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THE ROLE OF THE SBIR AND STTR PROGRAMS IN STIMULATING INNOVATION AT SMALL HIGH-TECH BUSINESSES

HEARING

BEFORE THE

SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

COMMITTEE ON SCIENCE AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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THE ROLE OF THE SBIR AND STTR PROGRAMS IN STIMULATING INNOVATION AT SMALL HIGH-TECH BUSINESSES

THURSDAY, APRIL 23, 2009

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

The Subcommittee met, pursuant to call, at 2:35 p.m., in Room 2318 of the Rayburn House Office Building, Hon. David Wu [Chair of the Subcommittee] presiding.

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL, TEXAS
RANKING MEMBER

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE AND TECHNOLOGY
SUITE 2320 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6301
(202) 225-6375
TTY: (202) 226-4410
http://science.house.gov

Subcommittee on Technology and Innovation's

Hearing on

THE ROLE OF THE SBIR AND STTR PROGRAMS IN STIMULATING INNOVATION AT SMALL HIGH-TECH BUSINESSES

Thursday, April 23, 2009
1:00p.m. – 3:00p.m.
2318 Rayburn House Office Building

Witness List

Dr. Robert Berdahl
President, Association of American Universities

Mr. James Greenwood
President and CEO, Biotechnology Industry Organization

Dr. Sally Rockey
Acting NIH Deputy Director, Extramural Research, National Institutes of Health (NIH)

Mr. Jere Glover
Attorney and Executive Director, Small Business Technology Council

HEARING CHARTER

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

The Role of the SBIR and STTR Programs in Stimulating Innovation at Small High-Tech Businesses

THURSDAY, APRIL 23, 2009
1:00 P.M.—3:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

I. Purpose

On Thursday 24 April, the Subcommittee on Technology and Innovation of the Committee on Science and Technology will hold a hearing to examine the role of the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) Programs in supporting innovation at small high-tech firms and how, in turn, this promotes the economic welfare of the Nation.

II. Witnesses

Dr. Robert Berdahl is the President of the Association of American Universities.

Mr. James Greenwood is the President and CEO of Biotechnology Industry Organization (BIO).

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

Mr. Jere Glover is the Attorney and Executive Director at the Small Business Technology Council.

III. Hearing Issues

- How could the SBIR and STTR effectiveness be improved in promoting innovation in today's global R&D enterprise?
- Are the current SBIR (2.5 percent) and STTR (0.3 percent) set asides appropriate?
- How effective are the SBIR and STTR programs at stimulating innovation at small high-tech firms?
- What is the role and importance of small high-tech firms to the US innovation cycle and to foster economic growth?
- Should small high-tech businesses with venture capital investment be allowed to participate in the SBIR and STTR programs?

IV. Background

SBIR

Congress has demonstrated an ongoing interest in the small business sector. Addressing issues related to economic growth and competitiveness, special consideration has been given to small, high tech firms for several reasons, including the fact that data indicates such companies tend to be highly innovative, play a significant role in technological advancement, and contribute to a high standard of living in the United States. Such was the rationale behind legislation creating the SBIR program, reflecting an effort to increase that portion of the federal research and development (R&D) budget provided to small enterprises for work associated with the mission responsibilities of government departments and agencies. Believing that small companies were under-represented in government R&D activities, P.L. 97–219 established agency SBIR programs to guarantee this sector a portion of the government's research and development budget to compensate for what was viewed as a federal contracting preference for large corporations.

Current law requires that every federal department with an extramural R&D budget of $100 million or more establish and operate a SBIR program. Generally, a set percentage of that agency's extramural research and development budget—currently set at 2.5 percent—is to be used to support mission-related work in small companies. To be eligible to compete in the program, a company must be independently owned and operated; not dominant in the field of research proposed; for profit; the employer of 500 or fewer people; the primary employer of the principal investigator; and at least 51 percent owned by one or more U.S. citizens or lawfully admitted permanent resident aliens.[1] Subsidiaries of SBIR-eligible companies are also eligible to participate as long as the parent company meets all SBIR requirements.

Agency SBIR efforts involve a three-phase activity. In the first phase, awards up to $100,000 (for six months) are provided to evaluate a concept's scientific or technical merit and feasibility. The project must be of interest to, and coincide with, the mission of the supporting organization. Projects that demonstrate potential after the initial endeavor may compete for Phase II awards of up to $750,000 (lasting one to two years) to perform the principal R&D. Phase III funding, directed at the commercialization of the product or process, is expected to be generated in the private sector. Federal dollars, but not SBIR funds, may be used if the government perceives that the final technology or technique will meet public needs. P.L. 102–564 directed agencies to weigh commercial potential as an additional factor in evaluating SBIR proposals.

As of FY 2008, 11 departments administer SBIR programs, including the Departments of Agriculture, Commerce, Defense (DOD), Education, Energy, Health and Human Services (HHS), Homeland Security, and Transportation; the Environmental Protection Agency; the National Aeronautics and Space Administration (NASA); and the National Science Foundation (NSF). Each agency's SBIR activity reflects that organization's management style. Individual departments select R&D interests, administer program operations, and control financial support. Funding may be disbursed in the form of contracts, grants, or cooperative agreements. Separate agency solicitations are issued at established times.

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

STTR

A pilot effort to encourage commercialization of university and federal laboratory R&D by small companies was created by P.L. 102–564 and reauthorized several times through FY 2009. The STTR program provides funding for research proposals that are developed and executed cooperatively between a small firm and a scientist in a research organization and fall under the mission requirements of the federal funding agency. Up to $100,000 in Phase I financing is available for one year; Phase II awards of up to $750,000 may be made for two years. Currently funded by a set-aside of 0.3 percent of the extramural R&D budget of departments that spend over $1 billion per year on this effort, the Departments of Energy, Defense, and Health and Human Services, NASA, and NSF participate in the STTR program.

The SBIR program has been extended several times and was scheduled to terminate on September 30, 2008. In the 110th Congress, several bills were introduced to reauthorize and alter the SBIR initiative. H.R. 5819 passed the House on April 23, 2008, and S. 3362 was reported from the Committee on Small Business and Entrepreneurship on August 22, 2008. Although no specific legislation reauthorized the program, the Small Business Administration determined that P.L. 110–235 temporarily extended the SBIR activity through March 20, 2009. P.L. 111–10 provides another extension of the program through July 31, 2009.

110th Congressional Hearings

Hearings were held in the 110th Congress on April 26, 2007 and June 26, 2007 (Serial Nos. 110–23 and 110–43, respectively).

The first hearing[2] focused on several important issues for the future of the SBIR and STTR programs, including: the degree to which the current programs are meeting their objectives; the adequacy of the award levels; strategies to maximize small businesses participation and increase participation by women and minority owned small businesses; the programs' effectiveness in promoting product commercializa-

[1] The House passed H.R. 5819 altered the previous eligibility requirements to permit majority venture capital ownership of small firms in the SBIR and STTR programs.

[2] The following is taken from the *Summary of Activities of the Committee on Science and Technology U.S. House of Representatives for the One Hundred and Tenth Congress,* 4.6(c).

tion; covering administrative costs; and the appropriate role for venture capital-backed small businesses.

Chair Wu opened the hearing by discussing the benefits of the SBIR/STTR programs, such as the stimulation of high-tech innovation and strengthening U.S. competitiveness. He then invited witnesses to address topics such as the size of the awards, broadening the participation of small business, creating funding within the program for administrative costs, and determining the extent of participation by venture capitalists. Both Chair Wu and Ranking Member Gingrey emphasized the role that these programs have in moving ideas from the laboratory to the marketplace, particularly innovative work on health care issues such as diabetes and Alzheimer's research.

Mr. Held, the Director of the Force Development and Technology at the RAND Arroyo Center at RAND Cooperation, stated that the DOD SBIR program could benefit from changes that would make the program more effective in generating technology and products that are utilized by the Armed Forces. He suggested that more flexibility in the solicitation and funding process would enhance the program. He called for increases in the minimum awards for Phase I and Phase II and advised a set-aside for administrative expenses.

Mr. Baron, the Executive Director of the Coalition for Evidence-Based program Policy at the Council for Excellence in Government, opened with examples of SBIR successes in the computer and biomedical fields and said that the program had led to multiple scientific breakthroughs and commercial successes. He cited GAO and DOD data that suggests that the projects which fail to meet commercial success are often in firms lacking entrepreneurial capabilities, and recommended that SBIR consider methods to build up entrepreneurial skills. In response to a question by Chair Wu regarding using a portion of funding for administrative costs, Mr. Baron as well as Mr. Schmidt and Mr. Held, cautioned that an administrative set-aside could draw funds away from program goals and create disincentives for good management.

Mr. Schmidt, the founder and Chairman of Cleveland Medical Devices and Orbital Research Inc., expressed concern that the U.S. was falling behind in the creation of technological products and jobs. He described some benefits of SBIR and STTR such as helping universities to strengthen commercialization and job creation at small high-tech firms. He cautioned against proposals that would give SBIR funds to large companies or blur its research focus and recommended a gradual doubling of the programs.

Dr. McGarrity, the Executive Vice President of Scientific and Clinical Affairs at VIRxSYS Corporation, explained that biotechnology research takes a lot of time and a large initial expenditure. He criticized the SBA decision to exclude some venture capital (VC) backed businesses from SBIR and stated that his firm had to abandon promising research in cystic fibrosis and laid off employees as a result of the ruling. He stated that his company is willing to compete with VC backed companies for SBIR funds on the basis of scientific and technical merit, and believes that science suffers from the exclusion of firms that have a commercialization track-record. In response to a question by Mr. Wu about the impact of the SBA ruling, Dr. McGarrity argued that the SBA rule led to ineligibility of businesses based not on the number of employees of their own business, but on the number of employees in their VC backing firms.

Mr. Ignati, the President and CEO of Synapse Biomedical Inc., recommended that the minimum award for Phase I and Phase II be increased from their 1992 amounts and that the agencies administering the SBIR program be granted more flexibility making administrative decisions. He also recommended that companies be allowed to apply for Phase II grants without having first received a Phase I grant. He then expressed his concern that the SBIR program is not able to increase participation of innovative high-tech firms as a result of the SBA ruling excluding VC backed firms. He recommended that all VC backed firms be allowed to participate in SBIR.

The second hearing[3] focused on the following issues: program trends; outreach to encourage new applicants and reaching out to a diverse pool of applicants; program data and tracking; and the role of procurement in enabling commercialization. Chair Wu opened the hearing by discussing the large growth of the SBIR and STTR programs, which are now the largest government programs supporting research and development at small companies. He emphasized the programs' duties to promote efficiency in operations and maximum public benefit. In Ranking Member Phil Gingrey's opening statement, he explained that every department and agency with an R&D budget exceeding $100 million must provide 2.5 percent of this budget for research at small companies, resulting in more than $2 billion in funds across the

[3] The following is taken from the *Summary of Activities of the Committee on Science and Technology U.S. House of Representatives for the One Hundred and Tenth Congress,* 4.6(e).

agencies. The goal of these programs, he said, is to stimulate competitiveness and innovation. He was optimistic about past achievements of the programs and the prospect of future success.

Mr. Caccuitto, the SBIR and STTR Program Coordinator at the Office of Small Business Programs and the DOD, said that the SBIR and STTR programs at the DOD are crucial in seeding innovation for defense technologies. Each "constituent" military department and defense agency has its own program, with centralized oversight and decentralized management, with the total DOD SBIR/STTR budget across all military departments at over $1.26 billion. DOD funds about one in seven SBIR Phase I proposals and one in five STTR proposals.

Ms. Goodnight, the SBIR and STTR Program Coordinator at the Office of Extramural Research of NIH at HHS, emphasized that program flexibility is the key to fulfilling SBIR and STTR goals at NIH. She noted that the programs have not grown at the rate of other NIH programs due to firms losing eligibility, going out of business, or perceived lack of participation incentives. She discussed NIH's development of Performance Outcome Data Systems for data tracking that help to monitor achievements of awardees. In response to a question by Ranking Member Gingrey about the effect of the 2003 SBA ruling on venture capital-backed companies' participation in the program, Ms. Goodnight stated that the nature of biotechnology research requires venture capital to fund expensive trials. She described some cases where important research was halted as a result of the ruling.

Mr. James, the SBIR and STTR Program Manager and Acting Director at the Small Business Research Division at the DOE, said that, like at the DOD, the Department of Energy has a balance of centralized and decentralized management for their SBIR and STTR programs. He explained that the Department hosts State-sponsored events to reach out to small businesses. These small businesses have excellent science skills but lack business skills; thus, DOE provides these professionals with assistance in designing business plans. He stated that in the past 24 years the DOE has invested almost $1.5 billion, 60 percent of the companies have had sales of more that $1.6 billion.

Mr. Comstock, the Director of the Innovative Partnership Program Office at NASA, noted that the SBIR and STTR programs were recently moved from NASA's four mission directorates to an agency-wide mission support office that reports to the Administrator's Office in response to the Innovative Partnerships Program of 2005. This more integrated approach helps to illuminate technology gaps and future technologies which will be infused into NASA, helping to reach mission goals. He cited Phase III authority to enter into sole source contracts as a benefit for NASA's programs. He stressed that NASA's outreach efforts have been successful in providing a fresh applicant pool. In response to a question by Chairman Wu on whether the agencies have adequate funding for administration, Mr. Comstock, as well as Mr. James and Ms. Goodnight, stated that administrative funding is not adequate to allow the optimal level of commercialization assistance.

Mr. Narayanan, the Director of the Division of Industrial Innovation and Partnerships in the Directorate for Engineering and NSF, stated that SBIR plays a critical role in moving discovery to innovation at NSF. He explained that in addition to the SBIR/STTR grants, NSF has pioneered a Phase II supplement for funding, providing greater incentive for third-parties to invest in the awardees' projects. He stated that follow up of 400 NSF SBIR grantees has shown a significant impact; however, limited funds prevent program managers from providing hands-on mentoring.

Summary of the SBIR/STTR Reauthorization Act (H.R. 5819)

H.R. 5819, the *SBIR/STTR Reauthorization Act,* a bill that would have reauthorized and made several significant changes to the SBIR and STTR programs, passed the House on April 23, 2008. Among these changes were:[4]

- The termination date for the SBIR program was extended from September 30, 2008 to September 30, 2010, while the STTR activity was reauthorized through September 30, 2010 rather than the current sunset date of September 30, 2009.
- The bill increases the level of awards made under the SBIR and STTR programs from $100,000 to $300,000 for Phase I awards and from $750,000 to $2,200,000 for Phase II awards.
- A recipient of a Phase I grant from one federal agency would be permitted to apply for a Phase II award from another agency to pursue the original

[4] The following points were all taken from the CRS Report *The Small Business Innovation Research Program: Reauthorization Efforts,* April 29, 2008.

work. A small business would be allowed to switch between the SBIR and STTR programs. In addition, a small company would have been allowed to apply for a Phase II award without first obtaining and successfully completing a Phase I grant as currently required. The bill also would have permitted sequential Phase II awards for a project.

- For the SBIR and STTR programs, H.R. 5819 would have allowed majority venture capital ownership in a small business if not more than 50 percent of the firm is owned by one venture capital company and the employees of the venture capital company are not a majority of the small firm's board of directors. If the venture capital company is controlled by a business with more than 500 employees, the small business would have been eligible if not more than two large venture capital companies have ownership interest in the small firm, these large venture capital companies do not collectively own more than 20 percent of the small business, and the venture capital companies "do not collaborate with each other to exercise more control over the small business concern than they could otherwise exercise individually."
- The bill would have directed agencies to focus on certain research areas for "special consideration" including energy-related work, R&D in the area of rare diseases, transportation-related topics, and nanotechnology.
- The bill would have mandated that each agency that administers $50,000,000 or more in SBIR grants establish a SBIR Advisory Board comprised of agency employees, private sector representatives, veteran small business owners, and others deemed appropriate. The Advisory Board was to make recommendations to the agency on programmatic topics including, among other things, mechanisms to encourage a broad range of applicants and commercialization efforts. An annual report was to be required.
- The bill would have reauthorized and made changes to the Federal and State Technology Partnership (FAST) program, which provides grants to organizations to provide outreach designed to encourage increased participation in the SBIR program.

Chair WU. I want to welcome everyone to this afternoon's hearing on the Small Business Innovative Research, or SBIR, and Small Business Technology Transfer, or STTR, Programs. This is the third hearing that this subcommittee has held on these very important programs.

Both of them were created over 25 years ago, designed to support and encourage small high-tech entrepreneurial firms and play a more important role than ever in the economy that we live in today.

Almost a year ago the House passed an SBIR Reauthorization Bill, H.R. 5819, which included the first significant changes to the program since its inception. This bill reflected not only the cost of research today but also reflected the international competitive market American high-tech firms face and the recommendations of various research bodies that have put about SBIR.

Much has changed over the past 12 months. Today we are looking to small, high-tech firms to create the new products, services, and technologies that can rejuvenate our economy and make us more competitive internationally.

When the SBIR and STTR Programs were created, we didn't fully appreciate the power of small entrepreneurial high-tech firms to create economic growth. Companies such as AMGEN, Apple, Genentech, and Microsoft all started as small entrepreneurial firms and now employ thousands or tens of thousands. Other companies started small and stayed small. All were innovators and drove economic growth.

When SBIR and STTR were created, these companies were either in their infancy or didn't yet exist. In part because of SBIR and STTR today the United States is a world leader in IT [Information Technology] and in biotech.

As the testimony indicates, SBIR and STTR-supported companies are still driving innovation in the IT and biotech fields. The authorization for SBIR and STTR expires at the end of July, and given the current economic situation, we need to ensure that we structure these programs to reflect the current economy and the globalization of R&D. We can't afford to think we are the only country with first-class science and engineering talent. We need to foster the innovation that creates economic growth, jobs, and new products and services right here at home.

Maintaining the status quo of programs created a quarter century ago makes neither good business nor policy sense. We must always keep in mind that it is the American taxpayer who pays for these programs. In these difficult economic times we need to ensure they receive the highest return on their investment.

We have a varied panel of witnesses here today representing small business and the NIH [National Institutes of Health], which provides the second largest amount of SBIR funding of any federal agency. I hope they can tell us more about the economic challenges facing those firms and their thoughts on the program. At over $2 billion per year the SBIR and STTR Programs are now far and away the largest technologic development programs or transfer programs in the Federal Government.

I want to thank our witnesses for appearing before us today.

And now I would like to turn to our Ranking Member, the gentlewoman from Illinois, for her opening statement.

[The prepared statement of Chair Wu follows:]

PREPARED STATEMENT OF CHAIR DAVID WU

I want to welcome everyone to this morning's hearing on the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) Programs. This is the third hearing the Subcommittee has held on these programs. Both of these programs, created over 25 years ago, were designed to support and encourage small high-tech entrepreneurial firms.

Almost a year ago, the House passed a SBIR reauthorization bill, H.R. 5819, which included the first significant changes to the program since its inception. This bill reflected not only the cost of research today, but also reflected the international competitive market American high-tech firms face.

Much has changed over the past 12 months. Today we are looking to small high-tech firms to create the new products and technologies that can rejuvenate our economy.

When the SBIR and STTR programs were created we didn't fully appreciate the power of small high-tech firms' ability to create economic growth. Companies such as AmGen, Apple, Genentech, and Microsoft all started as small entrepreneurial firms and now employ thousands. Others stayed small. All were innovators and drove economic growth. When SBIR and STTR were created these companies were either in their infancy or had yet to exist. In part because of SBIR and STTR, today the United States is a world leader in the IT and biotech industries. And as the testimony indicates, SBIR and STTR supported companies are still driving innovation in the IT and biotech fields.

The authorization for SBIR and STTR expires at the end of July. Given the current economic situation, we need to ensure that we structure these programs to reflect the current economy and the globalization of R&D. We can't afford to think we're the only country with first-class science and engineering talent. We need to foster the innovation that creates economic growth jobs and new products and services here at home.

Maintaining the status quo of programs created almost 30 years ago makes neither good business nor policy sense.

We must always keep in mind that it's the American taxpayer who pays for these programs. In these difficult economic times we need to ensure they receive the highest return on their investment.

We have a varied panel of witnesses here representing small business and the NIH, which provides the second largest amount of SBIR funding of any federal agency. I hope they can tell us more about the economic challenges facing those firms and their thoughts on the program. At around $2 billion a year, the SBIR/STTR programs are now far and away the largest technological development programs in the Federal Government. I want to thank our witnesses for appearing before us today.

Ms. BIGGERT. Thank you, Mr. Chair, and thank you for holding this hearing today on the role of SBIR and STTR Programs in stimulating innovation at small businesses. As you know, our Ranking Member Smith was unable to be here at this moment. He might be in a little bit later, but he had an immoveable conflict, but I am pleased to have the opportunity to take his place as we examine this important program today.

On this committee we are, of course, well aware of the importance of innovation to economic growth and improved quality of life, particularly as we work our way through this recession. We recognize that advances in science and technology will help to enable short-term economic recovery as well as sustain prosperity over the long-term.

To this end the SBIR and the STTR Programs play a key role as an important part of an overall federal R&D portfolio, serving to facilitate increased private sector commercialization of promising ideas, while leveraging the unique capabilities of small business to

help the government advance its R&D goals and meet its technological needs.

Today's hearing represents a continuation of the SBIR reauthorization efforts undertaken by this committee and the House Small Business Committee during the 110th Congress. As such it will focus on two primary changes under consideration last year. One is whether or not to increase the research set-asides that fund SBIR and STTR, and two, whether or not to relax restrictions on participation by venture capitalist-backed small businesses.

These are very important issues that this hearing provides an opportunity for us to hear from the key stakeholders involved. With respect to the set-aside, it is important to remember the unique funding structure through which the SBIR and STTR Programs are funded. Through an assessment on extramural national, extramural federal research that is carried out by our universities and national labs.

As a result an increase set-aside comes at the expense of basis and applied research performed at universities and the National labs, and because of the large base from which the funding is derived and even what might appear to be a minor increase in the set-aside from two and a half to three percent for SBIR and from .3 to .6, that would be 0.3 and 0.6, percent for STTR, would result in a rough reduction of roughly $650 million to core agency research programs.

For this reason and because SBIR and STTR budgets have grown substantially over the last 10 years, I am strongly opposing—I am strongly opposed to increasing this set-aside. The issue of eligibility of majority venture capitalist-based small businesses is significantly more complicated but no less important. The origin of the dispute over this eligibility is due to the lack of clarity in and changing interpretations of the existing statutory definition of a small business.

Regardless of what side of this issue one is on, I think we could agree that the solution is to define small business in a manner that maximizes the eligibility of legitimate small businesses while minimizing the inappropriate eligibility of large businesses. To this end I am concerned that the current SBIR rules may unreasonably exclude many legitimate small businesses, particularly in the biomedical sector due to its high dependence on venture capital to advance drugs and therapies through the regulatory approval process.

I hope this is something that we will address in this upcoming legislation. This committee and the Full House built a solid record of work on SBIR reauthorization during the 110th Congress, so I anticipate that we will be able to work cooperatively and swiftly to extend the SBIR Program before its July 31 expiration.

However, I hope and expect that we can do so through regular order so the Committee Members have an opportunity to review any changes to the legislation from last year and offer input and amendments as necessary.

And I thank your witnesses for being here today and waiting for us. We had those pesky votes, as you know, and I look forward to a productive discussion.

And I yield back.

[The prepared statement of Ms. Biggert follows:]

PREPARED STATEMENT OF REPRESENTATIVE JUDY BIGGERT

Mr. Chairman, thank you for holding this hearing today on the role of SBIR and STTR programs in stimulating innovation at small businesses. As you know, Ranking Member Smith was unable to make this hearing due to an immovable conflict, but I am pleased to have the opportunity to take his place as we examine this important program today.

On this committee we are of course well aware of the importance of innovation to economic growth and improved quality of life. Particularly as we work our way through this recession, we recognize that advances in science and technology will help to enable short-term economic recovery as well as sustained prosperity over the long-term.

