Chrysler recently announced a strategic partnership whereby A123 Systems will supply the energy storage systems for Chrysler's first iteration ENVI electric vehicles.

Due to low administrative overhead within the SBIR program, the program does not rigorously track job creation and retention data. The estimates I provide here are based on our own budget-related data for Phase I and findings of the 2008 National Research Council study that includes a survey of Phase II awardees.

With almost 5,000 Phase I awards made since 1982, we estimate that more than 3,000 FTEs have been directly supported through SBIR and STTR Phase I awards since the program began. With over 2,000 Phase II awards granted so far, we estimate that about 12,000 FTEs have been directly supported through SBIR and STTR Phase II grants.

In summary, the SBIR program has enabled successful collaborations between small businesses and the DOE R&D complex that have advanced the Department's missions to improve the Nation's energy, economic, and national security with new insights and innovative technologies while supporting a skilled technical workforce.

Thank you.

[The statement of Mr. James is included in the appendix at page 70.]

Chairwoman VELÁZQUEZ. Thank you, Mr. James.

Our next witness is Dr. Kesh Narayanan. He is the division director of the Industrial Innovations and Partnerships within the Directorate For Engineering of the National Science Foundation. The division of industrial innovations and partnerships is responsible for SBIR and several university-industry partnership programs at the NSF.

Welcome.

STATEMENT OF KESH S. NARAYANAN

Mr. NARAYANAN. Thank you, Chairwoman Velázquez and Ranking Member Graves and members of the committee. Thank you for the opportunity to testify on behalf of the National Science Foundation.

The SBIR program at NSF is aligned with the NSF vision of advancing discovery, innovation and education beyond the frontiers of current knowledge, and empowering future generations in science and engineering.

We recognize that over a third of all scientists and engineers work at small businesses, and NSF's SBIR program is well positioned to tap the innovation potential of those small businesses. We accomplish this by inviting proposals covering a wide spectrum of

technologies, including agriculture, biotechnology, medical applications, manufacturing, energy, environment, and nanotechnology.

Today I would like to share with you our efforts to spur the commercialization of technological innovation in small businesses and to help them grow employment and revenues.

One very successful mechanism is our flagship supplemental program Phase IIB which provides incentives to find investors and strategic partners. We also encourage partnerships with other NSF centers and programs to leverage discovery research supported by NSF in academia.

We are keen on workforce development through supplements enabling students and teachers to work in the entrepreneurial culture of these innovative small businesses. A key distinguishing feature of NSF's SNIR program is that we are focused on assisting small businesses in bringing innovative technologies to the marketplace. We are distinct among SBIR programs in that we do not procure any of these technologies ourselves.

Let me share with you two stories of how our awards impact society. One is Touch Graphics, which was founded in 1998 to commercialize technologies first demonstrated at the City University of New York. It has since grown to employ seven people. The company's first SBIR grant from NSF in 2000 allowed the development of an audio-tactile interactive device known as the Talking Tactile Tablet. The product was originally conceived as a tool for teaching advanced math to students with limited or no ability to use print graphics, and has since expanded to broader applications.

The tablet was awarded a gold medal in 2006 Industrial Design Excellence Awards. Under NSF's support Touch Graphics also developed a range of technologies for universally accessible displays and exhibits at science and technology centers, museums, and other venues. In fact, the company is now developing talking touchable models for use at the Smithsonian, including a map of the National Mall. This helps the growing population needing assistive technology in gaining broader access.

My second example comes from Divergence of St. Louis, Missouri, which is working to develop and market a safer method of preventing crop damage due to parasitic nematodes attacking plant roots. It is estimated that worldwide these parasites cost $80 billion in annual crop damage. This includes common U.S. crops such as soybeans. Divergence was able to take advantage of NSF Phase IIB funding, leveraging funds from Monsanto. This is long-term research which evaluates potential nematicidal molecules in a hairy root system rather than whole plants, saving time, money and greenhouse space. Successful molecules are then tested in whole plants by Monsanto.

I should note that NSF supported the original research at Washington University that led to the creation of this company.

These two firms are only a sample from a very broad portfolio of NSF-SBIR awards. With regards to the impact on employment, the National Academy Study of NSF-SBIR program and our own internal assessments indicate that our Phase II grants result in the hiring of 1.5 employees and retaining 2 employees which are critical factors in today's economy. In addition, we enable research and

entrepreneurial experience for roughly 100 college students each year through supplemental awards.

In summary, we are proud of the role NSF-funded SBIR companies play in bringing technological innovation to the marketplace, growing their firms, employing scientists and engineers, and meeting global competition.

Madam Chairwoman, this concludes my testimony. I am happy to answer any questions that you may have.

[The statement of Mr. Narayanan is included in the appendix at page 81.]

Chairwoman VELÁZQUEZ. Thank you.

As we heard from our own testimonies, SBIR has a record for funding cutting-edge research and spurring innovation. Companies that got their start through SBIR now employ thousands of individuals.

I would like to hear from any of the members of the panel: How can we strengthen the program's ability to create new jobs? Let's start with Mr. Brown.

Mr. BROWN. Again, since the program is currently up for reauthorization, and again, we are all familiar with the fine work of your committee as well as what has taken place on the Senate side, in addition to the evaluation by the National Academy of Science study, the current administration is looking at what is on the table now. They are considering what alternatives we should consider and what will be the best practices as we move forward.

Again, as I am sure you realize, our administrator has only been there for a few short weeks, and we have a lot of work ahead of us. We are looking forward to working with her. But again, we have not had a chance to address that issue.

Chairwoman VELÁZQUEZ. Mr. Caccuitto, the program is going to be up for reauthorization. Based on your experience, how can we strengthen it so we can create more jobs?

Mr. CACCUITTO. Well, Madam Chairwoman, I think the first thing I would focus on is what many of us believe is the strength of this program which is its inherent flexibility in how it is implemented among the various agencies that participate.

Giving the managers of the program at the agencies the greatest degree of freedom in the execution of the program in order to produce outcomes I think is the foremost thought that comes to mind if I was to give some sort of guiding observation relative to my experience with the program.

Chairwoman VELÁZQUEZ. Ms. Goodnight?

Ms. GOODNIGHT. I just want to thank you for that question, especially given our downturn in applications.

We appreciate the need to incentivize companies participating in this program. As I mentioned, we don't know all of the reasons. It could be as simple as the economic downturn in the biotech sector. But we actually believe that there are other issues related to the current eligibility rules, certain aspects of the program structure, for example. Companies who currently receive a Phase I SBIR cannot move to a Phase II STTR and vice versa. Companies who receive a Phase I STTR, where they may not need the university involvement at such the requisite level, can't transition to a Phase

II SBIR. So there is an inability to transition between the two programs.

The award levels have not been adjusted since 1992.

Chairwoman VELÁZQUEZ. Yes, I am going to touch on that issue.

Let me refer this question to you, Ms. Goodnight. In 2005, then NIH Director Mr. Zerhouni wrote in a letter to SBA that NIH aims to ensure that small business concerns with substantial venture capital companies' support in the biotechnology and public health R&D arena are able to receive SBIR awards from NIH. Why does a firm's access to venture capital have such a significant impact on the work that NIH does?

Ms. GOODNIGHT. Because many of the projects that we are funding, particularly in drug discovery, drug development, even developing medical devices, those types of companies, in order to be successful, are going to have to attract additional investments, be it through venture capital or raising funding. Even with strategic partners, in order for those projects to make it to the marketplace, they are not going to be able to go it alone and are going to look for those infusions of investment.

Those same companies have other ideas in the pipeline, and they need to do that because many of these projects are going to fail. That is the ″I″ in the SBIR program. In order for to us to be continually churning that innovation lifecycle engine, the issue we are facing now is companies who can take a lead product or drug molecule to a certain stage. They then may have other ideas that would be very fitting for SBIR, can't get the funding there nor can they get it elsewhere.

Chairwoman VELÁZQUEZ. NIH awards multiple Phase II grants to small firms in order to help prepare the most promising research programs for commercialization. Of course, larger awards means fewer awards. Some have suggested that such a pattern leads to lower quality research and poorer results. How would you respond to that?

Ms. GOODNIGHT. I would ask you to repeat the second part of the issue. Yes, we do provide larger awards when the science justifies deviating from the $100,000 or $750,000.

Chairwoman VELÁZQUEZ. And if we provide larger awards, that means there will be fewer awards to give to other applicants. Some have suggested that such a pattern leads to lower quality research and poorer results.

Ms. GOODNIGHT. I think that if companies are only submitting their mediocre ideas, I can understand where perhaps that concern is coming from. There are projects that are in the $150,000 to $200,000 range that are just as important as those that are in the higher level range. I can't really answer that concern.

Chairwoman VELÁZQUEZ. Occasionally a small company may have progressed beyond the Phase I feasibility studies of technical merit. In these cases, the company's research may be suitable for a Phase II award. Do you believe that under these circumstances, the company should be able to bypass Phase I if it can certify that it has completed the testing and feasibility studies required under Phase I? I will ask for any of the other agencies to respond to that question.

Mr. James?

Mr. JAMES. Yes. I already had a whole good answer for the last question, but I will work on this one, too.

I think that our program would probably not adopt this idea of awarding a Phase II without a Phase I. I just see a lot of difficulty. I don't see how we would work it out.

Chairwoman VELÁZQUEZ. Okay.

Do you have any comments, Mr. Narayanan?

Mr. NARAYANAN. I would agree with Larry James from Energy. Because we have an external peer-review mechanism for reviewing incoming proposals which is very rigorous, it somewhat relates to the first question in the sense that we have an SBIR advisory committee, external advisory committee, which has been looking at our program for more than a decade. One of the items they pointed out is the whole purpose of our SBIR funds, if all they have done is research and they have not commercialized and grown, it does not serve the purpose.

So, in order for a SBIR proposal to come in front, they need to have not only a really high research quality but a high commercial potential ability.

So one of the points they recommended, which we included in our SBIR evaluation, is in addition to having external technical reviewers, we have included in the last several years external what I will call commercial reviewers. The point being that the rigor we give would be difficult to evaluate from the outside.

Chairwoman VELÁZQUEZ. In looking at how can we strengthen the SBIR program, we have to answer the question about the valley of death that Ms. Goodnight made reference to. So it is critical that we see more research make it from the laboratory to the marketplace. Would a Phase III grant aimed specifically at commercialization help more small firms bridge this gap?

Ms. Goodnight, Mr. Caccuitto, you made reference to that issue?

Ms. GOODNIGHT. I think any additional resources, whether they are called Phase III or Phase II or Phase IIB, are definitely critical in helping these companies bridge that gap because they get to a stage, at least for our companies where the Phase I and the Phase II is only so much, to put them on this pier and they often have not progressed far enough to attract the additional investments that they need.

Chairwoman VELÁZQUEZ. Any other comments?

Mr. NARAYANAN. I mentioned in my testimony on the Phase IIB mechanisms that we are using currently to incentivize existing Phase II grants to move towards the Phase III, but one of the observations that we have made is the ability to commercialize. The examples I gave, for example, in the agricultural area, sometimes it takes almost a decade before it goes through all of the approvals, et cetera. And in the IT area, it may be very fast. So even in the Phase IIB, we try to do it within the timeline of the two years of the Phase II grant, but not all technologies are able to bring this third party commitment within the 2 years. So that puts some technologies in a bind which may have leveraged this. So I am answering not that we need more Phase III special funding, some mechanism that we could use as Phase IIB beyond the 2 years. Right now, once it is done, we can't go back.

Chairwoman VELÁZQUEZ. Mr. Brown, when Administrator Preston last testified before our committee on SBIR in March 2008, I asked him whether the SBA supported increasing the amount of SBIR awards. He responded that SBA was supportive of an increase, and that the administration has been working in-house on a rule to address that. Is SBA still planning on issuing a rule that will increase the size of SBIR grants? Are there any other regulatory changes that you envision in the coming year?

Mr. BROWN. Madam Chairwoman, in follow-up to your question and in follow-up of the testimony of former Administrator Preston, yes, SBA has looked at the issue. However, similar to my response to the earlier question, the current administration is looking that over. And once they have a chance to evaluate that, we will be reporting.

Chairwoman VELÁZQUEZ. I look forward to discussing it with the administrator.

Now I yield to Ranking Member Graves.

Mr. GRAVES. Thank you.

To follow-up on your question to Mr. Brown, the previous administrator always expressed concerns about the role of venture capital when it came to small businesses who participate in the SBIR programs. Does the administration have a stance, or are they looking at that?

Mr. BROWN. Again, the administration is looking at all of the reauthorization issues, the size of the awards, the VC issue, et cetera. Again, it is a wide berth of information and data. They are very challenging issues. So until the current administration has a chance to get it under their belt, they are not going to chime in, in terms of a position.

Again, after serving in this office for several years, I am very familiar with the issue. Going back to our advanced notice of proposed rulemaking back in 2004, the series of hearings that we had in 2005, so it is a very challenging issue. We understand the complexities of it, and we are evaluating it.

Mr. GRAVES. This committee is obviously very interested in that and how venture capital plays. And I hope you take the statements that have been made by the committee and what we have done in the past in terms of legislation into account.

I would also be very interested if you guys have any suggestions in improving outreach efforts in the rural areas, which have traditionally been underrepresented in the SBIR program. That obviously is an issue for me because I represent a very rural area. There is a lot of opportunities out there, I think. I don't know if you all have looked at that or are just starting to look at it or if you have any suggestions. I would certainly be open to any of those.

Mr. BROWN. Again, that is one of many areas that we are looking at. Yes, we are looking at it.

Chairwoman VELÁZQUEZ. And will you have an answer in the next 2 or 3 weeks? The program expires in July, you know that, right?

Mr. BROWN. Yes, ma'am. I will take your message back to the administration.

Mr. GRAVES. Thank you.

Chairwoman VELÁZQUEZ. Ms. Dahlkemper.

Mrs. DAHLKEMPER. Thank you, Madam Chairwoman.

I have a question for Dr. Narayanan. Federal agencies do not have a strong record when it comes to funding women and minority research firms. You have instituted the research assistant supplements for high school programs to address this. Do you think other agencies can emulate your approach, and what do we need to do to encourage more women and minorities to apply for these programs?

Mr. NARAYANAN. Mrs. Dahlkemper, obviously, I can't speak for other agencies.

But what you are referring to is what we call the RASHSS program, Research Assistance Supplements for High School Students. The proposal has to encourage efforts to bring minority students into supporting the research award that is going on.

We have had, even as I speak, limited success, and we need to do even more probably outreach and get our community to be energized. So we are excited by what the opportunities or possibilities are, and we find it is getting some traction. We need to do more of it.

Can other agencies emulate? I will have to allow them to answer that.

Mrs. DAHLKEMPER. I will open it up to the other agencies here and see if you have any ideas on how we can encourage those firms that are run by women and minorities to apply for this program.

Ms. GOODNIGHT. I will just add something for NIH. We also offer diversity supplements, and it is my understanding that our SBIR and STTR awardees can use those diversity supplements to their existing grants. But more importantly, I think it goes to Dr. Narayanan's point about the need for more outreach.

We have actually committed to doing a number of conferences this year that are specifically focused on minority and under-represented groups. I remember back when there was the FAST program, the Federal and State Technology Partnership Program and the rural outreach program. States actually were able to hold more outreach events and get the agencies there speaking one on one with these companies where they may have this intimidation factor to apply. But when they actually talk with us, they realized, oh, maybe I can go through this.

Mrs. DAHLKEMPER. What happened to that program?

Ms. GOODNIGHT. To my knowledge it expired with the last reauthorization, in 2005.

Mrs. DAHLKEMPER. Dr. Narayanan?

Mr. NARAYANAN. Thank you. I just want to elaborate a little bit if I may. There are several supplemental programs which we document in our written testimony which attempts to link the SBIR program with programs at NSF which serves the minority community, which include the community college connections, which include predominantly minority research institutions, and these are vehicles to make that connection to make the students and facility aware of the entrepreneurial opportunity.

One of the things our SBIR advisory committee, they formed a subcommittee on this very topic because this was of great interest to them. One of the recommendations they came forward with

which was very recently implemented is a mentorship program, what they said was it is not only outreach, you need to really help them, educate on putting forward high-quality proposals. So what we are offering as we speak is to existing grantees of ours who are seasoned, if you will, and telling them, you know, can you reach out to the new minority, new PIs, principal investigators, take them under your wing and help them put forward high-quality proposals. We just recently launched it, and we don't have any evaluation yet.

Mrs. DAHLKEMPER. I would be interested in seeing how that program goes forward.

Thank you very much.

Chairwoman VELÁZQUEZ. Mr. Luetkemeyer.

Mr. LUETKEMEYER. Thank you, Madam Chairwoman.

With the reauthorization, there is a discussion of changing the levels, or we need to discuss the levels. What percentage of your clients would require or could use additional moneys? Do they come back to you for more? What percentage could actually use more, just a percentage?

Mr. BROWN. Well, I would defer to my colleagues here since they have the specific data from their specific agencies, and they are where the rubber meets the road.

Mr. CACCUITTO. Congressman, it would be difficult to know what that number is because we don't track that sort of data; specifically, whether a firm requests more resources or not.

But looking at some data historically, for example the fiscal year 2000 year group, eventually about 31 percent of those Phase II awardees ended up being funded beyond the award guidelines in order to continue their technological development and increase their chances of success.

Mr. LUETKEMEYER. Where did they go to get the money?

Mr. CACCUITTO. Sometimes back to their respective agencies. Sometimes to different agencies within the Department.

Mr. LUETKEMEYER. So you have multiple agencies that may work together?

Mr. CACCUITTO. That happens sometimes, absolutely.

Mr. LUETKEMEYER. That was my question. I was going to follow here with each one of you.

Ms. GOODNIGHT. For NIH, I, too, am going to base this on fact.

Our SBIR median award for Phase I in 2008 was about $151,440; and for Phase II, $841,381.

For STTR, the median award size was $149,711; and for Phase II, $907,970.

So if that is the median, that gets to the percentage or so that are in need of those additional dollars. There are statutory guidelines, and so we have been given the ability to exceed where it is scientifically justified.

Mr. LUETKEMEYER. So are you basically going above it pretty regularly?

Ms. GOODNIGHT. As I mentioned, since they haven't been adjusted since 1992, we are at those medians. Science is becoming more expensive. In order for us to continue to encourage the most innovative ideas, rather than those that can just fit under the $100,000 or $750,000, we are going beyond.

Mr. LUETKEMEYER. How do you use your discretionary ability? Is it within the statute that allows you to do that, or do you need to go back to the SBA and get some waivers?

Ms. GOODNIGHT. It is a statutory guideline, but we have also spoken and worked very closely with SBA so that they understand the areas of research that typically need this additional funding.

Mr. LUETKEMEYER. So your average award is greater than what the level of award normally is, or should, or is statutorily there? Very good.

Mr. James.

Mr. JAMES. Well, we are a little bit like DOD. We don't keep facts on that, but I can give you some information. We did institute what we called a Phase II supplemental a couple of years ago. Those are the opportunity for a Phase II awardee to get another quarter million dollars in 12 more months on their Phase II award; but they have to be invited by the program officer. It has to show enough promise. It has to be important to the impact of their mission and so forth.

The number of those, we fund about 150 Phase IIs. We might get 10 percent, maybe 15 supplementals. So that is an order of magnitude.

Mr. LUETKEMEYER. Dr. Narayanan?

Mr. NARAYANAN. For us, as I mentioned, our mechanism is primarily Phase IIB. Our Phase II awards don't go up to the limit allowed. We give $500,000 Phase II awards. So we use the supplemental mechanism Phase IIB that I described to go beyond, depending upon the ability for them to bring additional third-party funds.

The need for additional funds is also strongly dependent on technology. Since we are in a wide spectrum of technologies, some areas do not necessarily need additional money and they can go very fast to the marketplace. In fact, they have to go fast. But some of them require a longer time.

Mr. LUETKEMEYER. One quick question for Mr. Brown.

How many dollars do you have left in the program at the end of the year with regards to the allocation that is allowed to you, or do you have to turn down a lot of applicants for these funds, very quickly?

Mr. BROWN. Again, SBA doesn't give out funding directly. It goes directly to the agencies that are here and the other seven that aren't here.

At the end of the year, speaking of the program as a whole, it varies from year to year. Sometimes there is an agency or two that may have a few dollars that went unspent. And in the other years, that same agency may go over the threshold. So it depends by year.

Mr. LUETKEMEYER. This past year, up or down?

Mr. BROWN. It is up. In terms of what went out, it was up.

Mr. LUETKEMEYER. There was more requested than what you had available?

Mr. BROWN. No, I am talking about the agencies that met the threshold as opposed to those that didn't. If you are talking about are there more applications, there are always more applications than the amount of money that is available, yes.

Mr. LUETKEMEYER. Thank you, Madam Chairwoman.

Chairwoman VELÁZQUEZ. Mr. Moore.

Mr. MOORE. Thank you, Madam Chairwoman.

You all have firsthand experience with the SBIR program. As Congress looks to reauthorize the program, what are some of the recommendations that you have for how the program can be improved?

Some of the reforms that are talked about include increasing the SBIR funding level, I am sure nobody wants that; increasing commercialization initiatives to provide a better bridge between research and development and the attraction of private-sector partners; improving the administration of agency SBIR programs; and improving outreach to small firms owned and controlled by women, veterans and minorities. I would like to hear if you have any response to those or thoughts about those or others? Mr. Brown.

Mr. BROWN. Once again, the administration is looking at all of these issues. It is a mouthful. There are a number of issues. Some of them are a lot more complex than others. Some of them are fairly basic, and some are more complex. And not only do they apply across the board for the entire program, but if you even look at the four other colleagues I have here, they apply differently at the agencies that are here.

But speaking in general, echoing what has been I said by my colleagues, as well as what has been said by the National Academy study, the flexibility that the program has needs to be moved forward.

So as we look at these issues, in terms of eligibility, the VC issue, the guidelines, size of awards, whether we should increase the 2.5 percent and other issues that we are discussing, that we just be mindful of how flexible the program has been. And it seems that is the one area that everyone agrees moving forward, that we need to try to maintain that flexibility, while at the same time maintaining a structure that will maintain the integrity of the program.RPTS MCKENZIEDCMN MAYER

Mr. MOORE. Do any other members of the panel have thoughts about that, any observations?

Ms. GOODNIGHT. I would echo Mr. Brown's comment about the importance of flexibility in this program. That is really what has helped these programs succeed, given our varying missions.

I think there is one area that is worth just sort of factually stating. That is that currently the set-aside amounts for SBIR and STTR must remain separate, and they can't combine into a total set-aside of 2.8 percent. So this gets more to the flexibility issue again, of managing the programs effectively to fund the most meritorious SBIR or STTR projects under that set-aside.

Mr. MOORE. Does anybody else have any thoughts?

Mr. JAMES. I think the technical assistance aspects of the current law have made it pretty difficult for us to provide commercialization assistance as we would like. I think there are some efforts in the new authorization to fix that. I think they need to raise the amounts and also specify in the Phase II that it is not inside the grant; the government has the ability to have a contractor and provide and so forth.

And you mentioned administrative resources. Certainly we would all like to have some more money to help us manage the program

better. I think a prime example of that here is, my colleague here, next to me, keeps talking about his Phase II(b); and I absolutely agree, I think it is a flagship. And I wish I could emulate it, but I don't have the resources in my procurement authority to do that. It takes quite a bit more procurement specialists to administer that kind of a program, and that is—

Mr. MOORE. Any thoughts, sir?

Mr. NARAYANAN. I think from—NFS's point of view, I will echo what others have talked about flexibility, because each of us has a different mission. And you have seen some of the things like Phase II(b), because of the flexibility, we are able to implement.

One area that we have raised in the past which is we are very fortunate at NSF that we have dedicated SBIR program managers from the topic generation to the evaluation to awards management by technology topics. These are technology managers who will manage the program. And the way we are structured is, I know they cannot use the program funds to actually go visit or, you know, help the companies in terms of mentoring or making connections. So we take reverse attitude of trying to bring all the companies to Washington, D.C., spend maybe like 10 minutes per company, which is not really all that, you know, the best practice.

Mr. MOORE. Thank you. And I yield back my 7 seconds.

Chairwoman VELÁZQUEZ. Mr. Ellsworth.

Mr. ELLSWORTH. Thank you, Madam Chair. I really don't have a question. I may use Dennis's 7 seconds. But I would just like to reach out to—is it Joe Caccuitto?

Mr. CACCUITTO. Caccuitto, sir.

Mr. ELLSWORTH. That was my second guess for the pronunciation.