To this end, the SBIR and STTR programs play a key role as an important part of the overall Federal R&D portfolio, serving to facilitate increased private sector commercialization of promising ideas while leveraging the unique capabilities of small businesses to help the government advance its R&D goals and meet its technology needs.

Today's hearing represents a continuation of the SBIR reauthorization efforts undertaken by this committee and the House Small Business Committee during the 110th Congress. As such, it will focus on the two primary changes under consideration last year: (1) whether or not to increase the research set-asides that fund SBIR and STTR; and (2) whether or not to relax restrictions on participation by venture-capital backed small businesses. These are both very important issues with potentially far-reaching impacts, so I am pleased that this hearing provides an opportunity for us to hear from the key stakeholders involved.

With respect to the set-aside, it is important to remember the unique funding structure through which the SBIR and STTR programs are funded—through an assessment on extramural federal research that is carried out by our universities and national laboratories. As a result, an increased set-aside comes at the expense of basic and applied research performed at universities and national laboratories, and because of the large base from which funding is derived, and even what might appear to be a minor increase in the set aside—from two and a half to three percent for SBIR and from 0.3 to 0.6 percent for STTR—would result in a reduction of roughly $650 million to core agency research programs. For this reason, and because the SBIR and STTR budgets have grown substantially over the last 10 years, I am strongly opposed to increasing the set aside.

The issue of eligibility of majority venture-capital backed small businesses is significantly more complicated, but no less important. The origin of the dispute over this eligibility is due to lack of clarity in—and changing interpretations of—the existing statutory definition of a "small business." Regardless of what side of this issue one is on, I think we could agree that the solution is to define "small business" in a manner that maximizes the eligibility of *legitimate* small businesses while minimizing the inappropriate eligibility of large businesses.

To this end, I'm concerned that the current SBIR rules may unreasonably exclude many legitimate small businesses, particularly in the biomedical sector due to its high dependence on venture capital to advance drugs and therapies through the regulatory approval process. I hope this is something that we will address in this upcoming legislation.

This committee and the Full House built a solid record of work on SBIR reauthorization during the 110th Congress, so I anticipate that we will be able to work cooperatively and swiftly to extend the SBIR program before its July 31St expiration. However, I hope and expect that we can do so through regular order so the Committee Members have an opportunity to review any changes to the legislation from last year and offer input and amendments as necessary.

I thank our witnesses for being here today and I look forward to a productive discussion.

Chair WU. I thank the gentlelady and would just add that it is fully my intent to move legislation on this very important subject through regular order, but as the gentlelady fully understands, sometimes we have our intentions changed for us.

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

[The prepared statement of Mr. Mitchell follows:]

PREPARED STATEMENT OF REPRESENTATIVE HARRY E. MITCHELL

Thank you, Mr. Chairman.

Today we will examine the role of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs in supporting innovation at small high-tech firms.

Small businesses are continuously growing in Arizona, especially those in the biotechnology field. Many biotechnology and other small firms are centered in my home district and frequently work with one of the largest universities in the country, Arizona State University.

ASU often partners with small businesses to apply for Small Business Innovation Research (SBIR) and Small Business Technology Transfer Program (STTR) grants. Through this partnership, businesses are able to benefit not just from grant money, but also the tools, facilities, and knowledge that ASU offers.

I look forwarding to hearing more from our witnesses about the effectiveness of the SBIR and STTR programs and how these programs could be improved.

I yield back.

Chair WU. I just want to note that I will be stepping away for a few minutes at about three o'clock, and I believe that the gentlelady from Maryland will be available to step in the chair for awhile. Thank you very much.

At this point it is my pleasure to introduce our witnesses. Dr. Robert Berdahl is the President of the Association of American Universities [AAU]. I would like to add a proud former Duck for almost 20 years. The Honorable Jim Greenwood is the President and CEO of the Biotechnology Industry Organization and well represented Pennsylvania for a dozen years, and I always thought that was such a long, long time, but I am hitting the dozen mark soon myself, and it is amazing how perspective changes. Dr. Sally Rockey is the Acting NIH Deputy Director for Extramural Research at the National Institutes of Health. And finally Mr. Jere Glover is the Attorney and Executive Director of the Small Business Technology Council. Welcome one and all. Your full written testimony will be included in the record of the Subcommittee. Please if you will summarize your written testimony. You will each have five minutes for your spoken testimony, and when you complete your testimony, we will hopefully have plenty of time for questions, and each Member will have five minutes to answer questions.

Dr. Berdahl, please proceed.

STATEMENT OF DR. ROBERT M. BERDAHL, PRESIDENT, ASSOCIATION OF AMERICAN UNIVERSITIES

Dr. BERDAHL. Good afternoon, Chairman Wu, Congresswoman Biggert, and Congresswoman Edwards. It is a great privilege to present our association's views on the Small Business Innovation Research Program and the Small Business Tech Transfer Program. I have to note at the outset that I had the privilege of being a faculty member and an administrator at both the University of Oregon and the University of Illinois, and so I have some familiarity with the role that those universities play in the economies of those respective states.

Chair WU. Your attempt to carry a favorable impression has been very successful.

Dr. BERDAHL. All right. Very good. Well, let me begin my testimony by stating that the AAU supports SBIR and STTR programs as they are currently structured. We agree with the National Academy's assessment of these programs as being sound in concept and

effective in practice. In the early years of SBIR many of our campuses were critical of the program, viewing it as coming at the expense of funding that would have otherwise supported university basic research.

In recent years, however, as our universities and faculty have become—they have become much more interested in commercializing new technologies, our universities have come to support SBIR and STTR Programs as they currently exist.

To drive this point home I would like to highlight a SBIR success story from Chair Wu's home State of Oregon and my former university, the University of Oregon. Electrical Geodesics Incorporated, EGI, was a University of Oregon spin-off company. It was founded by U of O neuroscientist Don Tucker to develop advanced, non-invasive ways to visualize brain activity. Over the last decade SBIR grants have played a key role in fueling EGI's maturation, growth, and expansion. As a direct consequence of SBIR support, EGI's geodesics sensor net can now be found in more than 350 laboratories in 28 countries around the world.

Given the success of EGI and other SBIR firms, it is clear that the SBIR and STTR Programs have played an important role in stimulating innovation at small high-tech firms throughout the country. The specific degree to which these programs are responsible for innovation, however, is not easy to assess due to a lack of sufficient data. According to the National Institutes of Standards and Technologies [NIST], more than 26 billion has been spent on SBIR and STTR grants, yielding 84,000 patents and attracting more than $36 billion in venture capital for more than 17,000 SBIR-funded companies.

Despite the success of these programs, the NRC [National Research Council] report makes significant recommendations about the need for better data collection and systematic assessment of SBIR and STTR Programs, and we commend those recommendations to you.

In your letter of invitation you asked us to assess the current SBIR and STTR set-aside percentages. While supportive of the current set-aside, we oppose any increases in the SBIR set-aside because there is no indication that highly-qualified SBIR proposals are currently being rejected for lack of sufficient funding.

Moreover, we question whether there is enough small business research and of sufficient quality to merit an increase in the SBIR set-aside, especially if such funding were to come at the expense of peer reviewed, basic, and applied research programs, where success rates have hit all-time lows in recent years.

Our view is that the best way to increase the amount of funding available to these programs is to provide steady and sustained funding increases for federally-supported basic scientific research. As research funding increases, the dollars available to these programs will also increase.

At this point the only modification we would encourage would be the slight increase recommended by the NRC in the percentage of set-aside that would be used for program management from the .03 percent to .05 percent.

You also asked our views about venture capital and SBIR. AAU supports the Subcommittee's view that firms with significant ven-

ture capital funding should be allowed to compete for SBIR and STTR awards. However, the current regulation effectively disqualifies small companies that have received significant venture capital or are owned by another company with significant venture capital investment from competing for SBIR or STTR funds.

The AAU shares the view of the NRC that venture capital investment in companies seeking SBIR funding confirms the quality of those projects and would raise the quality of the applicant pool overall.

You also asked for thoughts concerning ways to improve the effectiveness of these programs. In responding to this request I would commend to you the recommendations made by the National Research Council in its 2008 report.

There is one related issue that we would ask the Subcommittee to examine in reauthorizing the SBIR Program, Mr. Chair. Even with today's existing SBIR Program, there is a funding gap that often prevents universities from moving new research discoveries and technologies quickly into the marketplace. This bridge funding often crossing the "Valley of Death" as it is called, would be very, very important.

Let me conclude, I see my time is up here, let me conclude my remarks with a statement that I made earlier in my testimony that these are sound and effective programs. It is clear that these programs are at their core good programs that help foster successful entrepreneurial opportunities for our nation's scientists, engineers, and innovators. These programs were created well over 20 years ago. They can be improved by adopting some of the NRC's recommendations. I also believe that it might be time to consider supplementing these programs with a new program aimed at providing additional gap funding.

Mr. Chair, Members of the Subcommittee, once again, I thank you for the opportunity to share AAU's thoughts. I look forward to your questions.

[The prepared statement of Dr. Berdahl follows:]

PREPARED STATEMENT OF ROBERT M. BERDAHL

Introduction

Good afternoon Chairman Wu, Ranking Member Smith, and Members of the Subcommittee. I am Robert Berdahl, President of the Association of American Universities (AAU). I appreciate the opportunity to present AAU's views on the Small Business Innovation Research (SBIR) and Small Business Tech Transfer (STTR) programs to you today.

AAU is the association of 60 leading U.S. public and private research universities, and we also have two Canadian university members. AAU's 60 U.S. member institutions perform 60 percent of federally funded university-based research and award more than half of all Ph.D. degrees earned in our country.

I. AAU supports the current SBIR and STTR programs and set-aside percentages.

Let me begin by stating that AAU supports the SBIR and STTR programs as they are currently structured. We agree with the National Academies assessment of these programs as being "sound in concept and effective in practice." Both programs play an important role in the Nation's overall innovation ecosystem by transforming cutting-edge, innovative ideas and research into viable, market-ready products for the American consumer.

In the early years of SBIR, many on our campuses were critical of the program, viewing it as coming at the expense of funding that would have otherwise supported university-based basic research. In recent years, however, as our universities and

faculty have become more interested in commercializing new technologies, our universities' attitude towards the SBIR and STTR programs has become more positive.

Indeed, the SBIR and STTR programs are now widely viewed by many faculty and research administrators as an important tool that can help them transform the research generated in our university laboratories into new industrial products, goods, and services. As a result, more and more of our faculty are directly engaged in research funded through these two programs.

When the National Research Council (NRC) surveyed SBIR recipients for its 2008 report, "An Assessment of the SBIR Program," more than half of respondents reported that university faculty were involved in their SBIR-funded projects. Clearly, SBIR and STTR are encouraging university faculty to start or work with small companies in an attempt to commercialize their research results.

The NRC found that the SBIR and STTR programs not only provide a vehicle for commercialization of research but also stimulate scientific and technological collaboration between faculty and industry that yields a variety of "knowledge outputs." These "knowledge outputs" can take the form of "data, scientific and engineering publications, patents and licenses, analytical models, algorithms, new research equipment, prototype products and processes, and spin-off companies."[1]

To elaborate on this point, I would like to highlight an SBIR success story from two of our AAU universities.

The first example comes from Chairman Wu's home State of Oregon. Electrical Geodesics Inc. ("EGI"), a University of Oregon spin-off company, was founded by UO neuroscientist Dr. Don Tucker to develop advanced, non-invasive ways to visualize brain activity. Over the last decade, SBIR grants played a key role in fueling EGI's maturation, growth and expansion. As a direct consequence of SBIR support, EGI's Geodesic Sensor Net can now be found in more than 350 laboratories in 28 countries around the world, supporting human neuroscience research on topics ranging from child development to psychopathology to neuroeconomics. EGI's Geodesic Sensor Net has become an icon of advanced neuroscience technology, appearing on the covers of *National Geographic* and *Newsweek.* Electrical Geodesics has been a past winner of the Tibbetts Award for excellence in the SBIR program. This innovative, university-born small business—whose research, development and manufacturing provide high-quality employment to scores of Oregonians in the City of Eugene—received recognition as Oregon's Bioscience Company of the Year in 2006, and received the Emerald Award for Innovation from the Eugene Chamber of Commerce in 2008.

The second example comes from Nebraska, where, in 2002, GC Image, LLC, a Lincoln based company was incorporated based on software developed by a University of Nebraska–Lincoln Computer Science Professor, Dr. Stephen Reichenbach. GC Image delivers industry-leading software solutions for visualizing, analyzing, and reporting on scientific data from comprehensive two-dimensional gas chromatography and comprehensive two-dimensional liquid chromatography. The company has been awarded $1.5 million in SBIR and STTR Phase I and II awards over the last five years from the National Science Foundation and the National Institutes of Health. GC Image continues to grow and build on its successes through strategic partnerships to deliver software products in diverse markets.

So, to address the first of the questions posed by the Subcommittee, clearly the SBIR and STTR programs have played an important role in stimulating innovation at small high-tech firms in Oregon, Nebraska, and throughout the country. The specific degree to which the programs are responsible for innovation, however, is not easy to assess because of a lack of sufficient data.

According to the National Institute of Standards and Technology (NIST), more than $26 billion has been spent on SBIR and STTR grants, yielding 84,000 patents and attracting more than $36 billion in venture capital for more than 17,000 SBIR-funded companies. The NRC report cites Small Business Administration (SBA) data indicating that nearly 15,000 small companies received at least one Phase II SBIR grant between 1992 and 2005.

Despite the success of these programs, the NRC report makes significant recommendations about the need for better data-collection and systematic assessment of SBIR/STTR, and we commend those suggestions to you. We would agree with the NRC that is difficult to truly assess the economic and innovation impact of SBIR and STTR because there has not been systematic data-gathering on the part of sponsoring agencies. Requiring such data collection and program assessment and providing the resources needed to finance these activities would be one positive action that this subcommittee and the Congress could take to enhance the SBIR and STTR programs.

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[1] National Research Council, *Assessment of the SBIR Program,* National Academies Press, p. 3.

You also asked us to assess the current SBIR and STTR set-aside percentages. In response to this question, AAU is supportive of the current SBIR set-aside of 2.5 percent of R&D spending for major research agencies and the 0.3 percent set-aside for the STTR program.

While supportive of the current set-aside, we oppose any increases in the SBIR set-aside because there is no clear justification for such increases. We question whether there is enough small business research—and of sufficient quality—to merit SBIR funding that would come at the expense of peer-reviewed basic and applied research programs at agencies such as NIH and NSF, where success rates unfortunately have hit all-time lows in recent years. In our view, increasing the set-aside would reduce even further the number of successful research grants that are awarded by federal research agencies.

This is not to suggest that we do not favor increasing the amount of funds going to SBIR and STTR. Our view is that the best way to increase the amount of funding available to these programs are to provide steady and sustained funding increases for federally supported research. Indeed, we hope to work with the small business community to increase research budgets across all of the major research agencies, which would result in significant funding increases for the SBIR and STTR as well as other important research programs.

As for modifications to the set-aside, the only modification we would encourage would be the slight increase recommended by the National Research Council in the percentage of the set-aside that could be used for program management and assessment from .03 percent to .05 percent of the total program funding.

II. AAU supports allowing small businesses with significant amounts of venture capital investments to participate in the SBIR and STTR programs.

AAU supports the Subcommittee's view that firms with significant venture capital funding should be allowed to compete for SBIR and STTR awards. As you know, current Small Business Administration (SBA) regulations limit participation in these programs to companies that are at least 51 percent owned by individuals, rather than companies or other entities. This regulation effectively disqualifies small companies that have received significant venture capital investment or are owned by another company with significant venture capital investment from competing for SBIR and STTR funds. We would note that this was not always the case. Before 2001 and 2003 SBA administrative law judge rulings, companies with venture capital were allowed to participate in the SBIR program.

As then-NIH Director Elias Zerhouni said in a 2005 letter to the SBA, "this rule dries up Federal funding for early stage ideas from small companies that, by attracting substantial [venture capital] funding, show strong signs of likely success." AAU shares the view of the NRC that venture capital investment in companies seeking SBIR funding confirms the quality of those projects and would raise the quality of the applicant pool overall.

III. Recommendations on how the SBIR and STTR programs can be improved.

You also asked for thoughts concerning ways to improve the effectiveness of the SBIR and STTR programs. In responding to this request, I would commend to you the recommendations made by the National Research Council in its 2008 report, which we fully endorse.

Program Evaluation: We agree with the NRC that the agencies should conduct regular evaluations of their SBIR and STTR programs. As part of this overall evaluation process, we support the idea of agencies providing annual reports to Congress on the successes or disappointments of their programs, as well as developing a form of external evaluation of the programs' effectiveness.

SBIR Award Sizes: We also support the NRC recommendation that award sizes be adjusted. Currently, SBIR/STTR Phase I awards are limited to $100,000 at NSF and $150,000 at NIH, and Phase II awards are limited to $750,000 at NSF and $850,000 at NIH.[2] The statutory amount of SBIR and STTR Phase I and II awards should be adjusted to reflect the effects of inflation over the years and, more importantly, to make the awards more attractive. In its report, the NRC calls for a one-time adjustment in award sizes increasing Phase I awards from $100,000 to

[2] National Research Council, *An Assessment of the SBIR Program,* National Academies Press, p. 44; pp. 95–97.

$150,000 and Phase II to $1 million.[3] Embedded within this recommendation is the notion that standard award sizes simply serve as guidance for the agencies and that agencies should be given the flexibility to exercise their own judgment when determining the size of the award needed to meet the mission and goals of the SBIR project.

Post Phase II Awards: Another NRC recommendation that AAU supports is that agencies be given the flexibility to develop follow-on SBIR funding mechanisms beyond Phase II. NIH has improvised to provide such funding with its "competing renewal" mechanism for especially promising projects, and the Navy has a similar "Phase IIb" option. NSF also has a mechanism to match supplemental industry funding for Phase II awards. We agree with the NRC that such follow-on SBIR and STTR funding would enable small companies with highly promising projects to traverse "the "Valley of Death" between the end of Phase II research funding and the commercial marketplace." This is the single greatest challenge for SBIR and STTR-funded companies.

Additional "Gap" Funding: There is one other related issue that we would ask the Subcommittee to examine in reauthorizing the SBIR and STTR programs. Even with the existing SBIR and STTR programs, there still exists a funding gap which often prevents universities from moving new research discoveries and technologies quickly into the marketplace. SBIR and STTR funding presumes there is already sufficient evidence that a particular research advance or technology has enough commercial value to attract further investment for commercialization. Often times, however, there is not the funding available within our universities, or from other sources, to push these technologies across the "Valley of Death" to that point.

The current economic climate has left companies, angel investors and venture capitalists even less willing to invest in the proof-of-concept, scaling up, and modeling required to explore the commercial value of such advances. While the current SBIR program partially addresses this issue, it often still falls short of providing enough funding to allow emerging technologies to reach the level of development required for investment or adoption by the commercial sector. AAU would welcome the opportunity to work with the subcommittee to explore innovative new ways that would allow our universities to extend the horizon for development of research advances and new technologies, thereby making the end product easier to transfer to a small business and improving the success rate of these businesses.

Conclusion

If there is a consistent theme in these recommendations, it is that the SBIR and STTR are, at their core, good programs that help to foster successful entrepreneurial opportunities for our nation's scientists, engineers, and technology innovators. However, these programs, which were created well over 20 years ago, can stand to be improved by increasing award sizes, providing flexibility in program administration and management, and providing beyond Phase II award opportunities. We also believe that it might be time to consider supplementing these programs with a new program aimed at providing additional gap funding.

Chairman Wu, Ranking Member Smith, and Members of the Subcommittee, thank you for the opportunity to share AAU's thoughts and perspective on the SBIR and STTR programs. We would welcome the opportunity to work with you in fleshing out some of the recommendations we have made today. I look forward to any questions you may have at this time.

BIOGRAPHY FOR ROBERT M. BERDAHL

Robert M. Berdahl became President of the Association of American Universities (AAU) in May 2006. Prior to this position, Berdahl served as Chancellor of the University of California, Berkeley from 1997 to 2004. As Chancellor at Berkeley, he led the campus in a major effort to renew its infrastructure. During his tenure, more than $800 million was invested in a comprehensive plan to renovate and seismically upgrade numerous buildings, rendering them more suitable for modern scientific research and teaching. He worked to restore library collections to a preeminent position and undertook the construction of two new library buildings. Under his leadership, two new major interdisciplinary initiatives were undertaken: the Health Sciences Initiative and the Center for Information Technology Research in the Interest of Society. An advocate of enhancing and humanizing undergraduate learning, Berdahl expanded the highly popular Freshman Seminar Program, in which senior

[3] National Research Council, *An Assessment of the SBIR Program,* National Academies Press, pp. 84–85.

faculty teach small freshman classes. To integrate student life more fully with a challenging academic environment, six new residence halls were constructed. As the first Berkeley Chancellor to cope with the decline of minority enrollment after the elimination of affirmative action in California, Berdahl strengthened campus outreach programs for disadvantaged students in the public schools. Following his tenure as Chancellor at Berkeley, Berdahl remained as a faculty member. Prior to going to Berkeley, Berdahl served as President of the University of Texas at Austin from 1993 to 1997. While at Texas, he initiated a master plan for the physical development of the campus, worked to introduce data-driven planning in the allocation of resources to the academic colleges and schools, and endeavored to build a stronger sense of community within a large, diverse campus. While at the University of Texas and at Berkeley, Berdahl was an active member of AAU, including service as its Executive Committee Chair. Berdahl began his academic career in the History Department at the University of Massachusetts Boston in 1965. He joined the history faculty at the University of Oregon in 1967 and served as Oregon's Dean of the College of Arts and Sciences from 1981 to 1986, when he left Oregon to become Vice Chancellor of Academic Affairs at the University of Illinois at Urbana-Champaign. Berdahl received his B.A. from Augustana College in Sioux Falls, South Dakota, his M.A. from the University of Illinois, and his Ph.D. from the University of Minnesota, which also awarded him an honorary Doctorate of Science in 1997. He is recipient of numerous honors and awards, including an honorary doctorate and distinguished alumnus award from Augustana College, a Fulbright Research Fellowship, and an NEH Independent Study and Research Fellowship. He has been a Research Associate at the Institute for Advanced Study in Princeton and at the Max Planck Institute for History in Goettingen, Germany. Berdahl was elected to the American Academy of Arts and Sciences in 2001. He is the author of one book and the co-author of another, and has written numerous articles dealing with German history. Berdahl was born in 1937 in Sioux Falls, South Dakota. He and his wife Margaret (Peg) have three married daughters, Daphne (deceased), Jennifer, and Barbara, and six grandchildren.

Chair WU. Thank you, Dr. Berdahl. We very much appreciate AAU's input into this process.

Dr. BERDAHL. Thank you.

Chair WU. Mr. Greenwood, please proceed.

STATEMENT OF MR. JAMES C. GREENWOOD, PRESIDENT AND CEO, BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

Mr. GREENWOOD. Good afternoon, Chairman Wu and Congresswoman Biggert and Members of the Committee. I am Jim Greenwood, President and CEO of the Biotechnology Industry Organization, BIO, and I am privileged to be here this morning on behalf of BIO's more than 1,200-member companies, academic institutions, State biotechnology centers, and related organizations in all 50 states involved in health care, agricultural, environmental, and industrial biotechnology.

Congress created the SBIR Program in the early 1980s because it recognized that all too often promising early-stage scientific research lacked adequate funding and as a result perished in the "Valley of Death." The importance of advancing science through the "Valley of Death" has never been more important than it is right now.

In fact, in just the last several months at least 25 of our companies have either placed drug development programs on hold or cut programs altogether. This includes therapies for HIV/AIDS, cervical cancer, multiple sclerosis, and diabetes. Roughly a third of small publicly-traded biotechnology companies are now operating with less than six months of cash on hand, which is a 90 percent increase relative to this time in 2007. The total capital raised by the industry in 2008 is down 55 percent compared to last year. As such, it is more important than ever that government funding op-

portunities such as SBIR are made more accessible to America's cutting-edge companies.

My recommendation to strengthen and improve the SBIR program can be grouped under the following three general goals. First, increase competition and foster innovation and commercialization by the best small companies. For 20 years domestic biotechnology companies competed for SBIR grants. However, in 2003, the Small Business Administration's [SBA] Office of Hearings and Appeals ruled that a biotechnology company, Cognitics, did not meet the SBIR size standard because multiple venture capital investors in the aggregate, and that is more, that is important, in the aggregate, owned more than 50 percent of the company's stock.

The ruling, which is not based on the statutory language, ignores the reality of the marketplace where small biotechnology firms must raise tens of millions of dollars to conduct incredibly capital-intensive research. The SBA's 2003 ruling to exclude majority venture-backed companies inhibits the SBIR's Program's access to the most competitive pool of applicants possible, and it stifles the ability of SBIR to carry out its mission to fund projects that will have the most commercial potential.

The NIH's acting director recently reported that the number of SBIR applications has dropped over 40 percent since 2004, which is about the same time the SBIR-participating agencies implemented the new SBA restriction and majority VC [Venture Capital]-financed companies.

BIO respectfully requests that the Committee 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 will be awarded based on projects that show the most promise in bringing breakthrough therapies to the public.

Second, Congress should clarify the SBA eligibility rules to make the application process more straightforward and more user friendly. It is equally important the authorization 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 business employees. These affiliation rules create a situation where a small company with 50 employees could 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, even where the investor owns a minority stake in the business in question.

BIO recommends the Reauthorization Bill provide language to clarify that minority investment by a venture capital investor does not make the company an affiliate of another company for the purposes of determining size. This is a commonsense measure that will provide clarity and peace of mind for small business entrepreneurs looking to participate in the SBIR Program.

Third, Congress should maintain adequate agency flexibility within the SBIR Program. One of the great strengths of the SBIR Program is that Congress has provided participating agencies with flexibility in how they administer the program. Maintaining flexibility is 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."

BIO does not believe that a hard dollar 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 to commercialize new innovations. By making necessary reforms to the SBIR Program, Congress can continue to support the USA 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.

Thank you.

[The prepared statement of Mr. Greenwood follows:]

PREPARED STATEMENT OF JAMES C. GREENWOOD

Good morning Chairman Wu, Ranking Member Smith, Members of the Committee, ladies and gentleman. I am Jim Greenwood, President and CEO of the Biotechnology Industry Organization (BIO). I am privileged to be here this morning on behalf of BIO's more than 1,200 member companies, academic institutions, State biotechnology centers and related organizations in all 50 states involved in health care, agricultural, environmental and industrial biotechnology.

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 percent 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 fewer than 50 employees, no products on the market and must raise considerable funds through a combination of angel investors and venture capital firms 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 six months of cash on hand, a 90 percent increase relative to 2007. Forty-five percent of these companies have less than one year of cash remaining. The total capital raised by the industry in 2008 has seen a steep decline (down 55 percent in 2008 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. This is 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 in-

vestment approaches. They can no longer afford the high-risk 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 more clear.

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 sizable 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.

A small biotechnology companies is generally engaged in several projects with one lead product and an average of five other therapies or candidates in early stage/preclinical 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 percent 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 its lead product, these funds 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 which 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 percent of the company's equity—even though no one venture capital firm has more than 30 percent of total equity—is ineligible. A significant number of BIO's emerging companies 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 five to twelve 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 percent of the company. However, the investment group usually consists of several firms, none of which owns more than 15–25 percent 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 and deeper 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 that 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 stems from the fact 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 programs 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 projects they are funding are 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 that 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.

BIOGRAPHY FOR JAMES C. GREENWOOD

James C. Greenwood is President and CEO of the Biotechnology Industry Organization (BIO) In Washington, D.C., which represents more than 1,200 biotechnology companies, academic institutions, State biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative health care, agricultural, industrial and environmental biotechnology products. BID also produces the annual BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

Since his appointment in January of 2005, he has markedly enhanced the trade association's capacity increasing both its staff and budget by nearly fifty percent. BIO is now a world class advocacy organization playing a leading role in shaping public policy on a variety of fronts critical to the success of the biotechnology industry at the State and national levels as well as internationally.

Mr. Greenwood represented Pennsylvania's Eighth District in the U.S. House of Representatives from January 1993 through January 2005. A senior member of the Energy and Commerce Committee, he was widely viewed as a leader on health care and the environment.

From 2001 to 2004, Mr. Greenwood served as Chairman of the Energy and Commerce Committee Subcommittee on Oversight and Investigation with oversight authority over issues In the Full Committee's vast jurisdiction. He led hard-hitting investigations into corporate governance at Enron, Global Crossing and WorldCom; terrorist threats to our nation's infrastructure; and waste and fraud in Federal Government agencies.

Prior to his election to Congress, Mr. Greenwood served six years in the Pennsylvania General Assembly (1980–86) and six years in the Pennsylvania Senate (1986–1993).

Mr. Greenwood graduated from Dickinson College in 1973 with a BA in Sociology. From 1977 until 1980, he worked as a caseworker with abused and neglected children at the Bucks County Children and Youth Social Service Agency.

Mr. Greenwood resides in Upper Makefield, Pennsylvania with his wife and three children.

BIO represents more than 1,200 biotechnology companies, academic institutions, State biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

Chair WU. Thank you, Mr. Greenwood.

Dr. Rockey, please proceed.

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

Dr. ROCKEY. Good afternoon, Chairman Wu, Congressman Biggert, and other Members of the Subcommittee. Thank you for the opportunity to discuss the NIH SBIR/STTR Programs, and the role they play in stimulating innovation at small high-tech businesses.

NIH [National Institute of Health] is one of the largest funders of the SBIR/STTR Programs and the largest supporter of biomedical research that focuses on extending healthy life and reducing the burdens of illness and disability. The SBIR/STTR Programs are poised to fund early-stage, high-risk, high-quality research from

which important medical advances can be developed. In fiscal year 2009, the total SBIR/STTR set-aside will be about $672 million.

I would like to begin by highlighting several SBIR innovations that have made differences and can make differences in people's lives. Altea Therapeutics, a Georgia company, developed a needleless infusion patch called the passport system for a painless and controlled delivery of drugs such as insulin or vaccines such as hepatitis B antigen through the skin. Three Rivers Holding, an Arizona company, focused on assistive technology, developing better wheels for wheelchairs. This smart wheel optimized wheelchair route to route out the cause of chronic pain in the shoulder, hand, or wrist of wheelchair users.

SIG Technologies Inc. in Oregon developed a small molecule inhibitor, a small pox virus replication. While small pox has essentially been eradicated, it remains a formidable biowarfare threat. And finally, Biopsy Sciences in Florida developed hydroMARK, a novel water containing site marker used in breast cancer procedures. This technology is helping patients by replacing lengthy mammogram-guided localization wire procedures with a quick and accurate and more comfortable ultrasound localization. As a breast cancer survivor, I have personally experienced the excruciating procedure that this new technology can replace. I find it very satisfying that the NIH and the small business community contributes to helping women who are battling a life-threatening disease have one less painful procedure in what can be a grueling treatment regime.

Stories such as this 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 has designed programs such as the Phase I, Phase II Fast Track Program and competing renewal award to help our awardees negotiate the agonizing period between discovering commercialization or as we heard mentioned, the "Valley of Death."

In addition, NIH offers commercialization assistance by facilitating matchmaking. It is our version of match.com, with the NIH pipeline to partnerships. This is a virtual space where SBIR and STTR awardees can showcase their technologies, and it allows for potential strategic partners, licensing partners, or investors to find them on this virtual space. And currently we have over 100 technologies in this database.

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

We attribute the success and effectiveness of the program to several factors. The most significant of this is the existing flexibility in our administration of the 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 and an opportunity to resubmit unfunded applications. And the ability to exceed the 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 much more complex, and evermore expensive. Despite these program flexibilities and enhancements, as you already heard, what we have observed is there have been some troubling trends. Specifically, the numbers of our applications have declined from 2004 through 2008 by nearly 40 percent. Though the reasons are not fully understood for this decline, it is a disconcerting trend—this disconcerting trend may be related to certain distance incentives that are either rendering worthy companies ineligible or driving them away for other reasons.

For some the award amounts or the current phase structures are not sufficient incentives for applying. For others the process appears too competitive. New companies may find the process daunting or aren't sure how to match their skills with our research areas. Some firms have lost their eligibility or may be confused by the eligibility criteria.

For many biomedical technology companies the SBIR Program is an important source of seed funding for early-stage ideas of unproven feasibility, but venture capital financing is the only realistic way that their innovative product will enter the marketplace. Research and public health in biotechnology is characterized by high and intense capital needs, as you know, and to see these products from idea to market usually have very long development times, exceptionally high burn rates for investment funds, and often 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 the product to market.

The NRC study of the SBIR Program noted that the synergies between SBIR funding and venture capital are useful. As the innovative process is not linear, even small business benefiting from venture funding may well seek SBIR funding as a means of exploring a new idea. For example, a new drug candidate. Keeping the pipeline full of new ideas is important because in today's high-risk biomedical research environment, the reality is that fewer than one percent of the innovative promising projects reach the marketplace.

Therefore, I believe appropriate incentives can be—can strengthen the role of small businesses in stimulating technological innovation.

In conclusion, I want to reemphasize the NIH's commitment to supporting small businesses and maintaining the integrity of the SBIR/STTR Programs. We look to small businesses to stimulate technological innovation, help us face new challenges, and to 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.

That concludes my statement. I look forward to answering any questions you have.

[The prepared statement of Dr. Rockey follows:]

PREPARED STATEMENT OF SALLY J. ROCKEY

Good afternoon, Chairman Wu and Members of the Subcommittee. My name is Dr. Sally Rockey. I am the Acting Deputy Director for Extramural Research at the National Institutes of Health (NIH), an agency of the Department of Health and Human Services. Thank you for the opportunity to discuss the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs and the role they play in stimulating innovation. 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 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

[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.

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 anti-viral drug, Tyzeka, under the generic name of telbivudine, is used to treat chronic hepatitis B in adults.
- A needle-less 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., five to twelve years); exceptionally high "burn rates" for investment funds; investment by venture capital companies (VCCs), many of whom are not owned at least 51 percent 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.

BIOGRAPHY FOR SALLY J. ROCKEY

Dr. Sally Rockey has spent the majority of her career in the area of extramural research administration and Information Technology. She received her Ph.D. in Entomology (1985) from Ohio State University and held a post doctoral appointment at the University of Wisconsin. In 1986 she joined the U.S. Department of Agriculture's extramural research arm, the Cooperative State Research Education and Extension Service (CSREES), as a program officer for entomological grant programs. She quickly moved up in the organization and became Deputy Administrator for the Competitive Research Grants and Award Management Unit where oversaw extramural competitive research, education and extension portfolio. In 2002, Dr. Rockey became CSREES's Chief Information Officer where she applied her breadth of government knowledge to IT by aligning state-of-the-art information technologies with the goals and objectives of CSREES. In 2005 Dr. Rockey was appointed to the position of Deputy Director of the Office of Extramural Research (OER) within the Office of the Director, National Institutes of Health (NIH). OER serves as the focal point for policies and guidelines for extramural research administration within NIH where Dr. Rockey applied her experience in research and grants administration to public health. She also served as Acting Director of the Office of Research Information Systems in OER where she again used her CIO experience to oversee the eRA (electronic research administration) and OER reporting activities. Among her many other responsibilities Dr. Rockey serves as the NIH Agency Extramural Research Integrity Officer managing research misconduct issues for NIH extramural pro-

grams and Directed the OER Office of Planning and Communications. In 2008 Dr. Rockey became Acting NIH Deputy Director for Extramural Research and Acting Director of OER and will again apply her many skills to leading the extramural activities at NIH.

Rockey is a skilled public speaker and has given hundreds of presentations on extramural research priorities and policies, grantsmanship, the competitive peer review process, scientific integrity, and IT. She is active on a number of federal intergovernmental committees related to science, research, grants management and electronic government and collaborates closely with academic and scientific communities. She has been honored by receiving the Presidential Rank Award in 2004.

Dr. Rockey has actively participated in the science education of young children by giving presentations on insects to local elementary schools where she was known as the "Bug Doctor" coordinated her local pool's swim team, is an avid Bridge player and sings and plays the guitar.

Chair WU. Thank you, Dr. Rockey. We are very grateful for NIH's continuing support for SBIR and STTR.

Mr. Glover, please proceed.

STATEMENT OF MR. JERE N. GLOVER, ATTORNEY AND EXECUTIVE DIRECTOR, SMALL BUSINESS TECHNOLOGY COUNCIL, WASHINGTON, DC

Mr. GLOVER. Mr. Chairman, Congresswoman Biggert, other Members of the Committee, I want to thank you for the opportunity to be here. I am Jere Glover, Executive Director of the Small Business Technology Council of the National Small Business Association. We represent the 7,000 SBIR companies that are active in the SBIR Program today.

America is certainly not doing enough to promote innovation, especially given the state of competition from foreign countries that are graduating more scientists and engineers than we are and the state of our economy today. Our share of the global technology market is declining.

Ten foreign countries have copied the SBIR Program. Major countries. Witness after witness, GAO [Government Accountability Office] study after GAO study, report after report say the program is working remarkably well and has for 26 years. Please don't mess it up.

The SBIR Program isn't broken. It doesn't need fixing. Please make changes that are limited and monitored carefully and make sure the agencies, the GAO, and the National Academy of Sciences report fully on those changes and how they affect the program and how they affect the technology community. Asking small business to trust the government to allow the agencies to be flexible, to allow the government to change or modify the program that is small businesses' only real portal or access to the federal R&D dollars is like waving a red flag in front of small business.

Thirty years of experience with the government has proven that small business will come out on the short end. Little has changed in the federal R&D marketplace in the last 30 years. Small businesses' share of the federal R&D market was 3.5 percent in 1978. It has now increased to 4.3 percent in 30 years.

But the technology marketplace has changed, and changed significantly. In 1978, small business employed only six percent of the scientists and engineers in America. Today, according to the National Science Foundation's Science Indicators that number has gone up to 38 percent. Small businesses receive 38 percent of all

U.S. patents, and SBIR companies have received over 60,000 patents and are patenting at the rate of basically 5,000 patents per year.

Where do innovations come from? One of the more surprising studies recently is looking at where the innovation comes from. According to the R&D top 100 innovations, small business has gone from zero SBIR companies—from zero in 1980, '82, when the program started to now having 25 percent of all American key innovations. At the same time large firms have dropped from 40 innovations per cycle down to under ten. So small business is where the job creation is really happening.

Let me just mention that there is a lot of discussion to where the SBIR Program should be focused. It has always focused on the first three basic parts of this; basic research, applied research, and development. The commercialization has always been beyond the SBIR Program, and it should be.

For example, the entire HHS [Health and Human Services] budget would not fund one single drug going through their application [process at FDA]. My friend, Jim Greenwood, has pointed out that it takes $800 million. The HHS entire budget would not even fund one. We have to be realistic. When you get in the commercial arena, this program and the Federal Government simply don't have the funds to pick enough winners to make it work.

The economic impact of the SBIR Program, the job creation, just as a small business, if you look at this indication, small business has led us out of every recession, and they are doing a—will continue to do that. The economic impact of the SBIR Program, if you will look in the back of my testimony, you will see green pages, and they have information on each specific Congressional district or the states of the various Members. What is important to point out is that this SBIR Program, using a random selection of states, those represented on this subcommittee, have received $6.5 billion of SBIR awards. Currently in the last five years there are almost $2 billion involved, and those companies have created over 100,000 jobs, or maintained, I should say. Created—maintained 100,000 jobs and they filed 14 times just for the Members in the states that are represented on this subcommittee.

It is a wonderful program. It has worked extremely well. The universities and small businesses have worked well together, and that has been improving and working well. We are starving the most productive sector of the small business economy; the high-tech small business companies and underfunding the most prolific scientists and engineers. That in a nutshell, ladies and gentlemen, is why we are losing in the international market, market share, and what we need to do to improve our economy. We can't continue down this road with small business receiving less than five percent of the federal R&D dollars and expect technology innovation to lead out of the recession and into a larger share of the global technology market.

Thank you.

[The prepared statement of Mr. Glover follows:]

PREPARED STATEMENT OF JERE N. GLOVER

Chairman Wu, Ranking Member Smith, Members of the Subcommittee, thank you for the opportunity to appear here today to discuss the importance of technological innovation to the United States and the reauthorization of the SBIR and STTR Programs. I am Jere W. Glover, Executive Director of the Small Business Technology Council (SBTC) of the National Small Business Association in Washington, DC. I have been involved in federal science and technology innovation programs since 1978, when, as Counsel to the House Small Business Committee, I helped convene the first joint House-Senate hearings on the subject.[1] I subsequently testified before Congress regarding small business and innovation on numerous occasions, as Deputy Chief Counsel for Advocacy at SBA during the Carter Administration and as Chief Counsel during the Clinton Administration.[2]

An outgrowth of the White House Conference on Small Business in 1995, SBTC is the Nation's largest association of small, technology-based companies in diverse fields, and represents more companies that are active in the federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program than any other organization. SBTC also serves as the Technology Council of the National Small Business Association, the Nation's oldest nonprofit advocacy organization for small business, which represents over 150,000 small companies across the United States. I appear here today on behalf of both organizations.

This hearing comes at a critical time. For more than a decade, other nations have been chipping away at the U.S.' global leadership in technological innovation. Now a second powerful threat is upon us—the worst recession since the Great Depression.

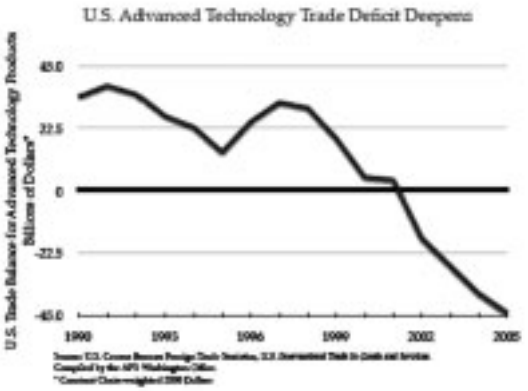
As the chart below shows, our global market share in this key economic area is declining:

While the pie is getting bigger, the U.S. share is getting smaller.

Another way of looking at this is to plot the balance of trade. Our trade surplus in advanced technology exports has disappeared; we now have a deficit:

[1] The 1978 hearings showed that, despite their demonstrated superior efficiencies at innovating, small companies received only 3.5 percent of federal R&D contract dollars. Today, with far more science and engineering talent at their disposal, and a far more widely acknowledged record of innovations, small companies still receive only 4.3 percent of those R&D contract dollars. And SBIR/STTR accounts for more than half of that.

[2] See "Small Business and Innovation," Report of the Joint House and Senate Small Business Committees, August 9 and 10, 1978. As an example of my testimony on the subject, see *Testimony of Jere Glover, Chief Counsel for Advocacy, Small Business Administration,* Senate Small Business Committee, August 4, 1999, *http://www.sba.gov/advo/laws/test99_0804.pdf*



The global challenge also shows up in U.S. patent statistics. Here again, the pie is getting larger, as more patents are issued each year. But here again, the U.S. share of the pie is shrinking. U.S. patents issued to Americans have fallen from two-thirds of all those issued in 1980, to less than half today.

Over the past seven months, technological innovation has faced a new menace: a deep global recession that is drying up both the supply of capital and the demand for technological goods and services. Unemployment is increasing.

To help restore our economy and strengthen our place in the world, we must encourage the growth of technology and innovation. As I hope to show in my testimony, small business generally, and the SBIR Program specifically, offer extremely efficient ways to meet the challenges we face. Of course, SBIR alone cannot do all that is needed. Programs such as the Department of Commerce's Advanced Technology Program (ATP) and the Technology Innovation Program (TIP) of the National Institute of Standards and Technology should be expanded, and new efforts to encourage and commercialize innovation should be explored. Likewise, we need to promote early-stage investments in technologies, like those provided by "angel" investors. We should also provide assistance for small businesses in filing foreign patents.

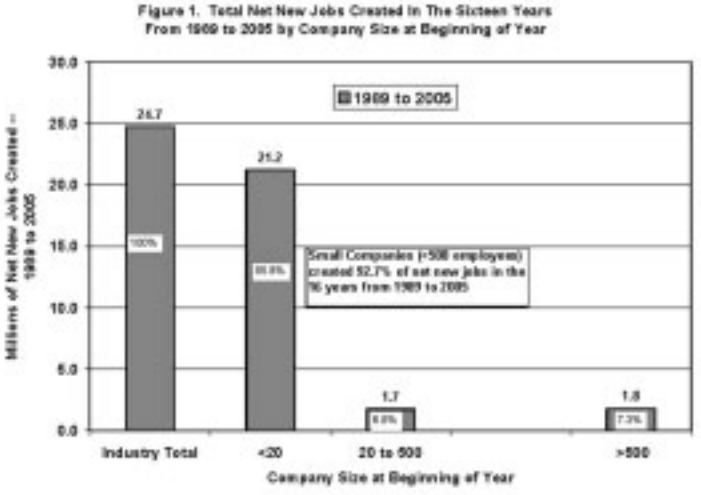
In this testimony, however, I want to concentrate on a few key themes:

1) Small business has a well-established track record of creating most new jobs in the U.S. economy, and particularly so when the economy is coming out of recessions. For purposes of today's discussion, what's especially important about small business job creation is that small business has now become the largest single source of employment for U.S. scientists and engineers, outstripping large business, universities and government.
2) Small business also has become the Nation's leading source of technological innovations, particularly breakthrough innovations, as measured by several indicators.
3) As demonstrated by the recent National Academy of Sciences reports and an array of earlier analyses, the SBIR Program has become uniquely and powerfully effective in harnessing these small business scientists and engineers, as well as their breakthrough innovations, to the task of meeting federal agency R&D needs.
4) While some modest adjustments in the SBIR Program would be helpful—such as those recommended by the National Academy studies—overall Congress should renew the Program without major design changes. An increase in the Program's allocation of federal funds would yield important benefits to the Federal Government and to the Nation's economy and global competitiveness.
5) The STTR Program, while newer and smaller than SBIR, shows great promise in uniting small business and university capabilities in innovation, and deserves to be expanded.

Let me expand on each of those points.

SMALL BUSINESS AND JOBS

For the past 40 years, small companies have created 60–80 percent of all net new jobs, on average.[3] In other words, add up all the new jobs created, subtract the jobs lost when businesses close their doors, and you find that, year in and year out, small business supplies our country with two-thirds to three-quarters of all the new jobs. This tempo may even be increasing. Recent data from the U.S. Bureau of Census and the Office of Advocacy, U.S. Small Business Administration,[4] shows that small businesses (with less than 500 employees) created *93 percent* of the net new jobs in the U.S. during the period 1989 to 2005.



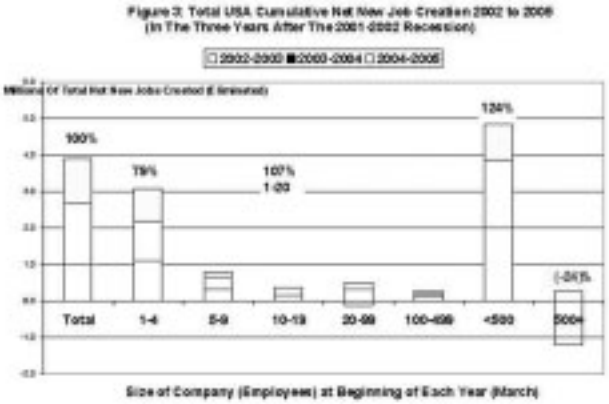
As striking as these figures are, the role of small business as a job creator during recessions is even more remarkable. The year-by-year table (based on the same data sources) shows the impact.

[3] U.S. Small Business Administration, *Small Business FAQ's,* 2009.