Admiral Sestak and I have been appointed to a six- or seven-person committee to look at the military procurement system, and I would just like to reach out to you, any suggestions you would have to streamline that system, make it more efficient and more cost effective for the taxpayers. You can contact one of our two offices if you have input in that.

So, with that, I don't have a direct question for small business. But I would yield back.

Chairwoman VELÁZQUEZ. Okay.

Mr. Thompson.

Mr. THOMPSON. Thank you, Madam Chairman.

My district is Pennsylvania Fifth. It is one of the most rural districts that are out there, and SBIR programs just play a tremendous role, mostly, thankfully, to—we have Penn State there, and we have a lot of kind of high kind of niche-type innovations that come out of that applied research lab. So this is such an important program for my district from many perspectives.

Let's start with—Mr. Brown, what are your suggestions to improve outreach efforts to rural areas that are traditionally underrepresented in the SBIR program?

Mr. BROWN. First of all, I think we need to have better collaboration amongst us. I think we are doing a fairly good job now of interacting with one another and sharing best practices in terms of what the respective agencies have done. But, again, when there is

a best practice at one particular agency, we need to highlight that and share it with others.

Another thing that we should consider is doing more outreach with the States. Again, we have quarterly SBIR national—excuse me—two SBIR national conferences a year to date, and we always have a meeting of the State representatives.

It is always a good networking session. You get key people from around the country that have the story from their particular State. And again it is the same thing, sharing best practices: What are you doing in your State? You may find out that a State has a Phase Zero that they have established in their particular State. And I am talking about something about the program itself, but the same with outreach, you know, what types of things are bringing back the best rewards for you?

In addition, I also know that there are several States that are doing some unique things. I know Maryland, for example, since they are one of our neighbors. I don't know if anybody on the panel is from Maryland, but Maryland had a very good program where they provided very good direct outreach for minorities in Prince George's County. It was targeted for that particular county to increase the number of technology-oriented minority companies; and I understand they had very good results. And, again, that is just a snapshot of the types of things that can be done.

I should also add that with the program managers we have established an outreach subcommittee, and we are exploring different ways of doing outreach as well as conducting the national conference.

Mr. THOMPSON. Okay. Thank you.

Well, actually, I had the same question which had to do with best practices. So I appreciate your getting into that question.

Ms. Goodnight, in your opinion, what is causing the drop in the applicant pool for SBIR grants at NIH?

Ms. GOODNIGHT. We don't know all the factors. We believe some of them may relate to the fact that some firms are losing their eligibility. Some firms don't see the incentive opportunities based on the current award amounts. Some are not reapplying even though they have that opportunity to reapply if they are not selected the first time. Some may find that process very daunting, and this gets back to the outreach efforts.

Those are just a few.

Mr. THOMPSON. Okay. Thank you.

Ms. GOODNIGHT. I would add one more. I would say with our receipt dates schedule, which are April 5, August 5 and December 5, the community is asking a lot of questions about, What about the August 5 and December 5 due dates? Because there is a lot of uncertainty about the program at this point.

Mr. THOMPSON. Okay.

And some of those first variables you identified as reasons, are there any strategies in place to address some of those contributing factors?

Ms. GOODNIGHT. With regard to the eligibility, I think that we have spoken enough about that; and given how much we can say about it, we certainly believe that the current rules are excluding some companies who used to participate and are no longer. With

regard to not feeling that the process is a daunting one, that gets back to the outreach and doing a lot of mentoring and helping these companies.

Mr. THOMPSON. Okay. Thank you.

One final question in my remaining seconds: Mr. James, can you talk a little bit about your outreach to rural areas and initiatives to promote that?

Mr. JAMES. I think we are very active in our regional meetings. We go to Johnstown, for example. We go up there and have an outreach. Several program managers from some of the agencies will go and we will describe the opportunities for its small businesses, encourage them to contact our program offices, sit down with them in one-on-ones, talk to them about what ideas they have, try to find a pipeline in the Department that would help them directly involve the Department in their development.

We probably do at least two or so every month, regional activities. Indianapolis. In other words, we do a lot of regional. I know we have an annual meeting but we do our best because we think this is helping us get more applications.

Our applications, we certainly can't claim that that is why our applications are going up. Obviously, our applications are going up because of the price of oil, for example. So it is something that we believe very strongly in.

Mr. THOMPSON. Okay. Thank you.

Thank you, Madam Chairman.

Chairwoman VELÁZQUEZ. Mr. Sestak.

Mr. SESTAK. Thank you, Madam Chairwoman.

When we come out of this economy—if the modeling is correct and things we have tried to do are correct, by about the middle of 2010 we will be back at GDP level of 2007. But we have lost a trillion dollars in our economy, and if GDP growth then begins to be 2.5 percent per year, which is what it averaged between 2001 and 2007, it will take us 3 years to soak up the $1 trillion that we have lost because that is what it shows in the model, about $350 billion a year. In short, we won't even recover the lost capability if we just get back to the decade of growth of GDP this year.

And this year we are going to lose 4.5 percent GDP. Japan is going to raise, go up 6.8 percent GDP.

The point of this is that unless we are able to really energize our economy above its typical growth, we aren't going to make it in any real time. So I would like to just talk about venture capitalists for a moment and ask a question, if you don't mind, ma'am.

Can you talk a bit about what you think the impact could be if, in one part of this effort to try to—not just stimulate our economy; we have got to get it going about 4, 4.5 percent if we want to be back beating China's kind of competitiveness pretty darn soon. Can venture capitalists in the SBIR, can they play an important role in that?

SBIRs aren't that large. They have got a lot of money. What is the impact of this on their portfolio if they do have access to this? Because, to me, it just seems like real opportunity here for the common good to get us going if we open this up again to the venture capitalist community.

Ms. GOODNIGHT. The SBIR and STTR programs, as you note, is probably not a significant amount of money when you compare it to what they are actually going to need to actually bring a product to the marketplace. It is the leveraging that it plays a huge role in.

And so these companies who are able to get Phase I and Phase II and Phase II(b), or for our agency a competing renewal, and further their progress into some of the clinical studies that are necessary, that is when individuals become more venturesome and will start putting additional dollars into those projects.

And then those same companies may have, as I mentioned, additional ideas in their pipeline for which the SBIR program is perfect because they have not taken them through that necessary feasibility study. And then we continue to see the dollars go into those projects, and those that show promise get furthered along that commercialization pathway to get attraction of additional investments.

So this is a cyclical process where SBIR has in the past played a large role. It has the potential to play a very important role for these types of companies that need to raise the financing.

Mr. SESTAK. So you would be a proponent of it?

Ms. GOODNIGHT. [witness nods.]

Mr. SESTAK. If I could ask you, Mr. James. There has been some discussion that potentially certain sectors should be focused upon; biologics, for example, from start until you get that product out there is about $1.2 billion—to your point, ma'am, about the cost of it. Should we not just let them in, but should we also try to focus this?

I mean, people have been talking here about retooling our economy in the midst of things in health care or energy or things like that. Should there be a way we look at it that way with venture capitalists or just leave it as it is? Because sometimes agencies kind of say, Come here, SBIR, help me do what my programs already are, rather than maybe being quite innovative and entrepreneurial.

And, again, I go back to the reason why I think it might be a good idea, which is, how do we quickly soak up the $1 trillion that we have lost? Growth of 2.5 percent is unacceptable for the next 5 years.

Mr. JAMES. As you know, DOE has a loan program, and I have been trying to work with our loan program to get them involved in looking at small businesses and see what we can do to fast-track loans. I don't know how that is going to happen. But I presume your question is, do you think we—do we believe that venture capitalists could play an important role in the SBIR program. Is that what you are asking?

Mr. SESTAK. Should we try to focus it on certain types of sectors? Most venture capitalists seems to be concentrated a lot of times in California or Massachusetts. That is demographics.

But should we be looking at sectors such as health or energy? Or should we just let them in and let the cards fall as they might?

Mr. JAMES. My experience has been that the venture capital community is not all that interested in our program. Our Phase II's are limited to $750,000, and that doesn't seem to—

Mr. SESTAK. All right.

How about for Ms. Goodnight? What would you say?

Ms. GOODNIGHT. It is important.

Mr. SESTAK. Do you understand why I am asking?

Ms. GOODNIGHT. I do. I am trying to phrase my question from where I sit.

So venture capitalists, as I understand how they play in this game, they put their money into a number of different sectors, whether it is biomedical, whether it is energy, whether it is IT; it is where the hot technologies are, and it is where they see that they are going to get a return on their investment.

Now that may take a number of years. And, certainly, from the SBIR companies participating in the program to get them to that stage, it is 5, 7, 10 years down the road. On the IT side, however, it is a very short turnaround. So it is a number of sectors where they are investing in.

Mr. SESTAK. So you would let it open. Thank you.

And do you feel the same way about angels?

Ms. GOODNIGHT. I believe angels are doing the same thing. They are investing in technology areas that are broader than biomedical research.

Mr. SESTAK. Okay. Thank you.

Chairwoman VELÁZQUEZ. Mr. Thompson, I understand you have another question.

Mr. THOMPSON. Well, actually, thank you, Madam Chairman.

More of a request and to kind of follow up to my first question I had for you, Mr. Brown, I was wondering—you had made reference to the good collaborative work that is going on. What I would like to request is, if we could get a copy of the report for the subcommittee on outreach, I think, as was described; I think that would be real helpful for myself and for the whole panel if we could get a copy of that, please.

Mr. BROWN. Will do.

Mr. THOMPSON. Thank you.

Chairwoman VELÁZQUEZ. Okay. Any other member that wishes to make any questions?

If not, Mr. Narayanan, I have one last question and I would like to ask that question to you.

NSF is widely recognized for its effective administration of the SBIR program. And how has NSF been able to administer its program so effectively without a separate line item for program management?

Mr. NARAYANAN. Madam Chairwoman, I think to start off, you fully recognize that SBIR programs started in NSF even before 1982 by Mr. Roland Tibbetts. So NSF had a certain degree of ownership to the program from day zero, if you will. So that culture has resulted in support from NSF management to staff our program with dedicated program officers who are experts in the specific technology areas.

As I mentioned earlier, we are very fortunate that we have program managers distributed by—in the broad technology areas from materials manufacturing to biotech to information communication technologies. So we have got—I would say the dedicated program officers makes a difference. And those dedicated program offices,

every one of them I can say has either—every one of them has an industrial background.

Chairwoman VELÁZQUEZ. Thank you.

For the record, can each agency tell the committee if they will benefit from a separate budget for SBIR administration and program management.

Mr. James.

Mr. JAMES. I think I mentioned earlier that we certainly could. Site visits, a whole list of things.

Chairwoman VELÁZQUEZ. Ms. Goodnight.

Ms. GOODNIGHT. NIH also would support additional funding for administrative costs for managing these programs.

Chairwoman VELÁZQUEZ. Mr. Caccuitto?

Mr. CACCUITTO. We funded a RAND study last year, looking at assessing the baseline overhead cost to the program. They came up with an estimate of at least 6 percent for us. So that indicates to me we have a very resource-intensive program, and therefore, I would say more resources are better than less.

Chairwoman VELÁZQUEZ. Okay. And I guess that you don't have an answer since we have a new administrator and it will take 2 or 3 more weeks.

Mr. BROWN. Yes.

Chairwoman VELÁZQUEZ. Thank you.

I want to thank all the witnesses for being here today and for your insightful testimony. Thank you very much.

And I will ask the second panel to please take your seats.

Okay. Well, welcome, lady and gentlemen.

Our first witness on the second panel is Mr. Joshua Green. Mr. Green is general partner with MDV-Mohr Davidow Ventures. He joined MVD's investing team with a focus on cleantech companies. Throughout his career, Mr. Green has guided entrepreneurs and helped to build successful companies, including Yahoo and Target Therapeutics. He is here to testify on behalf of the National Venture Capital Association. NVCA is comprised of more than 400 firms.

Welcome, Mr. Green.

STATEMENT OF MR. JOSHUA GREEN, GENERAL PARTNER, MDV-MOHR DAVIDOW VENTURES, MENLO PARK, CALIFORNIA, ON BEHALF OF THE NATIONAL VENTURE CAPITAL ASSOCIATION

Mr. GREEN. Thank you very much.

Chairwoman Velázquez and members of the committee, my name is Josh Green. I am a partner at Mohr Davidow Ventures, a venture capital firm in Menlo Park, California. I am also a member of the National Venture Capital Association, and my views today represent the 460 members of NVCA, which account for over 90 percent of all the venture capital under management in the United States.

Like all VC firms, Mohr Davidow invests in entrepreneurs that are creating innovative small businesses that will hopefully grow into large, successful enterprises. Our firm has been in business for more than 25 years, taking a hands-on approach to building start-

up companies in the high tech, life sciences and alternative energy sectors. As a cleantech investor myself, I am focused on creating businesses that will reduce our country's dependence on foreign oil and help preserve our environment while creating domestic jobs and more revenue.

In 2008, venture capitalists invested more than $4.6 billion into clean technology businesses alone, that are innovating in a wide variety of areas. Many of these companies are founded on discoveries made through basic government-funded research. I am here today on behalf of those current and future companies. As an industry, we strongly support the reauthorization of the SBIR grant program, and we hope that the past inequalities are corrected so that all small businesses can compete for these critical funding grants.

To begin, I would like to address several misconceptions that we believe exist and are used to argue against VC companies' participation in the SBIR program. The first is that venture-backed companies do not need SBIR programs because they are strong fully-funded entities. This is patently false. Venture-backed companies are quintessential small businesses; many are pre-revenue and most have fewer than 10 employees. Like all small businesses they operate on very tight budgets and are extremely fragile.

Venture-backed companies must consistently meet agreed-upon milestones to receive continued funding. Venture firms do not have unlimited funds and have contractually finite pools of resources to devote to any particular company.

The second misconception is about VC funding itself. Venture capital moneys are used to build businesses, not to perform research. However, a company that receives venture funding may have other innovations in the pipeline that are worth pursuing, and it is for these new projects that the company would apply for an SBIR grant.

Businesses must continue to innovate, and a current SBA interpretation forces these companies into an unfortunate dilemma for worthy new projects. This scenario has resulted in small businesses at best delaying important discovery projects and at worst abandoning this important work altogether.

Another misconception is that venture capital firms are equivalent to large corporations, and therefore the companies that they fund should be excluded from consideration for SBIR grants. We agree that large corporate-owned businesses should not be allowed to participate in the small business program. But venture capital firms and their portfolio companies are not large corporations; they are private partnerships existing to finance the growth of an emerging growth company.

At a time when the national debt is high and government resources are stretched thin, we believe the Federal Government should look toward the private sector for solutions to our Nation's health care, energy and national security challenges. Instead, the current SBA eligibility rules throw costly, time-consuming and unnecessary hurdles in the path of government agencies seeking to collaborate with venture capital-backed companies. We believe this is a huge loss for the country.

Throughout the history of the SBIR program, majority venture-owned small businesses have applied for and received SBIR funding. This historical precedent strongly suggests that their participation has caused no harm to the program or to other small businesses. In fact, the recent National Academy of Sciences study found no evidence that other small businesses have ever been crowded out by the participation of venture-backed businesses.

In recent years, as cleantech investing is growing, the venture capital industry has been working more closely with the Federal Government and key agencies like the Department of Energy and EPA. Those agencies have been touting the SBIR program as a mechanism to advance their research dollars with promising venture-backed companies. The industry is poised to work with them. The policies enacted by this Congress, this administration, will either help or hinder that effort.

The SBIR program is a wonderful mechanism for government and private sector to come together and do what desperately needs to be done to support a strong economic recovery, help these small companies grow and innovate. But the SBA's past policies have seriously negated the positive impact of venture-backed small businesses.

Venture dollars and SBIR dollars play complementary roles in financing innovation. One is rarely, if ever, a substitute for the other.

We urge Congress to reauthorize the program with provisions that ensure venture-backed companies have a fair chance to thrive under the SBIR program alongside their non venture-backed counterparts. Doing so, we believe, will only strengthen the future success of the program.

I would like to thank the committee for the opportunity to share with you today the challenges our small venture-backed businesses have faced under the past restrictions and why these grants are critical to the ongoing vitality of innovation and job creation in the United States.

I am happy to answer any questions you might have.

Chairwoman VELÁZQUEZ. Thank you, Mr. Green.

[The statement of Mr. Green is included in the appendix at page 93.]

Chairwoman VELÁZQUEZ. And our next witness is Ms. Rachel King. She is the founder and chief executive officer of GlycoMimetics Inc. GlycoMimetics has a specialized technology, which is producing proprietary drug candidates with focus on inflammation, cancer and infectious diseases. Ms. King is here to testify on behalf of the Biotechnology Industry Organization, the world's largest biotechnology organization with over 1,200 members.

Welcome.

STATEMENT OF MS. RACHEL KING, CHIEF EXECUTIVE OFFICER, GLYCOMIMETICS, INC., ON BEHALF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION

Ms. KING. Chairwoman Velázquez and members of the committee, thank you very much for giving me the opportunity to testify today. And I want to thank you for holding this hearing and

thank you for your support of the SBIR program and for your focus on this issue, because this is a critical issue to the biotechnology industry. And I think it is really very, very important that we understand the significance of the program, how important it is, particularly in this economic climate; and I do have some specific ideas about how we can improve it, to enhance the program even further.

As Congresswomen Velázquez mentioned, I am here to testify on behalf of the Biotechnology Industry Organization. I serve on the board of directors there, and I also chair the emerging companies section, which is where we particularly represent companies like ours—young, early-stage companies that are focused on cutting-edge research, but which are smaller, optimistically viewed as emerging because we look forward to the opportunities that we believe our new technologies will provide.

Our company has a lead program focused on developing a drug for sickle cell disease. We have 20 employees, and we do not qualify for SBIR funding. And that is really, I think, a clear example of why the eligibility program or why the eligibility requirements need to be changed.

Even more striking, though, when we opened the doors of our company, when we had four employees, we did not qualify as a small business for SBIR purposes. And that is because of our venture capital backing. So that is a critical issue, as far as I am concerned, that we really do need to address. This is particularly important in this economic climate, when everybody knows that there have been a lot of challenges to many sectors in the economy.

In the case of biotechnology, we have seen significant reductions in the venture capital investments that are going to biotech companies. We see increasing numbers of public companies that are running out of cash, and we see a real push to focus our resources on our latest-stage, most-advanced programs, which really increases the importance of having SBIR funding for those earlier-stage programs which, as Dr. Goodnight mentioned, are the high-quality, high-risk, early-stage scientific areas where we really could productively focus on some additional resources.

We have three specific recommendations that we would like to make in terms of improving the SBIR program. The first is to really address the eligibility requirements with respect to venture capital ownership. Again giving you a specific example from our case, because we happen to have more than 50 percent venture ownership, it means that we do not qualify. And I think that that is a significant reason why we saw such a significant drop in applications, the 40 percent drop that Dr. Goodnight referenced in terms of SBIR applications to the NIH. My opinion is that that is significantly influenced by the fact that venture-backed companies cannot apply for those grants to the extent that the VCs own more than 50 percent of our companies.

Remember, we are developing therapeutics, and particular companies developing therapeutics require lots of investment for long periods of time, so we can't do that without the backing of venture capitalists. By definition, we will have a lot of venture capital investment. And we can really count on the SBIR program if it is available to help us to fund the earlier-stage programs where we

are doing even more cutting-edge research. So it is critical for us to be able to access that.

A second recommendation gets to this question of affiliated employees. And again to give you a specific example from our company, we have, as I said, 20 employees. One of my large venture investors invests in all kinds of other types of businesses that have nothing to do with biotechnology. So if they invest in a software company, for example, that has 100 employees, those employees should not be counted in my eligibility for an SBIR grant. They have nothing to do with what I am doing. I have got nothing to do with what they are doing, and I really think we need to focus on employees of the company itself. So the affiliation rules really need to be clarified.

And the third recommendation, which again supports some of the comments from the earlier panel is that we really do believe that agencies need to have flexibility in terms of how they implement their programs. Different scientific approaches are going to require different amounts of funding, different timing for the types of funding that would be helpful to their ventures. And so I really think as a third point to give more flexibility to the agencies in how they administer their own particular aspects of the program, I think, would be very productive.

So as I said at the outset, I think this is a critical program. You are able to support early-stage important innovations. You are able to do it in small businesses and significantly effect employment generation in this country. I think it is a win-win for all parties, and I really thank you for your interest and for your support of this important program.

Chairwoman VELÁZQUEZ. Thank you, Ms. King.

[The statement of Ms. King is included in the appendix at page 104.]

Chairman VELÁZQUEZ. Our next witness is Mr. John Stocker. He is the senior vice president of Federal Solutions for Lynntech, located in College Station, Texas. Lynntech is a research and technology development company with a 20-year history of successful innovation. Lynntech is a member of the Small Business Technology Council.

Welcome.

STATEMENT OF MR. JOHN STOCKER, SENIOR VICE PRESIDENT, FEDERAL SOLUTIONS, LYNNTECH, INC., COLLEGE STATION, TEXAS

Mr. STOCKER. Thank you, Madam Chairwoman. And I appreciate the opportunity to appear before the committee this afternoon and would ask that my full statement be entered into the record.

Chairwoman VELÁZQUEZ. Without objection.

Mr. STOCKER. Madam Chairwoman Velázquez and members of the committee, it is with great pleasure that I appear before you today to offer Lynntech's views on the need to reform the Small Business Innovation Research program. And I should add that I am speaking on behalf of Lynntech and not on behalf of the Small Business Technology Council.

It is true that we are headquartered in College Station, Texas, but some of us have small farms in Spencer County, Indiana. And

we are the largest SBIR contractor in the State and one of the largest in the country. So it is fair to say that this program is an important one, and it has been beneficial in the past to the company.

The company was founded back in 1989. Our primary objective is to intensify our efforts to transition technologies into the marketplace. Our technologies are concentrated in the areas of the electrochemical synthesis, energy storage and conversion, chemical biological defense systems and environmental remediation. About two-thirds of our contracts are with the Department of Defense, although we have performed under contracts to a number of the agencies that have SBIR dollars; as a result, our interest in this debate regarding the reform legislation is quite high, as our efforts to transition technologies will be driven by the framework of future reforms.

In sum and with all due respect to the participants in the past, we think that the debate regarding last year's bill as passed by the House is focused on the wrong set of issues. We believe that ownership of SBIR companies by venture capital firms should not be guiding our discussions regarding reform of the program. We should be looking forward to all possible resources, both public and private, to advance technologies into the future. The only ground rule should be that this is a small business program and should be closed to activities of large corporations.

We believe that the need really is on technology transition. There are a number of great technologies out there that have never made it to the marketplace, in part because the technology readiness level of those technologies is insufficient to attract the attention of prime contractors or even acquisition managers in the Defense Department because they are not sufficiently advanced. And without having a clearly defined program to move from Phase II into the marketplace, it will be difficult for those transition efforts to be successful.

Currently, companies like Lynntech have to rely on a fairly ad hoc system to approach acquisition managers and to identify technologies that could be of interest and necessary to downstream weapons systems that they are procuring for the needs of our warfighters. And as a result, we find that it is very, very difficult to move beyond Phase II into a Phase III-type effort in large part because there is no Phase III funding available to the acquisition managers to take advantage of our technologies.

For example, we have developed a technology for producing hydrogen peroxide in the field. Hydrogen peroxide is an important element in cleaning spaces and equipment that have been hit with biological agents. Right now the ability of the military to deliver hydrogen peroxide is through air transport and then having to store the hydrogen peroxide on site in the deployment areas.

Hydrogen peroxide is an extremely volatile material and is dangerous to transport in cargo planes. As a result, we have a system of relying only on air, water and electricity that would provide them the hydrogen peroxide as needed in the field and would reduce the transportation costs and the logistics burden of providing that hydrogen peroxide in its current form.

However, because of the long process which defense budgeting goes through, it is difficult for our customer—and we have a cus-

tomer clearly identified in the Defense Department—to reach out and take advantage of our technology because we have landed in the middle of the budget cycle. And so for them to look at us, they would need to put us into line for funding 2 years from now, in which case, we would go 2 years without developing the technology any further, which means 2 more years in which our warfighters don't have access to our system.

So we believe that the most serious question is our ability to continue the development beyond the early-stage capabilities that you will get at the end of Phase II.

We have a number of issues that we have discussed with various players in this arena. We think that there is a possibility of having a compromise to go forward, arranging across the board with whether we are talking about Phase I's, Phase II's, whether we are talking about the level of allocation to SBIR programs, the size of contract awards, et cetera.