[4] SBA Office of Advocacy, from data provided by the U.S. Bureau of the Census, Statistics of U.S. Business. See: *http://www.sba.gov/advo/research/dyn_b_d8905.pdf.* This data series runs from 1989 through 2005 only.

As Figure 2 shows, in the recession years of 1990–1 and 2000–2002, small businesses created *all* net new jobs. In fact, one can say that small businesses created *more than 100 percent of all net new jobs,* since large companies were actually shedding jobs during these periods. In 2001–2, at the trough of the recession, more than two million net jobs disappeared at large companies.

Moreover, this pattern of large business job loss persists until well after the country has ended its recession by statistical measures. In 1992, large companies continued to shed jobs. In 2002–3, they shed more than a million of them. Small businesses offset *all* of these large business job losses in 1992 and again in 2002–4. For these years, small business created 124 percent of all net new jobs, by offsetting the 25 percent loss in large business employment.



In other words, if recent history is any guide, we can look to small businesses to do most of the hiring in this recession for now and the foreseeable future.

This strongly suggests that supporting small businesses in stimulus legislation is likely to have the maximum short-term and medium-term payoffs on Main Street, and more broadly, on the population as a whole. (The population as a whole seems

to grasp this. According to a recent Zogby Poll, 63 percent of the public believes that "small business and entrepreneurs will lead the U.S. to a better future" while only 21 percent believe that "large corporations and business leaders" will do so.[5])

There are obviously many worthy objectives to be supported in the economic stimulus legislation. It's unfortunate, however, that much of the legislation seems to have overlooked this major point of economic leverage.

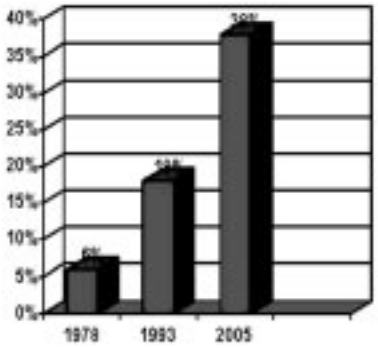
SMALL BUSINESS AND SCIENCE AND ENGINEERING

Our focus today is on one aspect of how small business supports the broader economy—its role as a technological innovator.

1. SCIENCE AND ENGINEERING EMPLOYMENT

One reason why small business seems to be getting better and better at technological innovation is that it employs more and more scientists and engineers. The trend over the past generation is shown in the chart below.[6]

Percent of U.S. Scientists and Engineers Employed by Companies with Fewer than 500 Employees (Figure 4)



Strikingly, there are now more scientists and engineers working in smaller companies (38 percent) than in any other sector. Some 27 percent of U.S. scientists and engineers currently work for large companies, 16 percent for universities, 13 percent for government, and six percent for non-profits.[7]

The SBIR Program, which may be at least partly responsible for small business' growing science and engineering firepower, has deployed it to remarkable effect.

2. PATENTS

Since a major consideration at today's hearing is stimulating the economy through science and engineering innovations, consider an important but often overlooked measure of wealth and poverty—patent productivity.

For a striking illustration of the relationship between patents and wealth, we can turn to a recent economic study for the Federal Reserve Bank by Paul Bauer, Mark Schweitzer and Scott Shane.[8] The authors measured eight determinants of personal income growth per capita, in the 48 contiguous states of U.S., from 1939 to 2004.

By far the most important growth determinant for the 1939–2004 period proved to be knowledge stocks. For this, the authors used three indices: high school and college attainment rates, and patents per capita. Upon closer examination, the overwhelmingly dominant indicator of income growth proved to be *patents per capita.*

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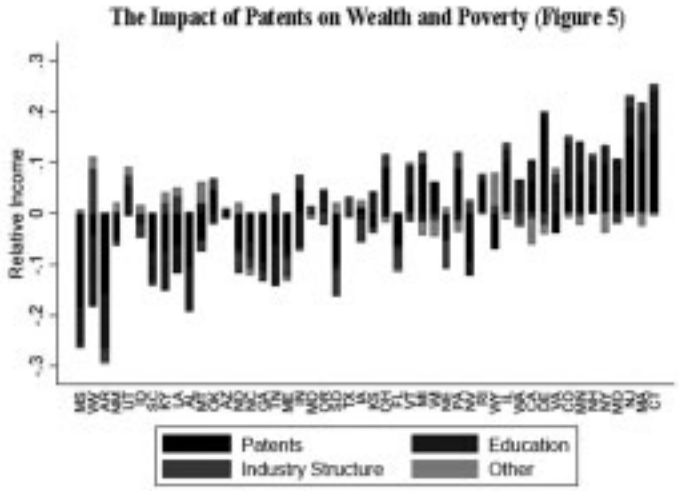
[5] WE Media Zogby Poll, 25 February 2009, *http://www.zogby.com/news/ReadNews.cfm?ID=1678*

[6] National Science Foundation, *Science and Engineering Indicators,* 2007.

[7] *Ibid.* (For a very thoughtful and nuanced analysis of this shift, see the White Paper by SBIR Founder Roland Tibbetts that is attached as an annex to this testimony.)

[8] "Altered States: A Perspective on 75 Years of State Income Growth," Federal Reserve Bank of Cleveland, Annual Report 2006. For more detail, see Paul Bauer, Mark Schweitzer, Scott Shane, *State Growth Empirics: The Long-Term Determinants of State Income Growth,* Working Paper 06–06, Federal Reserve Bank of Cleveland, May 2006. *www.clevelandfed.org/research/Workpaper/2006/wp0606.pdf*

The chart[9] below shows the power of this indicator in each of the 48 states studied:



Broadly speaking, the above chart can be read from left to right. States with lagging growth over the period studied are on the left; those with higher growth, on the right. Remarkably, the patent indicator is the top predictor of both wealth and poverty. States with low patents per capita tend to be poor. Those with higher patents per capita tend to be affluent.

Overall, patents are more closely associated with economic growth than education, industry structure, or any of the other variables tested.

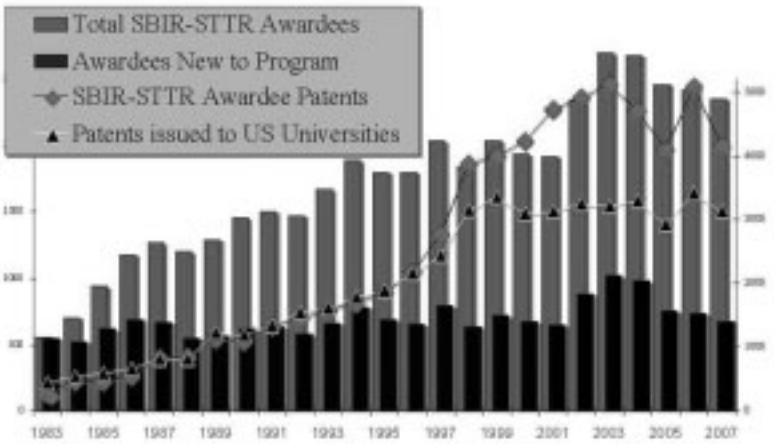
This finding underscores the importance of an earlier study of *patent productivity,* which showed that small technology-based companies produce 13 times more patents per employee than larger technology-based companies, and that these smaller company patents are twice as likely to be among the most cited in other patent applications.[10]

Firms in the SBIR Program are among the most prodigious producers of patents in the United States. Figure 6 below, provides a glimpse.[11]

[9] *Ibid.,* p. 46.

[10] Diana Hicks, *Small Serial Innovators: The Small Firm Contribution to Technical Change,* CHI Research, 2003, produced under contract to the Small Business Administration, contract SBA01C–0149.

[11] Innovation Development Institute, 2009, from U.S. Patent and Trademark Office data.



As of today, more than 60,000 patents have been issued to SBIR companies—despite the fact that the program is only 25 years old. A relatively modest program, representing only 2.5 percent of extramural R&D spending at 11 federal agencies, *SBIR nevertheless is accounting for 40 percent more patents than all U.S. universities combined, and is generating new patents at an average speed of 13 a day.*

SBIR also does a remarkable job of spreading contract dollars, and therefore the resulting patents, around the country. By way of contrast, in 2005 about 70 percent of venture capital investments went to just five states—versus only 45 percent of SBIR contract dollars. The "middle 20" states—those ranked 15–25 in SBIR contract dollars—obtained 25 percent of SBIR dollars but only six percent of VC dollars. Although venture capital investments exceed SBIR funding by about ten to one, there were still 15 states that received little or no venture investment—and five states that received virtually none. SBIR dollars reach virtually every state.[12]

3. INNOVATION QUALITY

Is the *quality* of SBIR innovation output matched by its quantity? Are these innovations really ground-breaking and economically significant?

From the perspective of the Federal Government, for whom the SBIR research is performed, the quality would appear to be quite high. The U.S. Government Accountability Office has studied the SBIR Program on at least ten occasions since the program began, and offered positive assessments in each case.[13] So have several earlier reports by the National Academy of Sciences and the National Academy of Engineering.[14]

One indication of the importance of a patent is the number of times that it is cited in other patent applications. A study of companies that were "serial innovators" (with 15 or more patents over five years), found that over one-third were small companies, many of them SBIR companies. Patents from these small "serial innovators" were cited 28 percent more often by other inventors, were twice as likely to be

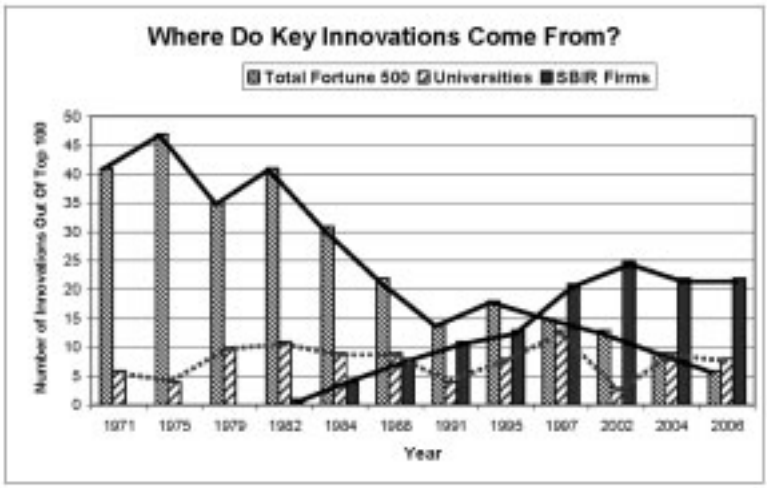
[12] SBIR data from U.S. Small Business Administration, *www.sba.gov/sbir/2004SBIRStateChart.xls* Venture capital data from National Science Foundation, *Science and Engineering Indicators,* 2006, Table 8–42.

[13] *Federal Research: Assessment of Small Business Innovation Research Programs,* GAO Report RCED89–39, January 23, 1989; *Federal Research: Small Business Innovation Research Program Shows Success But Could Be Strengthened,* GAO Report T–RCED 92–3, October 3, 1991; *Federal Research: Interim Report on the Small Business Innovation Research Program,* GAO Report 95–59, March 8, 1995; *Federal Research: Observations on the Small Business Innovation Research Program,* GAO Report RCED 98–32, April 17, 1998; *Small Business Innovation Research,* GAO report 06–565, April 2005; *Federal Research: Observations on the Small Business Innovation Research Program,* GAO Report GAO–05–861–T, June 28,2005.

[14] *Conflict and Cooperation in the National Competition for High Technology Industry,* National Academy of Sciences, 1996; *Small Business Innovation Research Program: Challenges and Opportunities,* Board on Science, Technology and Economic Policy, National Academies of Science and Engineering, 1999; *SBIR: Assessment of the Department of Defense Fast Track Initiative,* STEP Board, National Academies of Science and Engineering, 2000.

among the top one percent of the most widely cited patents, and were twice as closely linked to scientific research than were the patents from the large "serial innovators."[15]

From a different perspective, the Information Technology and Innovation Foundation recently analyzed the annual lists of the 100 most technologically-important innovations, as selected each year by a panel of judges for *R&D Magazine.*[16] In the chart below (Figure 7), the authors compared the performance of innovations from SBIR companies on these annual assessments, with those from Fortune 500 companies and universities.



As the chart indicates, for the past decade, about one-fourth of the most important technological innovations in the Nation have been coming from the SBIR Program. Or, as the authors themselves put it:

> "The results show that these SBIR-nurtured firms consistently account for a quarter of all R&D 100 award winners—a powerful indication that the SBIR Program has become a key force in the innovation economy of the United States."[17]

It perhaps bears repeating that this is surely a unique level of economic performance for such a relatively small federal program.

4. WHY?

The metrics suggesting both the value and the profusion of SBIR innovations raise a very important question: Why? Why would a modest program produce such outsized results?

The National Academy of Sciences team studying the SBIR Program wondered about that, too.

Part of the answer, the NAS says, can be found in the scrupulously meritocratic design of the SBIR Program. SBIR is founded on competition, peer review, and the milestones of Phase I, Phase II and Phase III that are gated by rigorous demonstrations of scientific validity and commercial potential.

In their recent report on the SBIR Program at the National Science Foundation, the Academy also suggests that a new and different model of innovation appears to be emerging from the SBIR Program.[18]

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[15] Hicks, *Small Serial Innovators: The Small Firm Contribution to Technical Change, op. cit.*

[16] Fred Block and Matthew Keller, *Where Do Innovations Come From? Transformations in the U.S. National Innovation System 1970–2006,* Information Technology and Innovation Foundation, July 2008.

[17] *Ibid.,* p. 15.

[18] *An Assessment of the SBIR Program at the National Science Foundation,* National Academy of Sciences, 2008, page 17. See: *http://www.nap.edu/catalog/11929.html.* As noted in Footnote

Figure 1–1 below shows the "Linear Model of Innovation" that is presumed to occur in most R&D programs, whether public or private: basic research gives way to applied research, which in turn is developed and commercialized.

The NAS believes that something very different is happening in SBIR.

Figure 1–2, just below 1–1, attempts to describe the new process—as a "Feedback Model of Innovation." At each step of the way between basic research and commercialization, feedback loops evolve, altering the previous and succeeding steps. These loops recalibrate and revise innovations, delivering much more commercializable end products. But the process doesn't end there. The commercialization step itself, rather than being the end point, is the source of yet another feedback loop—leading to new characteristics, tradeoffs, and unanticipated applications. Thus, while the "Feedback Model" appears to be more complex than the "Linear Model," it is actually far more efficient at delivering usable innovations.

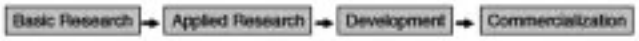

FIGURE 1-1 The Linear Model of Innovation.

FIGURE 1-2 A Feedback Model of Innovation.

Notably, the NAS extracted this analysis and schematic from its report on the National Science Foundation and reiterated it in the final report on the SBIR Program as a whole.

Further insights into the why the design of SBIR Program seems to work so well are provided throughout the Academy reports on the various federal agency SBIR Programs, as well as in the White Paper on the SBIR program written by its founder, Roland Tibbetts, which is attached to this testimony as an annex. The Tibbetts paper, in particular, focuses on the way in which SBIR is aligned with the motives of scientists, inventors, and investors. (Tibbetts also comments on how changes that were proposed by H.R. 5819 of the last Congress would have weakened the foundations of the SBIR Program's success since 1982.)

THE NAS EVALUATION OF THE SBIR PROGRAM

This committee was instrumental, during the last SBIR reauthorization cycle, in directing that the National Research Council should conduct a broad scientific review of the SBIR Program. This ambitious effort, which the NRC assigned to the National Academy of Sciences, cost over $5 million and took more than five years. The result was a series of agency studies, and a broad program overview, that offers

13 of this study, "This view was echoed by Duncan Moore: 'Innovation does not follow a linear model. It stops and starts.'" See also National Research Council, *SBIR: Program Diversity and Assessment Challenges,* Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2004, p. 24.

the most comprehensive analysis of SBIR—and for that matter virtually any federal science and technology program—ever undertaken.

Completed just this past January, the NAS findings paint a remarkably positive portrait of the Program. The studies and even the summaries are extremely rich and detailed, and worth careful consideration. SBTC's own précis of the research, which we hope and believe is a fair overview of the studies, follows:

The SBIR program is sound in concept and effective in practice.

The SBIR is an efficient program that is successfully achieving important public objectives.

SBIR's results meet the key Congressional objectives for the Program.

(1) Stimulating technical innovation.

The NRC study found that, by a wide variety of metrics, the program is contributing to the Nation's stock of new scientific and technical knowledge.

(2) Using small business to meet federal research and development needs.

The NAS study found that the SBIR program objectives are aligned with, and contribute significantly to, fulfilling the mission of each of the studied agencies. This is also true across a wide variety of metrics. The inherent flexibility of the SBIR Program makes it especially valuable to agencies with widely-varying missions.

(3) Increasing private sector commercialization of innovations.

SBIR is successfully commercializing innovations. Commercial success includes sales, license revenues, R&D investment, research contracts and the sale of equity. The average sales per Phase II project were $2.4 million and the average investment for Phase II was $1.5 million. Given the inherent technical risks involved, "the fact that a high proportion of the projects reach the market place in some form is significant, even impressive."

(4) Supporting the growth of a diverse array of businesses.

SBIR provides market access, funding, and recognition to a wide array of businesses, including those owned by women and minorities.

Conclusions:

The program is achieving its goals of successfully 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.

Recommendations:

- No fundamental changes should be made to the program.
- The basic Phase I, Phase II, Phase III structure should be preserved. Allowing firms to apply directly for Phase II would be detrimental to the program.
- Experimentation by the agencies, such as the Fast Track program should be encouraged.
- Agencies should be encouraged to develop pilot programs to experiment with potential improvements to the SBIR program.
- Funding mechanisms beyond Phase II, such as the NSF Phase IIB program and NIH continuation awards, could be adopted at other agencies.
- Any such "Phase IIB" type program should be carefully monitored and evaluated to ensure the result is positive.
- The standard limits on award size have not changed since 1995. The Phase I limit should be increased to $150,000 and Phase II should be increased to $1,000,000.
- The processing periods for awards vary substantially by agency. Agencies should also specifically report on initiatives to shorten decision cycles.
- Multiple award winners do not appear to be a problem. Awards should be based on merit. Setting an arbitrary limit to the number of awards that a company receives is neither necessary nor desirable in light of the contributions made by these firms.
- Additional attention should be paid to outreach efforts, including the existing FAST and Rural Outreach programs, and further outreach to women and minorities.

- Some internal tracking mechanisms should be upgraded, and Congress should consider a provision for additional program funds for management and evaluation.
- Should Congress decide to allocate additional funds to the SBIR Program, those funds could be utilized effectively.

SBTC RECOMMENDATIONS FOR THE REAUTHORIZATION OF THE SBIR AND STTR PROGRAMS

Congress could take no action with a better promise of stimulating the U.S. economy over the short-, medium-, and long-term than to reauthorize and strengthen the SBIR Program.

SBTC specifically recommends that Congress:

1. Make the Programs permanent. SBIR has just been given a strong endorsement by one of the most extensive studies of any federal program ever undertaken by the National Academy of Sciences. This follows three previous studies by the NAS and the National Academy of Engineering that positively evaluated SBIR, as well as ten favorable GAO studies.

SBIR is now the largest single source of patents in the United States, accounting for 40 percent more patents annually than all U.S. universities combined. It is also the source of a quarter of the most important technological innovations in the United States each year. It is generating, directly or indirectly, billions of dollars in wealth, far outstripping its cost.

It has stimulated the creation of thousands of successful companies, provided the Nation with a host of vital defense, homeland security, and life sciences technologies, resulted in billions of dollars in economic activity, and created tens of thousands of high-paying jobs.

If this is not a successful and cost-effective federal program, one may reasonably ask what is.

SBIR should not have to re-justify its existence every three or four years. Delays in Congressional approval of reauthorization that were totally unrelated to SBIR caused the Program to temporarily shut down in 2000. Uncertainty about its future, as each reauthorization looms, puts thousands of jobs, and hundreds of companies, in jeopardy. SBIR has proved its worth. Congress should make it a permanent program, conduct normal cycles of Congressional oversight and management hearings, and make occasional adjustments as needed to the Program's legal framework.

2. Increase the allocation of R&D dollars going into the Program. As the foregoing data have shown, SBIR has become a vital contributor to the Nation's technological development and wealth creation. The Program leverages federal R&D resources in uniquely efficient ways. Given the global competitive challenges faced by the United States, SBIR should be given the resources to access America's untapped innovation resources. SBTC recommends that the SBIR share of federal R&D dollars be gradually increased from today's two and a half to five percent, at the rate of .5 percent per year. At a five percent level, smaller companies would still be receiving less than one-sixth of the dollars that their numbers of scientists and engineers, and their patent production, should entitle them to. Today they receive less than one-seventh. A portion of this increase should be allocated to expanding SBIR commercialization programs in the federal agencies, such as the Defense Department's highly-successful Commercialization Pilot Program (CPP).

3. Take the steps recommended by the National Academy of Sciences to strengthen the Program.

The NAS studies include several valuable recommendations for strengthening the management of SBIR Programs in the various agencies, and for improving SBIR outreach, among other subjects.

The NAS also recommends that SBIR Phase I awards be increased to a limit of $150,000 and the Phase II awards to $1.25 million limit, to adjust for the inflation and cost increases that have occurred since the last such adjustment 14 years ago.

At the same time, the Academy correctly notes, Congress must be careful not to extend the dollar limits too high. Companies with promising technologies will be driven out of the Program if fewer firms and fewer innovations absorb more of the available dollars in each funding cycle. (Multiple awards to single firms in single funding cycles would have a similar effect.) Awards in excess of statutory limits, or multiple awards to a single company during a single award cycle, should be approved in advance on the basis of a written justification and a higher level of review. They should be monitored and compared to the performance of other contract awards.

SBTC agrees with the Academy on giving federal agencies ample space to experiment with "Phase IIB" and similar development efforts.

4. Maintain the integrity of SBIR as a small business program.

At various times in the past, legislation has been proposed that would allow large firms and universities, either alone or acting through intermediaries, to have unrestricted access to the SBIR Program.

Such an action would violate the foundation of small business law in this country, and more than half a century of legal precedents. It would also violate the "common sense" understanding of most citizens about the proper definition of a small business and the proper use of taxpayer dollars intended for small business.

The most persistent controversy in this area has been about the conditions under which venture capital companies can participate in the SBIR Program.

It is often stated that venture capital companies are "prevented" from participating in the SBIR Program.

This is incorrect.

VC's can participate in the SBIR Program.

The only limitation on VC participation is determined by a two-pronged test.

Prong # 1: Does the VC seek (or hold) *a minority or a majority* ownership position in the SBIR company?

If the answer is *a minority position*, then any VC-backed SBIR company – and any VC – is free to participate in the SBIR Program as it wishes.

Prong # 2: Is the VC itself a large business, with 500 or more employees, including affiliates and subsidiaries?

If the answer is no, then the VC may participate in the SBIR Program in any manner it wishes, as *either a majority or a minority* shareholder in an SBIR company.

If the answer is yes, then the VC may seek (or hold) only *a minority* position in an SBIR company.

In other words, VC's can and do have access to the SBIR Program. In fact, the percentage of VC-backed companies in the SBIR Program has been *rising*. The sole purpose of the VC restriction in the SBIR Program is to prevent an SBIR company from becoming a subsidiary of a large business and still access funds that Congress intended for small businesses.

Subsidiaries of large companies have not been able to access funds or programs legally designated for small business since the enactment of the Small Business Act and the related "affiliation rule" in 1953, long before SBIR's enactment in 1982.

SBIR receives only 2.5 percent of extramural federal R&D. SBTC sees no reason to divert any of these funds to large companies that are eligible for the other 97.5 percent. We have, however, repeatedly offered to work with the large venture capital companies that are seeking innovation funding from Congress, to try to address their concerns in other ways. The matching of VC investments in biotechnology with funds from the National Institutes of Health, which the VC and biotechnology industries reportedly are seeking from Congress and NIH, represents one such path.