We believe a compromise is not only feasible, but is possible within this environment; and we are here and pledge our assistance to you and the committee, Madam Chairwoman, to seek those promise compromises. Thank you.

Chairwoman VELÁZQUEZ. Thank you, Mr. Stocker.

[The statement of Mr. Stocker is included in the appendix at page 109.]Chairwoman VELÁZQUEZ. -- and our next—I will recognize Mr. Luetkemeyer for the purpose of introducing our next witness.

Mr. LUETKEMEYER. Thank you, Madam Chairman.

Mr. Rosellini is the President and CEO of MicroTransponder in Dallas, Texas. MicroTransponder is a privately held medical device company. The company is developing a wireless neurostimulation system for the treatment of chronic pain.

Mr. Rosellini is here to testify on behalf of the Advanced Medical Technology Association. Advanced Med advocates for a legal regulatory and economic environment that advances global health care.

Welcome, Mr. Rosellini.

STATEMENT OF MR. WILL ROSELLINI, CHIEF EXECUTIVE OFFICER, MICROTRANSPONDER INC., DALLAS, TEXAS, ON BEHALF OF ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

Mr. ROSELLINI. Good afternoon. I am honored to appear before the Small Business Committee to share an example of how the SBIR program has made it possible for MicroTransponder to not only develop treatments for chronic pain, but a variety of other neurological disorders, including tinnitus, traumatic brain injury, post-traumatic stress, autism and motor disorders. Taken together, these conditions affect over 50 million people in the U.S. and represent an economic burden of over $100 billion annually.

Utilizing SBIR funding, in the last 2 weeks Drs. Michael Kilgard and Navzer Engineer have recently collected preliminary data that suggest our devices may soon be able to reverse the cause of a neurological disease. As a neuroscientist, every time I read that I get goosebumps. This disease severely affects 12 million people in the United States, 500,000 veterans, 93,000 of whom have recently returned from Iraq.

This disease is tinnitus. Tinnitus is a debilitating constant ringing sensation that originates in the brain itself. Tinnitus is caused by hearing loss often from trauma related to explosion. The VA alone has projected to spend $1 billion annually in 2011 in tinnitus disability compensation. We expect to move our promising treatment for tinnitus into clinical testing in humans within 2 years.

We treat tinnitus by implanting a small device near a nerve in the side of the neck. The device emits small electric pulses near the nerve, which sends a signal up to the brain to produce chemicals that allow the brain to reprogram itself. When a tinnitus patient receives this device therapy while listening to a series of auditory tones, the brain is able to reprogram and eliminate the painful ringing sensation of tinnitus.

If successful in humans, our technology will be the first time a neurological disease has been reversed using medical devices. It is a very exciting time for us at MicroTransponder and it would not have been possible without the SBIR program.

MicroTransponder Incorporated was formed to commercialize Dr. Lawrence Cauller's innovations related to a wireless medical device which interfaces with the nervous system. As a former Army medic, Dr. Cauller had been inspired to use the wireless devices to communicate with robotic prosthetic limbs to replace lost limbs in combat.

Now, I have an M.B.A., J.D., Masters of Neuroscience, Masters of Accounting, Masters of Computational Biology, Masters of Regulatory Science and an entrepreneurial track record in the medical field. But apparently raising funds for robotic prosthetic limbs and devices that can reprogram the brain is not a straight step to profitability. Instead we turned to the SBIR program.

In 2007 we received our first Phase I grant award from Joseph Pancrazio, Program Director of the extramural research program at NIH/NINDS to convert this into a clinical product. This award allowed us to obtain important data to show that we could power our devices wirelessly. With this feasibility established, we began a search for ways to use this technology to deliver electricity to peripheral nerves to treat chronic pain.

At roughly the same time, a colleague and friend of Dr. Cauller, Dr. Kilgard, told me about his idea to use the device to stimulate nerves to selectively alter brain function in a predictable and potentially therapeutic manner. MicroTransponder and UTD submitted a research plan to the SBIR program; and with these funds, Dr. Kilgard's team has turned this idea into a potentially groundbreaking new therapy for tinnitus. We expect this therapy to be able to be used for motor deficit, post-traumatic stress, autism and a variety of other neurological conditions.

These SBIR grants serve a number of important roles in getting high-risk, high-reward companies off the ground. First, they enable the companies to inexpensively test the feasibility of their technology. Second, when a company is able to show feasibility and garner additional funds, this independent scientific validation of the company's approach opens the door for venture capital and other private fundraising.

After receiving our first funds from the NIH, we were able to obtain additional funds from the Texas Emerging Technology Fund.

This fund awarded us a $1.4 million award. The combined funding has allowed us to obtain ″proof of principle″ laboratory data and finalize our prototype device. We are now preparing to enter clinical trials at the end of the year for treating chronic pain as well as possibly reversing tinnitus.

This progress could never have been made without SBIR funding. Without the SBIR program, many high-risk, high-reward technologies would not have been developed and the public would have fewer new treatments for serious illnesses.

Chairwoman Velázquez and Ranking Member Graves, I thank you for your leadership and the reauthorization of the program and giving the SBA a very hard time about their lack of commitment in this area. I appreciate the opportunity to share with you how the SBIR program has been instrumental in allowing MicroTransponder to move forward in developing treatments and cures for a number of unmet needs.

I would be happy to answer any questions you may have.

Chairwoman VELÁZQUEZ. Thank you.

[The statement of Mr. Rosellini is included in the appendix at page 115.]

Chairwoman VELÁZQUEZ. If I may, Mr. Rosellini, I would like to address my first question to you.

We have heard how long it takes in terms of money and time required to bring a new medical device to market. And most medical device firms need investors or partners to commercialize promising research, so in the current economic climate it is extremely difficult to raise capital to transition research from the lab to the marketplace.

What effect is this lack of venture capital having on the rate of innovation in the medical device industry?

Mr. ROSELLINI. My comment on that would be that venture capitalists are now espousing focus, focus, focus. So our device, if it works, is going to be worth hundreds of millions of dollars to a strategic partner. So the venture capitalists would approach our company and say, the only thing you should be allowed to develop and work on and spend money on is a chronic pain indication, meaning only use your device for that.

What we have done is we have mobilized other neuroscientists to use our device in different ways. And the way we motivate them is to say, Hey, go after these SBIR funds so we can come up with further innovation in a nondilutive way for other disease indications. And we have done that with four different disease indications. If we didn't have that opportunity, all of these innovations would have stopped.

Chairwoman VELÁZQUEZ. But once you develop your device and you use the money from Phase I and you want to take that device to commercialize it in the market, you will need resources to go to that other phase.

What type of resources do you think will be available for you to be able to move that product from the lab into the marketplace?

Mr. ROSELLINI. Our approach for the first indication, we think that we could raise venture capital. So for chronic pain, we think we could raise that money. However, we will not be able to develop any of the other indications without SBIR funds, meaning it would

stop. So we need both to be able to develop the program that we would like to develop.

Chairwoman VELÁZQUEZ. Okay.

Mr. Stocker, much of the debate on modernizing the SBIR program has revolved around the issue of venture capital and the role that it should play in the program. So what are your thoughts on this? And is it the most important issue that we here in Congress should be focused on, or are there other pressing matters that we need to consider?

Mr. STOCKER. Madam Chairwoman, I think the most pressing issue is this whole issue of transitioning these technologies into the marketplace.

So my colleague here on the right is describing some of the difficulties they will have in attempting to move their device into the marketplace. There is no clear path. Perhaps there is not only a single path, but there is no clear path within the agencies right now that would allow you to develop your device to the point where you could effectively present it to a private investment group of any kind and have them wholeheartedly enter into an arrangement with you to go ahead and develop that device to go into the marketplace.

So there needs to continue to be a combination of public and private resources to make that happen.

The affiliation rules that were devised for SBA programs in the past—and I don't need to tell you this—was largely directed at ensuring the set-aside programs were not invaded by large corporations. Those affiliation rules don't necessarily apply in an era when there are multiple resources out there and you cannot equate a private financial institution of any kind with a major corporation that is looking to get access to set-aside programs.

So we need to be able to rely on both. But our major problem is that there is not enough money in the base contracts. Those award levels need to be increased. The allocations need to be increased so that we can underwrite more programs with larger contract awards.

And then, finally, there need to be specific appropriations for Phase III development that would then allow you to move beyond the technology readiness levels that we are able to achieve at the end of Phase II. The most common complaint I hear from the technical monitors that we deal with in the Defense Department is that we do not have access to enough money to really develop our ideas.

Chairwoman VELÁZQUEZ. Thank you.

Ms. King, in the biotech industry, investors often tie their funds to the development of the company's lead therapy. As a result, companies can be blocked from spending the funds from investors on other applications.

If small, venture-backed biotechnology companies could participate in SBIR, would more research be conducted on these secondary applications?

Ms. KING. Yes, absolutely. And I have a specific example from our company.

We have a program, very early stage. We think it is very exciting where we have some—a family of compounds that we think could be useful in a number of infectious diseases, including HIV and tu-

berculosis. We cannot work on that program because we have to focus on our lead program.

Now, we think our lead program is exciting and has a lot of value too. And it is on the basis of that program that we have attracted the venture capital investment. But I would love to be able to support my earlier-stage programs with SBIR funding.

And, again—I mean, to open that program to allow companies like ours to apply of course doesn't guarantee that we are going to get the awards. But I would be happy to let our science be judged on the basis of the quality of our data. Let the NIH decide. Open up the competition. Let them choose on the basis of the quality of the science and on that basis make the awards, not on the basis of who owns what percent of our company.

But you are exactly correct. If we were able to access that funding source, then we and other companies would be able to invest in more early-stage, very promising research than we can now.

Chairwoman VELÁZQUEZ. Thank you.

Mr. Green, I think you were here when the first panel was testifying.

Mr. GREEN. Yes.

Chairwoman VELÁZQUEZ. And it caught my attention, the statement made by the rep from DOE, when he said that the VC industry is not interested in the DOE-type of industries.

Mr. GREEN. It caught my attention as well. The truth is, it is just the opposite of that.

In fact, I participated in a panel in front of approximately 200 entrepreneurs yesterday morning in Silicon Valley where the entire focus and the highest amount of interest was about how to get in front of DOE in order to access dollars.

Now, this was beyond the SBIR program, but the interest levels in participation, whether it be in the $2 billion that is looking at developing advanced battery technology or its SBIR programs is truly palpable right now. It is, in fact, as least as great as coming up to Sand Hill Road in Menlo Park and seeking venture capital dollars.

Chairwoman VELÁZQUEZ. Mr. Luetkemeyer.

Mr. LUETKEMEYER. Thank you, Madam Chairwoman. I don't have a whole lot of questions. I just want to make a couple of comments.

I appreciate all of you being here today from the standpoint that you represent the entrepreneurial spirit and what makes this country great, in my mind. I am excited to see you there, and I see the excitement and patience in your voice as you testify for each individual company and the things that you do. The only question I have is for Mr. Green.

You made a comment that—it was kind of interesting and intriguing. You said venture capital is used to build and not do research. I think really—if that is accurate, it really tells us where the SBIR program can be really instrumental in helping get that first step taken so that down the road the venture capitalists can come in and be able to have funds accessible to folks to continue to build their business. I appreciate that point of view.

And if you would like to elaborate on it a little bit more, I would appreciate it.

Mr. GREEN. To drill in on it, there is the conception that venture capitalists will take a significant number of their projects directly out of university labs. In the case of my firm, about 40 percent of what we fund comes directly out of university labs. However, there is a significant portion that needs just a little more of a nudge to get to that commercialization stage. They are not quite there, not quite ready.

The examples that are in Phase I and Phase II grants is that necessary element to push it over the edge. It is very much akin to what is called ″seed funding″ in Silicon Valley, where you will put in a small amount of money in order to get it to that commercialization stage. So this performs an absolutely vital function to get it to a point where we can then build a business around that technology.

Mr. LUETKEMEYER. Very good.

With that, I will yield back, Madam Chairman.

Chairwoman VELÁZQUEZ. Thank you.

Mr. Thompson.

Mr. THOMPSON. Thank you, Madam Chairwoman.

Mr. Green, picking back up on venture capital and the SBIR process, obviously a lot of discussion there. My question is, are there other ways to structure venture capital investment contracts as to not include ownership and, you know, like a greater share of profits or a sliding scale of ownership that corresponds to success?

Mr. GREEN. Yeah. It is an excellent question.

The way the venture capital industry has developed over the last 40 to 50 years has been, we raise our money from university endowments and private foundations under charter documents that require us to take an equity interest in those enterprises. That is the way the model, that is the way the industry has developed.

So, for example, even a slight change like taking an interest in a limited partnership agreement, as opposed to a regular seed corporation, is something that we can't do, in general because we are constricted to taking that equity interest and, hopefully, appreciation of that interest as the enterprise grows.

So it would take a whole sea change in the entire VC industry in order to do it in some other manner.

Mr. THOMPSON. Do you see any movements in that direction at all?

Mr. GREEN. I have not.

Mr. THOMPSON. Okay. Thank you.

Mr. Stocker, in your testimony you mentioned that we should focus on ensuring that large corporations should not directly benefit from a small business program. I certainly agree with that.

How would you suggest that we ensure that?

Mr. STOCKER. In terms of the rules that have been discussed in the past and some subsequent discussion that we have had with committee staff with regard to how you would go forward, we think there should be a percentage limitation on ownership of any SBIR company by a large corporation. And we think that that is workable going forward.

Mr. THOMPSON. Many of the recommendations that you advocated were included in last year's reauthorization bill. You know, what would you like to not see in this year's bill?

Mr. STOCKER. Well, I am not sure that the allocation increase that we are advocating was included in last year's bill for a lot of different reasons. We would like to see that issue addressed at least by the time the bill comes out of conference.

I think, secondly, we don't think there should be a complete elimination of Phase I. Phase I is a very useful exercise in testing whether concepts can be made to work. This notion of having privately financed Phase I's and then being asked to enter into Phase II competition, I think that is an issue that we can look at, but I don't want to see us abandon Phase I.

Phase I is—the incidence of failure is very high in Phase I. But that is a useful result because it tells you you shouldn't be wasting your time in that particular approach. So we think in that context the Phase I's need to be kept in the program.

We would like to see more policy direction in regard to the commercialization exercise. I think the agencies need to be reporting back to this committee on a more frequent basis in regard to how successful the transition efforts are. I would like to see the SBA's data, for example, the 50 percent of Phase II's do become commercialized. That was a little surprising to me.

I would like to see the Defense Department—as good as we have seen progress made within DOD—and, for this, I would single out the Navy; the Navy does a fantastic job in looking at technology transition from an early stage. The other services probably need to do some work in catching up to where the Navy is currently. So in that context, I think that would be important for the committee to include in any bill as a policy directive in regard to this whole technology transition effort.

We would also like to see an appropriation dedicated to covering management costs. You have heard the representatives of the first panel address that. I have actually been in meetings with people saying they didn't want to review SBIR proposals because they didn't have time to do it. And people saw it as a burden on their already busy day of having to undertake an evaluation of SBIR proposals.

So I think if there are additional management resources provided to the agencies, I think that would help them do a better job of being able to articulate topics that make sense to the acquisition people, to be able to do the proper valuation of the proposals and to manage the program as it goes through execution.

Mr. THOMPSON. Very good. Thank you.

Thank you, Madam Chairwoman.

Chairwoman VELÁZQUEZ. An argument often used against venture capital involvement in the SBIR program is that small firms will lose day-to-day operational control of their companies. Can you discuss this subject and tell the committee what impact a venture capital investment would have on the management of a company, on Lynntech for example, Mr. Stocker.

Mr. STOCKER. One of the realities of private capital coming into a company is that those people who are writing the checks usually like to know what the company is doing. So I would not be surprised to see VC firms require a board representation and some oversight of day-to-day responsibilities.

However, I would also be surprised that VC firms would want to run a company on a day-to-day investment because obviously, one of the reasons they are investing in that firm is they are impressed by the quality of the management team, and they are impressed by the quality of the work that firm is doing.

To be concerned about venture capital or investment bank participation in any firm, be it small or large, I think ignores the role of private capital in American enterprise. So I am not too concerned about this whole question of operational control.

Chairwoman VELÁZQUEZ. Thank you.

For the last 18 years, the SBIR set-aside has not been increased from 2.5 percent. Could each one of you explain your views on whether or not this level should be raised, and if so, how high it should be increased?

Mr. Stocker, you already answered my question.

Mr. Green?

Mr. GREEN. As I think about it, I do equate the SBIR program in very many aspects to what a seed financing would be like. And there is a bit of a cottage industry that exists in Silicon Valley around seed financings.

I look at that number as being somewhere around $1.2 million to $1.5 million in today's world to get yourself in general to a point where you can figure out whether or not you have a commercializable business to fund around.

Chairwoman VELÁZQUEZ. Ms. King?

Ms. KING. I would agree with that as a general rule. I think we are in an environment where we want to adopt economic stimulatory policies for the economy, broadly speaking.

We need to focus the investments that we make in areas where we are going to increase employment and support innovation. So I think, to the extent you are looking at trade offs between let's say increasing an SBA program versus other policies that you are looking at in your role as Members of Congress, I think that this is one where you will get a lot of benefit for the investment dollars that you put into it.

I don't have a specific number in mind in terms of how much I would like to see the program increased. But I would say that I believe added dollars in this program will have an economic stimulatory effect. I believe they will increase employment, and I also believe they will support innovation which, over time, will lead to other further economic benefits.

I wanted to comment briefly on the previous question about operational control of VCs. We need to look at the venture capital investors as partners in the enterprise with management. I think, in a good situation, that is how companies work.

I agree with what was said earlier that most venture capital investors in my experience don't want to run the company on a day-to-day basis. What they would really like to do is make the investment, get the regular reports of the progress, and eventually reap the benefit of the risk that they took in making the investment.

They can provide counsel. In our case, I believe our investors give us a lot of benefit by virtue of their experience and their connections and help. I think we need to view them as partners in the enterprise, not somehow as adversaries in the enterprise.

Mr. ROSELLINI. My comment on that is, 30 years ago, you called yourself a chemist or a biologist or a botanist. Today, our scientists like to be referred to as neuroengineers. So the amount of translational research and expertise that goes into a product today is much different than it was 30 years.

The billions of dollars of research for consumer products like TVs and cell phones, we are taking these really interesting parts and putting them into the body. Well, that is a very difficult team to keep together. You have an engineer, an electrical engineer, software engineer and biologist, neuroscientist. So, for us, a movement away from the traditional one scientist working in a laboratory by himself into a way for a business to organize 5 to 10 different people that have to be experts to translate this medicine, so I think it should be increased.

Chairwoman VELÁZQUEZ. Any other questions?

Thank you again.

We will continue to assess and to work and to discuss with the SBIR community the best way to proceed regarding the reauthorization and modernization of the SBIR program. So thank you again for participating in this hearing.

I ask unanimous consent that members may have 5 days to submit a statement and supporting materials for the record. Without objection, so ordered.

This hearing is now adjourned.

[Whereupon, at 3:13 p.m., the committee was adjourned.]

NYDIA M. VELAZQUEZ, NEW YORK
CHAIRWOMAN

SAM GRAVES, MISSOURI
RANKING MEMBER

Congress of the United States
U.S. House of Representatives
Committee on Small Business

2361 Rayburn House Office Building
Washington, DC 20515-6315

STATEMENT
Of the Honorable Nydia M. Velázquez, Chairwoman
United States House of Representatives, Committee on Small Business
Full Committee Hearing: *"Spurring Innovation and Job Growth: An Overview of the Small Business Innovation Research (SBIR) Program"*
April 22, 2009

As Americans, we take great pride in our ability to innovate. Let's not forget, it was *our* engineers who created the Model T, *our* scientists who sent the first man to the moon, and *our* tech entrepreneurs who created the world's favorite new distraction -- yes, we can all thank Mark Zuckerberg for Facebook.com. From cyberspace to the healthcare sector, this country has an impressive track record of innovation. While the economy may be suffering, that pioneering spirit is still alive and well. This is largely thanks to our nation's entrepreneurs.

If we've learned anything from the economic crisis, it's that the policies of the past don't work. We need to change the way that America does business, beginning with an increased focus on small firms. Those are the companies bringing fresh ideas to the table, and new products to market. In fact, entrepreneurs produce 13 times more patents per employee than big businesses. Much of that innovation is powered by research and development grants, the largest of which is the Small Business Innovation Research, or SBIR, program.

In today's hearing, we are going to take a look at that initiative. We will also examine its role in spurring innovation, and discuss obstacles preventing SBIR from reaching its full potential.

First established in 1982, SBIR has helped launch tens of thousands of successful research projects. Every year, the program makes a $2.2 billion investment in small firms, an infusion that gets 1,500 new companies off the ground. It also serves as a driving force behind our most inventive businesses. As a result of SBIR, we have seen breakthroughs in everything from antivirus software to wireless technology for BlackBerrys. But the program doesn't just spark new ideas-- it helps generate jobs, too.

High growth startups-- the kind that receive SBIR grants-- are prolific job creators. In fact, the employment growth rate for these businesses is nearly 4 times that of

bigger firms. Meanwhile, 40 percent of all high tech workers-- from engineers to computer programmers-- are employed by these kinds of companies.

The only thing more impressive than the jobs created through SBIR are the products that come out of it. Year after year, SBIR-backed businesses account for a quarter of U.S. R&D winners. And yet it is clear that the initiative has not reached its full potential. The majority of products developed through the program never make it to market. There are a number of reasons for this, not least of all being a lack of capital.

Innovation is a resource intensive process. It takes time and money to carry a new product from the laboratory to the marketplace. As a result, entrepreneurs often struggle to bridge the gap. SBIR-backed firms should have access to all the tools they need, including venture capital. At a time when capital is increasingly hard to come by, it doesn't make sense to limit funding options for small businesses. It should be up to entrepreneurs themselves-- not Washington bureaucrats-- to decide how these firms are financed.

Last Congress, the House passed a bill to modernize and extend SBIR. Unfortunately, that legislation never made it out of the Senate. With people losing their jobs and businesses closing their doors, programs like SBIR need to be running at full capacity, especially considering the role that entrepreneurs play in economic recovery. These are the businesses willing to take risks and help rebuild the economy. With the necessary tools, they can lay the groundwork for a better, more innovative way of doing business.

Opening Statement for Hearing on
The Importance of Technology in an Economic Recovery
Sam Graves
Ranking Member
Committee on Small Business
United States House of Representatives
Washington, DC
April 22, 2009

Good Afternoon. I appreciate everyone taking the time to be here today to talk about the Small Business Innovation Research, or SBIR, program. We have quite a few witnesses that we will be hearing from today, so I would like to give brief remarks and move right into the testimony.

Today's hearing represents the beginning of this committee's work to review and reauthorize the SBIR program. Today we will focus on how the SBIR reauthorization can be better structured and its role as a vehicle in the early stage development of innovative technologies.

This program is an example of a highly successful federal initiative designed to encourage economic growth and innovation within the small business community. Government assistance in funding can be critical to the startup and development stages of a small business. Not only does it spur growth in individual companies, the program stresses the importance of expanding and diversifying research opportunities to small business.

Created in 1982, the SBIR program offers competition-based awards to stimulate technological innovation among small firms while providing government agencies new, cost-effective, technical and scientific solutions to meet their diverse needs. The development of this program is not only critical to the unique needs of each of the participating federal agencies, but also to our national economy.

Small businesses invigorate the U.S. economy by introducing new products and cheaper ways of doing business, sometimes with substantial economic benefits. They play a key role in introducing technologies to the market, often responding quickly to new market opportunities. Some of the greatest technological innovations came about from small business owners tinkering in their laboratories and workshops. The SBIR program provides these innovators with an opportunity to grow their ideas into practice, provide jobs, and improve our economy.

I remain hopeful that legislation drafted by the Committee will maintain the integrity of the program while not limiting participation. We must work to find an appropriate solution that funds the best science while wisely investing tax-payer dollars.

The SBIR program's track record speaks for itself and I am eager to hear the testimony this afternoon. With that, Madam Chair, I look forward to working with you on this issue and yield back.

Statement of

Edsel M. Brown Jr.

Assistant Director
Office of Technology
U.S. Small Business Administration

Before the

House Committee on Small Business
United States House of Representatives

April 22, 2009

Madam Chairman, Ranking Member, and distinguished members of the committee, thank you for inviting me here today to discuss the Small Business Innovation Research (SBIR) program. I am Edsel M. Brown Jr., the Assistant Director, Office of Technology, at the U.S. Small Business Administration (SBA). My office has responsibility for innovation policy and programs at SBA and for the oversight of the SBIR program.