A further danger, should large VCs be permitted to hold majority interests in SBIR companies, is that absent extensive monitoring and evaluation, such VC control could quickly shift from be allowed to being required, as a selection criteria for SBIR contract awards. A concentration of large VC influence in the SBIR Program would also skew SBIR dollars more toward the handful of local areas, such as Boston and San Francisco, where most VC investments tend to be directed. As noted on page 7, above, the SBIR Program is far more egalitarian in its investments.

SBIR/STTR and the Universities—expanding a successful partnership

The STTR Program, enacted in the 1990's, provides an important adjunct to SBIR by facilitating partnerships between small, technology-based businesses and Universities. Like SBIR, STTR offers an important venue for public-private, and nonprofit-private, partnerships in pursuit of technological innovation. SBIR researchers often have ties to universities, and STTR researchers always do. The National Academy of Sciences report found that SBIR collaboration and subcontracting with universities was widespread. The STTR program has allowed this collaboration to grow.

In a separate and revealing study, the New England Innovation Alliance (NEIA) surveyed in depth 17 of its members that are participating in the SBIR Program.

The NEIA study found that these 17 SBIR companies had 175 subcontracts with 101 different universities worth over $28 million, while employing 243 university professors and graduate students.

So this avenue of collaboration offers the promise of a classic win-win situation. Together, SBIR/STTR companies and the Universities can:

- Identify University R&D with potential downstream commercial applications, strengthening this awareness and focus,
- Develop new revenue streams for the Universities through R&D sales and licensing,
- Supplement the income of University-based researchers that work on SBIR and STTR projects, thus aiding the Universities in attracting and retaining talented faculty,
- Expose students who work on SBIR/STTR projects, or intern at SBIR/STTR companies, to the world of commercial R&D, and
- Jointly transfer valuable technology to the Nation as a whole.

As the shift in science and engineering talent from large companies to small ones makes clear (see Figure 4), large firms are a declining source of employment for university science and engineering graduates. In fact, large firms out-source many of these jobs to foreign companies.

At the same time, however, the growth in science and engineering talent in *small businesses* makes SBIR companies a crucial source of future employment opportunities for University science and engineering graduates. Such attractive and realistic opportunities to collaborate with leading-edge technology companies can help Universities attract students to science and engineering careers in the first place.

Moreover, the STTR program is a locus of contracts and subcontracts that provide financial support to Universities.

A more robust STTR Program would hold significant promise of reinvigorating the growth in University patents (see Figure 6) and in improving University performance in developing key innovations (see Figure 7).

To enhance cooperation between Universities and small, technology-based companies, SBTC further recommends that the STTR share of federal R&D dollars be increased from the current 0.3 percent to 0.6 percent in FY 2010 and 0.9 percent in FY 2011 and thereafter.

Annex 1: SBIR's Contribution to Economic Development, Selected States

State	SBIR employment (est.)	SBIR patents	SBIR $ 1983-2008
Arizona	7,772	950	$432,883,657
Georgia	4,825	631	$242,583,673
Illinois	5,731	1,017	$414,004,010
Maryland	28,172	2,578	$1,290,340,195
Michigan	10,683	1,655	$539,891,230
Missouri	4,031	415	$114,289,277
Nebraska	951	300	$41,751,188
New Mexico	42,872	603	$422,922,243
New York	25,938	3,431	$1,203,963,026
Oregon	9,537	1,084	$89,312,577
Tennessee	6,153	235	$220,677,490
Texas	24,432	2,620	$1,050,945,751

Source: © Innovation Development Institute, 2009

Annex 2: Jere W. Glover Biographical Statement

Jere Glover is an attorney with the Brand Law Group in Washington, DC, representing small businesses on SBIR-related issues. He also serves as the Executive Director of the Small Business Technology Council (SBTC), a group of small high tech companies most of whom are involved in the Small Business Innovation Research (SBIR) program. He served on the Board and the investment committee of the Telecommunications Development Fund and is a Board member of Homeland Ventures Partners. In 2006 Jere was selected as SBIR Man of the Year.

As one of the creators of the SBIR program, Jere's experience with SBIR is extensive. He was Counsel to the House Small Business Committee, where he directed an extensive set of hearings on small business and innovation that laid the ground work for SBIR in 1978. He was also the lead-off witness before Congress in 1982 when SBIR was first proposed. He was later Counsel to the Senate Small Business and Entrepreneurship Committee, where he worked on Small Business Technology Transfer (STTR) Program Reauthorization. Throughout SBIR's existence, he has been one of its most active supporters.

Jere has a unique blend of private and public sector experience. A former CEO and attorney in private practice, Jere also spent many years in government service, most of it focused on minimizing the regulatory burden on business. For more than six years, he was the Federal Government's lead defender of small businesses in the regulatory process. In that capacity, he systematically analyzed hundreds of regulatory actions by federal agencies, identifying flaws and shortcomings in many of those actions and helping the affected businesses seek relief, without undermining the broad public purposes of the regulations. The work that Jere directed saved the private sector more than $20 billion in annual regulatory costs, and it cut a wide swath across many types of businesses—including mining, fishing, telecommunications, transportation, financial services and agriculture. He has testified before Congress over 30 times and appeared in over 100 agency proceedings, including rule-makings, adjudications, and enforcement proceedings.

In the private sector, Jere previously was the CEO or principal of a biotech company, a medical technology company and a group of medical clinics. Since re-entering the private sector last year, he has become the managing director of another medical technology company and counsel to a variety of SBIR and technology companies.

Jere obtained his undergraduate and law degrees from the University of Memphis and an L.L.M. in Administrative Law and Economic Regulation from George Washington University.

Annex 3: SBIR White Paper, by SBIR Founder Roland Tibbetts

REAUTHORIZING SBIR: THE CRITICAL IMPORTANCE OF SBIR AND SMALL HIGH TECH FIRMS IN STIMULATING AND STRENGTHENING THE U.S. ECONOMY

ROLAND TIBBETTS
SBIR PROGRAM MANAGER, 1976–1996
NATIONAL SCIENCE FOUNDATION

The proposed Small Business Innovation Research (SBIR) reauthorizing legislation (H.R. 5819) is of great concern to thousands of small technology-based firms and should be of similar concern to Congress.

The bill would significantly weaken the basic elements of the SBIR program by:

(1) Cutting the number of awards, probably in half. Far larger SBIR awards would be allowed. Companies could receive multiple development awards. Agencies could waive even the higher award caps. Yet the overall size of the program would not be increased. Together, these steps would eliminate funding for a large number of innovative and breakthrough ideas.

(2) Allowing firms to avoid SBIR's competitive "proof of concept" step and move directly to much larger "development" awards. This is an irresponsible policy for a program that is funding very high-risk ideas. The "proof of concept" requirement, Phase I of SBIR, is necessary to weed out ideas that are not feasible, so that large sums of taxpayer dollars aren't wasted on them.

(3) Substituting SBIR's R&D funding for private investment capital in the commercialization phase of SBIR (Phase III). Phase III is a market-based reality check. A project that can't attract private-sector funding or mainstream government procurement contracts at that point should not be pushed forward with more R&D funding from SBIR.

(4) Threatening the integrity of SBIR as a small business program by weakening the safeguards against large business access to SBIR funds.

With each of these changes, the needs of the SBIR Program, and the history of its best practices, call for doing exactly the opposite of what the bill proposes.

What SBIR Is Designed to Do

SBIR was created to address a need that is still critical: to provide funding for some of the best early-stage innovation ideas—ideas that, however promising, are still too high-risk for private investors, including venture capital firms. As happened with Microsoft, Apple and hundreds of other firms, technology innovations can mushroom into major products and businesses once private sector investors make a commitment. But they'll only make that commitment once the innovation is well along. *In 2005 only 18 percent of all U.S. venture capital invested went to seed and early stage firms while 82 percent went to later stages of development that are lower risk.*

The positive role of innovative small technology firms in the economy is evident not only in the dozen or so geographic strongholds of tech entrepreneurship across the Nation, but also in the increased productivity of the companies that buy and use the innovations. That is perhaps the most compelling reason to maintain a strong, effective SBIR Program.

SBIR addresses a paradox at the heart of innovation funding: capital is always short until the test results are in. At the idea stage, and even the early development stage, the risks are too great for all but a few investors. But innovations can't get beyond that stage without funding.

There is another paradox, too. The Federal Government has R&D needs that, for a variety of reasons, will never interest private sector investors. The business models of most investors focus on generating many sales to many customers. When the government is the only buyer, and buys on a one-time or very occasional basis, investors get skittish.

Large government contractors typically aren't interested in such R&D, either. The amounts involved are too small, and most large contractors don't have early-stage R&D capabilities anyway.

So needed innovations in fields like defense, space exploration and homeland security may not occur. The same can be true for innovations in science, especially the health sciences, when the projected patient populations are small or the innovation may only be needed once per person (such as with a vaccine).

SBIR was designed specifically to solve both of these paradoxes:

First, it provides a transparent, competitive and reliable source of early-stage funding for R&D, based entirely on scientific merit. Today, SBIR is the Nation's largest source of such funding.

Second, it allows the government itself to obtain needed R&D that the private sector could not otherwise provide.

Why SBIR Has Been Successful

SBIR's success, as recently documented by the major National Research Council/National Academy of Sciences study, is rooted in a number of the program's characteristics.

Drawing on small business scientific talent. SBIR draws on the six million scientists and engineers that are now employed by small firms. That compares to the five million employed by medium-sized and large firms. In fact, small business employs more scientists and engineers than large business, universities, federal labs, or nonprofit organizations. A great many of these small business scientists and engineers are entrepreneurial. To see the entrepreneurial zeal of these technology-based small companies, one has only to look at the extent to which the SBIR Program and the Nation's venture capital companies—the only important sources of risk capital for such companies—are swamped with proposals. Or one can look at patents granted. The SBIR Program accounts for more than 50,000 of them. Currently, it accounts for an average of seven patents a day, which is more than all U.S. universities combined. SBIR has given us Qualcomm, Symantec and dozens of other highly successful technology companies.

Providing the primary source of government R&D funding for small business. Despite their huge numbers of scientists and engineers, and despite their well-documented science and technology successes, small businesses have virtually no access to federal R&D contracts outside of the SBIR Program. According to the National Science Foundation's annual *Science Indicators* report, large firms receive 50.3 percent of federal R&D, universities receive 35.3 percent, non-profits 10 percent, and small businesses just *4.3 percent.* SBIR accounts for over half of that 4.3 percent. This is an astonishingly small figure for a nation that expects technological innovation to lead it to new economic heights, but there it is. For small companies, SBIR remains the only game in town, just as it was in 1983, when it began.

Adopting best practices.

In designing the SBIR program, I drew on my own experience as a founder, director and treasurer of Allied Capital here in Washington and as operational VP for two small tech firms, one of which grew to 600 employees before being sold to TRW. I read about 50 articles on innovation and R&D management. I talked with a few dozen economists and directors of research in large firms and universities. I met with ten or so venture capitalists. I asked them, and others like the DuPont R&D advisory committee, about best practices.

Best practices 1: managing portfolio risk. One thing everyone agreed on was the need to manage R&D portfolio risk through diversification. With the high risk involved in early-stage R&D, there is need to diversify the federal investment by betting on many, rather than fewer, technologies and ideas. (The R&D risk is high not only because of the technical challenges but also because cutting-edge R&D requires expensive equipment. Such R&D is the furthest away in time from the market, and the market may change during that period.)

The size of SBIR awards and thus the dollars at risk per innovation was therefore a major topic. Most of those I worked with in developing SBIR agreed that the technologies involved were such inherently high risks that smaller bets should be made on many projects before making a few larger bets.

Best practices 2: making the largest number of awards possible. Making many smaller awards was not only good risk management practice. Virtually everyone I spoke with argued, and my own 20-year experience as an SBIR Program Manager subsequently confirmed, that the economic payoffs would be higher this way. Many smaller awards mean that more ideas can be evaluated for their potential. More and better choices for further development become available.

Probably a few thousand CEO's of small tech firms have talked with me about SBIR over the years. In general, they liked almost everything about SBIR, except the terrible odds against winning an award. Many no longer submit proposals because of the large investment of time and cost required to prepare a competitive pro-

posal when only one in 15–20 receive the larger Phase II funding. Others still compete because there are almost no alternative sources of such funding.

If there are fewer SBIR awards in the future, not only will fewer technologies get evaluated and funded. Fewer companies will compete, because the odds against winning will get even higher. I believe we have been seeing some of this occur already at the National Institutes of Health, where larger award sizes and fewer awards have been accompanied by a fall off in applicants.

Best practices 3: creating scientific gates and milestones. Another best practice that we adopted for SBIR was the use of science-based gates and milestones before letting projects obtain more funding. Often an idea can be found to be infeasible through the Phase I "proof of concept" process. Other ideas show only a low probability of success. No further expenditures should be made on such technologies.

Unfortunately, some companies always came to us seeking to obtain as much SBIR funding as possible in both Phases I and II. Indeed, during my 20 years as an SBIR program manager, we frequently heard such requests from both the companies and the agency scientists and engineers. However, no proposer was ever allowed to go directly to Phase II. Even if they had done relevant work earlier, we expected Phase I to show further progress. Our strict policy on this point proved to be a good thing. The companies that argued that they had already done the early R&D, and therefore should be able to go directly into Phase II, almost always were unsuccessful when faced with competition. Their requests had been sales ploys. A company's success on earlier projects was no guarantee that its newest idea was competitive. It is important to always remember that SBIR provides funding for *ideas,* not for *companies.* Competitive, science-based gateways are vital for identifying the best ideas.

Best practices 4: making SBIR a powerful economic development tool.

The past. The roots of SBIR actually go back to Congress' concern over the "Rust-Belt Recession" of the 1970's. Unemployment in Detroit was high, due to the growing sales of new smaller automobiles and machine tools from Japan and Germany. The question was asked whether National Science Foundation research was focused on economic needs. The result was a new NSF program in applied research called "Research Applied to National Needs" or RANN. For the first time in NSF history, ten percent of a program budget—the RANN program budget—was set aside for small business. This was the basis for the design and initiation of the Small Business Innovation Program at NSF in 1977. That program grew each year. Its successes led to legislation in 1982 that required all agencies with an extramural R&D budget over $100 million (today 11 such agencies) to participate. There were some early successes, such as Symantec, that gave us confidence in the basic design of the program.

A little background here: Individuals and small firms are the primary source of category-creating inventions and technical breakthroughs. It is not the successful wagon company that invents the automobile. And it's not the large business that risks up-ending its business model and its product lines. Small company major economic breakthroughs include the digital computer, microchips, the personal computer, software, the successful cell phone, the internal combustion engine, diesel engine, steam turbines (steamships and railroads), the electric motor, typewriter, telephone, refrigerator, electric transmission, phonograph, incandescent lights, vulcanized rubber, pneumatic tire, photo plate, airplane, motion picture, anesthesia, x-ray MRI; and even earlier the cotton gin, power looms, the sewing machine, the mechanical reaper, and other agricultural machines.

Fast forward a few generations: The great technology-based economic successes of the late 1970's and 1980's—along the Route 128 corridor near Boston and in Silicon Valley—as well as the communications and information technology companies that have proliferated since the 1990's, were the result of tens of thousands of scientists and engineers annually opting to start or join small firms. Often this included many of the best and brightest, the most creative, the most entrepreneurial, and the shrewdest risk takers: exactly the qualities that private sector investors, particularly venture capital companies, were looking for.

Think about what happened as Internet-based businesses grew in the 90's. It wasn't all boom and bust. The core of the "dotcom" era was a series of rapid and related breakthroughs in new and emerging technologies. Most of the breakthroughs came from startup companies. Five "dotcom" era startups are now in the "20 Most Widely Held Stocks in the U.S": Intel (microchips), Microsoft (software), Apple (personal computers), Oracle (relational databases) and Cisco Systems (networks). In 2007 alone, their combined sales were $166 billion and they employed 221,000. Add to this the thousands of smaller new firms with directly related new products and

services, both in the U.S. and worldwide. Overall, the "dotcom" era was probably the largest economic growth breakthrough in history.

The future. Just as we have seen small-business-driven technological breakthroughs throughout our history, we can see them again in the future. There are a whole series of new and emerging technology areas where innovations could have powerful economic impacts. They include:

- global warming and other environmental areas, such as water purity;
- alternative energy and energy conservation;
- all kinds of security—national, military, commercial, and economic;
- ever-changing communications;
- health care improvements and cost reduction measure;
- disease prevention;
- more effective education;
- improved transportation;
- agricultural challenges addressed;
- nano- and miniaturization technology;
- automated manufacturing; and many more.

All of these needs represent potentially large markets. Today, the technological risks are still too great for most private investors. But the technologies still need funding. SBIR is perfectly situated to explore ideas in these areas.

SBIR funding is necessary because large firms, despite their public relations, do not in fact invest extensively in these areas. Big companies do not take major risks on unproven technologies, except with massive government funding, such as in defense, NASA, and nuclear power. Large firm R&D budgets focus on improving product competitiveness and the processes for fabricating their goods, solving specific problems, and overall growth in sales and profits. Universities and non-profits also cannot raise high-risk money for private sector technological innovations.

The mechanism. Generally only small high-tech firms can raise sufficient amounts of high-risk capital to pursue commercially and economically relevant innovations. The key reason for this is that only small companies can realistically offer the promise of their stocks multiplying dozens of times. It's the prospect of that exponential growth in stock value which makes the rewards worth the risks to investors.

When SBIR is guided well, it fosters breakthroughs by such small companies. These breakthroughs get the technologies to the point where they can deliver great economic benefits.

At that point, when the scientific evidence is starting to come in, innovations attract not only additional VC investments, but also investments by individual "angels," mutual funds, insurance companies, endowment funds, and others. Longer-term bank lending becomes possible. All of that financing lays the foundation for stock offerings. Then these stock offerings attract more capital. This business growth, plus the revenues from subsequent product sales and spin-offs, is the money that stimulates the economy.

Successful SBIR-funded technologies can thus generate many multiples of their federal investments, often in a much shorter time frame than traditional investments.

Again, the key steps are: casting the net as widely as possible, attracting entrepreneurial individuals and small companies, insisting on technical feasibility in a competitive and transparent environment, and then moving to a commercialization phase that requires private sector investment equaling or exceeding the federal investment.

What To Avoid in the Future

Avoid needless disruptions to the SBIR Program.

SBIR has proven itself over 25 years. It is known and understood by hundreds of thousands of scientists and engineers, most of them in small firms, but many of them also in the 11 participating federal R&D agencies, in universities, in venture capital companies, in larger firms, in Congress and in other parts of government, including the 50 State governments and a number of foreign countries. SBIR is successful. The National Research Council/National Academy of Sciences comprehensive assessment of the SBIR program last year confirmed the effectiveness of SBIR along the broad general lines that it exists today. Other studies, too, such as those by GAO and by Professor Josh Lerner of Harvard Business School have been highly

favorable. No reputable independent study in the past 25 years has called for major changes in SBIR.

Rather than implementing the constructive recommendations offered by the NRC/NAS study, the House-passed bill (H.R. 5819) mandates a vast upheaval in SBIR. Such a re-write of the program would make the NRC/NAS changes far more difficult to execute. How, for example, can the agency Advisory Committees that the study recommends do their work when agencies in the program would be spending the next few years redrafting all their SBIR program rules and retraining all their personnel?

Worse, the extensive reworking of the program would confuse everyone who uses the program—all those people in the small firms, universities, VC firms, large companies, State programs, and Congress that tap into the program. It would lead to lengthy award delays as the program is retooled in one agency after another.

Small technology-based companies will suspect, probably correctly, that all these changes will self-destruct and that SBIR will have to be re-tooled again in a few more years. So they'll hold back and shift to other activities. This will intensify the upheaval.

And for what? H.R. 5819 is designed to sharply increase the amount of SBIR funding that goes to maybe half the current number of companies, and to explore perhaps half as many promising ideas. This bill is more like special interest legislation than national interest legislation.

All available evidence suggests the major changes proposed by H.R. 5819 would be highly detrimental to SBIR's mission and effectiveness. Congress has never examined the full implications of these changes and should not embark on them without doing so. Unraveling SBIR now, at a time when the Nation urgently needs the economic boost that the program can provide, would be a national tragedy.

Avoid excessive increases in award sizes.

SBIR is not intended to pay for the entire R&D costs required for every project. Some ideas could require tens of millions and even hundreds of millions of dollars ultimately. The purpose of SBIR, as stated earlier, is to lower the R&D risk to the levels that can attract private investment.

H.R. 5819 triples the Phase II award cap, making it $2.2 million. The bill would also allow agencies to make multiple Phase II awards, and even to waive the $2.2 million cap. One effect of doing all this will be to divert tremendous amounts of energy to negotiations about how much of an award each project will get. It is difficult, unwise and unfair to most small firms and program officers to have to judge how much to request or award over such a vast range of dollars. Determining the award size will become a time consuming negotiation, complicated by questions of fairness to other participants. Those other applicants often will be equally qualified, and their projects will always be in need of more money. Ultimately, the size of many awards will end up being decided by salesmanship and personal connections, not by science. This will be a very corrosive influence on SBIR.

Just as important, larger awards reduce the number of ideas that can be funded. An $8 million Phase II award, if cut back to $1 million, could free up funding for seven other $1 million Phase II awards. Or, that $7 million difference could fund 35 "proofs of concept" ideas at $200,000 each. Similarly, a $1 million Phase I "proof of concept" award eliminates the possibility of four others at $200,000 each. We need to remember that research on innovative ideas at the idea stage is often primarily a one person job.

Avoid bypassing Phase I.

The foundation of the SBIR program is competition and openness. Take away the need to prove an innovation against other worthy innovations, in an above-board competition, and SBIR will degenerate into salesmanship and influence-peddling. Its genuine scientific accomplishments will diminish, year by year. If companies are allowed to apply directly for Phase II funding, SBIR will become little more than a traditional procurement program, not an innovation program. Phase I must not be by-passed; it is the seed bed of the entire SBIR Program.

Avoid using SBIR funds for commercialization.

If an SBIR firm cannot obtain a commercialization commitment from private sources, or from federal agencies (using non-SBIR funds), that at least equals the SBIR investment in an innovation, then SBIR's involvement in that innovation should end. The far more pressing public need is to fund additional recommended early-stage innovations, not to keep projects afloat that cannot attract financial support from the government or the private sector.

If SBIR award levels rise moderately to keep pace with inflation, an approach that the NAS/NAS study recommended, and that I agree with, then the SBIR investment in an early-stage technology idea should not exceed $1.2 million ($200,000 for Phase I and $1 million for Phase II). An innovation that cannot match or exceed that $1.2 million in the commercialization phase (Phase III) of SBIR, using non-SBIR funding, should not be rewarded with more SBIR funding.

In other words, no SBIR funds should be spent for Phase III. SBIR dollars are urgently needed to support additional promising ideas and to keep the high-risk SBIR portfolio diversified. If an agency feels that an innovation deserves financial support beyond a single Phase II award, then it can provide this further investment with non-SBIR funding. An agency that lacks that much faith in an innovation developed under its own guidance should not expect the taxpayers, via the SBIR program, to supply that faith.

Avoid steps that would diminish the small business character of the program.

Large companies view innovation much differently than small companies. A large company wants to protect its product lines and its customer bases. It looks for incremental innovations that make those existing products a little better and a little cheaper to produce. It looks for new products that are familiar and comfortable. For large companies, "re-defining" types of innovations are frightening. They upset settled ways of doing business. the Nation needs both incremental innovations and quantum-leap innovations, but right now and for the foreseeable economic future, it needs those out-sized innovations the most. SBIR can deliver sweeping innovations, but to do so it must avoid taking on the coloration and biases of large companies.

Even if there were only a modest national need for "out-of-the-box" innovations, there would still be a powerful need for SBIR, because nothing else in the country, and certainly nothing else in the Federal Government, supports early-stage innovation by small companies. Despite having more scientists and engineers than large business, universities, nonprofit organizations, or the Federal Government itself, small business gets only 4.3 percent of federal R&D dollars. And SBIR accounts for over half of that. Those other institutions draw more than 90 percent of federal R&D dollars. And here's the rub: there aren't any *other* sources of that early-stage innovation funding for small business. Capital for small business innovation research is so short in the United States that SBIR rapidly became, and remains, the largest source of it.

I come from a long and deep background in venture capital and I am a great believer in it. SBIR won't be nearly as successful unless VCs can participate in it. But VCs that directly or indirectly report back to large companies shouldn't be in Phase I or Phase II of the SBIR program. Nor should VCs that are big companies themselves.

VCs that are large firms in fact or spirit will inevitably focus on companies more than innovations. That's fine in Phase III, but not earlier. If big VCs get into Phase I and Phase II, they will push for bigger bets on fewer companies. They will want to shift SBIR funding away from high-risk Phase I ideas and toward Phase II development, which is closer to market and therefore less risky for them. Sooner or later, they will back SBIR funding for Phase III, which will also offset some of their risk. And the kind of innovations they ultimately favor will be those that big companies favor—safer and more familiar ones, incremental rather than quantum leap. SBIR can do much more than this. SBIR's current restrictions on big VCs are therefore wise. By contrast, H.R. 5819's approach to this issue is dangerously unwise.

What to Do in the Future

We must meet the competitive challenge.

We are currently the world leader in small high tech firms, in venture capital, and in basic research. These strengths are critical to our future economic growth. But others are catching up.

China, Japan, and Western Europe are rapidly increasing their investment in all three areas.

In a recent *Harvard Business School Bulletin* article, Jim Breyer, founder of Accel Partners and past chairman of NVCA, stated that there are now 6,000 venture-backed companies in Beijing alone! Accel has recently closed its second Chinese venture fund for $510 million. "Many of the very best [VC] firms in Europe and in Asia are affiliated with firms here in the United States," he notes.

The UK has just announced a new innovation program. Dozens of countries, notably including those that came here to study the SBIR program, are now increasing

their investment in innovations by small technology firms, venture capital development, business schools, and basic research.

Seeking out technology breakthroughs should be a far more important objective of government R&D than ever before. The single most important initiative we could mount would be to increase the SBIR to five percent of extramural federal R&D in a series of steps.

Such an initiative would be opposed by the current recipients of over 90 percent of federal R&D, like large companies, universities, non-profits, and the organizations representing them, but these were the same groups that opposed the creation of SBIR in the first place and have opposed every modest increase in the program ever since. The NAS/NAS report clearly shows that SBIR can successfully deploy additional funding.

Think what the Internet and the telecommunications revolution have done for our economy. This was accomplished primarily by small, high-tech firms with major VC support. Now the investment risk is even higher for initial funding. Seed-stage and early-stage VC support has plummeted. If there are only rare investments at the idea stage, there will be no storehouse of proven ideas ready for later development funding. As bad as our economic problems are today, with budget deficits, trade deficits, a shaky dollar, and so on, where would our tax revenues, our productivity, and our technology leadership be today if we had not had that technological revolution?

The SBIR program should be carefully strengthened.

The following are my recommendations to Congress about some specific issues in the SBIR reauthorization:

1. Small firms with 500 or fewer employees should remain eligible for SBIR awards as long as one or more large firms, including large venture capital firms, do not acquire a majority of ownership. Broad eligibility is necessary to identify and accelerate those innovations that can lead to technical and market success and superior economic growth. the Nation needs these potentially fast-growing firms far more than those that do not grow. Outside investors can, and often must, obtain more than 50 percent of the stock to protect their investment. That should be acceptable in SBIR as long as these investors are individuals and as long as the companies that they represent are small, as is required today. However, these investors must not be controlled, directly or indirectly, by large businesses. SBIR was created to provide small companies with innovation funding. The program remains too small to allow funds to be siphoned off by large companies, which already receive over half of federal R&D.

2. There should be a set review period for Phase I results, as well as a set period for Phase II proposals, based upon Phase I results. Some firms are obtaining early reviews, before other firms. That is not fair to others and should not be allowed.

3. Agencies should not allow companies to extend the break between Phase I and II except for illness or similar reasons. On the other hand, agencies themselves sometimes need to extend the breaks between Phase I and Phase II due to budgetary issues. This should be allowed when truly necessary, despite justifiable company concerns about cash flow. In the end, SBIR's purpose is to fund ideas, not to support a company's financial picture.

4. *SBA is still the proper organization to manage SBIR, not the Department of Commerce.* Criticism of SBA over the years has been due in great part to significant under-staffing by SBA management that should not have been allowed. SBA's SBIR staff is less than half the level any evaluator would recommend. When SBIR was a much smaller program, SBA had eleven staff members assigned to it. Today, there are only four. This headquarters staffing crisis is responsible for many complaints. But some agencies, such as DOE, also grossly under-staff SBIR. This leads to reductions in the number of award topics, in order to reduce agency workloads, and to the temptation to use jumbo awards, far in excess of the program's legal guidelines. I suggest some kind of a brake on agency proposal cutbacks and stricter enforcement of the caps.

5. Breakthroughs occur in new and emerging areas that cannot be predicted. I suggest that all agencies should allow innovation proposals in all areas that are relevant to their R&D programs. This openness to innovation proposals should be outlined in agency solicitations. Many agencies think in terms of relatively few topic areas. The original interagency innovation program essentially opened entire agency R&D programs for proposals. Solicitations now have become far more

restrictive, which cuts against the national economic interest. Breakthrough ideas that are relevant to an aspect of an agency's R&D should be invited.

6. *The commercial results of SBIR need to be strengthened.* Awards should not be made by agencies solely on the basis of technical merit and without any consideration being given to downstream commercial potential. Unfortunately, some SBIR firms favor agency approaches that minimize commercial potential, because the firms are really only interested in having their R&D ideas funded, not in commercializing the results. I suggest that proposers and agencies require a commercialization plan in both phases with a more detailed and specific plan in Phase II. Reviewers should consider both technical and commercial merit in their recommendations. This would include the proposer's plan for obtaining non-SBIR funding for Phase III. I would also support an SBIR funding cutoff for firms that win many Phase I awards without advancing any of them to Phase II, along the lines of what H.R. 5819 proposes. SBIR was specifically designed to force the small firm to focus on innovation, technology breakthroughs, and commercialization for their economic benefits to the Nation. Defense and NASA should also seek SBIR projects that have potential Phase III follow-on funding from non-SBIR sources. SBIR funds should not be used for mainstream procurement.

7. Award sizes should be increased in size in this reauthorization, to keep pace with inflation since the last adjustment in 1992. I recommend increasing Phase I awards to a $200,000 cap and Phase II awards to a $1 million cap. These are both substantial amounts of risk capital to explore technical feasibility. SBIR is not intended to build up the capabilities of a company, based on considerations like its other projects, but to explore the promise of the specific idea proposed. And SBIR's budget must fund as many ideas as possible.

8. *The SBIR set-aside should doubled as soon as possible.* SBIR is a major national asset. It accelerates technological innovation and technology breakthroughs. It helps attract private sector investment to the most promising innovations. It increases economic growth. We need to reinvigorate the economy, and we need more technological innovation. Yet despite the history of small company innovations, notably relating to the Internet and to telecom, and despite the fact that there are six million scientists and engineers employed by small firms, over half of the government's external R&D, (50.3 percent) goes to *large* firms, 35.3 percent to universities, and 10 percent goes to non-profit institutions. Small business firms received only that 4.3 percent. (2005 figures from NSF.) Even a modest increase in the award caps, such as I recommend, will *diminish* the number of SBIR awards and companies unless Congress takes the sensible step that it took last time award steps were increased—increasing the program size by a large enough amount to offset the larger awards. Shrinking SBIR would be exactly the wrong thing for Congress to do at this point in our economic history.

Finally, I must say that as I review the SBIR recommendations made to Congress by the Biotechnology Industry Organization (BIO) and by my former VC colleagues in the National Venture Capital Association (NVCA), I am deeply troubled. It is mainly these two organizations that are calling for the far-reaching changes in the program. Many of the changes they are proposing would, in my judgment, significantly and perhaps irreparably harm the program. I can understand the desire of any organization to represent its members and prospective members, but this is a case when we must think of the broader national interest.

Without open and competitive early R&D efforts, spread as widely as possible, innovations will never reach the level of maturity that can draw in venture capital or other follow-on funding. BIO and especially NVCA should understand this. The need is to explore as many ideas as possible and lower the risk as much as possible to attract follow-on Phase III investment. There will be no shortage of great new innovations to invest in if we allow SBIR to do its work in supporting truly innovative small companies by objectively assessing which ideas are wheat and which ones chaff.

Congress supported the current SBIR objectives with the first SBIR legislation in 1982. The program is working well, but can be improved, as stated in the comprehensive NRC/NAS report. SBIR can stimulate thousands of high-risk, economically promising ideas like no other program. Given the opportunity to work as designed, and as proven, SBIR can make a major contribution to the national economic welfare.

111th Congress. House Science Committee. Sub-Committee Technology and Innovation.

Data Relevant to Extent and Form of SBIR Participation by Awardees in the Congressional District of Sub-Committee Members: Numbers of SBIR-STTR Awardees, Awards (Phases I and II), and Dollars awarded to date (April 2009)

Sub-Committee Members			SBIR-STTR Data over life of program 1983-present				Currently Active*			
	State	District	Total # Awardees	Total SBIR-STTR Awards		Total SBIR-STTR Dollars***	Total # Awardees	Total SBIR-STTR Awards		Total SBIR-STTR Dollars***
				Phase I	Phase II**			Phase I	Phase II**	
David Wu *Chair*	OR	1st	85	254	85	$82,945,465	30	131	53	$51,720,289
Donna F. Edwards	MD	4th	129	869	316	$280,325,752	37	672	245	$225,196,410
Ben R. Luján	NM	3rd	63	304	105	$84,169,744	22	234	77	$65,275,117
Paul D. Tonko	NY	21st	80	438	172	$149,437,341	34	327	141	$123,205,055
Daniel Lipinski	IL	3rd	5	10	3	$2,574,236	0	0	0	$0
Harry E. Mitchell	AZ	5th	72	274	118	$104,418,354	25	170	85	$76,620,615
Gary Peters	MI	9th	50	108	46	$36,729,170	18	31	17	$15,942,755
Bart Gordon *ex officio*	TN	6th	7	11	4	$2,884,167	4	6	3	$2,383,077
Adrian Smith *Ranking Member*	NE	3rd	6	59	23	$21,295,288	2	55	22	$20,854,588
Judy Biggert	IL	13th	58	222	65	$56,242,476	7	63	30	$26,861,453
W. Todd Akin	MO	2nd	33	78	24	$24,022,914	12	43	16	$16,268,818
Paul Broun	GA	10th	24	43	10	$8,879,328	6	15	4	$4,097,700
Ralph M. Hall *ex officio*	TX	4th	11	22	7	$6,559,353	3	11	3	$3,196,411
		Totals	*623*	*2092*	*979*	*$860,483,588*	*200*	*1758*	*696*	*$631,622,288*

* In compilation of these type of aggregate data analyses, "Currently Active" refers to any firm in receipt of an SBIR-STTR Phase I award in period since 2004. It is common that a project may convert to Phase II up to three-four years following the Phase I award. In practical terms, there may be any number of reasons why a particular company may not in fact be considered currently SBIR-involved. They applied for - but were not selected - to Phase II; they have outgrown SBIR employment limitations; ben acquired etc. Nonetheless, as an indicator of the Exent and Form of SBIR participation in a particular region, this aggregate approach is useful.

** Later year projects (post 2004) should properly be considered as still part of the SBIR-STTR active pool. It can be assumed that in the next year or two, several more Phase I projects will continue into the more sophisticated work that is Phase II

*** Always in NIH, but to a lesser extent also in DOD, Phase II dollar are allocated incrementally over two-three years. It can be assumed that, even with no more Phase I or Phase II awards made - not alikely prospect, total award dollars will increase, probably quite substantially.

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SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II	Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II*	Total SBIR-STTR Dollars*
AZ	298	1,415	526	$451,127,095	119	405	139	$141,427,259
GA	264	775	279	$244,752,579	113	258	82	$80,898,537
IL	469	1,362	492	$415,514,121	193	441	139	$136,626,663
MD	905	4,073	1,477	$1,301,997,446	331	1,132	325	$344,019,750
MI	449	1,572	640	$538,096,278	198	542	181	$187,069,940
MO	160	423	137	$121,933,905	73	143	35	$38,792,430
NE	46	128	51	$56,039,628	17	43	8	$10,841,625
NM	269	1,429	517	$410,966,134	92	342	91	$98,407,761
NY	890	3,519	1,385	$1,209,357,487	334	1,024	345	$359,553,589
OR	240	952	422	$354,994,290	95	256	81	$87,934,701
TN	201	708	304	$215,150,316	70	139	58	$52,201,905
TX	773	3,178	1,175	$1,107,069,558	284	1,033	336	$364,426,216
Totals for these 12 states	4,984	19,534	7,405	$6,426,998,837	1,919	5,758	1,820	$1,902,200,376
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II.It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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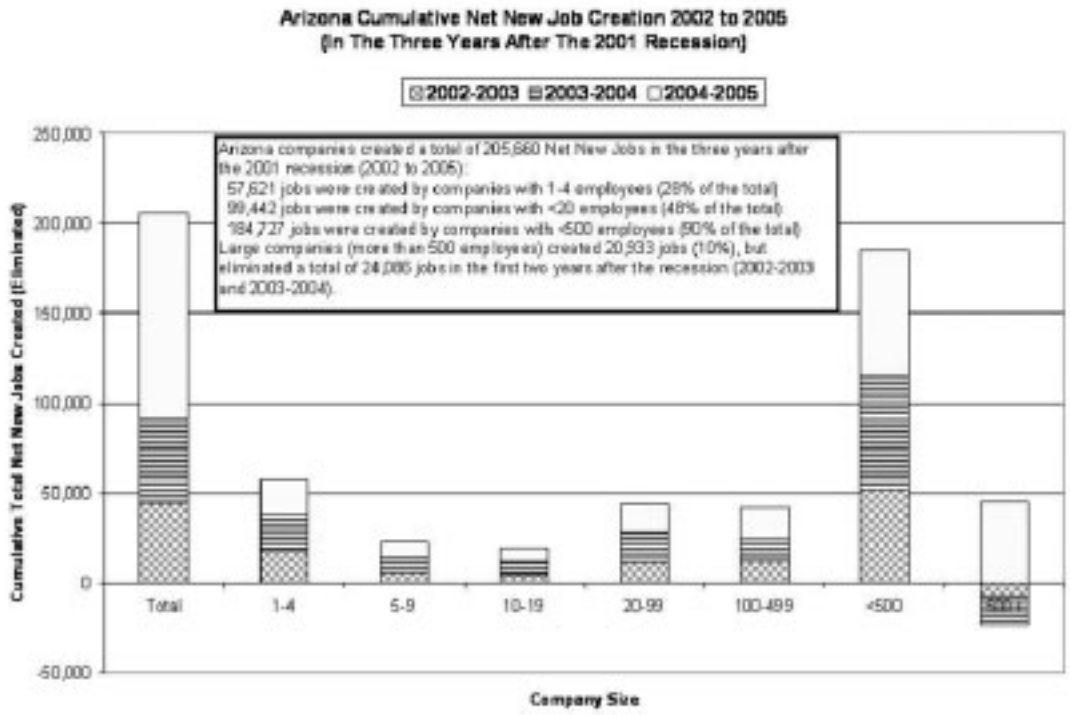
Arizona


Arizona Cumulative Net New Job Creation 2002 to 2005
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
Arizona companies created a total of 205,660 Net New Jobs in the three years after the 2001 recession (2002 to 2005):
57,621 jobs were created by companies with 1-4 employees (28% of the total)
99,442 jobs were created by companies with <20 employees (48% of the total)
184,727 jobs were created by companies with <500 employees (90% of the total)
Large companies (more than 500 employees) created 20,933 jobs (10%), but eliminated a total of 24,086 jobs in the first two years after the recession (2002-2003 and 2003-2004).
250,000
200,000
150,000
100,000
50,000
0
-50,000
Cumulative Total Net New Jobs Created (Eliminated)
Total
1-4
5-9
10-19
20-99
100-499
<500
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II	Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II*	Total SBIR-STTR Dollars*
AZ	298	1,415	526	$451,127,095	119	405	139	$141,427,259
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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SBIR/STTR

Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of Arizona

High Tech Jobs (2006)	111,623
Estimated SBIR employment	7,772
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	6.79%

realizing the value of SBIR

SBIR/STTR

Patent Information on SBIR-STTR Awardees in the State of Arizona

- Of the 5,893 SBIR-STTR firms having patents, 86 are from the State - 1.46%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	950
Percentage of SBIR-STTR Patents in the State	1.40%

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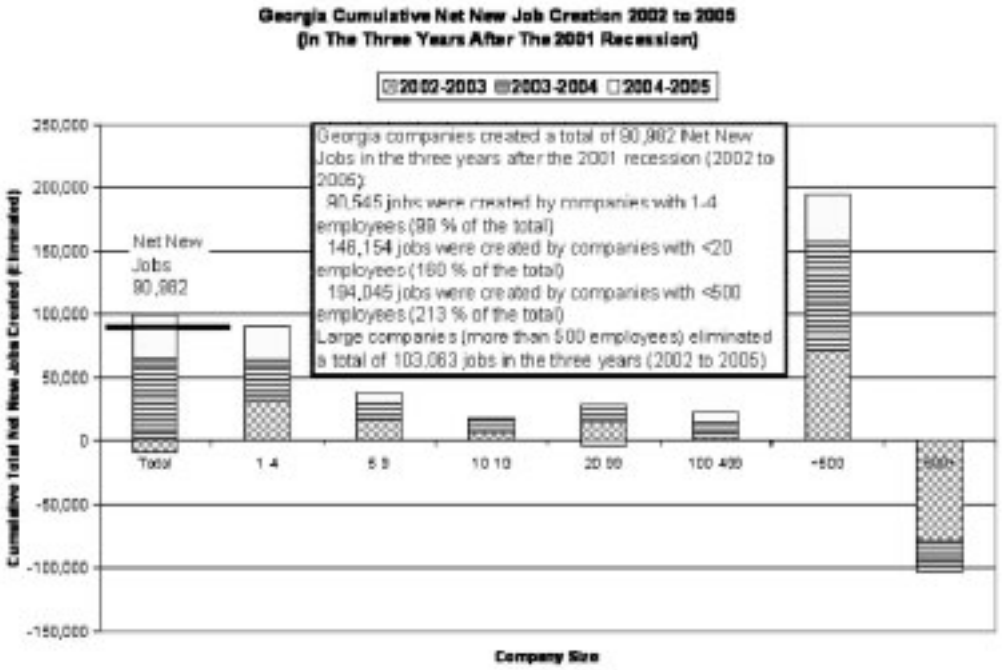
Georgia


Georgia Cumulative Net New Job Creation 2002 to 2005
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
Net New Jobs 90,982
Georgia companies created a total of 90,982 Net New Jobs in the three years after the 2001 recession (2002 to 2005):
90,545 jobs were created by companies with 1-4 employees (99 % of the total)
146,154 jobs were created by companies with <20 employees (160 % of the total)
194,045 jobs were created by companies with <500 employees (213 % of the total)
Large companies (more than 500 employees) eliminated a total of 103,063 jobs in the three years (2002 to 2005)
250,000
200,000
150,000
100,000
50,000
0
-50,000
-100,000
-150,000
Total
1-4
5-9
10-19
20-99
100-499
+500
500+
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards		Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards		Total SBIR-STTR Dollars*
		Phase I	Phase II			Phase I	Phase II*	
GA	264	775	279	$244,752,579	113	258	82	$80,898,537
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	6,920	22,801	7,339	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and repeated incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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SBIR-STTR.com

Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of Georgia

High Tech Jobs (2006)	162,497
Estimated SBIR employment	4,825
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	2.97%

Realizing the value of SBIR

SBIR-STTR.com

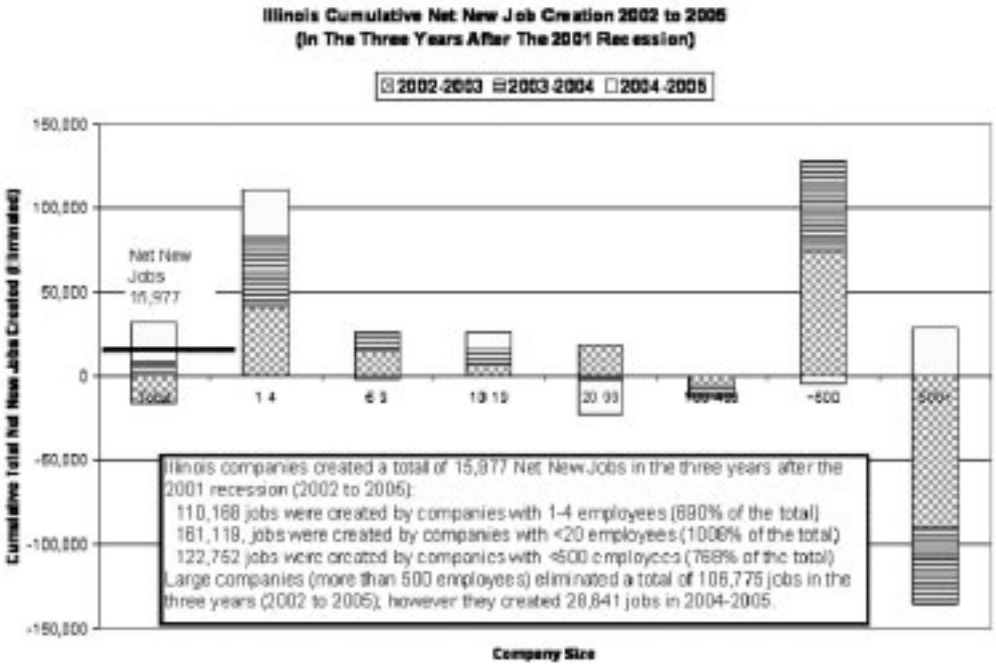
Patent Information on SBIR-STTR Awardees in the State of Georgia

- Of the 5,893 SBIR-STTR firms having patents, 65 are from the State - 1.10%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	631
Percentage of SBIR-STTR Patents in the State	0.93%

Realizing the value of SBIR

Illinois


Illinois Cumulative Net New Job Creation 2002 to 2006
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
150,000
100,000
50,000
0
-50,000
-100,000
-150,000
Net New Jobs 15,877
1-4
5-9
10-19
20-99
100-499
>500
500+
Illinois companies created a total of 15,877 Net New Jobs in the three years after the 2001 recession (2002 to 2006):
110,168 jobs were created by companies with 1-4 employees (690% of the total)
161,119, jobs were created by companies with <20 employees (1006% of the total)
122,752 jobs were created by companies with <500 employees (768% of the total)
Large companies (more than 500 employees) eliminated a total of 106,775 jobs in the three years (2002 to 2005), however they created 28,841 jobs in 2004-2005.
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards		Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards		Total SBIR-STTR Dollars*
		Phase I	Phase II			Phase I	Phase II*	
IL	469	1,362	492	$415,514,121	193	441	139	$136,626,663
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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SBIR STTR Innovation

Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of Illinois

High Tech Jobs (2006)	205,702
Estimated SBIR employment	5,771
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	2.81%