The SBIR program, established in 1982, was designed to strengthen the role of innovative small business concerns in federally-funded research/research and development, and to utilize federal research and development (R&D) as a base for technological innovation to meet agency needs and to contribute to the growth and strength of the Nation's economy. This competitive award program attempts to promote innovation and commercialization from small companies by restricting a portion of 11 Federal agencies' external R&D spending to small businesses. A National Academies of Science (NAS) review of SBIR concluded that the program is "sound in concept and effective in practice", meets its major Congressional objectives, and is a driver of innovation and commercialization for small businesses. Since its inception, the program has awarded more than $24 billion to small firms.

Program Structure

Federal agencies with an extramural research or R&D budget in excess of $100 million are required to set aside 2.5% of that budget for the SBIR Program. The 11 participating agencies are: the Departments of Agriculture, Commerce, Defense, Education, Health and Human Services (including the National Institute of Health), Transportation, Energy, Homeland Security, Environmental Protection Agency, the National Aeronautics and Space Administration, and the National Science Foundation.

The Program is structured in three phases: Phase I awards provide up to $100,000 to evaluate the feasibility and the scientific and technical merit of an idea. Phase II awards are funded up to $750,000 for 2 years for the further development of the ideas proposed in Phase I.

In Phase III, the awardee firm secures additional private sector or government funding, either as sales or investment.

SBA's Role

SBA helps ensure that the program fulfills its mission of stimulating innovation from small businesses that meet a private sector or government need. SBA coordinates the policy development for the program among the participating agencies, provides oversight of the policy implementation, and reports on various aspects of the program.

SBA's policy role is enshrined in its Policy Directive, which was last updated in 2006. The Directive contains rules and guidelines that agencies follow as they manage their SBIR programs. The Directive contains detailed descriptions of procedures to be followed and guidance on all aspects of the Program and is available on SBA's website. We revise the Policy Directive as needed to clarify Program issues or incorporate new elements into the Program.

SBA's oversight activities include monitoring the calculation of agency extramural budgets, overseeing agencies' solicitation schedules and award timelines, and ensuring that policies, rules, or interpretations promulgated by an agency are consistent with the SBIR Policy Directive. SBA also hosts quarterly meetings with SBIR Program Managers. These quarterly meetings provide the opportunity to keep Program Managers informed of interpretations of the Policy Directive, issues impacting individual agencies and the program, and provides a forum to communicate directly with the Program Managers about any concerns or difficulties they may be having.

In reporting program information, SBA maintains the TechNet database and reports annually to Congress on each agency's SBIR Program award activity and other achievements.

Agencies' Role

Each of the 11 participating agencies is responsible for the administration and management of its SBIR program. Agencies provide all of the project funding (collectively, about $2 billion per year), post SBIR solicitations, receive and evaluate proposals, select awardees, monitor projects, conduct reviews, require a commercialization plan with each proposal submitted for Phase II award, collect and maintain awardee information, administer SBIR funding agreements, ensure intellectual property developed with SBIR awards are properly protected, and submit annual reports to the SBA containing complete records of their awards. Each agency has its own technology needs, consistent with its mission, as well as its own set of regulations and protocols. As a result, the SBIR Program as a whole encompasses 11 very different types of SBIR programs. One important distinction is between agencies such as DOD and NASA, with clear technology needs, and agencies such as NSF or NIH, that do not procure technology themselves but rather have broader public interest missions.. The SBIR program allows flexibility to adapt to each agency's mission, while conforming to the rules and framework we established in the Policy Directive. For example, several of the agencies with larger budgets have developed agency-specific programs to support the commercialization phase of their projects. DOD has implemented Phase II enhancements and the Commercialization Pilot Program, and the NSF

administers its Phase IIb program. We also permit and encourage agencies to develop outreach programs that are consistent with their agencies

The number of awards given annually has grown over time in proportion to the extramural R&D budgets of the participating agencies. More than 100,000 awards have been made over the life of the program, totaling about $24 billion. Awards have been made to firms in all 50 states, Puerto Rico and the District of Columbia. Today, agencies evaluate over 25,000 proposals each year and make about 6,000 awards to about 3,000 small high-tech companies each year.

Assessing the impact of the program

The Small Business Administration and SBIR's partner departments and agencies recognize the importance of assessing the SBIR program's outcomes and achievements. The recent NAS study provided a first step for assessing the program. In part, NAS found that SBIR "is increasing innovation, encouraging participation by small companies in federal R&D, providing support for small firms owned by minorities and women, and resolving research questions for mission agencies in a cost-effective manner". The study's findings highlight the SBIR program's contributions to:

- ***Job and Revenue Growth:*** SBIR awardees generate 26 more jobs and $4 million in additional revenue after SBIR funding (vs. 6 additional jobs and $1 million in additional revenue for comparable, non-SBIR firms).
- ***Commercialization:*** Nearly 50% of SBIR Phase II awardees bring their innovations to the market place
- ***Small Business Reach:*** From 1992 to 2005, nearly 15,000 small businesses received SBIR awards .

While NAS study provides an interesting initial view of program performance, SBA believes that further quantitative measures of the program's success and impact are essential. SBA is currently updating its TechNet data system, which will provide a comprehensive and real-time searchable database on all SBIR awards, as well as implementing an online system to increase the reliability of data.

SBA is also developing program-wide performance information to measure commercialization and innovation success rates for all SBIR awards. SBA will include this information in its annual reports to Congress, as it is developed. The NAS Study found that just under half (47%) of respondents to its Phase II survey had generated sales. By assessing performance more regularly, we hope to gain a better understanding of the program's ability to meet its mission and ensure that R&D funding is optimized.

Along with quantitative measures, case studies can often inform decision makers about program performance. Each of the agencies participating in the SBIR Program has experienced success, and I encourage each of you to go to the agency SBIR websites to view these successes. For illustrative purposes, I am going to describe one of these successes with you this afternoon.

The success story is ArmorWorks, LLC. ArmorWorks has developed a high performance, low cost composite armor for the U. S. Marine Corps' (USMC) new Expeditionary Fighting Vehicle (EFV).

ArmorWorks developed the composite armor system in response to a Navy requirement for a lightweight armor component that can be affordably produced and assembled. The system is made from low cost composite ballistic materials, providing the EFV with maximum ballistic protection while adding as little weight as possible. The ballistic protection suite, using state of the art composite materials was evaluated, tested and presented to the Navy and USMC.

In early 2004, ArmorWorks won a contract from the Army for procurement of armor kits for the High Mobility Multipurpose Wheeled Vehicles (HMMWV). In 2005, the company received a contract from the USMC to replace the existing steel armor on its fleet of CH46 helicopters, and an additional contract in 2006, from the USMC for Enhanced Small Arms Protective Inserts (ESAP). The technology is presently being used to provide extra armor for protective vests worn by marines and soldiers serving in Iraq and Afghanistan.

Again, this story is just one of many. The story clearly illustrates the SBIR Program at its best – assisting small companies leverage their resources and providing the country with cutting edge innovation and technology.

The commercial success of SBIR projects is often determined not just by actions taken in Washington, but by the resources and infrastructure available to the small business in its home state. Because of this, SBA works with organizations at the state level to encourage the development of innovation infrastructures to help SBIR firms after Phase II. Many states have programs to provide small firms, including SBIR awardees, a range of business assistance services including business mentoring, matching the firms with venture capital companies or angel investors, providing basic business training, and integrating the projects with resources and expertise at universities and other research institutions.

A measure of success of the SBIR program is that it is being replicated elsewhere. Countries from across Europe, Asia, and Latin America are establishing innovation programs based on the successful SBIR model.

Thank you for the opportunity to appear before you today. I will be happy to answer any questions you may have.

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TESTIMONY OF

MR. MICHAEL CACCUITTO

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SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS

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OFFICE OF THE UNDER SECRETARY OF DEFENSE

(ACQUISITION, TECHNOLOGY & LOGISTICS)

BEFORE THE

HOUSE COMMITTEE ON SMALL BUSINESS

April 22, 2009

FOR OFFICIAL USE ONLY UNTIL RELEASED BY THE COMMITTEE

Testimony of

Mr. Michael Caccuitto

Assistant Director, Office of Small Business Programs

SBIR/STTR Program Administrator

Office of the Under Secretary of Defense (Acquisition, Technology & Logistics)

House Committee on Small Business

Review of the Department of Defense (DoD)

Small Business Innovation Research (SBIR) Program

April 22, 2009

Chairman Velazquez, Ranking Member Graves and Members of the Committee on Small Business:

Thank you for the opportunity to testify on the Small Business Innovation Research (SBIR) Program. I welcome this opportunity to provide a perspective on how the program is implemented and managed within the Department. The program is used as a tool for the Department of Defense (DoD) to seed innovation in our industrial base, and, in so doing, develop leading-edge technologies with the potential to meet warfighter needs today and in the future. Now, more than ever, we need to leverage our nation's small businesses responsiveness, efficiency, and capacity to innovate.

One of our central obligations as public officials is to ensure that we are using taxpayer dollars as productively and efficiently as possible for their intended purpose. In that vein, today I will provide an overview of the SBIR program and its impact, and also

highlight some actions the Department has undertaken to improve the program. We at the Department are always ready to work with the congressional oversight committees, and other participating federal agencies, including the Small Business Administration (SBA) to ensure the SBIR program is as effective as possible.

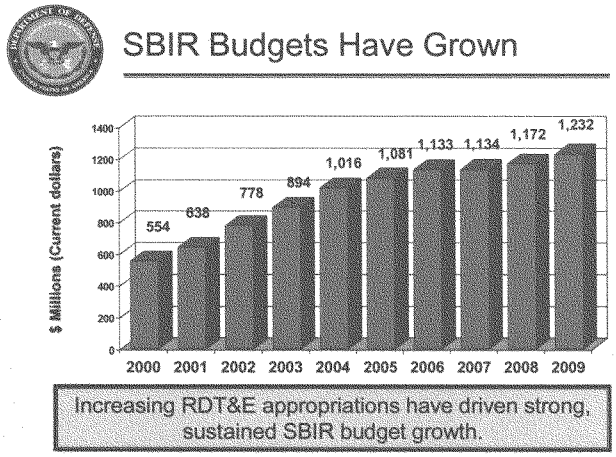
SBIR at DoD

The DoD SBIR Program comprises twelve Military Department, Defense Agency, and other Defense Activity programs, with oversight provided by the DoD Office of Small Business Programs. These participating elements, hereafter referred to as "Components," in order of largest to smallest budget in Fiscal Year 2008 (FY08), are the: Air Force, Navy, Army, Missile Defense Agency (MDA), Office of the Secretary of Defense (OSD), Defense Advanced Research Projects Agency (DARPA), Joint Science and Technology Office of Chemical and Biological Defense (CBD), US Special Operations Command (SOCOM), Defense Threat Reduction Agency (DTRA), Defense Logistics Agency (DLA), Defense Microelectronics Activity (DMEA), and National Geospatial-Intelligence Agency (NGA).

The Department's SBIR budget is determined by a statutory 2.5 percent assessment of the extramural research, development, test and evaluation (RDT&E) budget. Each Component's portion of the overall program is managed to be responsive to specific mission and corresponding technology research and development needs while also being consistent with overarching Department science and technology guidance. In

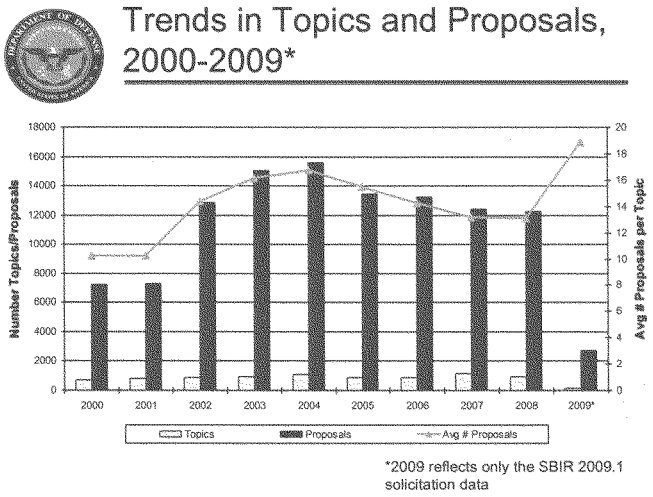
terms of budget, the Department's Program represents over 50 percent of the total federal SBIR budget, which exceeds two billion dollars.

As shown in the chart below, the DoD SBIR Program has experienced substantial growth in recent years, more than doubling in size from FY00 to FY06 to over one billion dollars, and it continued to grow through FY09 to over $1.2 billion. This expansion is driven directly by growth in the underlying RDT&E budget, as the SBIR percentage has remained constant over this period of time. The number of SBIR solicitations has also increased from two to three per year, spaced almost evenly throughout the year.



Likewise, the number of proposals received and contracts awarded have increased proportionally with budget growth. The number of topics, statements of research and development needs, solicited annually has not grown as much. This reflects a trend

towards a greater number of Phase I and II contract awards[1] per topic; effectively increasing the relative degree of investment focus. To illustrate, in FY00, 701 topics attracted 7,201 Phase I proposals; while for FY08, 935 topics drew 12,280 proposals. As shown below, for several years, topics received about 14 proposals each, on average. After a brief dip in FY07 and FY08, we are seeing a substantial surge in early FY09. This increased interest in the program is not surprising as SBIR remains a stable source of innovation capital and opportunity during this time of economic downturn.



The SBIR program funds a great deal of research and development in a given year. The chart below summarizes program activity by DoD component for FY08. In total, 12,280 Phase I and 1,672 Phase II proposals were received and evaluated, 1,826 Phase I

[1] Phase I contracts fund effort to assess the technical feasibility of a proposal while Phase II efforts fund technology development and demonstration and typically result in a prototype. Phase I guidelines are currently $100,000 and

and 1,072 Phase II contracts were awarded. These contracts were awarded to 1,319 different firms. Additionally, 469 FY07 Phase II contracts continuing into FY08 received funding and 34 Phase II "Enhancements" were done to co-fund additional development with sources of non-SBIR federal funding or other non-federal funds.

Annual Report Summary: FY 2008 SBIR Program Activity

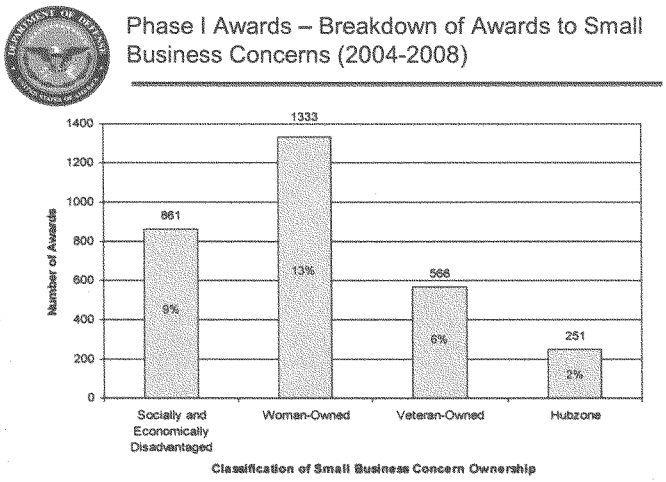
DoD Component	SBIR Budget	# Topics	# Ph I proposals	# Ph I awards	# Ph II proposals	# Ph II awards
Army	$270,409,000	204	2,774	305	335	187
Navy	$273,662,000	221	2,708	567	334	315
Air Force	$337,299,630	310	3,967	485	647	319
DARPA	$66,579,000	64	965	108	106	44
DTRA	$7,124,000	13	173	13	17	7
MDA	$122,689,000	51	600	159	98	90
SOCOM	$8,655,000	5	74	11	12	6
CBD	$12,570,000	8	114	14	13	13
OSD	$68,626,000	58	837	155	100	88
DLA	$2,672,000	1	65	0	8	1
DMEA*	$1,162,250	0	0	5	2	2
NGA*	$649,795	0	0	4	0	0
All DoD	**$1,172,097,675**	**935**	**12,280**	**1,826**	**1,672**	**1,072**

* DMEA began participating in FY07 and fully executed FY08 funding supporting awards derived from FY07 solicitation; NGA is a voluntary participant and also fully employed FY08 funds through awards derived from prior year solicitations.

While awards in the SBIR program are made to small business concerns, no preference is given to small business concerns owned or controlled by socially or economically disadvantaged individuals, Woman-owned small business concerns, Veteran-Owned small business concerns (VOSB), and Small Business Administration (SBA)-certified small business concerns located in Historically Underutilized Business

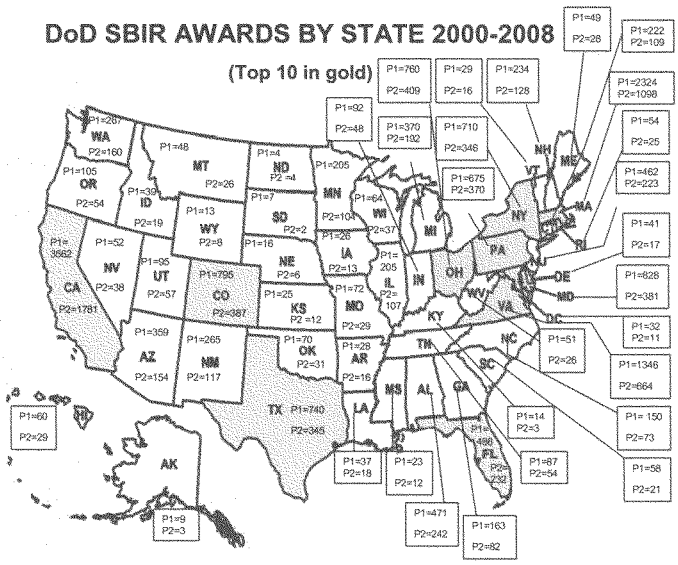
6months duration and Phase II guidelines are currently $750,000 and 2 years duration.

Zones (HUBZone) or awards to these firms account for 30% of all Phase I awards in the past five reporting years, as shown below. WOSB and VOSB firms, in particular, are capturing an increasing percentage of SBIR contract awards. Within the VOSB category, there has been dramatic growth in the percentage of total awards going to Service-Disabled Veteran-Owned small business concerns.



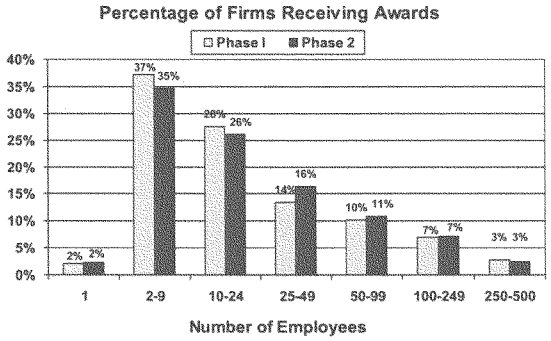
While program participation occurs throughout the United States and awards are made to firms from every state, participation from a few states stands out, as shown below. The states with firms receiving the most awards from 2000 through 2008, in descending order, are: California, Massachusetts, Virginia, Maryland, Colorado, Ohio, Texas, New York, Pennsylvania, and Florida. States that have experienced the greatest percentage increase in the number of awards over this period, starting with the greatest

percentage increase are: Iowa, Indiana, Kentucky, Hawaii, Oregon, Arkansas, Oklahoma, Delaware, Idaho and Utah.



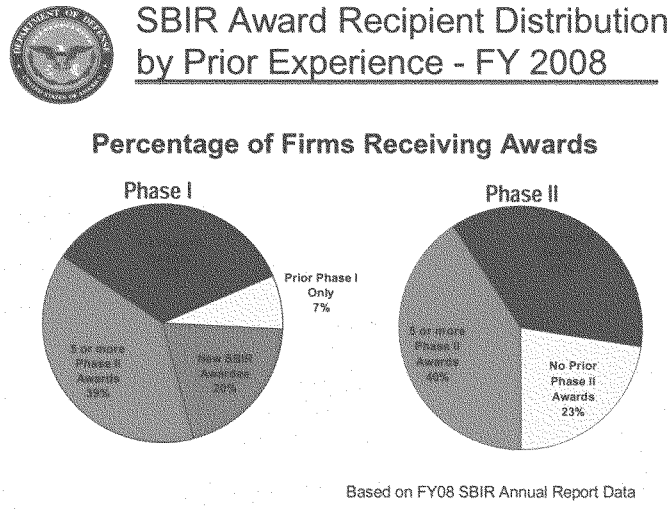
Looking at the size of firms among the DoD SBIR award base, historically, a high percentage are very small. The chart below shows the distribution of firms receiving Phase I and Phase II contracts in FY08 by number of employees. 67% of Phase I award winners had fewer than 25 employees at the time of contact award. Similarly, 63% of Phase II award recipients had fewer than 25 employees at the time of award. The distribution suggests that firm size in not a strong determining factor with respect to reaching Phase II.

SBIR Award Recipient Distribution by Firm Size – FY 2008



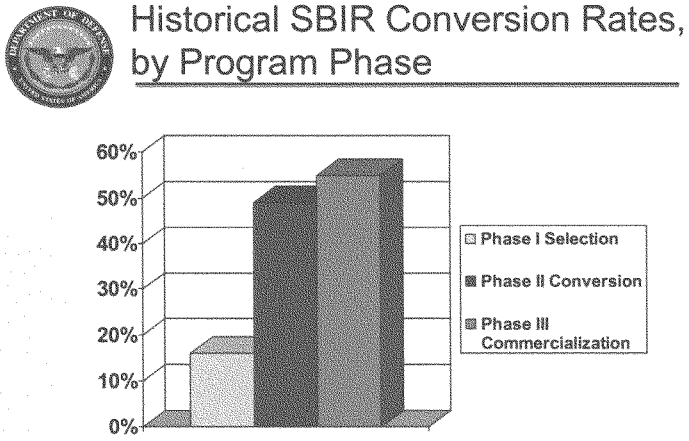
Based on FY08 Annual Report; Firm Data taken from Company Commercialization Report, 2008

The next chart shows the prior experience level with the DoD SBIR Program of FY08 award recipients. 20% of Phase I award winners had never received a DoD Phase I award, while an additional 7% had never received a Phase II award. Among Phase II award recipients, 23% of Phase II award recipients had never before been awarded an SBIR Phase II contract by the Department, while an additional 37% had received four or fewer Phase II awards. These statistics show that the SBIR program is attracting a significant number of new or relatively new program participants.



The SBIR Program is quite competitive. The chart below shows that the Phase I proposal selection and funding rate for a ten-year window of program activity is about 16%, or approximately one in six. While this can be a daunting figure for candidate firms, the percentage that "convert" to Phase II is much higher, almost 50%. Since 2000, the Department has collected data on "Phase III" activity to gauge commercialization[2] of Phase II technology efforts. Over 55% of Phase II contracts deriving from solicitations conducted between 1994 and 2003 report receiving non-SBIR revenue or investment which derives from, extends or concludes the Phase II work.

[2] The SBIR Program Directive, September 24, 2002, section 3(e) defines commercialization as: "The process of developing marketable products or services and producing and delivering products or services for sale (whether by the originating party or by others) to the Government or commercial markets." Phase III is defined in section 4(c) as "...work that derives from, extends or logically concludes effort(s) performed under prior SBIR funding agreements, but is funded by sources other than the SBIR Program."



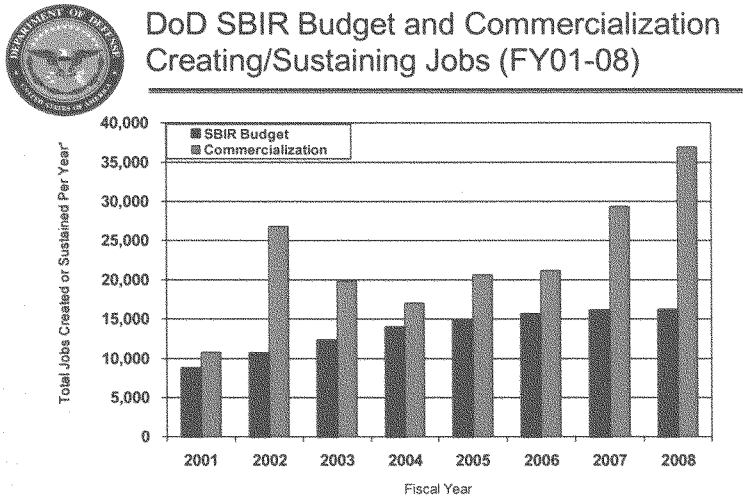
Based on all Phase I and Phase II contracts derived from 1995-2004 solicitations. Commercialization data taken from January 2009 DoD SBIR Commercialization Database.