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SBIR STTR Innovation

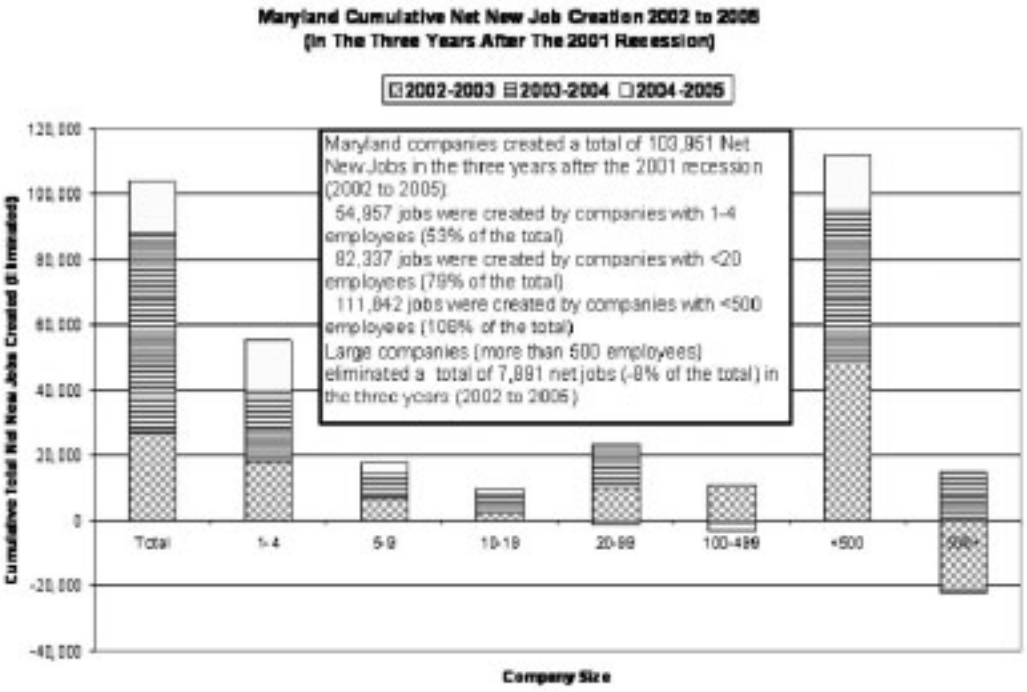
Patent Information on SBIR-STTR Awardees in the State of Illinois

- Of the 5,893 SBIR-STTR firms having patents, 138 are from the State - 2.34%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	1,017
Percentage of SBIR-STTR Patents in the State	1.50%

...realizing the value of SBIR

Maryland


Maryland Cumulative Net New Job Creation 2002 to 2005
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
Maryland companies created a total of 103,951 Net New Jobs in the three years after the 2001 recession (2002 to 2005).
54,957 jobs were created by companies with 1-4 employees (53% of the total)
82,337 jobs were created by companies with <20 employees (79% of the total)
111,842 jobs were created by companies with <500 employees (108% of the total)
Large companies (more than 500 employees) eliminated a total of 7,891 net jobs (-8% of the total) in the three years (2002 to 2005)
120,000
100,000
80,000
60,000
40,000
20,000
0
-20,000
-40,000
Cumulative Total Net New Jobs Created (Eliminated)
Total
1-4
5-9
10-19
20-99
100-499
<500
500+
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards		Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards		Total SBIR-STTR Dollars*
		Phase I	Phase II			Phase I	Phase II*	
MD	905	4,073	1,477	$1,301,997,446	331	1,132	325	$344,019,750
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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SBIR/STTR

Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of Maryland

High Tech Jobs (2006)	162,230
Estimated SBIR employment	28,172
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	17.38%

Realizing the value of SBIR

SBIR/STTR

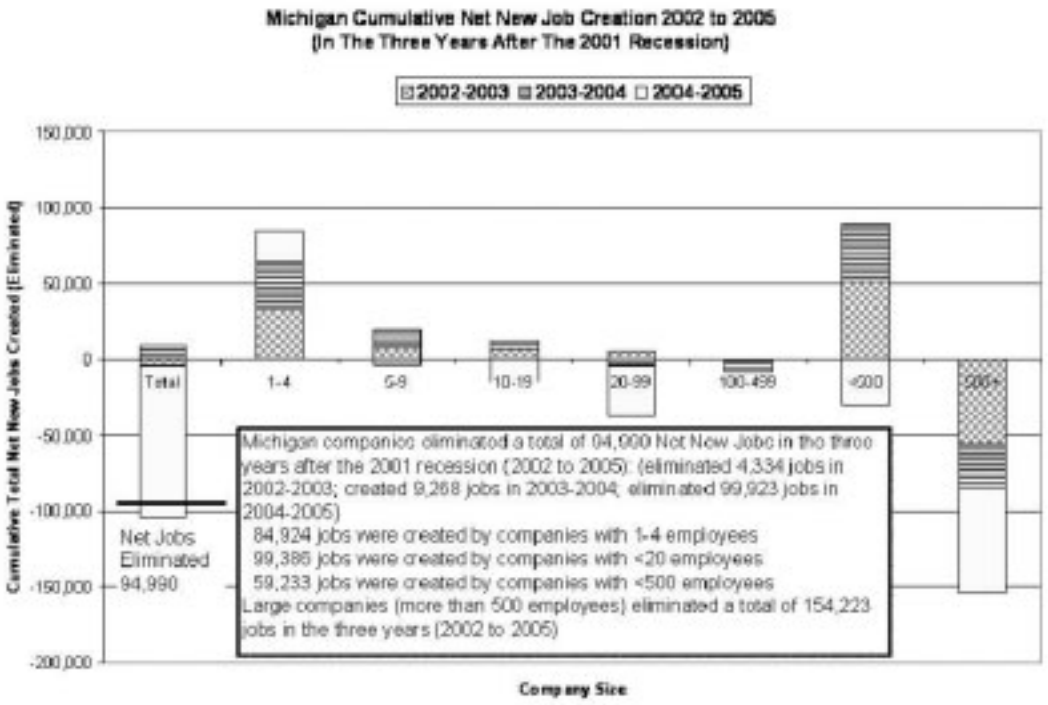
Patent Information on SBIR-STTR Awardees in the State of Maryland

- Of the 5,893 SBIR-STTR firms having patents, 281 are from the State - 0.90%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	2,578
Percentage of SBIR-STTR firms in the State	3.80%

Realizing the value of SBIR

Michigan


Michigan Cumulative Net New Job Creation 2002 to 2005
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
150,000
100,000
50,000
0
-50,000
-100,000
-150,000
-200,000
Cumulative Total Net New Jobs Created (Eliminated)
Total
1-4
5-9
10-19
20-99
100-499
<500
500+
Net Jobs Eliminated 94,990
Michigan companies eliminated a total of 94,990 Net New Jobs in the three years after the 2001 recession (2002 to 2005): (eliminated 4,334 jobs in 2002-2003; created 9,268 jobs in 2003-2004; eliminated 99,923 jobs in 2004-2005)
84,924 jobs were created by companies with 1-4 employees
99,386 jobs were created by companies with <20 employees
59,233 jobs were created by companies with <500 employees
Large companies (more than 500 employees) eliminated a total of 154,223 jobs in the three years (2002 to 2005)
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (no include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards		Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards		Total SBIR-STTR Dollars*
		Phase I	Phase II			Phase I	Phase II*	
MI	449	1,572	640	$538,096,278	198	542	181	$187,069,940
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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SBIR STTR

Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of Michigan

High Tech Jobs (2006)	177,163
Estimated SBIR employment	10,683
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	6.03%

building the value of SBIR

SBIR STTR

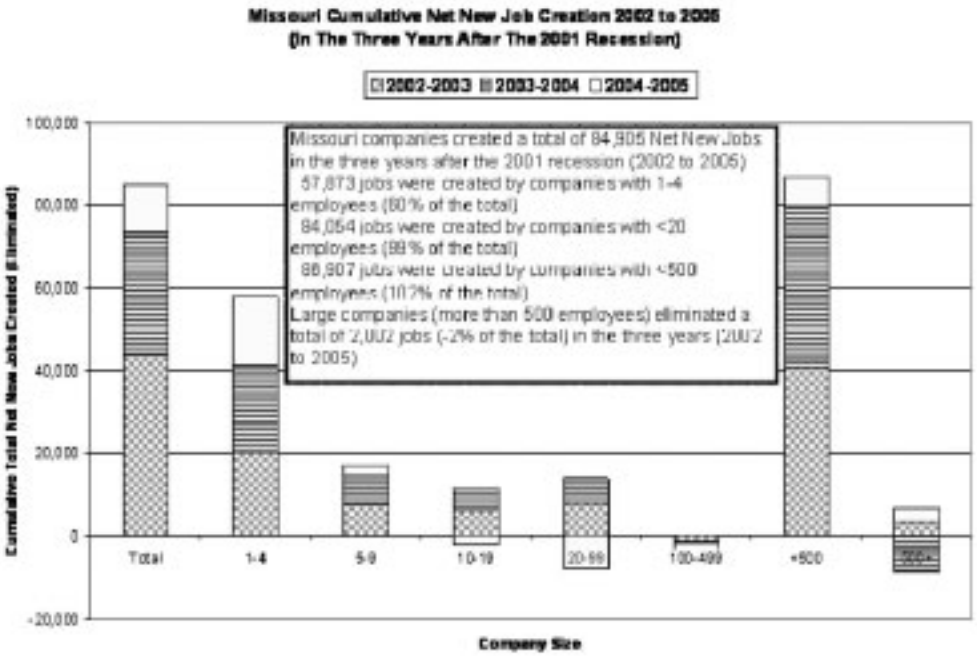
Patent Information on SBIR-STTR Awardees in the State of Michigan

- Of the 5,893 SBIR-STTR firms having patents, 142 are from the State - 2.41%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	1,655
Percentage of SBIR-STTR Patents in the State	2.44%

building the value of SBIR

Missouri


Missouri Cumulative Net New Job Creation 2002 to 2005
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
Missouri companies created a total of 84,905 Net New Jobs in the three years after the 2001 recession (2002 to 2005)
57,873 jobs were created by companies with 1-4 employees (68% of the total)
84,054 jobs were created by companies with <20 employees (99% of the total)
88,907 jobs were created by companies with <500 employees (101% of the total)
Large companies (more than 500 employees) eliminated a total of 2,002 jobs (-2% of the total) in the three years (2002 to 2005)
100,000
80,000
60,000
40,000
20,000
0
-20,000
Cumulative Total Net New Jobs Created (Eliminated)
Total
1-4
5-9
10-19
20-99
100-499
+500
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (do include FY 09 announcements so far made: April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II	Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II*	Total SBIR-STTR Dollars*
MO	160	423	137	$121,933,905	73	143	35	$38,792,430
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in a NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of Missouri

High Tech Jobs (2006)	88,326
Estimated SBIR employment	4,039
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	4.57%

SBIR/STTR Innovation Consortium

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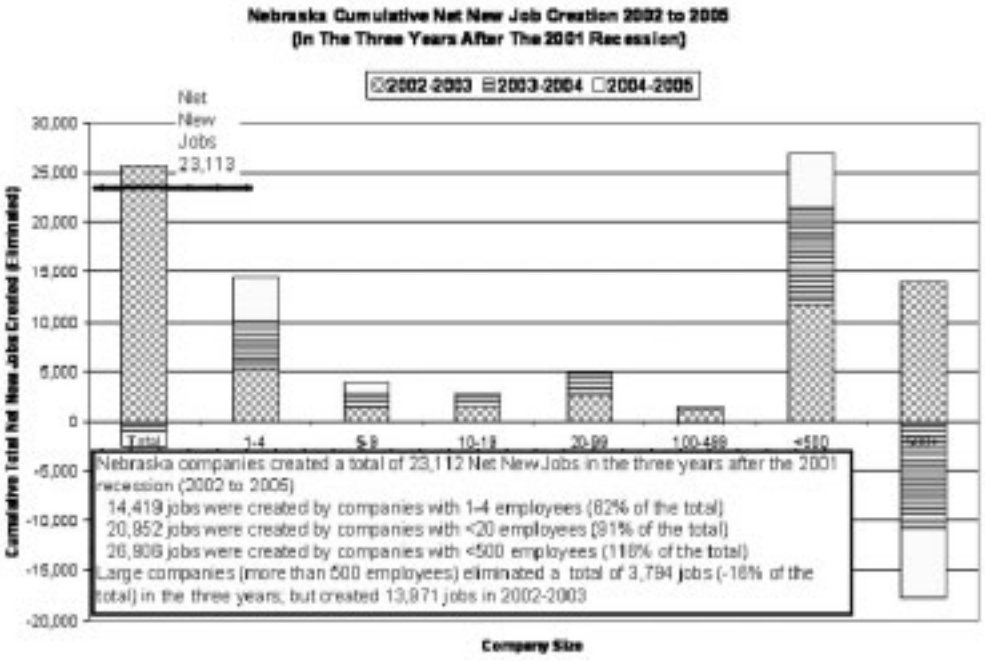
Patent Information on SBIR-STTR Awardees in the State of Missouri

- Of the 5,893 SBIR-STTR firms having patents, 48 are from the State - 0.81%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	415
Percentage of SBIR-STTR Patents in the State	0.61%

Nebraska


Nebraska Cumulative Net New Job Creation 2002 to 2006
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2006
Net New Jobs 23,113
30,000
25,000
20,000
15,000
10,000
5,000
0
-5,000
-10,000
-15,000
-20,000
Cumulative Total Net New Jobs Created (Eliminated)
Total
1-4
5-9
10-19
20-99
100-499
<500
500+
Nebraska companies created a total of 23,112 Net New Jobs in the three years after the 2001 recession (2002 to 2006)
14,419 jobs were created by companies with 1-4 employees (62% of the total)
20,952 jobs were created by companies with <20 employees (91% of the total)
26,906 jobs were created by companies with <500 employees (116% of the total)
Large companies (more than 500 employees) eliminated a total of 3,794 jobs (-16% of the total) in the three years, but created 13,971 jobs in 2002-2003
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II	Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II*	Total SBIR-STTR Dollars*
NE	46	128	51	$56,039,628	17	43	8	$10,841,625
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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SBIR/STTR Innovation

Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of Nebraska

High Tech Jobs (2006)	30,034
Estimated SBIR employment	951
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	3.17%

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SBIR/STTR Innovation

Patent Information on SBIR-STTR Awardees in the State of Nebraska

- Of the 5,893 SBIR-STTR firms having patents, 18 are from the State - 0.31%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	300
Percentage of SBIR-STTR Patents to the State	0.44%

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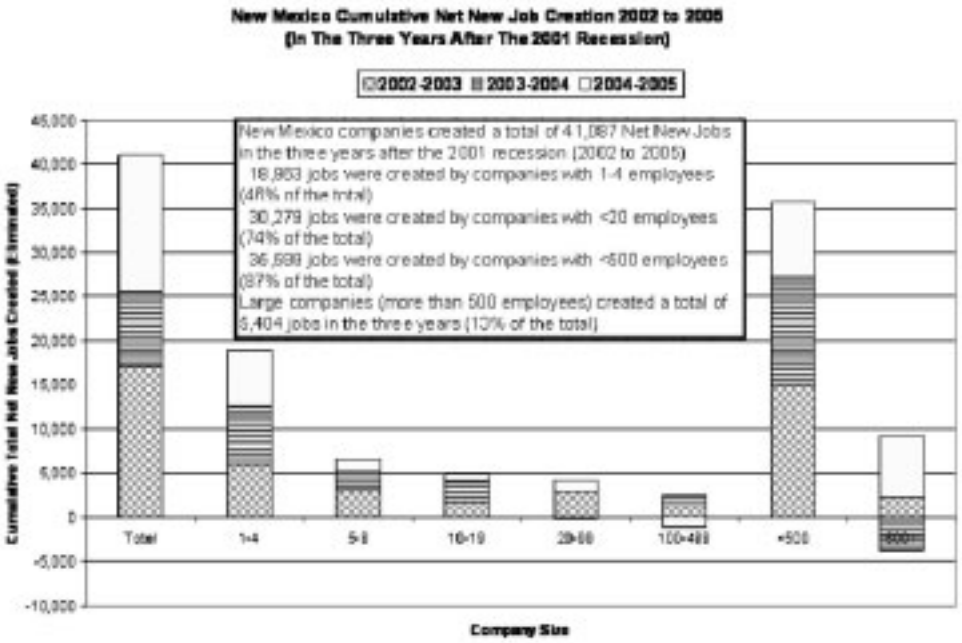
New Mexico


New Mexico Cumulative Net New Job Creation 2002 to 2005
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
New Mexico companies created a total of 41,087 Net New Jobs in the three years after the 2001 recession (2002 to 2005)
18,863 jobs were created by companies with 1-4 employees (46% of the total)
30,279 jobs were created by companies with <20 employees (74% of the total)
36,698 jobs were created by companies with <500 employees (87% of the total)
Large companies (more than 500 employees) created a total of 5,404 jobs in the three years (13% of the total)
45,000
40,000
35,000
30,000
25,000
20,000
15,000
10,000
5,000
0
-5,000
-10,000
Cumulative Total Net New Jobs Created (Estimated)
Total
1-4
5-9
10-19
20-99
100-499
+500
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II	Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II*	Total SBIR-STTR Dollars*
NM	269	1,429	517	$410,966,134	92	342	91	$98,407,761
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or over 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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SBIR/STTR

Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of New Mexico

High Tech Jobs (2006)	42,872
Estimated SBIR employment	7,650
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	17.88%

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SBIR/STTR

Patent Information on SBIR-STTR Awardees in the State of New Mexico

- Of the 5,893 SBIR-STTR firms having patents, 76 are from the State - 1.29%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	603
Percentage of SBIR-STTR Patents in the State	0.89%

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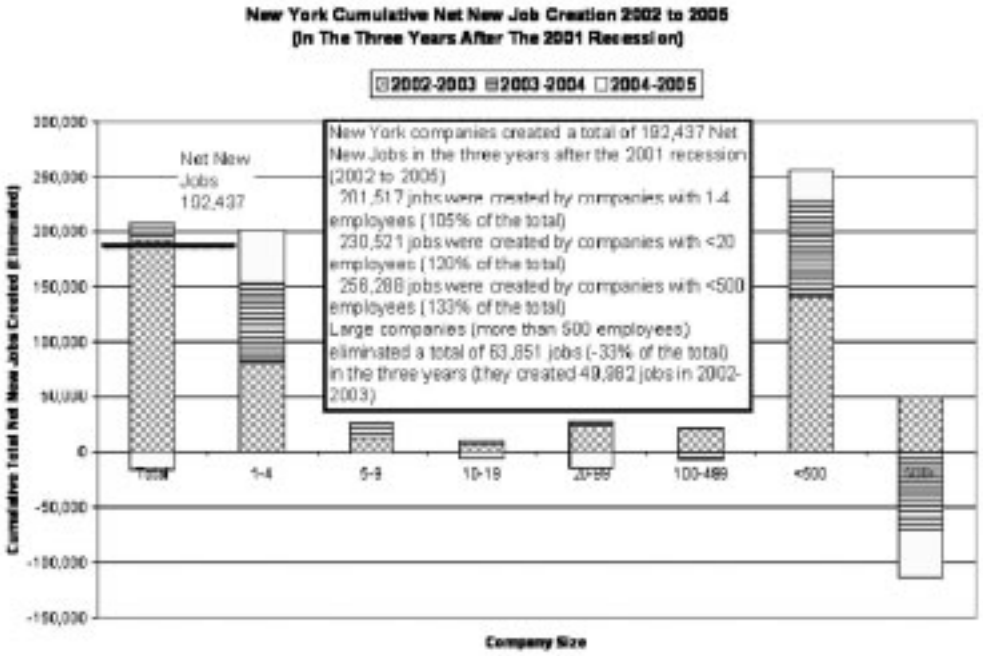
New York


New York Cumulative Net New Job Creation 2002 to 2005
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
Net New Jobs 102,437
New York companies created a total of 102,437 Net New Jobs in the three years after the 2001 recession (2002 to 2005)
201,517 jobs were created by companies with 1-4 employees (105% of the total)
230,521 jobs were created by companies with <20 employees (120% of the total)
256,288 jobs were created by companies with <500 employees (133% of the total)
Large companies (more than 500 employees) eliminated a total of 63,851 jobs (-33% of the total) in the three years (they created 49,982 jobs in 2002-2003)
300,000
250,000
200,000
150,000
100,000
50,000
0
-50,000
-100,000
-150,000
1-4
5-9
10-19
100-499
<500
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II	Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II*	Total SBIR-STTR Dollars*
NY	890	3,519	1,385	$1,209,357,487	334	1,024	345	$359,553,589
Totals for whole program	*18,073*	*61,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the award of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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SBIR-STTR.com

Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of New York

High Tech Jobs (2006)	299,921
Estimated SBIR employment	25,938
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	8.65%

Quantifying the value of SBIR

SBIR-STTR.com

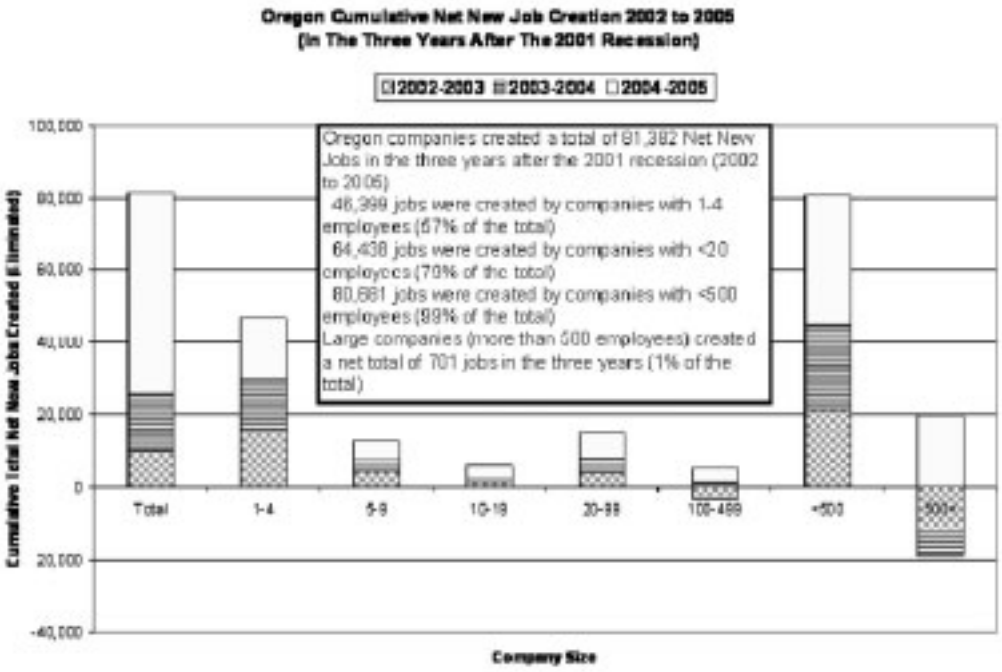
Patent Information on SBIR-STTR Awardees in the State of New York

- Of the 5,893 SBIR-STTR firms having patents, 293 are from the State - 4.97%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	3,431
Percentage of SBIR-STTR Patents in the State	5.06%

Quantifying the value of SBIR

Oregon


Oregon Cumulative Net New Job Creation 2002 to 2005
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
Oregon companies created a total of 81,382 Net New Jobs in the three years after the 2001 recession (2002 to 2005)
46,399 jobs were created by companies with 1-4 employees (57% of the total)
64,438 jobs were created by companies with <20 employees (79% of the total)
80,681 jobs were created by companies with <500 employees (99% of the total)
Large companies (more than 500 employees) created a net total of 701 jobs in the three years (1% of the total)
100,000
80,000
60,000
40,000
20,000
0
-20,000
-40,000
Cumulative Total Net New Jobs Created (Eliminated)
Total
1-4
5-9
10-19
20-99
100-499
<500
500+
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II	Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II*	Total SBIR-STTR Dollars*
OR	240	952	422	$354,994,290	95	256	81	$87,934,701
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of Oregon

High Tech Jobs (2006)	83,091
Estimated SBIR employment	9,537
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	11.48%

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Patent Information on SBIR-STTR Awardees in the State of Oregon

- Of the 5,893 SBIR-STTR firms having patents, 72 are from the State - 1.22%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	1,084
Percentage of SBIR-STTR Patents to the State	1.60%