In the course of administering the SBIR Program, the Department does not collect data specifically measuring job creation. However, we can estimate program job creation or sustainment by calculating the employment associated with SBIR budget expenditure and reported commercialization. Using a conversion factor of 13.8 jobs per one million dollars,[3] DoD SBIR funding supported the creation or sustainment of between 9,000 and 16,000 jobs per year between fiscal years 2001 and 2008 (shown in blue below). New commercialization, in the form of follow-on sales or investment, supported the creation or sustainment of between 10,000 and 37,000 jobs per year (shown in green below).

[3] Figure based on work performed by Dr. Robert Pollin of the University of Massachusetts, Amherst to estimate the impact of public building retrofits. The Department used this figure to estimate the impact of power and energy research and development projects funded through the American Recovery and Reinvestment Act of 2009. The estimate includes direct and indirect jobs. The Alliance for American Manufacturing estimated and impact 18 jobs

Note that this is trending upward at a higher rate than jobs directly supported by the SBIR budget because these jobs are driven by market activity produced by the aggregate of SBIR Program investment to date. This estimate is believed to be conservative as many firms outgrow the SBIR program, are acquired by large firms, or otherwise do not continue to participate and thus report. Further, we do not collect data on commercialization derived directly from Phase I efforts and therefore cannot estimate the follow-on impact of Phase I efforts which do not receive Phase II funding. Additionally, the estimates do not account for any economic spillover effects of knowledge generated through SBIR efforts that create or affect other market activity. On the other hand, this process of jobs creation and sustainment has opportunity costs associated with it. Therefore the foregoing numbers have uncertainties associated with them and one should use some degree of caution in extrapolating to overall program effects.

for every $1 million spent on new infrastructure spending and the US Commerce Department estimated an impact of 16.7 jobs per $1 million spent on "green investments."



*based on 13.8 jobs/ $1million conversion factor

Source: DoD SBIR Commercialization Database, captured in October every year 2000-2008. Data includes only DoD SBIR phase II Awards reported at time of capture. DoD began systematically collecting this data in 2000.

The Department has many efforts underway to promote more SBIR commercialization in the defense and broader marketplaces. The Military Departments are implementing Commercialization Pilot Programs (CPP), under authority granted by section 9(y) of the Small Business Act, as amended by section 252 of the National Defense Authorization Act for Fiscal Year 2006, to accelerate the transition of certain SBIR-funded technologies to Phase III and into the acquisition process, where the successful transition is expected to meet high priority requirements. The Army, Navy and Air Force are taking different approaches to this challenge and efforts to date show great promise with initial commercialization rates exceeding those of the broader SBIR

Program. The Department plans to transmit our comprehensive annual report to Congress on FY08 CPP activity soon.

The Department plans to hold its fourth *Beyond SBIR Phase II Conference and Technology Showcase* in September 2009 to bring together key technology and acquisition personnel from government and industry to enable the commercialization of SBIR-funded research and development into products. Recent Phase II award recipients from across the country are invited to showcase their technologies at this conference, which features pre-scheduled "technology matchmaking" meetings between these firms and representatives of prime contractors, government technology and acquisition activities, the investment community and manufacturing firms. This conference event is open to all federal agencies and their recent contract or grant recipients.

With regard to policy, we have taken several steps to improve SBIR program utilization as a source of innovation within the Department. A policy memorandum was issued clarifying SBIR Phase II responsibilities to reinforce the imperative of SBIR data rights protection and highlight SBIR as a source of innovation to address Department needs. Additionally, the DoD regulation governing the acquisition system was modified to require that program managers include SBIR in program technology planning and give favorable consideration to successful SBIR technologies. We plan to roll out a new Continuous Learning Module at the Defense Acquisition University and incorporate the module into the training curricula for personnel in systems planning, research, development and engineering, acquisition, and contracting.

Conclusion

In summary, again I thank you for the opportunity to testify on the DoD SBIR Program, its value, and impact. I hope my testimony has provided you with an understanding of how the program is implemented at the Department of Defense. I would be happy to answer any questions you may have.

Testimony
Before the
Committee on Small Business
U.S. House of Representatives

Statement for Hearing entitled, "The Importance of Technology in an Economic Recovery"

Statement of
Jo Anne Goodnight
NIH SBIR/STTR Program Coordinator
Office of Extramural Research
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 1:00 p.m.
Wednesday, April 22, 2009

Good afternoon, Chairwoman Velázquez and members of the Committee. My name is JoAnne Goodnight. I am the Coordinator of the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs 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 SBIR program, particularly the role the program plays in advancing innovation and creating jobs. 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.

IMPORTANCE OF SBIR PROGRAM AT NIH: IGNITING IMAGINATIONS AND SPURRING NEW DISCOVERIES

The NIH SBIR Program is ideally suited for creating research opportunities for U.S. small businesses to stimulate technological innovation. Part of a complex innovation system, the NIH SBIR program provides 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 will lead to better health for everyone. The NIH SBIR program is one means by which the NIH Institutes and Centers (ICs) accomplish their R&D objectives. A unique feature of the SBIR program is a focus on commercialization of the outcomes of research. Thus, the program serves to supplement the more basic and applied research programs of NIH.

TYPES OF RESEARCH NIH SUPPORTS UNDER SBIR

Examples of the types of research that NIH supports through the SBIR program include, but are not limited to, drug discovery, medical devices, biosensors, nanotechnologies, proteomics, imaging, bioengineering, behavioral research, and 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 also encourage small businesses to propose their own innovative research ideas that are relevant to our mission.

NIH SBIR PROGRAM OVERVIEW

The NIH, in accordance with statute, must set aside 2.5 percent of its extramural research and development budget for a SBIR program. In fiscal year (FY) 2008, the NIH SBIR set-aside was about $580 million. NIH awarded 806 new Phase I and 288 new Phase II SBIR projects to small businesses working in many different technology areas across the country. 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 commercialization status, when a small business concern has received more than 15 Phase II awards in the prior five fiscal years (FYs).

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

[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

29.9 FTEs. In addition, respondents estimated as a result of their SBIR projects their companies were, on average, able to hire 2.7 full time employees (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. These data suggest that the SBIR program has positive employment effects on small business job creation and growth.

PROGRAM EFFECTIVENESS: BRINGING IDEAS TO LIFE

The SBIR program seeks to fund the most scientifically promising projects for which private and public funds are not traditionally available. As noted from the few examples below, the program has shown that tangible scientific benefits can result from a small investment in early-stage ideas with commercial potential.

NIH SBIR projects are stories of discovery. Following are a few examples of how SBIR products are touching people's daily lives:

- An antiviral drug, Tyzeka, under the generic name of telbivudine, is used to treat chronic hepatitis B in adults.
- A needleless infusion patch called the *PassPort™ System* is capable of delivering drugs such as insulin. This novel technology bypasses metabolism in the intestinal tract which typically results in low bioavailability of oral drugs.

- A new cholesterol test, called the VAP™ (Vertical Auto Profile), can identify twice the number of people at risk for heart disease than traditional cholesterol tests developed in the 1970s.
- The HydroMARK™, a novel, visible marker used in ultrasound, is addressing an unmet clinical need and has helped patients by replacing lengthy mammogram guided wire localization procedures with quick, accurate ultrasound guided localization procedures that are more comfortable.
- The Lifeline™, which is tissue engineered blood vessels comprised entirely of the patient's own living cells, is targeted to help hemodialysis patients, lower limb amputation candidates, pediatric patients with cardiac defects and coronary bypass candidates.

Examples such as these demonstrate ways the SBIR program is stimulating technological innovation and underscore why the NIH SBIR program is important to our mission and to the entire innovation process.

PROGRAM FLEXIBILITY IS KEY: ONE SIZE DOES NOT FIT ALL

NIH is continually focused on ways to address the needs of a diverse business community, multiple industries, different technology sectors, and diverse product outcomes. NIH attributes the success and effectiveness of its program to several factors, the most significant of which is flexibility in our proactive administration of the program to accommodate the changing nature of biomedical and behavioral research while increasing the efficiency and effectiveness of the 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 exceed the Phase I and Phase II award guidelines when the science proposed warrants such a deviation to produce successful outcomes. The SBIR median award size in FY 2008 was $151,440 for Phase I and $841,381 for Phase II projects. For STTR, the median award size was $149,711 for Phase I and $907,970 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 agonizing period between discovery and commercialization. For example, the Phase I/Phase II Fast-Track award and Phase II Competing Renewal award are aimed at accelerating research projects that have great potential to produce products; and, our commercialization assistance programs are targeted to the specific needs of small businesses funded by NIH.

For many biomedical technology companies, the SBIR program is an important source of seed funding for early-stage ideas of unproven feasibility, but a venture capital financing strategy is the only realistic way that their innovative product will enter the marketplace. Research in public health and biotechnology is characterized by high and intense capital needs to see a product from idea to market (e.g., it takes an average of $1.2 billion to bring a drug to the market); unusually long development times (i.e., 5-12 years); exceptionally high "burn rates" for investment funds; investment by venture capital companies (VCCs), many of whom are not owned at least 51% by individuals; and often, the necessity for multiple rounds of financing to fund the extensive and

essential clinical research. Individuals, alone, simply cannot finance the hundreds of millions of dollars for necessary clinical phases to bring products to the market that will improve the health of Americans.

The NRC's study of the SBIR program noted 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, more interdisciplinary, and ever more expensive.

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 National Research Council's study found no evidence that participation of companies with multiple VC 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 VCCs.

KEY TRENDS

Overall, the SBIR program has complemented NIH's mission to advance science while reducing the burden of illness on public health. In spite of our commitment to small businesses and our proactive enhancements to the NIH SBIR program, the program has not increased participation of applicants at the same rate observed for other sectors of the NIH extramural community at NIH. Specifically, the numbers of SBIR applications and new firms participating in the program declined from fiscal years 2004 through 2008. Though the reasons for this near 40 percent drop in applications are not fully understood, this disconcerting trend appears to be the result of disincentives in the program that are either rendering worthy companies ineligible or driving them away for other reasons.

CONCLUSION

In conclusion, I want to reemphasize the NIH commitment to supporting small businesses, maintaining the integrity of SBIR program, and ensuring that technology developments will help improve the health and extend the lives of all people. We are looking to small businesses, primarily through the SBIR program, 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 program 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. This concludes my statement. I will be pleased to answer any questions you may have.

STATEMENT OF
LARRY JAMES
SMALL BUSINESS INNOVATION RESEARCH AND SMALL BUSINESS
TECHNOLOGY TRANSFER PROGRAM MANAGER
U.S. DEPARTMENT OF ENERGY
BEFORE THE
COMMITTEE ON SMALL BUSINESS
U.S. HOUSE OF REPRESENTATIVES

APRIL 22, 2009

Madam Chairwoman and Members of the Committee: Thank you for inviting me to speak today about the Small Business Innovation Research (SBIR) program at the Department of Energy (DOE).

The Office of Science manages the SBIR program for the Department and has done so since the SBIR program was formed in 1982. In addition to the Office of Science (SC), six other DOE programs participate in the SBIR program: Defense Nuclear Nonproliferation, Electricity Delivery and Energy Reliability, Energy Efficiency and Renewable Energy, Environmental Management, Fossil Energy, and Nuclear Energy. Some areas of the Department are exempt by law and do not contribute to SBIR, including Naval Reactors and other national security programs.

The statutory SBIR program has several purposes: to stimulate technological innovation; to use small businesses to meet Federal research and development (R&D) needs; to foster and encourage participation by socially and economically disadvantaged small businesses; and to increase private sector commercialization of innovations derived from Federal research and development.

The Department's SBIR goals include: funding high quality projects with relevance to the Department's mission needs; increasing private sector commercialization of technology developed through DOE SBIR-supported R&D; stimulating technological innovation in the private sector; and improving the return on investment from federally-funded research for economic and social benefits to the nation.

In accordance with the U.S. Small Business Administration's (SBA) SBIR Policy Directive, the SBIR program is administered in three phases. Phase I is to evaluate the scientific or technical merit and feasibility of ideas that appear to have commercial potential. Phase II builds on Phase I work and encompasses the core of the research and development effort. Phase III refers to work that derives from, extends, or logically concludes efforts performed under SBIR funding agreements, but is not itself funded by the SBIR program. Phase III work funded by the respective program office is typically oriented towards commercialization of the SBIR research or technology. That is, the SBIR funding pays for research or R&D meeting DOE objectives identified by the DOE

(Phases I and II); non-SBIR investment provides follow-on developmental funding to meet commercial objectives (Phase III).

The Office of Science also manages the Small Business Technology Transfer (STTR) program, which was established in 1992. The major difference between the SBIR and STTR programs is that STTR grants must involve substantial cooperative research collaboration between the small business and a research institution. At least 40 percent of the research or analytical effort must be allocated to the small business, and at least 30 percent of the effort must be allocated to a single research institution. The budget for DOE STTR program is also much smaller than SBIR. In Fiscal Year (FY) 2008, the STTR program was funded at $15 million, while the SBIR program was funded at $124 million. FY 2009 funding levels and awards are still being determined.

A portion of DOE's funds appropriated under the American Recovery and Reinvestment Act of 2009 are eligible for the SBIR set-aside. The Department plans to award these funds in accordance with current allocation procedures discussed later in this Statement.

SBIR PARTICIPATION

Over the 26 years of its existence, the SBIR program has matured and evolved significantly. We have issued 26 Phase I solicitations, reviewed approximately 34,600 proposals, and funded over 4,900 Phase I projects and 2,000 Phase II projects. Each year we have issued the solicitation on schedule, met the deadline for the selection of both Phase I and Phase II awards, and published abstracts of our Phase I and Phase II projects.

In FY 2008, the Department received 1,494 Phase I grant applications from 756 companies of which 1,246 were sent out for external peer review. We selected 318 applications for Phase I awards resulting in grants to 191 small businesses in 33 states. Sixty of the 318 grantees were first time winners with DOE. Eleven of the applicants selected for funding were from socially and economically disadvantaged small businesses and 15 were from small businesses located in a HUBZone (historically underutilized business zone).

Below are additional statistics:

Year	**2005**	**2006**	**2007**	**2008**
Number of Applications Submitted	1558	1387	1318	1494
Number of Applications Peer Reviewed	1100	1062	1075	1246
Number of Awards Made	389	289	318	318
Number of Individual Companies that Submitted	823	700	672	756
Number of Companies with Funded Projects	179	173	189	191
Number of First-time Awardees	80	62	74	60

Year	2005	2006	2007	2008
Number of Small & Economically Disadvantaged Small Business Awardees	31	33	22	12
Number of Woman-owned Small Business Awardees	33	29	32	31
Number of HUBZone Awardees	9	14	23	15

PROGRAM EFFECTIVENESS

Awards from the SBIR program help small businesses attract investment by affirming that the companies have excellent technical capability, thus reducing some of the uncertainty involved in early-stage investment. Several comprehensive reviews of the SBIR program by the Government Accountability Office (GAO) have found it to be successful in enhancing the role of small businesses in Federal R&D, stimulating commercialization of research results, and supporting the participation of small businesses (Testimony before the Subcommittee on Environment, Technology, and Standards, Committee on Science, House of Representatives, *Federal Research: Observations on the Small Business Innovation Research Program,* June, 28 2005, GAO-05-861T, and references therein). Furthermore, a recently completed National Research Council (NRC) of the National Academies study entitled *An Assessment of the SBIR Program at the Department of Energy* concludes that the DOE SBIR program "is making significant progress in achieving the congressional goals for the program. The SBIR program is sound in concept and effective in practice..." DOE's SBIR program has supported excellent research, resulting in spin-off companies and technologies, and is a model with respect to the commercialization assistance program. According to the SBA, DOE was the first agency to offer commercialization assistance to awardees beginning in 1990.

PROGRAM MANAGEMENT OVERVIEW

The SBIR program complements the Department's other R&D funding mechanisms. SBIR is regarded within the Department like any other R&D program, namely, as a vehicle by which the Department accomplishes its R&D objectives. SC's long history of using merit-based review of grant applications and its thorough understanding of scientific and technical research are key elements in our successful management of the SBIR program. As with other SC programs, the scientific/technical evaluations of SBIR grant applications are performed by external researchers expert in the subject area. SC's relationship with the scientific community, from which the peer reviewers are drawn, is extensive.

Cooperation throughout the Department in administering the SBIR program is achieved through a balance of centralized and decentralized management. The SBIR program is centralized in the setting of schedules, procedures, scoring guidance, final award selections, and all logistics relating to the processing of proposals. It is decentralized in that the SC and DOE technology program offices are responsible for developing specific

research topics that support their mission goals, identifying peer reviewers, and providing a priority ranking of grant applications to be considered for funding.

Some current technical topic titles include: technology to support Basic Energy Sciences user facilities; technologies related to energy storage for hybrid and plug-in hybrid electric vehicles; advanced water power technology development; climate control technology for fossil energy applications; high-speed electronic instrumentation for data acquisition and processing; carbon cycle measurements of the atmosphere and the biosphere; nuclear physics instrumentation, detection systems, and techniques; scalable system software for petascale computer systems; advanced technologies and materials for fusion energy systems; simulation and software tools for nonproliferation R&D; advanced technologies for electricity systems; improved characterization of waste in tanks and ancillary piping; advanced technologies for nuclear energy.

Within the SBIR office, an oversight review of the scoring of SBIR grant applications is conducted to assure that any proposal recommended for funding is supported by the set of peer reviews for that grant application. We believe that SC's management practices, with emphasis on quality science and technology, are critical to maintaining the integrity of this process.

METHODOLOGY FOR DETERMINING GRANT RECIPIENTS

The Department issues an annual combined solicitation for the SBIR and STTR programs. The solicitation typically contains approximately 50 research topics, and small businesses with strong research capabilities in science or engineering are encouraged to apply. The solicitation is advertised on Grants.gov, the Federal Government's Web Portal for all federal grant applications and also the Department's E-Center (http://e-center.doe.gov) for all DOE Business and Financial Assistance opportunities available.

Additionally, we use the internet, regional and national conferences, and trade journals to ensure the applicant community is well informed about SBIR and to encourage a high number of grant applications. The SBIR electronic mailing list consists of over 12,000 small businesses.

Phase I grant applications are judged on a competitive basis against other applicants within the same technical program area (e.g., Fossil Energy, Energy Efficiency and Renewable Energy) in several stages. First, all are screened initially by DOE technical managers to ensure that they meet stated funding opportunity notice requirements; are responsive to the topic and subtopic category; contain sufficient information for a meaningful technical review; are for research or for research and development; and do not duplicate other previous or current work. Grant applications which fail to pass the initial screening are declined.

Second, grant applications that meet the conditions above are further evaluated by outside independent scientific and engineering experts who are selected by DOE technical program managers. About 1800 experts completed over 3,900 merit reviews of the

approximately 1,200 Phase I applications that made it through the first step. Similarly, about 670 individuals also completed over 890 merit reviews of 280 Phase II applications. The external reviewers evaluate each proposal in terms of three criteria:

- **Strength of the Scientific/Technical Approach,** as evidenced by the innovativeness of the idea and the approach; the significance of the scientific or technical challenge; and the thoroughness of the presentation.

- **Ability to Carry out the Project in a Cost Effective Manner,** as evidenced by the qualifications of the principal investigator, other key staff, and consultants, if any, and the level of adequacy of equipment and facilities; the soundness and level of adequacy of the work plan to show progress toward proving the feasibility of the concept; and the degree to which the proposed project budget is justified by the research plan.

- **Impact,** as evidenced by the significance of the technical and/or economic benefits of the proposed work, if successful; the likelihood that the proposed work could lead to a marketable product or process; and the likelihood that the project could attract further development funding after the SBIR project ends.

DOE makes selections for Phase I awards from those grant applications judged to have the highest overall merit within their technical program area, with approximately equal weight given to each of the criteria above. DOE will not fund any grant application for which there is a reservation with respect to any of the three evaluation criteria, as determined by the review process. In addition, because DOE has developed a process intended to support only high quality research and development, grant applications will be considered candidates for funding only if they receive strong endorsements with respect to at least two of the three criteria.

Third, from the candidates for funding following peer review, each of the participating DOE program areas make selections. Final decisions are made by the DOE SBIR/STTR program manager based on the recommendation of the technical managers and consideration of other factors such as budget and program balance. On average, about 1 out of every 5 grant applications is selected for funding.

The Phase II methodology is the same, except that a commercialization plan is also evaluated as part of the Impact criterion. As with Phase I, Phase II grant applications are sent out for external peer review by independent experts. Phase II applicants must be prior DOE Phase I recipients. About half the Phase II grant applications are selected for funding.

The Department's SBIR program does not provide Phase III funding; however, we offer commercialization assistance to Phase I and II awardees, which I will describe later.

DOE SBIR ADVISORY BOARD

Because the SBIR program impacts six DOE organizations in addition to the Office of Science, a Department-wide SBIR Advisory Board, comprised of Deputy Assistant Secretary-level representatives from the twelve DOE program offices (including six program Associate Directors within the Office of Science) participating in SBIR, was established in 1996 to provide policy advice to the Director of the Office of Science on the conduct of the SBIR program.

All major policy decisions affecting the SBIR program must be endorsed by the SBIR Advisory Board before being implemented. Over the years, the SBIR Advisory Board has expressed a high level of satisfaction with the management of the SBIR program within the Office of Science in cooperation with the other DOE program offices.

ALLOCATION OF FUNDING

Within the Department, individual programs separately determine their methodology for taking the 2.5 percent assessment on the extramural R&D budget to fund SBIR projects. Typically, about 25 percent of the funds are spent on Phase I grants and 75 percent are used for Phase II. Each technical program area participating in SBIR is allotted its contribution of the set-aside to spend on projects pertaining to its particular research program, provided a sufficient number of high quality grant applications are available. The SBIR office oversight procedures assure that only high quality grant applications are awarded in each program area. The technical managers from the programs across the Department are very supportive of this funding allocation process.

COMMERCIALIZATION ASSISTANCE

Many of the SBIR awardees have excellent skills in science and engineering research but lack experience in product development, financing business growth, raising venture capital, and marketing. In accordance with a statutory program purpose of increasing private sector commercialization of innovations derived from Federal R&D, the Department provides funding for commercialization assistance. The SBIR law allows each agency to use a portion of the SBIR set-aside funds for discretionary technical assistance like commercialization. Companies participate in DOE's commercialization assistance services at no cost and participating research programs benefit from early introduction of mission-related technology into the marketplace.

These services are delivered through a competitively selected contract that includes the following:

Trailblazer™, initiated early in Phase I to support Phase II application, develops market data and participation required for concurrent engineering-based product or service development. Both literature searches and interviews are conducted. The program runs six weeks and helps businesses identify major market niches for commercialization, determine key requirements and traits for market-viable products or services, develop a value for the technology that gives it a competitive advantage, identify feasible vehicles for commercialization, and map out a path into the market.

Deal Advisories™, initiated mid-Phase II to evaluate the value of the technology to prospective Phase III partners, uses computer-based templates to explore commercialization deals by establishing a sequence of tasks for the completion of R&D, transitioning the technology development into production, and transitioning the technology product into the market. Deal Advisories™ also identifies critical path tasks and milestones for commercialization. The program helps to identify associated costs, required resources, outputs, and metrics for success, duration, and intellectual property concerns for each task, which can be used to track and evaluate post-deal progress. Deal Advisories™ can also be used to identify potential technology, knowledge, and capability gaps in product development and in transitioning into the market and make suggestions for risk reduction. The duration of this program is six weeks.

Technology Niche Analysis™, initiated mid-Phase II to identify Phase III partners, assesses potential applications for a technology. Both literature searches and interviews are conducted. For each viable application, Technology Niche Analysis™ identifies the needs and concerns of end-users which drive the competitive opening; competing technology and products; the competitive advantage of the technology and market drivers; key standards, regulations, and certifications influencing buyer acceptance; potential customers, licensees, investors, or other commercialization partners (targets specified by participant preferences); and a commercialization strategy, together with tasking and a schedule for implementation of the strategy and design suggestions for the product. Targets are contacted to ensure they are viable leads and to collect important information for follow-up deal-making. Points of contact are included. This program lasts for six weeks.

ADVANCING INNOVATION

The NRC's "Assessment of the SBIR Program at the Department of Energy" noted that the DOE SBIR Program has made significant progress in stimulating technological innovation in three important ways:

1) Generating patents and publications: A significant number of the projects responding to the NRC Phase II survey (43 percent) reported at least one patent application and nearly half of the projects surveyed resulted in at least one peer reviewed article.

2) Stimulating the transfer of technology from universities to the market: About one-third of the projects in the same survey had some alignment with a university, through the use of university faculty as contractors on the project, use of universities as sub-contractors, or employment of graduate students.

3) Indirect paths: Case studies in the NRC study provided anecdotal evidence that projects provide investigators and research staff with knowledge that may later become relevant in a different context (e.g. in another project or as an employee of another company).

Furthermore, the DOE SBIR program conducts its own annual survey of Phase II grantees. The survey requests companies to: (1) list all products and services derived from their DOE SBIR projects; (2) report on both sales and/or Phase III investment related to these products and services; and (3) identify which Phase II projects contributed to the development of the products and services. Approximately 90 percent of Phase II grantees respond to the annual surveys.

Since the inception of the SBIR/STTR programs, the Department has invested $1.6 billion in SBIR and STTR Phase I and Phase II grants. Survey data indicate that in return, approximately 60 percent of Phase II-supported companies have earned a total of more than $1.7 billion in sales and $1.4 billion in additional Phase III development funding – although the precision of those self-reported numbers cannot be verified. Sixty-seven percent of this additional Phase III development has come from non-federal sources, thus further helping the nation capitalize on its substantial R&D investment.

Projects funded by SBIR tend to be high-risk, however, and therefore a relatively small percentage of these companies received a significant portion of the $3 billion in Phase III funding. The survey data indicate that 61 percent of the businesses had received Phase III sales or further development investment. Similar to small start-up companies supported by non-Federal and venture capital funds, a small percentage of the small businesses funded by the DOE SBIR program achieve large commercial successes.

In addition to the potential for commercial success, SBIR funded innovations advance the DOE mission in critical areas. The lithium-ion batteries developed by A123 Systems, for example, have an unprecedented combination of power, safety, and long-life compared to previous lithium-ion batteries. A123 Systems and Chrysler recently announced a strategic partnership whereby A123 Systems will supply the energy storage systems for Chrysler's first-generation ENVI Electric Vehicles. This innovation also has applications to cordless power tools and hybrid-electric vehicles. SBIR funds also allowed Green Wood Resources to begin a poplar hybridization program, which is part of a larger study examining ways to make poplars a better source of renewable fuel. Further examples of SBIR innovations are found in the table below.

Company	**Technology/Process developed**	**Technology's purpose**	**Technology's application and benefit**
A123 Systems	Lithium-ion battery technology based on doped nanophosphate cathode materials	Produce lithium-ion batteries with unprecedented power, safety and life using low-cost, widely available, environmentally-friendly raw materials	Higher powered solutions for the aerospace, electric (including hybrid) vehicle, and defense industries

Company	Technology/Process developed	Technology's purpose	Technology's application and benefit
Advanced Fuel Research	Optical technique for measuring radiative properties	Analysis of gases and surfaces	Better quality products for the semiconductor industry.
Amonix, Inc.	Photovoltaic Power System	Create cost-effective solar generating systems	Generate clean, renewable power at low cost
Atlantia Offshore, Limited	Floating platform	Enable deep water oil and gas drilling	Oil and gas development of new U.S. offshore fields in the Gulf of Mexico
Ceramatec, Inc.	Shock resistant and temperature-tolerant ceramics	Components for diesel engines and diesel filters	Energy efficient engines and turbines
Deep Web Technologies	Web-based search engine with relevance-ranking	Optimize desired search results in multiple database internet searching	Obtain desired information from publicly accessible government R&D databases
Duly Research	Photoelectron linear accelerator	Create a cost effective injector for use in accelerators	Improve future linear colliders, synchrotrons, x-ray sources for research and medical applications
Fuelcell Energy, Inc.	Ceramic fibers	Carbonate- based fuel cells	Increases life and availability of Direct FuelCell that can achieve electric efficiency greater than 70%
Green Wood Resources	Energy feedstock	Analysis to improve caloric value and chemical composition of poplars by selective breeding	Make poplars a better fuel source
MacConnell Research Corp.	Automated blood purifier for molecular biology applications	Smaller, faster, cheaper instrument for DNA purification and analysis	DNA sequencing, genomic research, drug development

Company	Technology/Process developed	Technology's purpose	Technology's application and benefit
Precision Combustion	Catalytic combustor	Reduce engine pollution of gas turbines	Cost-efficient retrofits of existing gas turbine engines to meet emission requirements
Wind Tower Systems, LLC	Wind turbine tower	Towers that can support turbines at greater heights with less weight and cost	Develop lighter-weight, modular wind turbine towers
X-Ray Optical Systems, Inc. (XOS)	Polycapillary Optics and Doubly Curved Crystal Optics	Enhance the performance of X-ray and neutron analytical instrumentation	Improved spatial resolution, orders of magnitude increases in intensity, and a significant reduction in background radiation for materials analysis

JOBS CREATION AND RETENTION

Due to low administrative overhead within the SBIR program, the program does not rigorously track job creation and retention data. The estimates presented here are based on our own budget-related data for Phase I, and findings of the 2008 National Research Council study, "An Assessment of the SBIR Program at the Department of Energy," that includes a survey of Phase II awardees.

Our Phase I budget data show that about 90 percent of Phase I awards go to labor costs. We conservatively estimate that these awards employ one person for the six to nine month duration of the award. With over 5000 Phase I awards made so far, we estimate that over 3,000 person-years have been supported through SBIR and STTR Phase I awards since the program began.

The NRC study found that, on average, Phase II awards employ about three people per project (averaging about 1.5 hires and 1.5 retentions.) With over 2,000 Phase II awards granted so far, we estimate that about 12,000 person-years were supported through SBIR and STTR Phase II awards since the program began.

The NRC assessment further finds that nearly one-quarter of all small business SBIR grantees surveyed indicate that their companies were founded entirely or partly because of an SBIR award; and that DOE SBIR support directly resulted in noticeable, though minor, employment growth among DOE respondents.

Potential Areas for Improvement

The DOE SBIR program provides a mechanism for the Department to support high-risk, high-return research through small businesses, resulting in innovative new technologies. The commercial impact of this innovation could be strengthened by increasing the provisions for discretionary technical assistance within the existing set-aside allowed by law under SBIR.

SBA project funding limits in Phase I and Phase II are not adequate to support a strong technical assistance program, including commercialization assistance. Currently up to $4,000 above the awarded amount can be used per Phase I award for commercialization assistance activities and up to $4,000 per year (included within the awarded amount) can be used for each Phase II award for commercialization activities. SBIR Phase II recipients have indicated in qualitative surveys that the commercialization assistance programs and services offered by DOE's SBIR program are valuable to their product development and commercialization efforts.

The SBIR and STTR programs currently do not rigorously track the impact of awards on employment. Measuring this impact is not trivial. Making a small fraction of the existing SBIR set-aside available for agency administrative purposes would provide the resources needed to do rigorous tracking. These administrative funds could also improve the evaluation of the successes of participating small businesses and their impacts on DOE mission goals. More comprehensive, long-term data collection would allow better assessment of the results of the programs and enable the programs to adjust management practices as appropriate

CONCLUSION

The DOE SBIR and STTR programs currently provide about $150 million each year to small businesses to help entrepreneurs take their ideas from conception to reality. The Department has benefited from small business participation through the technologies the small businesses have developed and the new knowledge gained from SBIR funded research that contributes to the Department's R&D activities. Successful collaborations between small businesses and the DOE R&D complex have advanced the Department's missions to improve the Nation's energy, economic, and national security with new insights and innovative technologies, including improved batteries for energy storage, advances in particle accelerator technology, experiments to develop poplar trees as energy sources, and development of improved wind turbine towers.

Small businesses are usually agile, tend to produce quickly with low overhead, and have demonstrated success in developing niche technologies, which often support the Department's larger projects. High-technology small business grantees, many of whom started in business as a result of SBIR awards, have become a valuable resource for solving high risk, high technology problems. Solving these high technology problems will continue to be essential to meeting the Nation's current and future energy challenges.

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United States House of Representatives

The Importance of Technology in an Economic Recovery

April 22, 2009

Chairwoman Velázquez, Ranking Member Graves, and Members of the Committee, thank you for the opportunity to testify today regarding the Small Business Innovation Research (SBIR) program at the National Science Foundation (NSF). From its earliest days, NSF has been tasked "To promote the progress of science; to advance the national health, prosperity, and welfare; and to secure the national defense." The SBIR program at NSF serves all these goals.

I will focus my remarks on two main areas: ensuring the benefits of technological innovation, and the impact of NSF SBIR funding on the growth of small businesses, including the growth of employment in these firms. But first I feel that I should provide you with a brief outline of the history of the SBIR program at NSF.

History of the NSF-SBIR Program

In 1977 the National Science Foundation (NSF) initiated a pilot program called the "Small Business Innovation Research" (SBIR) program. This program solicited research proposals from profit-seeking small firms. Subsequently in 1982, Congress established the SBIR program in order to provide increased opportunities for small businesses to:

- meet federal research and development needs,
- stimulate technological innovation,
- foster and encourage participation in technological innovation by socially and economically disadvantaged persons,
- increase private-sector commercialization of innovations derived from federal research and development.

The primary objective of the NSF-SBIR program is to increase incentives and opportunities for small firms to undertake cutting-edge, high-risk, high-quality, scientific, engineering, and science-education research that has the potential for economic payoff if the innovation is successful. Additionally, the program seeks to stimulate technological innovation in the private sector, increase commercial application of NSF-supported research, and improve the return on our investment in Federally funded research for its economic and social benefits to the nation.

It is important to note that NSF is not a "mission agency" and our SBIR program is not focused on developing applications for NSF's own use. Instead we are focused on ensuring that innovative technologies and products based on those technologies make it to the market to benefit the American people.

Overview of the SBIR program at NSF

The SBIR program at NSF is managed within the Division of Industrial Innovation and Partnerships in the Directorate for Engineering. In addition to the SBIR program, the division manages several university-industry partnership programs: Small Business Technology Transfer, Industry/University Cooperative Research Centers, Partnerships for Innovation, and Grant Opportunities for Academic Liaison with Industry. This testimony will primarily address the SBIR program. The FY2008 allocation for SBIR at NSF was $95.5 million and 305 new awards were made. With the anticipated $50 million additional FY2009 funding through the American Recovery and Reinvestment Act, we plan to substantially increase the number of awards to small businesses this year.

The program funds firms innovating in a wide spectrum of technologies including agriculture, biotechnology, medical applications, materials, manufacturing, energy, environment, electronics, information technology and nanotechnology. NSF is currently soliciting new proposals in four broad areas:

- Biotechnology and Chemical Technologies,
- Education Applications,
- Information and Communication Technologies, and
- Nanotechnology, Advanced Materials and Manufacturing.

At NSF, SBIR grants are divided into two competitive phases. Phase I awards have a duration of six months and were recently raised to a maximum of $150,000. These awards provide support to conduct feasibility research into new techniques or products. All Phase I awardees subsequently are eligible to apply for a Phase II award which can be for up to $500,000 and two years in duration.

NSF actively supports the SBIR program goal to increase private sector commercialization. To do this, we have designed several supplements to further the commercial success of our awardees. The flagship amongst these is the Phase IIB supplement. Supplements are also available to provide additional support for college and high school students, and for teachers to participate in research with SBIR awardees; to form partnerships with minority-serving universities, colleges, and community colleges; to help firms form partnerships with NSF-funded research centers, and to provide mentoring to other NSF-funded SBIR firms. These NSF SBIR supplemental funding opportunities are listed in the appendices and therefore I will only touch on a few of them that are unique to NSF.

In 1998, NSF introduced the Phase IIB supplemental grant opportunity for its Phase II grants. The Phase IIB helps bridge the gap in funding between Phase II and ultimate commercialization. The Phase IIB provides additional funds to Phase II awardees who

obtain third party funds. The objective of the Phase IIB is to extend the R&D efforts beyond a current grant to meet the product, process, or software requirements of a third party investor to accelerate the Phase II project to the commercialization stage and/or enhance the overall strength of the commercial potential of the Phase II project. A Phase IIB Supplement up to $250,000 extends the Phase II grant for one year while a Phase IIB supplement in excess of $250,000 extends the Phase II grant for two years; the size of a Phase IIB award is determined by the amount of third-party investment the grantee has secured. We have found that awardees that are able to secure the outside funding to qualify for Phase IIB have had better success in commercializing their innovations. After five years, about 69% of firms that received Phase IIB funding were beginning to see success, whereas only 31% of those not having a IIB supplement were successful. Many of the Phase IIB firms have grown in both revenue and employment and some have been acquired by larger firms.

Phase IIB
External Investments in Awardee Companies

Year	Investment
2008	$18.5 million
2007	$36.7 million
2006	$57.8 million
2005	$43.5 million
2004	$10.6 million

NSF also encourages the Phase II awardees to participate in NSF-wide funding opportunities that stimulate job creation. The Research Experience for Undergraduate Program (REU) is a supplemental opportunity used to support the inclusion of undergraduate students in SBIR projects and expose them to an entrepreneurial small business environment. The Research Assistantship Supplements for High School Students (RAHSS) program offers women and minority students an opportunity to work on scientific and engineering projects to foster interest in pursing science, technology, and engineering studies in college, and the Research Experience for Teachers Program (RET) provides an opportunity for high school teachers and community college professors to work at a small business on projects in order to bring knowledge of engineering and technological innovation into their classrooms. These programs enhance the capabilities of the students/teachers that participate, and reflect NSF's core commitment to education and work force development. These supplemental funding programs have also proven to be excellent sources for future hires for successful small business firms to support their growth.

The NSF SBIR program continually strives to encourage awardees to start early in forming partnerships with strategic partners or investors. We do this in order to leverage the government funding. As we all know, it takes far more than the SBIR investment to move an innovation from the research lab to the market place. As you will see in the examples that follow, several small businesses accomplished this successfully. We believe that these examples illustrate the NSF role in stimulating technological innovation that benefits the US in its global competitiveness.

Innovation through partnerships

An important goal of SBIR at NSF is to move technologies evolving out of scientific and engineering discoveries funded by NSF to the market place. To achieve this, partnerships are critically important. NSF-funded collaborative research centers both spur innovation and provide a fertile synergy between universities and industry. Within the Directorate for Engineering (ENG) at NSF, there are several centers programs including Engineering Research Centers (ERC) and Industry/University Cooperative Research Centers (I/UCRC). Both programs require substantial industry involvement, and SBIR firms can benefit from the expertise and talent of the students and faculty at these centers. We have established programs to help our SBIR awardees leverage industrial and academic talent through membership arrangements with NSF-funded Engineering Research Centers, and Industry/University Cooperative Research Centers, and sixty-four firms have taken advantage of this option.

SBIR/STTR Firms Joining Centers		
	I/UCRC	ERC
FY2007	13	12
FY2008	23	0
FY2009	9	7
Some memberships are longer than one year		

Beyond academic centers, the NSF recognizes the need to help new awardees connect with industrial companies and investors for successful commercialization of their innovative products and services. As noted earlier, for the past ten years, NSF has provided incentives for awardees to form these partnerships by making Phase IIB supplements available. Industrial partners help with the marketing and distribution of the product and even manufacturing, and the venture capitalists or angel investors invest capital to finance continued business development.

Not all grantees on their own will be successful in attracting partners, so the NSF SBIR program launched the MatchMaker program to actively connect awardees with potential partners. For the industrial companies this is a win-win situation since the corporate R&D function now relies heavily on "Open Innovation" whereby large companies aggressively scout external sources for new technologies. The NSF SBIR companies are excellent candidates for such partnerships because the industry executives recognize that the NSF SBIR companies have been scrupulously screened by experienced program managers along with technical and commercial external reviewers at NSF. Occasionally these partnerships become so strong that the large corporation will opt to bring the small company directly into their mainstream operations. Consequently the NSF MatchMaker program not only supports commercialization of the small business' technologies but also uses the energy and innovative capacity of the small entrepreneurial companies in driving the nation's industrial engine.

Acquisitions of NSF-SBIR Firms	
Year	Number acquired
2006	17
2007	19
2008	8

Currently there are about forty industrial companies and twenty venture capitalists and angels currently in the MatchMaker program, seeking technology partnerships and attractive investments. The industries include electronics, communications, information technology, advanced materials, energy, chemicals, paper, food, agriculture, biotechnology and medical devices.

Innovation Success

One measure of a company's success is certainly external recognition, from industry groups, investors, professional organizations, and others. Six of the innovations highlighted in R&D Magazine's R&D 100, came from NSF-funded SBIR firms[1].These firms are representative of the national breadth of our awards, coming from Arizona, California, Connecticut, Florida, Illinois, and Massachusetts. In total, small firms now account for over 25% of the R&D awards given out today, a big change from the same period twenty five years ago when large corporate R&D labs dominated. This is just another indicator of how critical a role small entrepreneurial companies play in the nation's innovation capability.

I would like to highlight two firms to illustrate that in addition to funding great technologies, NSF is keenly interested in the broader impacts of our awards.

Touch Graphics is a small firm in New York City, which has received NSF SBIR awards to develop assistive technologies for visually impaired persons. Touch Graphics was founded in 1998 as a commercialization vehicle for technologies first demonstrated at Baruch College, part of City University of New York. As of 2009, Touch Graphics, Inc. employs seven people. Touch Graphics, Inc. received its first SBIR grant from NSF in 2000 for development of an audio-tactile interactive device known as the Talking Tactile Tablet (TTT). The product was originally conceived as a tool for teaching algebra, trigonometry and calculus to students with limited or no access to print graphics, and has since expanded to broader applications. In 2004, Touch Graphics teamed with another NSF SBIR awardee, Exceptional Teaching, Inc., to bring to market a self-teaching Braille literacy training system known as SAL. The SAL system has become Touch Graphics' big seller, and this has driven general awareness of this new possibility for teaching and learning about materials that usually require access to maps, diagrams, graphs and other illustrations. Over 600 TTT units are in use. The TTT was awarded a Gold Medal in the 2006 IDEA Awards.

[1] R&D Magazine July 2008 (Picarro Inc., Sunnyvale, CA, Advanced Fuel Research, Inc., East Hartford, CT, Materials & Electrochemical Research Corp., Tucson, AZ, Engineering Matters, Inc., Newton, MA, Advanced Diamond Technologies, Romeoville, IL, Sinmat, Inc., Gainesville, FL)

Another area for Touch Graphics that has been supported by NSF SBIR funding is in the world of informal education in Science, Technology, Engineering, and Mathematics (STEM). The company has developed a range of technologies for universally accessible displays and exhibits at science and technology centers, planetaria, and other museums and exhibit spaces. As a direct outcome of this SBIR project, the company is now developing talking touchable models for the National Park Service and the Smithsonian Information Center at the Castle, including a map of the National Mall.

Divergence, Inc. of St. Louis, Missouri is working to develop and market a safer method of preventing crop damage due to parasitic nematodes attacking plant roots. Worldwide the company estimates that parasitic nematodes are responsible for $80 billion in crop damage annually, including significant damage to common US crops such as soybeans. Using Phase II/IIB funds together with funds from Divergence and corporate partner Monsanto Company, Divergence put in place an efficient program for testing biotechnology-based nematode control. Their program evaluates potential nematicidal molecules in a hairy root system rather than in whole plants, saving time, money, and greenhouse space. Several molecules from Divergence's STEM™ plant protein library are currently being tested for their ability to confer nematode resistance. Successful molecules will be tested in whole plants by Monsanto.

I should note that the first applications of this approach to fighting plant parasitic nematodes was led by Divergence founder James McCarter at Washington University and Divergence ,and Divergence's Scientific Advisory Board member David Bird at North Carolina State University, who were both supported by NSF academic funding. Divergence has also received funding from the National Institutes of Health for related work. Technologies like those being developed by Divergence and other NSF-SBIR grantees can assure food security and drive economic growth through agriculture.

The two firms that I have highlighted here are each just single pieces in the broad mosaic of NSF-SBIR firms. A large number of these companies are engaged in the critically important areas of renewable energy, environmental technology and advanced information technology, as may be involved in electronic health records. One notable company is A123 Systems, Inc of Cambridge MA. A123 Systems has developed leading edge lithium-ion battery technology for the next generation hybrid and electric vehicles built in part upon technical breakthroughs by NSF SBIR grantees such as the minority-owned firm T/J Technologies of Ann Arbor, Michigan. A123 Systems has plans for a major electric battery manufacturing plant in Michigan, again demonstrating that small businesses are leading the ways towards new manufacturing industries in the United States.

We have been very conscious of the impacts of our program beyond technical and economic development, to supporting future researchers, engineers, and educators in STEM fields as well. I would like to highlight a few of the programs that we have developed to help nurture the next generation of technically driven innovators.

Job Creation

There are several ways in which NSF SBIR awards contribute to job growth: firms hiring or retaining employees as result of a grant, students and teachers brought in on a temporary basis through an Research Experiences for Undergraduates (REU), Research Experiences for Teachers (RET), or Research Assistance Supplements for High School Students (RAHSS) supplement, and the indirect and secondary effects the firms' purchases of material goods and services. NSF has good estimates of the first two direct impacts, but we do not have a good estimate of secondary effects.

The direct impact of the firms' hiring and retaining employees as the result of an NSF-SBIR award was addressed in a study by the National Research Council[2]. The study found that firms hired an average of 1.5 employees and retained two employees as a result of a Phase II grant. In parallel, NSF engaged in a systematic Phase II Commercialization Study that followed growth of revenues and employment by SBIR companies for eight years starting from the launch of a Phase II research project. A group of 201 8th year projects, representing most (about 85%) of the 8th year companies interviewed, was examined to determine the overall revenue and personnel growth rates. The analysis is complicated by a few confounding factors, such as frequent reorganizations, spin-offs, mergers, etc, and by changing market conditions. However, because of the large number of companies examined, and the length of time involved, the data provides a useful insight into the company growth patterns. The reported growth over the 8 years averaged 21% in revenues and 7% in personnel annually. Since the mean size of the companies under study was roughly 10 people we can estimate that on average each company added almost one person per year, which aligns well with the NRC number of 1.5 people per two-year Phase II award.

Professional development of students through entrepreneurial exposure and research experience is an important part of NSF's SBIR program. Currently, 36 of 475 active grantees are supporting or will be supporting a total of about one hundred students through Research Experience for Undergraduates (REU) supplements. These students typically work ten weeks in the summer and receive an average stipend of $5000. Throughout NSF, REU is a critical program to creating the next generation of STEM professionals, and REU slots are hotly competed for by students.

The Research Assistance Supplements for High School Students (RAHSS) program is designed to foster both opportunity and interest in science and engineering among female and minority high school students. The program provides an opportunity to work on scientific and engineering projects, and we hope fosters these students' interest in pursing science, technology, and engineering studies in college. This program is unique to NSF and three of our Phase II grantees took advantage of it last year.

The Research Experiences for Teachers (RET) program brings high school teachers and community college professors to work at a small business in SBIR-funded research

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[2] An Assessment of the SBIR Program at the National Science Foundation, Charles W. Wessner, Ed., The National Academies Press (2007), www.nap.edu

projects. They can then bring their experiences in engineering and technological innovation into their classrooms, and ultimately to their students.

Together these supplement programs enhance the capabilities of these students and teachers, and synergistically develop interest in technical innovation, engineering, and entrepreneurship in the broader community. These supplemental funding programs have also can be excellent sources for future hires as SBIR firms grow.

Concluding Remarks

In conclusion, the NSF SBIR program is uniquely positioned to foster private sector technological innovation and create jobs in small business firms. NSF's mission is very broad and thus is not constrained to focus on developing applications for NSF's own use but to support innovation research that could lead to commercialization and broad societal benefits. In other words, the SBIR program seeks to ensure that innovative technologies and products based on those technologies make it to the marketplace and benefit the American people. We are constantly engaged in assessing our performance against that simple test and the four broad goals of the SBIR program in general.

Madam Chairwoman, this concludes my testimony. On behalf of the National Science Foundation, the SBIR program and our awardees, I want to thank you for this opportunity to highlight a program that provides small businesses with the means to create innovative products and to develop the next generation of innovators. We look forward to working with Congress to strengthen America's small businesses and helping them develop and commercialize innovative processes and products to sustain our national economy. I would be pleased to provide any additional information that would be useful to you.

Supplements Available to NSF-SBIR Awardees

Supplement Name	Goal of Supplement	Additional Dollar Amount (from NSF)	Grant Performance Period Extended	Latest Date to Submit	Special Requirements
Phase IB	Bridge the gap between Phase I and Phase II funding while at the same time encouraging partnering as a means to increase the potential for SBIR/STTR grantees to successfully commercialize their technology http://www.nsf.gov/eng/iip/sbir/ibinstructions.jsp	$50,000.00	6 months	Deadline (April 15 & October 15)	Must be an active grantee
Phase IIA	Foster partnerships between the academic and small business communities; increase participation of underrepresented groups in both academic and small business research; and encourage members of underrepresented groups to pursue careers in science and engineering. http://www.nsf.gov/pubs/2006/nsf06004/nsf06004.jsp	$150,000.00 With 70% to CREST/ HBCU	up to 2 years		Centers of Research Excellence in Science and Technology (CREST) CREST and/or HBCU as partners
Phase IIB	Bridges the gap in funding between Phase II and Phase III; extends the R&D efforts beyond a current grant to meet the product/process/software requirements of a third party investor to accelerate the Phase II project to the commercialization stage and/or enhance the overall strength of the commercial potential of the Phase II project. http://www.nsf.gov/eng/iip/sbir/phase_iib.jsp	$500,000.00	up to 2 years	60 days prior to expiration	Must be submitted during the original 24 month period of the Phase II award; need permission from PD to submit. For STTR Phase IIB applications the required partnering percentages applies.

Supplements Available to NSF-SBIR Awardees

Phase IIR	Research that is mutually beneficial to the ERC and the SBIR/STTR grantee and thus it will serve the following dual purposes: (1) to speed the transition of ERC-generated research and technology advances to the market place and engage ERC students more directly in the innovation process, and (2) to strengthen the research capacity of the SBIR/STTR grantee and broaden its portfolio of marketable products. http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf07035	$200,000.00		Inactive
Phase IICC	Foster partnership between Minority-Serving Community Colleges (MSCCs), which educate large numbers of underrepresented students, and the small business community. NSF is seeking to increase the participation of underrepresented groups in both academic and small business research by encouraging careers in science and engineering. These supplements are in collaboration with EHR. http://www.nsf.gov/pubs/2006/nsf06008/nsf06008.jsp	$40,000.00 With 40% to the CC	at least 6 months from expiration	

Supplements Available to NSF-SBIR Awardees

Phase II M	Intended to broaden participation and to increase the diversity of small businesses within the NSF SBIR/STTR program. The supplements will enable small businesses to be mentored by existing NSF SBIR/STTR grantees by leveraging the NSF SBIR/STTR program knowledge with non-NSF SBIR/STTR companies. The mentors will guide the mentored small businesses through the proposal life cycle process, which covers the development, submission and potential award of a proposal. http://www.nsf.gov/pubs/2009/nsf09004/nsf09004.jsp?org=IIP	up to $50,000	2 years	no limit	Proven Track record of successful bringing products or services to market.
REU	Supports active research participation by undergraduate students; students must be citizens or permanent residents of the United States or its possessions http://www.nsf.gov/eng/iip/sbir/Supplement/REU.jsp	$12,000.00	no	at least 6 months from expiration	$6,000 per student (up to 2 students per year) 25% of the $6,000 can be used for an administrative allowance (in lieu of indirect costs)
RET	Supports the active involvement of K-12 teachers and community college faculty in engineering research in order to bring knowledge of engineering and technological innovation into their classrooms. http://www.nsf.gov/pubs/2003/nsf03554/nsf03554.htm	$20,000.00	no	at least 6 months from expiration	$10,000 per teacher (up to 2 teachers per year); $1,000 stipend for materials, equipment, software, and other supplies for developing classroom instruction; 25% of the $10,000 can be used for an administrative allowance (in lieu of indirect costs)

Supplements Available to NSF-SBIR Awardees

RAHSS	Research Assistantship Supplements for High School Students (RA) supports active research participation by high schools students in the SBIR/STTR Program. This opportunity broadens the participation of women and minority students in academic and small business research to foster interest in pursuing science, technology, and engineering studies at the college level. http://www.nsf.gov/eng/iip/sbir/Supplement/RAHSS.jsp	$12,000.00	no	at least 6 months from expiration	High School Students (women, under-represented minorities, and persons with disabilities); $6,000 per student (up to 2 students per year) 25% of the $6,000 can be used for an administrative allowance (in lieu of indirect costs)
I/UCRC Membership	Aims to accelerate the innovation process by partnering industry-relevant academic research with commercialization focused small business research. It is designed to open the doors for small businesses to the benefits from the collaborative research performed at Industry/University Cooperative Research Centers (I/UCRCs) http://www.nsf.gov/publications/pub_summ.isp?ods_key=nsf08066	$50,000.00	no	for active Phase II within 60 days of expiration date; for non active the supplement is submitted directly to the Center	Enables NSF SBIR/STTR grantee firms to purchase one or two year memberships in an I/UCRC

Testimony of:
Joshua Green, General Partner
Mohr Davidow Ventures

Hearing on
The Importance of Technology in an Economic Recovery
April 22, 2009

Committee on Small Business
US House of Representatives

Introduction

Chairwoman Velazquez, Ranking Member Graves, and members of the Committee, my name is Josh Green and I am a partner at Mohr Davidow Ventures (MDV), a venture capital firm in Menlo Park, California. I am also a member of the National Venture Capital Association based in Arlington, Virginia. My views today represent 460 member firms which currently comprise approximately 90 percent of all the venture capital under management in the United States.

Mohr Davidow invests in entrepreneurs creating businesses that address significant challenges and opportunities associated with the digital world, personalized medicine, and alternative energy. We have been in business for more than 25 years during which time we have taken a hands-on approach to architect and help build hundreds of start-up companies from the ground up. We work best with entrepreneurs who welcome our involvement as well as our venture capital funding. Once invested we typically take a seat on a company's Board of Directors and we pride ourselves in rolling up our sleeves and diving in — whether it's collaborating on product and marketing strategies, developing smooth operations, establishing effective distribution strategies, attracting and retaining superior employees, or fine-tuning business models. For this reason we limit the number of venture capital investments we make so that each company gets the attention it needs and deserves.

I personally invest in the clean technology sector and am focused on creating businesses that offer economic value in the form of jobs and revenues and also promise to reduce our country's dependence on foreign oil and help preserve our environment. Cleantech is the fastest growing sector of venture investment.

I would like to thank the Committee for the opportunity to share with you today the challenges that our small, venture-backed businesses have faced under past restrictions related to Small Business Innovative Research (SBIR) grants and why these grants are critical to the ongoing vitality of innovation and job creation in the United States. As an industry, we strongly support the re-authorization of the SBIR grant program, particularly if past inequalities are corrected so that all small businesses can compete for these critical funding grants. At a time when our country needs to build new businesses, the venture capital industry is committed to working with the government to bring a steady stream of innovation and economic value to market. We thank the Committee for your past attention to our concerns and are hopeful that the re-authorization will at long last provide a level playing field so that we can move forward together in supporting our country's most promising products and businesses.

Venture Capital Investment Overview

I would like to briefly explain how the venture capital industry creates and grows small businesses. Typically a venture capital firm is a small business itself, often with fewer than 25 employees. MDV, for example has just 9 full time investing professionals. We raise our funds of money by contributing our own capital while also seeking resources from institutional investors such as University endowments, foundations, and pension funds with the charter to invest those funds in promising young start-up businesses. Once a fund is raised, my partners and I look for the best and brightest entrepreneurs in which to invest, usually within a specific industry sector in which we have an expertise. Venture capitalists most often look for companies that are developing disruptive innovations and have the potential to grow from small businesses

into large enterprises. For this reason, we are often investing in high technology areas such as IT, life sciences, and clean technologies. Over 40% of our entrepreneurs are scientists or engineers to whom we reach out at university and government labs, to whom we are introduced through others who are already in our network, or with whom we have worked in the past on building successful businesses.

Venture capitalists are focused on commercializing *applied* research. In order to be considered for venture capital investment, the entrepreneur typically has a product or service that has gone through the discovery process and is ready to be clinically tested and commercialized. If we believe the product has commercial promise, we will make an initial investment and look for the company to achieve certain milestones before we offer follow-on funding. We stay invested in these companies —both financially and through the sweat equity we offer — for anywhere from 7-10 years, often longer and rarely less. The ultimate goal is to build the business until it can go public or become acquired, generating a return for all employee shareholders and investors. In 2008, the venture capital industry invested more than $28 billion into over 3800 start-up companies in the United States.

Venture-backed Companies Drive US Economic Growth and Innovation

Despite the recession, the venture capital industry is open for business. We have money to invest in innovative promising businesses. We recognize that our industry is one of the only asset classes able to create new jobs at this challenging economic time. According to an IHS Global Insight Study soon to be released, in 2008 venture-backed companies provided 12.05 million jobs and $2.9 trillion in US revenues, corresponding to 10.5% percent of US private sector

employment and 20.5% percent of US GDP. From 2006 – 2008 venture-backed companies grew jobs at three times the rate of the private sector overall. Companies that were once small venture-backed businesses include: Google, Genentech, Intel, Cisco, Starbucks, Microsoft and FedEx.

Traditionally, venture capitalists have focused on investments in information technology and life sciences businesses. However, within the last five years, our industry has committed to investing in the highly compelling area of clean technology. In 2008, venture capitalists invested more than $4.6 billion into clean technology businesses that are innovating in the wide ranging areas of alternative energy such as solar, coal gasification, geothermal, and biofuels as well as green building materials, batteries, transportation, and carbon capture and sequestration. Many of these companies have and will be founded on discoveries made through basic, government funded research. I am here today on behalf of those current and future companies.

Venture-backed Small Businesses

These venture-backed companies are quintessential small businesses. Many are pre-revenue and most have fewer than 10 employees. They operate on very tight budgets and must meet designated milestones if they are to receive additional funds. They remain extremely fragile as they face a challenging road fraught with obstacles including regulatory approvals, beta tests, larger competitors, human capital needs, ongoing financing, and ultimately customer acceptance.

It is critical to understand that venture capitalists do not fund basic research projects at our portfolio companies. The venture capital funds our companies receive are specifically directed

to building a business around a discovery that has made it through the basic research process and is ready to be commercialized. Yet, these companies may have other early innovations in the pipeline worth pursuing. It is for these *new* projects that these businesses would apply for an SBIR grant, as we venture capitalists can not and will not fund early stage research. Unfortunately today, these companies are forced to make a choice between pursuing SBIR funding for the new project or continuing to access venture capital to bring existing projects to market since the Small Business Administration's (SBA) current interpretation will not allow most venture-backed small businesses to apply for SBIR grants. This scenario has resulted in small businesses at best delaying important discovery projects and at worst, abandoning this important work altogether.

Public/Private Partnerships

In past eras (e.g., the space race or the early days of DARPA), the best and brightest scientists worked in the government and the most exciting innovations emerged from work done by the Federal government. Over time, many of these innovators moved to the private sector and worked for large corporations such as Bell Labs or IBM. Today, some of the best and brightest minds, developing the truly disruptive innovations, are found at small start-up companies. Large corporations simply do not have the internal resources to fund the necessary R&D needed to keep ahead of the innovation curve.

At a time when the national debt is high, government resources are stretched thin, and our need for advancements in clean energy, healthcare, and national security are great, it seems prudent that government agencies would seize the opportunity to work collaboratively with venture

capitalists. Only the venture capital industry can make the claim that solutions for which we advocate will truly create a significant number of new jobs through entirely new sectors, reduce our dependence on foreign oil, and help save our environment from the ravages of global climate change. Our track record is clear. In the same way that venture capital helped bring about the high tech revolution and quite literally created the biotech industry, venture-backed entrepreneurs and investors stand ready to meet the challenges that have thus far stymied advancements in solving global climate change.

VCs are continually seeking out the next generation of technology, but the current SBA eligibility rules throw costly, time-consuming, and unnecessary hurdles in the path of government agencies seeking to collaborate with venture capital-backed companies. We believe this is a huge loss for our country. With Congress attempting to reduce greenhouse gas emissions, power our national grid, and transform our vehicles using alternative energy, innovations from the venture capital industry very likely hold the key to resolving the most daunting challenges addressing these complicated issues. The venture industry is poised to meet that challenge and the policies enacted by this Congress, and this Administration will either help or hinder that effort.

Key agencies like the Department of Energy and the EPA have recognized this and have reached out to venture capitalists and our trade association to tout the SBIR program as a mechanism to advance Federal research dollars by backing the most promising companies. We hope that this will be an area in which government policies and the venture industry work together to find solutions for the nation.

Common Misconceptions

With the reauthorization of the SBIR program, Congress has the opportunity to correct a significant injustice that has gone on too long. It has been eight years since an administrative law judge redefined an "individual investor" to mean a "natural person," thereby opening the door to exclude from the SBIR program small businesses that have received venture capital funding. While there has never been an actual change in law or regulation, the SBA used this interpretation in recent years to deny grants to many of our country's most worthy small businesses. Under the past Administration, the SBA's policies regarding SBIR eligibility and how they determined if an entity qualifies as a small business were inconsistent, and based on serious misconceptions which I would like to address.

One of the largest misconceptions is that venture capital firms are equivalent to large corporations, and therefore the companies that they fund should be excluded from consideration from SBIR grants. We agree that large corporate owned businesses should not be allowed to participate in small business programs and have supported past provisions to ensure that this misdirection of small business dollars does not take place. But venture capital firms (and their portfolio companies) are not large corporations with deep pockets and ulterior motives. They are almost entirely private partnerships that are typically comprised of less than two dozen professionals whose sole business is to invest in small emerging growth companies. Venture capital firms focus on the growth of the small business, not to further the agenda of any large corporation. Most often, these small businesses are competing with large enterprises.

Another common mistake is to assume that venture-backed companies are controlled by venture capitalists. While venture capitalists as investors typically take a Board seat, we do not exert day-to-day control of a company for several reasons. The partners at venture firms work with a number of portfolio companies at once. Our time is divided between all investments of the venture fund and it would be impossible and impractical to spend that limited time on the hundreds of nitty-gritty, day-today decisions that the internal management team must make instead of helping the management team make the strategic level decisions necessary to grow. Unlike corporations, venture capital funds are usually limited life entities that make their return on investment only when the portfolio company is sold or makes a public offering of its securities. And lastly, no particular venture capital firm typically has a controlling interest. The 51 percent or more ownership of a company is often achieved because there are several venture firms invested, giving each a smaller, more diluted share in the company. The governance of these companies is most often the result of consensus-building, and the most important voice in the room is that of management, not the investors.

The current policy particularly hurts the regions of our country that the SBIR program was designed to support. The scarce venture capital dollars available in mid-America for instance must cover a greater geographic footprint than in the concentrated areas such as Boston or the San Francisco Bay Area. For this reason, venture funds generally join together to fund a promising start-up, as a single firm indigenous to the region will not have the capital to fund a company fully. As each firm takes an equity stake in the company, the total venture ownership percentage can quickly rise above the 51 percent threshold, thereby making the mid-America start-up company ineligible to apply for an SBIR grant.

SBIR and VC Have Worked Well Together

Throughout the SBIR program's history, majority venture-owned small businesses have applied for and received SBIR funding. This historical precedence strongly suggests that their participation has caused no harm to the program or to other small businesses. To wit, the recent National Academies of Sciences study on the SBIR program offered no evidence that other small businesses have ever been crowded out by the participation of venture-backed businesses.

The NAS report also found that there are useful synergies between venture capital investment and SBIR funding in terms of selecting the most promising companies. During the first two decades of the program, when participation of venture funded firms was not at issue, some of the most successful NIH SBIR award-winning firms were able to perform at high levels because they were allowed to receive venture funding as well as SBIR awards. By excluding venture-backed firms, the SBA removed some of the most worthy applicants from consideration. This clearly should not be the intent of the SBIR program, which seeks to benefit meritorious small businesses.

Conclusion

The SBIR program is a wonderful mechanism for the government and private sector to come together and do what desperately needs to be done to support a strong economic recovery – help small companies to grow and innovate. But the SBA's past policies have seriously negated the positive impact of venture-backed small businesses on innovation. Both venture dollars and SBIR dollars play complementary roles in financing innovation. One is rarely, if ever, a substitute for the other. Venture-backed companies seek SBIR dollars because they are needed to help finance

research targeted at innovations that are too early in their development for the venture capitalists to cover. SBA has cut off the innovation pipeline so that many of the most promising projects never see the light of day. It is time for a positive change.

No other asset class supports the premise more that small businesses are the life blood of the US economy than venture capital. As investors in these important entities, we are advocates for their viability and growth. We believe that the best use of government dollars is to leverage public/private partnerships in which we all have a role in bringing innovation out of the garages, labs and tiny businesses into the marketplace, the healthcare system, our military, and renewable energy enterprises. The venture capital community is committed to contributing significantly to this endeavor. We have consistently over the years asked Congress and the Administration to join us. We hope that this year Congress will reauthorize the program with provisions that ensure venture-backed companies have a fair chance to thrive under the SBIR program alongside of their non-venture-backed counterparts. Doing so will strengthen the future success of the program our economy and our nation.

Thank you.

HEARING TESTIMONY

RACHEL K. KING
CHIEF EXECUTIVE OFFICER
GLYCOMIMETICS, INC.

ON BEHALF OF THE

BIOTECHNOLOGY INDUSTRY ORGANIZATION

BEFORE THE HOUSE OF REPRESENTATIVES COMMITTEE ON SMALL BUSINESS

"THE IMPORTANCE OF TECHNOLOGY IN AN ECONOMIC RECOVERY"

April 22, 2009

Good morning Chairwoman Velázquez, Ranking Member Graves, Members of the Committee, ladies and gentleman. I am Rachel King, Chief Executive Officer of GlycoMimetics, Inc. I am appearing before this Committee on behalf of the Biotechnology Industry Organization (BIO), where I serve on the Board of Directors and as Chair of the Emerging Companies Governing Board. BIO represents more than 1,200 companies, academic institutions, state biotechnology centers and related organizations in all 50 states.

I have been the Chief Executive Officer of GlycoMimetics, Inc. located in Gaithersburg, MD since 2003 and part of the biotechnology industry for 20 years. GlycoMimetics currently has 20 employees who are developing carbohydrate mimics representing an important new class of drugs. We have developed a specialized platform technology which is producing first-in-class drug candidates with an initial focus on inflammation, cancer and infectious disease. Our lead compound, currently in Phase I clinical trials, will provide treatment for patients suffering from sickle cell disease, an area of substantial unmet medical need.

The role of the SBIR program in bringing breakthrough therapies to the American people is a matter of record. There are 252 FDA approved biologics that have been developed by 163 companies. Thirty-two percent of those companies have received at least one SBIR/STTR award. Despite its noble past, the ability of the SBIR program to provide critical funding for medical research projects will remain hampered unless SBIR reauthorization updates the program to address the current realities facing small, innovative American companies.

As you know, Congress created the SBIR program in the early 1980's because it recognized that promising, early stage scientific research all too often failed to be funded through the markets because it was viewed as too high risk. This failure of the markets is often referred to as the "valley of death." The importance of advancing science through the valley of death has never been more important than it is right now as numerous small biotechnology companies are being forced to shelve promising therapies as

result of the current economic crisis. In fact in just the last five months, at least 25 U.S. public biotech companies have either placed drug development programs on hold or cut programs all together. These programs include therapies for HIV, cervical cancer, Multiple Sclerosis, and diabetes.

For twenty years small, domestic biotechnology companies competed for SBIR grants. In addition to providing funding, these grants were a powerful signal to the private sector that a company's research was compelling and possessed scientific and technical merit. However, in 2003 the Small Business Administration's Office of Hearings and Appeals (OHA) ruled that a biotechnology company, Cognetix, did not meet the SBIR size standard because multiple venture capital investors, in the aggregate, owned more than 50% of the company's stock. The ruling, which is not based on the SBIR statutory language, ignores the realities of the marketplace where small biotechnology firms must raise tens of millions of dollars to conduct incredibly capital-intensive research. It is estimated that it takes between 8 and 12 years to bring a biotechnology therapy to market and costs between $800 million and $1.2 billion. These small biotech firms typically have less than 50 employees, no product on the market and must raise considerable funds through a combination of angel investors and venture capital firms in order to make a therapeutic commercially available to patients.

The impact of the current economic crises on small biotechnology companies has been and continues to be severe. According to the latest available data, 30 percent of small, publicly-traded biotechnology companies are now operating with less than 6 months of cash on hand, a 90 percent increase relative to 2007. Forty-five percent of these companies have less than 1 year of cash remaining. The total capital raised by the industry in 2008 has seen a steep decline (down 55% compared to 2007).

The SBIR program has always been critical to helping innovative biologic therapeutic development programs traverse the valley of death and move towards a publicly available product. A role that has never been more critical than it is today. A recent joint study by BIO and Thompson Reuters found that the current economic crisis has forced over 80 percent of biotech investors to change their investment approaches. They can no longer afford the high risk that is characteristic of investment in biotech. The decline of the biotech industry jeopardizes not only America's patient population, but also America's competitive edge in the 21st century global economy. The importance of restoring eligibility to small biotechnology companies has never been clearer.

SBA has stated that the ownership rule is meant to be a proxy for determining that a company is domestic. However, the use of capital structure as a proxy for determining domesticity and the subsequent OHA ruling has had the unintended consequence of excluding a sizeable portion of U.S. biotechnology companies that would otherwise be eligible to participate in the program. Even more alarming is the fact that NIH SBIR applications have decreased 40 percent since 2004, about the time that SBIR-participating agencies implemented the new SBA restriction on majority VC-financed companies.

Small biotechnology companies are generally a collection of research projects with one lead product and an average of 5 other therapies or candidates in early stage/pre-clinical research. Typically, a biotechnology company will begin fundraising for its lead product in development. Companies generally raise between $5 million and $15 million in their first round of venture financing, an amount that often results in multiple venture capital companies collectively owning more than 50% of the company. This is especially the case with very young companies whose valuation may reflect their high-risk, early stage

nature. However, it is typically the case that no single venture capital company will own more than 15 to 25 percent of the company's equity.

Despite the extensive fundraising a biotechnology company undertakes for their lead product, these funds are not interchangeable, as they are tied to very specific milestones to support the lead product's development. As such, in order to develop secondary or tertiary candidates/therapies a company has to find secondary sources of fundraising capital. At the very earliest stages of development other sources of financing, such as SBIR grants, have been instrumental in advancing research and development in biotechnology.

Opportunity to Strengthen/Restore SBIR Program

I appreciate the opportunity to discuss much-needed changes to the current SBIR program. I believe these changes would strengthen the program and ensure that it is funding the best small biotechnology businesses who are working on innovative programs that have the most potential to benefit the public. My recommendations can be grouped under three general goals. First, increase competition for SBIR grants and, as such, foster innovation and commercialization by small companies with the most promise. Second, clarify SBIR eligibility rules to make them easier to understand and increase transparency regarding the program's operation. Third, maintain agency flexibility to make certain the SBIR program continues to serve the needs of individual agencies.

I will briefly discuss each of these important goals.

Increase Competition and Foster Innovation and Commercialization by the Best Small Companies

SBA's 2003 ruling that excludes majority venture-backed companies inhibits the SBIR program from receiving the most competitive pool of applicants possible and stifles the ability of SBIR to carry out its mission to fund projects that will improve public health and have the most commercial potential.

The current SBA interpretation would deem eligible a public company with 499 employees and significant – perhaps hundreds of millions – of dollars in revenue. . However, a private company with 20 employees, no annual revenue and $8 million in venture capital by multiple venture capital funds equaling 56% of the company's equity – even though no one venture capital firm has more than 30% of total equity – is ineligible. Among BIO emerging companies, a significant amount are ineligible, the majority of which would apply to SBIR if able. These companies are working on breakthroughs for the treatment of diseases such as cancer, Alzheimer's, lupus, and leukemia.

The National Institutes of Health (NIH) have documented disturbing trends since the 2003 ruling. Applications for SBIR grants at NIH have declined by 11.9 percent in 2005, 14.6 percent in 2006, and 21 percent in 2007. Additionally, the number of new small businesses participating in the program has decreased to the lowest proportion in a decade.

Small biotechnology companies have high and intense capital needs (over $1 billion) and an unusually long development time of 5-12 years. The vast majority of biotechnology companies raise between $5 million and $15 million in their first round of venture financing for their lead product(s), an amount that usually results in the venture capital firms collectively owning more than 50% of the company. However,

the investment group usually consists of several firms, none of which owns more than 15-25% of the company.

SBIR plays a critical role in aiding small biotechnology companies in their early stage research to navigate through the "valley of death" where the concept is too high-risk for private market support. This has never been more important as the "valley of death" is only getting wider in these difficult economic times.

BIO respectfully asks the Committee to reinstate the eligibility of small, VC-backed biotechnology firms to compete for SBIR awards. This will ensure the most competitive pool of applicants and that grants awarded will be based on projects that show the most promise in bringing breakthrough therapies to the public.

Clarify SBIR eligibility rules to make the application process more straightforward and user-friendly

It is equally important the reauthorization clarify SBA affiliation regulations. Under current SBA regulations, when determining the size of a business, the SBA considers the number of direct employees at the business as well as affiliated businesses' employees. Businesses are affiliates of each other if the SBA determines that another business has either affirmative or negative control. Current regulations state that a venture capital company that holds a minority share in another business can be considered an affiliate of that business. If the SBA determines a venture capital company is affiliated with the business, not only are the employees of the venture capital company included in the size determination but so are the employees of other businesses in which the venture capital firm is invested.

As a result of these affiliation rules, a small company with 50 employees could be deemed to be affiliated with hundreds of other employees of companies with which the small company has no relationship whatsoever, simply because the companies share a common investor. It is important to note that this can be the case where the VC investor owns a minority stake in the small business applying for SBIR.

Not only are these affiliation rules nonsensical, the manner in which they are applied is often a mystery to the small business applying for the SBIR grant. As a result, a small company may certify in good faith that it is eligible for an SBIR grant, only to later find out that the SBA has affiliated it with a large number of employees at other unrelated companies, thus making the small business ineligible.

BIO recommends the reauthorization bill provide language to clarify that minority investment by a venture capital operating company does not make that company an affiliate of another company for the purposes of determining size. This is a common-sense measure that will provide clarity and peace of mind for small business entrepreneurs looking to participate in the SBIR program.

Maintain Agency Flexibility

BIO also supports maintaining agency flexibility in the SBIR program. One of the great strengths of the SBIR program is that Congress provided the affected departments and agencies with flexibility in establishing the program. Maintaining flexibility in the program is also supported by a National Research Council 2007 report which states, "...flexibility is a positive attribute in that it permits each agency to adapt its SBIR program to the agency's particular mission, scale and working culture."

The reality is that various government agencies may structure their SBIR program in different ways to meet differing agency needs. This is a good thing, so long as the original goals of the SBIR program are preserved. Certain agencies, for example, may need the flexibility to award larger grants, if the project they are funding is in an area where research is typically more expensive. This is sometimes the case for biotechnology companies researching therapies that are especially novel or cutting-edge. For this reason, BIO does not believe that a hard cap should be applied to the SBIR grant amounts. Agencies should be the best judge of how to use their SBIR funds to advance science and commercialize new innovations.

Additionally, any caps on SBIR grants, if imposed, should apply to particular SBIR phases and should not apply to the entire amount that the agency spends on a particular project. The NIH, for example, has chosen to implement a commercialization assistance program for those companies who may need extra funding before they can attract private dollars. A hard dollar cap in the SBIR program could threaten such a program and this would be, in BIO's opinion, very unfortunate.

CLOSING REMARKS

Congress can continue to support the United States biotechnology community by allowing the government to partner with small biotechnology companies that have promising science but need additional resources at key stages of development not readily available in the private capital markets. SBIR should be an aggressively competitive program that fulfills federal research and development goals of bringing breakthrough public health discoveries to the public.

TESTIMONY OF JOHN J. STOCKER
SENIOR VICE-PRESIDENT
LYNNTECH, INC.

Before

THE HOUSE SMALL BUSINESS COMMITTEE

On

Reform of the Small Business Innovation Research Program

Washington, D.C.
22 April 2009

Madame Chairwoman Velazquez, Mr. Graves and Members of the Committee, it is with great pleasure that I appear before you today to offer Lynntech's views on the need to reform the Small Business Innovation Research Program (SBIR). Lynntech, headquartered in College Station, Texas, is the largest SBIR contractor in the State and one of the largest in the country. It is fair to say that we have found the program to be beneficial for our company.

Lynntech was founded in 1989 by two former faculty members of Texas A&M University. Lynntech's primary objective is to intensify its efforts to transition the many technologies the company has developed into the marketplace. These technologies are concentrated in the areas of electrochemical synthesis, energy storage and conversion, chemical/biological defense systems, and environmental remediation. Two-thirds of Lynntech's contracts are with the Department of Defense.

As a result, Lynntech's interest in the debate regarding the SBIR Reform legislation is quite high as our efforts to transition technologies will be driven by the framework of future reforms.

In sum, Lynntech believes that the debate regarding last year's bill, H.R. 5819, has focused on the wrong set of issues. Ownership of SBIR companies by venture capital firms should not be guiding our discussion regarding reform of the program. In fact, venture capital firms and other private capital resources should be available to SBIR firms to grow their technology development efforts. The only ground rule should be that large corporations should not directly benefit from a small business program. The issue that the debate should be focused on, in Lynntech's opinion, is that of technology transition.

Lynntech has found that significant applied research and engineering remains to be performed in its technologies before those technologies result in demonstrable prototypes suitable for testing and pre-manufacturing design. Many agencies, such as the National Science Foundation, believe that once technologies reach the end of Phase II, that those technologies are capable of being launched into the marketplace. The typical result of a Phase II project is a very preliminary prototype that where internal components are shown to be capable of producing the desired result, but in no way are these prototypes capable of being transitioned to the marketplace without significant system design and development (engineering).

Due to the early stage technology level of most Phase II projects, it is unlikely that private capital resources will be motivated to support further development and bridge the market entry costs, due to the fact that too many unknowns exist in the technology. Without a clearly defined path to technology transition, SBIR programs will not achieve the ultimate objective of taking new and innovative technologies to market.

Part of the problem is that Government is not well-organized to assist in the transition effort. There is no definable path available to technologists to move their product forward. For example, Lynntech's success in moving some of their defense technologies into the hands of the warfighters has been the result of ad hoc efforts by the company to reach out to acquisition managers. We have developed a technology for producing hydrogen peroxide in the field that can be used in conjunction with a system that cleans interior spaces and sensitive equipment that have been exposed to biological agents. This system, which requires electricity, air, and water, could be deployed in forward areas and would not require the logistics support in transporting and storage of hydrogen peroxide liquid in glass bottles, which is hazardous in handling. We have a customer in the Defense Department who wants the device. However, due to the long lead time in DOD's planning and budgetary process, our customer is scrambling to find the resources needed to fund continued development because we have fallen into the cracks of the budgeting process.

Therefore, the following represents a path forward. The proposed solution has been discussed with the National Venture Capital Association and has been shared with the Biotech community. It represents Lynntech's attempt to bridge the gaps in the debate and develop a program that makes sense for all players.

SBIR Reform Recommendations

With the SBA's SBIR program expiring in July 2009, the new Congress and Administration have the opportunity to make improvements to the program that will vastly improve the introduction of emerging technologies to the market by small businesses. Since the inception of the SBIR program in the early 1980's there has not been any significant changes in administrative procedures to the program to help keep pace with technological innovation. This includes the methods to finance that innovation which have changed enormously over the last several years. It has also led to situations where technology development has not been optimized.

Allow SBIR dollars to cover administrative and contract processing costs.

Allow the SBIR program offices in each of the Federal agencies to withdraw up to 3% of SBIR funding to cover administrative and contract processing costs. Currently, agencies have to absorb the cost of management and many in Government are not enthusiastic about providing "free services" to the SBIR program. If the perception of the provision of "free services" could be changed, then agencies would support a more aggressive pursuit of the broad capabilities and talents of the SBIR community. In lieu of withdrawing a piece of the allocation, a direct appropriation in the 11 agencies would be required.

Ensure that maximum effort to "commercialize" technologies is adopted within agencies.

A common agency complaint is that many SBIR technologies are never utilized because once the contract tasks are completed then the benefits of the research, even in failed projects, never result in a "lessons learned" exercise or in an attempt to link the research to downstream procurement activities. In a recent mark-up of the Department of Homeland Security appropriation bill, Congressional leaders complained that there was no "business plan" developed within the Agency to link innovative research to a downstream need. This complaint is probably widespread, but it specifically exists in the Department of Defense, where Program Executive Offices are unaware that there are technologies developed in the SBIR program that could improve or enhance future combat system development. Thus, the Defense Department should examine the inclusion of acquisition executives in the development of the SBIR topics by the Government labs to ensure that SBIR topics are truly addressing future warfighter needs and the result of SBIR research should be broadly disseminated within the acquisition community. Programs that utilize SBIR research should be rewarded.

SBIR dollars should stay focused on applied research.

The Government should keep the focus of SBIR on applied research. Basic Research is the purview of the nation's Universities. The combination of basic University-centered research and the applied R&D within the SBIR community contributes to the overall achievement of the science and technology professions in the United States. R&D funding should be expanded to help maintain and strengthen the U.S. lead in the science and technology arena. It takes all elements of the science and technology community, Universities, Government labs, and the SBIR firms to ensure this leadership. However, whether it is measured in patents issued or in fielded technology, the SBIR community has established a leadership position within the applied research environment. Universities should conduct basic research, while SBIR granted companies should continue their focus on applied R&D governed by a commercial business plan to bring projects to market.

The allocation of dollars to the SBIR program and the average size of a Phase I and II contract award should be increased to keep pace with inflation.

The SBIR program is funded through an allocation of funding from the Federal Agencies extramural R&D budgets. The allocation was last increased in 1998. Given the need for the US economy to continue to rely on the small business community for economic development, it is vital that another allocation increase should be considered. It is proposed that the allocation be increased by .25% per year over the next six years to reach a level of 3.75% by FY 2016. An allocation increase is budget neutral since it does not increase the overall funding level for extramural Federal R&D, but only directs the Agencies to devote the allocation percentage to the SBIR program. If there is an allocation increase then the average size of a contract award should be increased. Currently, Phase I contracts are typically $100,000 in size while Phase II are $750,000. These award sizes have not been adjusted since 1992, which means that the real dollar size of the contracts have

been diminished with more than 15 years of inflationary impact. Contract awards should be increased to $250,000 in Phase I and to $2 million in Phase II. Extraordinary authority to award in excess of these levels should be vested in the Senior Acquisition Executive of each Department with specific reporting to the Congress on a semi-annual basis of these "outside the norm" awards.

Do not allow companies to evade Phase I efforts.

The Phase I SBIR contract is a real opportunity to test concepts and it should be accepted that failure will be endemic. Phase I failures will lead to greater knowledge. Once proof of concept has been accepted then make the Phase II more meaningful by requiring expansion of technology application. However, if SBIR firms have privately supported Phase I-like research, they should be allowed to submit a Phase I level report to the acquiring agency and to have that report considered for invitation to a Phase II competition.

The SBIR program should encourage the participation of venture capital (VC) firms rather than limit their participation.

In keeping with the intent of the Small Business element of the SBIR program, venture capital firms that participate in the program should follow clearly defined rules that maintain the small business qualifications of their participation and should not be penalized by the mere presence of multiple firms in their portfolio. In fact, the SBA should not be permitted to "look through" an SBIR grantee company to determine eligibility in regard to size. The clear intent should be that SBIR companies should not simply be "fronts" for large firms or "non profit" research institutions trying to access Federal funds to simply reduce their risk exposure.

Venture capital firms have the practical experience in discovering and financing emerging technology companies in both the commercial or government markets and have the best chance for success. They help move the project from the Phase II applied research and development stage, to the development, testing, and evaluation stages that will deliver a manufacturing prototype. While, the SBIR program initiates applied research, VC firms and Government agencies working together with the SBIR firms can become more successful in moving projects to commercialization.

The government should also recognize that not all SBIR opportunities lend themselves to situations where very large markets will develop; however, there may be a public interest in supporting applied research and engineering in a market where the dominant interest is in the achievement of a public good. For example, there is little likelihood that many of the Defense Department's developments in the Chemical Biological Warfare arena would be attractive in commercial market terms (i.e., large numbers of units produced and sold), but there is clearly extensive societal value in these projects. Therefore, SBIR projects that have been identified by Program Executive Offices as having an important impact on the mission would be

supported. This does not mean that a VC controlled firm could not be a participant but that the paramount concern of the Agency takes precedence over the achievement of a large market presence. In other words, there will be SBIR topics and programs that will always stress the public good as opposed to the economic good.

Furthermore, the issue of a VC presence in the SBIR program needs to be guided by an understanding that holding an equity stake in a company's ownership does not equate to control over day-to-day management operations.

If the above issues are incorporated into the legislation that is currently on Capitol Hill, it should help to trigger a revitalization of the SBIR program and continue to improve an already stellar level of performance.

On behalf of Lynntech, Inc., I want to thank the Committee for the opportunity to appear here today and stand ready to answer any questions that you may have.

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HOUSE SMALL BUSINESS

COMMITTEE

"The Importance of Technology in an Economic Recovery"

April 22, 2009

STATEMENT BY

Will Rosellini

Chief Executive Officer, MicroTransponder Inc.

ON BEHALF OF

The Advanced Medical Technology Association (AdvaMed)

Chairwoman Velazquez, Ranking Member Graves and members of the Committee, thank you for holding this important hearing today on the importance of technology in an economic recovery and the role that the Small Business Innovation Research (SBIR) grant program plays to promote job growth and medical research advances. My name is Will Rosellini, CEO of MicroTransponder Inc, a small medical device company located in Dallas, Texas.

MicroTransponder Inc. is a member of AdvaMed, the Advanced Medical Technology Association, which represents over 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of AdvaMed member companies are relatively small companies with sales of less than $30 million per year. The members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, the members manufacture nearly 90 percent of the $86 billion in life-enhancing health care technology products purchased annually in the United States, and nearly 50 percent of the $220 billion in medical technology products purchased globally.

The medical technology industry is a critical component of the U.S. health sector. In addition to the profound contributions of medical technology to the health and well-being of the public, in 2006 the industry employed 357,700 workers; paid $21.5 billion in salaries; and shipped $123 billion worth of products. Taking into account the national multiplier impacts, the industry created (direct plus indirect plus stimulated impacts): 1.96 million jobs; payrolls that totaled $93 billion; and $355 billion in shipments/sales. However, we are not just a major contributor to the U.S. economy based on revenues and jobs. The devices we make also help patients stay healthier longer as well as recover more quickly after treatment, thus allowing patients to participate more fully at work and in the community.

The medical technology industry is fueled by intense competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

Overview of MicroTransponder Inc.

The SBIR program has made it possible for MicroTransponder to develop treatments for chronic pain and other neurological disorders, including Tinnitus, Traumatic Brain Injury, PTSD, motor disorders, Autism, and others. Taken together, these conditions affect over 50 million people in the US and represent an economic burden of over $100 billion dollars annually.

Utilizing SBIR funding, Drs. Michael Kilgard and Navzer Engineer have recently collected preliminary data that suggest that our devices may soon be able to reverse the cause of a neurological disease. This disease severely affects 12 million people in the United States, and

500,000 veterans ---93,000 of whom have recently returned from Iraq. This disease is tinnitus. Tinnitus is a debilitating constant ringing sensation that originates in the brain itself. Tinnitus is caused by hearing loss, often from trauma related to explosions. The VA alone is projected to spend $1 billion annually by 2011 in tinnitus disability compensation alone. We expect to move our promising treatment for tinnitus into clinical testing in humans within 2 years. We treat tinnitus by implanting a small device near a nerve in the side of the neck. The device emits small electric pulses near the nerve, which sends a signal up to the brain to produce chemicals that allow the brain to reprogram itself. When a tinnitus patient receives this device therapy while listening to a series of auditory tones, the brain is able to reprogram itself to eliminate the painful ringing sensation of tinnitus. If successful in humans, our technology will be the first time a neurological disease has been reversed using medical devices. It is a very exciting time for us at MicroTransponder and it would not have been possible without the SBIR program.

I started MicroTransponder in 2006, while I was a graduate student in the neuroscience program at the University of Texas at Dallas (UT Dallas). I saw the potential of an invention by Dr. Larry Cauller. With funding from DARPA, Dr. Cauller had invented a wireless micron size nerve interface device aimed at interfacing nerves with prosthetic devices. However, I realized that this same wireless nerve interface device could also be applied more generally to the medical field, whereupon I started MicroTransponder to realize this vision. Using SBIR funding, our collaborator Dr. Michael Kilgard, also of UT Dallas has shown that our general approach can indeed be used to induce neuroplasticity in the brain. Dr. Kilgard's lab has shown that it is now possible to selectively alter brain function in a predictable and potentially therapeutic manner—it is this finding that may lead to an effective treatment for tinnitus and possible solutions for a host of other neurological disorders. More information on our neuroscience research can be found on our website www.microtransponder.com.

However, raising private money to bring this type of invention into the medical field is not easy. Even though I have an MBA, a JD, masters of neuroscience and have an entrepreneurial track record in the medical field, private funding was difficult to find. Our technology is so new that it represents a very high risk/high reward proposition and venture funding is difficult to obtain. However, the SBIR program is specifically designed to fund research on promising high risk projects. This type of risk is what leads to paradigm shifting discoveries.

In 2007, we received our first Phase 1 grant award from Joseph Pancrazio, program director of the extramural research program at NIH NINDS. Dr. Pancrazio not only approved our funding, but has remained inextricably interested and engaged in our research progress – he funded us truly believing that Dr. Cauller's neuroprosthesis technology will significant change the world someday. This award enabled us to obtain important data for the chronic pain indication. In the course of these efforts, we found that our technology could also be applied to a wide variety of nervous system based diseases, including tinnitus. This funding was part of the reason we were able to develop a robust research program at UT Dallas.

Last year, we applied for 5 SBIR grants and obtained funding for 3—the normal funding rate is

less than 1 out of 5, so this success rate spoke well about our technology and our team. We received support from program directors Roger Miller at NIH NIDCD and John Kusiak from NIH NIDCR, both believed that our technology could help the millions of patients suffering from neurological illness.

The SBIR grants serve a number of important roles in getting high risk/high reward companies off the ground. First they enable the companies to inexpensively test the feasibility of their technology and obtain additional funding if the technology does prove to be feasible. Secondly, when a company is able to show feasibility and garner additional SBIR funds, this provides an independent scientific validation of the company's approach and opens the door for venture capital and other private fundraising. For example, after receiving our first funds from the NIH, we were able to obtain additional funds from the Texas Emerging Technology Fund, which awarded us a $1.4 million grant. The combined funding has allowed us to obtain proof of principle laboratory data and finalize our prototype device. We are now preparing to enter clinical trials at the end of this year for treating chronic pain as well as possibly reversing tinnitus using medical device. This progress could never have been made without SBIR funding.

Without the SBIR program, many high risk/high reward technologies would not be developed and the public would have fewer new treatments for serious illnesses.

The Need for Alternative Funding Mechanisms Beyond SBIR/STTRs

There are a tremendous number of costs associated with any start-up company and SBIR funding only covers a small part of those costs. The program is limited in the funds that it provides and is very strict as to how that money can be spent. For example, those monies cannot support market research or the bulk of lawyer fees for intellectual property protection.

In addition, there is a long runway for obtaining funds. It can take one to two years to obtain funding. Even for a perfect proposal with clear scientific merit, there is a nine month time window between submission and receipt of funds. Those funds are very limited and we would suggest an increase in the amounts of funding for both Phase I and Phase II grants by 50%. That would help alleviate some of the burdens on small business. However, it is important that other sources of funds be available as well, since costs of device development continue to accelerate due to elevated FDA standards and higher healthcare industry costs.

There are three main sources for the large amount of capital that is needed to bring a new medical product to market. One is company revenues, another is VC funding, and a final one is to license the technology to or partner with an already established company.

Some small companies already have products on the market and use that revenue and experience to bring their SBIR supported products to market. Such companies do not have the capital to

support the risky R&D efforts that SBIRs support. The SBIR mechanism therefore allows these types of companies to develop innovative technologies that would otherwise not be developed.

A start-up company with no revenue other than SBIRs and a small seed amount of investment is in a different situation for getting their product to market. They will need considerable non-SBIR funds. These funds can come from VCs or a partner. Partnering is usually a preferred method of getting one's product to market because the start-up company does not have to develop the expertise needed in this area. However, not all products and not all companies are right for partnering. Many products may help patient populations that are very small and thus not as commercially attractive. In addition, and perhaps more importantly, in order to partner a technology, it is necessary to develop the technology to a later stage than SBIR funding alone can take it. This is where VC funding is needed.

The Impact of SBIR Eligibility Rules on VC Funding

A series of rulings from 2001 – 2003 by the Small Business Administration's Office of Hearings and Appeals resulted in the determination that small businesses that were majority-backed by venture capital investors were no longer eligible for SBIR grants. This regulation excludes many small medical technology companies from participating in the SBIR program – including many that have received SBIR grants in the past and are emblematic of the success of the program – even though these small businesses still have a tremendous need for assistance. This does not seem to be within the spirit of the original intent of the SBIR program, which is to help small businesses develop promising, early stage technologies.

It is far more attractive for a venture group to invest in risky technology if there is a track record of SBIR successes. This greatly reduces the risk of investment, however as the rules are today, many companies would have to give up their SBIR funding in order to obtain venture funding.

This is a catch-22 situation. In order to attract VC funding, a company must obtain SBIR funding first. However, they will lose that funding if the VC invests too heavily. This greatly reduces the amount of VC funds that can be raised, which reduces the probability of success and in the end reduces VC investments.

This regulation also makes it less likely that VCs will invest in a given company because they know that SBIRs are no longer possible. Start-up companies that have scientists from academia with solid track records of grant funding lose an important leverage tool for bringing in VC monies. This reduces overall investment and decreases the chance that many important technologies will not be developed.

Finally, the NIH is certainly interested in funding the very best ideas available. By removing many small companies from the pool of possible ideas, the current regulations remove some of the best ideas from consideration by the SBIR program.

Legislation to Restore SBIR Eligibility for Small Businesses

Addressing the VC funding issue is a concern to MicroTransponder and other small companies that rely on SBIR funding to develop new medical technologies for patients. By removing the VC funding mechanism from us, it decreases our chances of success. We may or may not eventually require VC funding on the order of over 50% ownership, however by not having that option, our overall probability of success is diminished.

Legislation for NeuroTechnology Research - National Neurotechnology Initiative Act (H.R. 1483)

Brain research has been underfinanced for decades relative to its economic burden on society. For example, the economic burden a prominent viral infection on the U.S. is approximately $40 Billion annually; and thus the federal research budget in 2008 was $18.2 Billion. In comparison, the economic burden of neurological diseases is approximately $100 Billion annually and the federal brain research budget for the NIH, DoD, and other sources is less than $10 Billion. Brain research is comparatively more expensive and many projects that show scientific merit to create treatments for neurological indications are currently going unfunded due to lack of resources dedicated to brain research. H.R. 1483 provides funds for neuroscience research to the 16 NIH agencies conducting brain research and SBIR companies in the field.

Within MicroTransponders's experience in the neurotechnology field, the biggest bottleneck is probably the FDA approval process. The FDA approval process costs far more and takes far longer for brain-related drugs, devices, and diagnostics than it does for other drugs, devices, and diagnostics. This means that when investors have a choice between funding two potential medical advances, it makes much more financial sense for them to fund the one that is not brain-related. As a result, treatments that could save and improve millions of lives are languishing. The key to solving this problem is not to make FDA's approval process any looser, but to get FDA the resources necessary to hire and train people who specialize in neurotechnology. AdvaMed is proud to partner with consumer groups, patient groups, and other industry organizations as a Member of the Alliance for a Stronger FDA, whose sole mission it to advocate for increased funding for the FDA. Getting the FDA more funding to hire the staff needed to specialize in neurotechnology, which will free up private capital for investment in companies like mine, which will allow us to expand.

The disincentives associated with the FDA approval process, as well as the difficulty and lack of SBIR funding, and the insufficiency in collaborations between the 16 institutes of NIH, the VA, and the DoD, all create deterrent forces against translational innovation. Many of these bottlenecks are addressed in a bill called the National Neurotechnology Initiative Act (H.R. 1483), sponsored by Representatives Kennedy and Ros-Lehtinen. Along with the Neurotechnology Industry Organization, I strongly support this bill as a way to ensure that our nation's basic research investments are effectively translated into diagnostics, treatments, and cures that save and improve lives, while generating jobs and moving our economy forward.

Conclusion

The United States spends a tremendous amount of money on basic research. We lead the world in research funding, in new discoveries, in scientific publications. Our research commitment is important and should be continued. But in order for this research to have a role in the economic recovery, it must be translated into applications. Only when new technology reaches the application stage does it begin generating jobs and improving people's lives.

Chairwoman Velazquez and Ranking Member Graves, we thank you for your leadership in the reauthorization of the SBIR program. We look forward to working with the Committee as legislation for SBIR reauthorization and for neurotechnology initiatives specifically move forward. We want ensure that small businesses will continue to drive medical innovation and develop promising new technologies for patients, especially as our nation seeks economic recovery. I'll be happy to answer any questions you may have.

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