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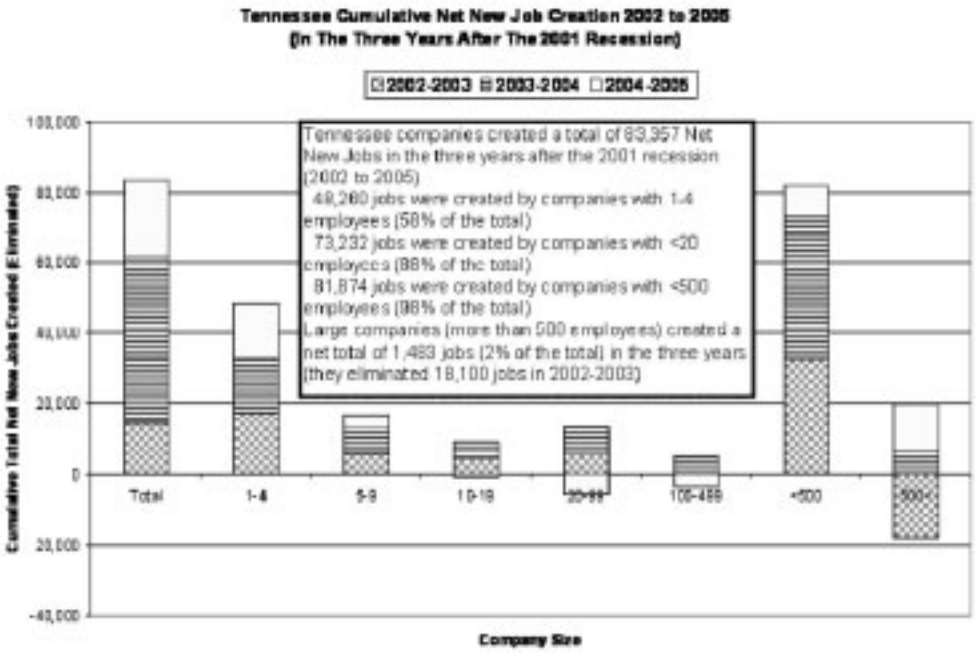
Tennessee


Tennessee Cumulative Net New Job Creation 2002 to 2005
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
Tennessee companies created a total of 83,357 Net New Jobs in the three years after the 2001 recession (2002 to 2005)
49,260 jobs were created by companies with 1-4 employees (58% of the total)
73,232 jobs were created by companies with <20 employees (88% of the total)
81,874 jobs were created by companies with <500 employees (98% of the total)
Large companies (more than 500 employees) created a net total of 1,483 jobs (2% of the total) in the three years (they eliminated 18,100 jobs in 2002-2003)
100,000
80,000
60,000
40,000
20,000
0
-20,000
-40,000
Cumulative Total Net New Jobs Created (Eliminated)
Total
1-4
5-9
10-19
20-99
100-499
+500
500+
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II	Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II*	Total SBIR-STTR Dollars*
TN	201	708	304	$215,150,316	70	139	58	$52,201,905
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and reported incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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SBIR/STTR innovation.com

Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of Tennessee

High Tech Jobs (2006)	63,089
Estimated SBIR employment	6,153
estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	9.75%

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SBIR/STTR innovation.com

Patent Information on SBIR-STTR Awardees in the State of Tennessee

- Of the 5,893 SBIR-STTR firms having patents, 58 are from the State - 0.98%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	275
Percentage of SBIR-STTR Patents to the State	0.41%

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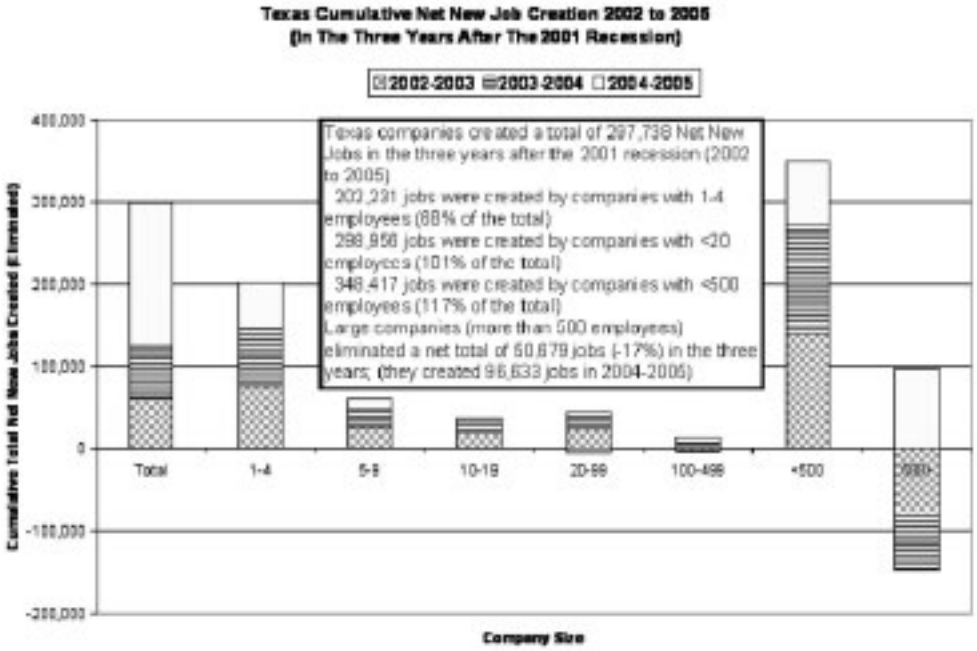
Texas


Texas Cumulative Net New Job Creation 2002 to 2005
(In The Three Years After The 2001 Recession)
2002-2003
2003-2004
2004-2005
Texas companies created a total of 297,738 Net New Jobs in the three years after the 2001 recession (2002 to 2005)
202,231 jobs were created by companies with 1-4 employees (68% of the total)
298,956 jobs were created by companies with <20 employees (101% of the total)
348,417 jobs were created by companies with <500 employees (117% of the total)
Large companies (more than 500 employees) eliminated a net total of 50,679 jobs (-17%) in the three years; (they created 96,633 jobs in 2004-2005)
400,000
300,000
200,000
100,000
0
-100,000
-200,000
Cumulative Total Net New Jobs Created (Eliminated)
Total
1-4
5-9
10-19
20-99
100-499
<500
500+
Company Size

SBIR-STTR Data by State of Member of House Science Sub-Committee: Technology and Innovation. Total Numbers of SBIR Awardees, Phase I-II and Total Dollars (April 2009)

State	Life of Program: 1983-present (to include FY 09 announcements so far made- April 2009)				Current SBIR-Activity: relevant data for the FIVE year period 2004-present			
	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II	Total SBIR-STTR Dollars	Total # Awardees	Total SBIR-STTR Awards Phase I	Total SBIR-STTR Awards Phase II*	Total SBIR-STTR Dollars*
TX	773	3,178	1,175	$1,107,069,558	284	1,033	336	$364,426,216
Totals for whole program	*18,073*	*81,139*	*31,416*	*$27,227,402,761*	*6,920*	*22,801*	*7,339*	*$7,683,661,597*

* There is a considerable time-lag between a Phase I and the onset of a Phase II. It is not unusual to see a Phase II begin 2,3,4 or even 5 years after the Phase I award. Similarly, especially in in NIH, Phase II award segments are awarded and repeated incrementally (usually annually). Consequently, one can properly assume that Phase totals and Phase II dollars on current projects will continue to increase, sometimes substantially.

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SBIR/STTR Innovation

Contribution of SBIR-STTR Involved Firms to High Tech Employment in State of Texas

High Tech Jobs (2006)	445,785
Estimated SBIR employment	24,432
Estimated percentage of High Tech Jobs in State Resident in SBIR involved firms	5.48%

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SBIR/STTR Innovation

Patent Information on SBIR-STTR Awardees in the State of Texas

- Of the 5,893 SBIR-STTR firms having patents, 223 are from the State - 3.78%

Patenting Activity in SBIR-STTR Program	
Total Number Patents program-wide	67,859
Total Patents in State	2,620
Percentage of SBIR-STTR Patents to the State	3.86%

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DISCUSSION

Chair WU. Thank you very much, Mr. Glover, and while I may not completely agree with all your substantive points, I sure do wish that I could talk like you. I have always wanted to have a southern accent. I have always wanted to be a western cowboy, but there are just some things that aren't going to happen in this life.

I do want to mention that I believe our Ranking Member needs to step away at 3:15, and we have agreement that the hearing may continue in the absence of any Republican Members. And we look forward to Mr. Smith joining us, and I just want to reiterate that Ms. Edwards will be stepping in for me momentarily, and I aspire to return to continue some of the discussion.

Now it is appropriate for us to open to questions, and the Chair recognizes himself for five minutes.

Mr. Glover makes a point in both his oral and his written testimony for a five percent set-aside, and I am sympathetic to some set-aside increase, but I would like to get the views of Dr. Berdahl, even though you have stated your preference, and Mr. Greenwood and Dr. Rockey.

First of all, Dr. Berdahl, when you said that you would like the program to stay the same, I assume you mean that you want the set-aside to stay the same and that you are not stating that you want every aspect of the program to stay the same.

Dr. BERDAHL. That is correct.

Chair WU. Microphone, please.

Dr. BERDAHL. We favor the current set-aside provision. We also favor greater flexibility in the agencies' ability to apply as many of my colleagues here at the table have also recommended, but we believe that the current set-aside is sufficient and that in many instances clearly adequate.

Chair WU. Thank you very much, Dr. Berdahl.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chair. Obviously it would be in the interest of our company if we had a larger share of the NIH pool available to us, and I would like to see that day arrive.

Having said that, I served in the Congress when we doubled the NIH budget. It was a good and noble thing that we did. I think many of us failed to understand why providing level funding, at best, after that was a mistake. We sort of took the attitude that, you know, doubling—nobody gets their budget doubled, so, you know, stop complaining about lack of growth.

So as—but it was a mistake, and we really need—we need to continue to grow the NIH budget at a reasonable, at least inflationary factor annually. I would presume that an effort to get much beyond where we are now would meet resistance from my friend to my right and his colleagues and perhaps such——

Chair WU. And perhaps the friend on your left also.

Mr. GREENWOOD. Perhaps. But so perhaps if and when the time comes that the Congress can see fit to significantly increase the size of the pie, that would probably be the best time to discuss changing the ratio of the slices.

Chair WU. May I take your answer to mean in an ideal world, yes.

Mr. GREENWOOD. Yes.

Chair WU. Thank you, Mr. Greenwood.

Dr. Rockey, please.

Dr. ROCKEY. NIH would favor keeping the set-aside at the current 2.8 percent level.

Chair WU. Combined for both?

Dr. ROCKEY. Combined for both. We would find it sufficient to meet our current mission. And as Mr. Greenwood had just mentioned, we have appreciated that as the NIH budget had grown and doubled essentially through—from 1998, to 2003, we were able to also sustain a doubling in the SBIR Program as well. So we feel that that level is appropriate just to meet the mission of NIH and to support innovation in the small business community.

Chair WU. Terrific. Thank you very much, Dr. Rockey, and I just want to say that I think everyone that I can think of in this institution is a fan of NIH and for good reason. It is because you all do really, really good work. I am also happy to hear that you do support a 2.5 percent set-aside for SBIR and a 0.3 set-aside for STTR.

So that leads to my next question. In the American Recovery Act, ARRA, better known as the stimulus bill, the additional billions that NIH is to receive were specifically exempted from the SBIR requirement.

Do you know if anyone from NIH asked for that exemption?

Dr. ROCKEY. Well, I can tell you that I had concerns. At the time that the ARRA or the *American Recovery and Reinvestment Act* was being discussed, I had concerns regarding the ability to have enough SBIR/STTR applications in the pool. Originally when we were discussing ARRA, the methodology that NIH was going to use to use the ARRA funds was to take existing applications, both in the SBIR Program and all of our programs, and to fund those to get those funds out the door immediately.

Because of the decreasing numbers of SBIR applications and the increasing success rate, the applications that we would have had at hand were the 2008 applications, and we simply would not have had enough applications to meet the——

Chair WU. Well, let us return to the question. Did you or anyone else at NIH ask for that exemption?

Dr. ROCKEY. I raised concerns. Yes.

Chair WU. You raised that concern with Congress?

Dr. ROCKEY. No, I did not.

Chair WU. Did someone from NIH raise that concern with Congress?

Dr. ROCKEY. I can't tell you exactly how the process was. The negotiation with——

Chair WU. Someone did.

Dr. ROCKEY.—Congress. Congress has indicated that they asked questions of if there were any concerns with the entire——

Chair WU. Someone at NIH volunteered that?

Dr. ROCKEY. Yes. I expressed my concerns. How the process—I can get back to you for the record of how the process——

Chair WU. Yes. I would be very interested in hearing that for the record.

Dr. ROCKEY. Sure.

Chair WU. I have a letter for the record from two Senators, Mary Landrieu and Olympia Snowe, and it is answered by a letter from Acting Director Kington?

Dr. ROCKEY. Yes.

[The information follow:]

United States Senate

COMMITTEE ON SMALL BUSINESS & ENTREPRENEURSHIP
WASHINGTON, DC 20510-6350

March 10, 2009

VIA FACSIMILE & FIRST-CLASS MAIL

Mr. Charles E. Johnson
Acting Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

RE: Department of Health and Human Services' Small Business Innovation Research and Small Business Technology Transfer Programs

Dear Acting Secretary Johnson:

We are writing in regard to the recently enacted American Recovery and Reinvestment Act of 2009 (P.L. 111-5) and its impact on small business firms and our nation's high-tech industry. As you know, the Recovery Act provides $8.2 billion in additional funding for the National Institutes of Health (NIH) to support scientific research and development and, at NIH's request, exempts the allocations associated with such research from the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. As Chair and Ranking Member of the Senate Committee on Small Business and Entrepreneurship, we are concerned about the detrimental effects on small technology businesses that help our nation stimulate innovation and create jobs.

As you may know, the SBIR and STTR programs allow small research and development firms – our nation's innovation lifeline – to create high-quality jobs and cutting-edge products and therefore are fundamental to our country's economic recovery. Consequently, it is of great concern to us that the NIH maximize the benefits of the Recovery funding and provide not less than the statutory percentages of the Department's extramural research and development funding to the SBIR and STTR programs.

During the past two Congresses, the NIH has objected to increasing the SBIR and STTR allocations of 2.5 and 0.3 percent on the grounds that more research funding for the department would automatically be an increase for small business funding because such firms would get a percentage of the increase. The passage of the Recovery Act, with its exemption for the small business requirement, undermines this argument and raises questions about the NIH's and the Department of Health and Human Services' (HHS) commitment to small, high-tech firms and the success of the SBIR and STTR programs.

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While the $8.2 billion allocated through Title VIII of the Recovery Act is relieved from specifically funding SBIR and STTR projects, the Act does not exempt the HHS from its continued statutory obligation of allocating a minimum of 2.5 percent and 0.3 percent, respectively, of its total extramural budget for research and development for SBIR and STTR projects. Specifically, of the $8.2 billion allocated to the NIH for extramural research and development, an equivalent amount of 2.8 percent must be allocated for small businesses from this $8.2 billion or from other HHS extramural research and development funds. At stake is as much as $229 million.

A similar situation occurred in 2001 when a provision enacted as part of the Fiscal Year 2002 Department of Defense (DoD) appropriations bill exempted certain Missile Defense Agency (MDA) funds from the SBIR program. The provision would have reduced by about half the amount of research dollars awarded to small business. Ultimately, DoD verified to the Committee that it would indeed meet the 2.5 percent statutory requirement, either compensating from other agencies within the Department or from the MDA.

In order to clarify how HHS will meet the required amount of overall research dollars awarded to small businesses and to ensure that the Department complies with the Small Business Act, we respectfully request an analysis of where HHS will make up the difference in its extramural research and development budget equivalent to 2.8 percent of the relevant $8.2 billion provided in the Recovery Act for extramural research and development. We also ask that you explain to us how much of the $8.2 billion will be dedicated to extramural research and development. We would appreciate a response, in writing, by the close of business on Tuesday, March 24, 2009.

In moving forward, we respectfully request that HHS specifically consult us when making legislative recommendations that affect these programs that are squarely within our Committee's jurisdiction.

Thank you for working with us on this important small business issue. If you have any questions or need any additional information, please do not hesitate to have your staff contact Ms. Kevin Wheeler (Senator Landrieu) or Mr. Erik Neeciai (Senator Snowe), at 202-224-5175.

Sincerely,

Mary L. Landrieu
Chair

Olympia J. Snowe
Ranking Member

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

APR 01 2009

The Honorable Olympia J. Snowe
Ranking Member, Committee on Small Business &
Entrepreneurship
United States Senate
Washington, D.C. 20510

Dear Senator Snowe:

Thank you for your letter of March 10, 2009, to Acting Secretary of Health and Human Services Charles E. Johnson requesting information about how the National Institutes of Health (NIH) will meet the requirements of the Small Business Act, particularly in reference to the American Recovery and Reinvestment Act (ARRA).

The NIH is grateful to the President and Congress for recognizing the role of research in stimulating the economy, and in particular, for providing $8.2 billion in extramural funding that will facilitate the NIH's efforts to advance biomedical science and create public health benefits. The NIH remains fully committed to supporting small businesses through the SBIR/STTR program, as well as through several other NIH funding opportunities supported by ARRA to which small businesses may apply.

Please be assured that NIH will continue with its well-established SBIR/STTR program to fulfill its mandate to use 2.5 percent and 0.3 percent, respectively, of its FY 2009 appropriated extramural research and development funds to support SBIR and STTR projects. Although the number of applications for the program has dropped significantly over the years (about 40 percent since FY 2004) resulting in a climbing success rate, we expect to have sufficient high-quality applications to expend these funds appropriately.

In addition to applying for funding through the SBIR/STTR program, small businesses are also eligible to apply for NIH funding through grant opportunities supported by ARRA that our agency has already announced. For these reasons, we expect that in FY 2009, more NIH funds will be directed towards small businesses than in prior years.

For example, the NIH encourages small businesses to apply for funding through the recently announced Challenge Grant opportunity (http://grants.nih.gov/grants/funding/challenge_award/), which is supported by funds provided to the NIH under ARRA. Another program supported by ARRA funds to which small businesses may apply is the newly established Research and Research Infrastructure "Grand Opportunities," or "GO" grants, which are for applicants proposing to develop and implement critical research innovations to advance the research enterprise, stimulate future

Page 2 – The Honorable Olympia J. Snowe

growth and investments, and advance public health and health care delivery. Since small businesses are anticipated to compete for these new programs, the NIH intends to have appropriate representation from the SBIR/STTR community on the scientific review groups.

In an effort to accelerate the tempo of ongoing science through targeted funding to current grants, the NIH has also announced administrative supplements and competitive revision (formerly known as "competitive supplements") funding opportunities under which small businesses may apply. In fact, the NIH Institutes/Centers intend to support SBIR/STTR administrative supplements and competitive revisions and to continue to support recently peer-reviewed, meritorious SBIR and STTR applications from FYs 2008 and 2009 that were approved but not funded, if these applications meet the program needs and scientific priorities of the individual Institute or Center.

Again, thank you for the opportunity to make science and health research part of the recovery process and for your interest in the NIH. This response will also be sent to Senator Landrieu.

Sincerely yours,

Raynard S. Kington, M.D., Ph.D.
Acting Director

Chair WU. And in it the Acting Director commits to leaving the 2.8 percent set-aside for SBIR and STTR, that NIH intends to adhere to that, and I take it that you agree with the Director's answer in that letter.

Dr. ROCKEY. Yes. That letter he agreed to the 2.8 percent out of our appropriation. We are also—NIH is also using ARRA funds to support SBIR applications.

Chair WU. ARRA is an appropriation.

Dr. ROCKEY. I understand that.

Chair WU. Yes.

Dr. ROCKEY. So——

Chair WU. So we are in agreement on that.

Dr. ROCKEY. Two point eight percent of our $30 billion appropriation. Yes.

Chair WU. But 2.8 percent of also the ARRA funds.

Dr. ROCKEY. Those funds according to the legislation were not subject to the set-aside.

Chair WU. But take the letter as a voluntary commitment to maintain the 2.8 percent set-aside.

Dr. ROCKEY. Again, I guess it is in the interpretation of the letter. I would not interpret the letter to say that. I believe what he is saying is that he was——

Chair WU. Then can we have a resolution of that——

Dr. ROCKEY. Sure. Sure.

Chair WU.—disagreement perhaps with the NIH staff and with the Senate Small Business Committee and the House——

Dr. ROCKEY. Sure.

Chair WU.—Small Business Committee?

Dr. ROCKEY. Uh-huh.

Chair WU. Deeply appreciate that.

Dr. ROCKEY. I appreciate that.

Chair WU. Thank you for going over a little bit with me.

Dr. ROCKEY. Can I——

Chair WU. Mr. Greenwood, do you have a further point to make?

Mr. GREENWOOD. If I may, Mr. Chair. I have spoken with both Senator Specter and his staff on this and we all know, Senator Specter was instrumental in this, and my understanding is that the language, while it may not require the NIH to set aside 2.8 percent, nor does it prohibit them from setting aside up to——

Chair WU. That is——

Mr. GREENWOOD.—that——

Chair WU.—my interpretation of the statutory language also. It is a pretty clearly crafted carve out. Things like that don't happen by accident, but it does seem quite permissive.

With that I would like to recognize the Ranking Member for five minutes.

Ms. BIGGERT. Thank you, Mr. Chair, and thank you to all the witnesses for your testimony.

I have Argonne National Lab in my district, and I have a lot of spin-off companies. And what happens so many times is that they have a product that they are working on, and they get through the original, the first couple of steps until they get to, you know, they get through the demonstration project. And then they want to get to the commercialization, and so they might have gotten the loans and whatever, and then they come to me to see what we can do to help them with that further step. They can build the small demonstration project, but to go to that full step, and obviously this is something that either venture capital funding is necessary or they want an earmark, which obviously is a lot of money, which makes that kind of out of the question.

But what—and you don't want to expand the program. What can we do for that "Valley of Death" that can bridge the gap there? Is there any—there was some talk about gap funding or whatever. Is there—Dr. Rockey.

Dr. ROCKEY. Sure. Again, we have a number of programs or, excuse me, we fund a fast track program that allows Phase I and

Phase II. We also give a renewal of the Phase II, which in part addresses this issue, although it only gets you a small way to funding the gap, and that is why I believe that the NRC's report which discusses the importance of venture capital, is significant in this case, particularly for biomedical research projects that may be very long term, very expansive, take a long time between the—for the clinical portion of it. And so we recognize that this is a serious issue and would like to look at ways to provide some flexibility for that more extensive research and development that needs to be going on.

Ms. BIGGERT. Do you see also with this economic situation that we are in that the venture capitalists aren't as—don't have the ability to fund, too? Are there some projects that you see that are going, you know, that are not going to go through because they don't have that?

Dr. ROCKEY. I think that is a possibility. I think what you may be seeing is venture capitalists are not taking on new ventures, and they are digging into the current investments that they have made, and thus, if we had a way also to allow them to also take on new venture as well, I think that would be very beneficial to the whole small business community.

Ms. BIGGERT. Dr. Berdahl, why do you think that this was put in with the affiliation, if a venture capitalist company that have to include those members of the venture capital as well as any other business that they are involved in counting the number of employees?

Dr. BERDAHL. Why was it put in——

Ms. BIGGERT. Yeah.

Dr. BERDAHL.—in the initial legislation do you mean?

Ms. BIGGERT. Why, which really, I think, causes a lot of these companies not to be able to get the funding as well as venture capital.

Dr. BERDAHL. I think that obviously the availability of venture capital is harder to come by in the current climate. It is more difficult for young scientists or investigators who have developed something that has commercial value to be able to move to the proof of concept and scaling-up phase of this and the modeling that is required to assure a venture capitalist that it has commercial value and potential commercial success. And although the current SBIR Program partially recognizes this issue, it often falls short of being able to reach the level of development necessary to assure investors that a product has commercial viability. And so I think that we should be thinking very hard about how we can push these new technologies over this "Valley of Death" or across the gap, however anyone wants to describe it.

And that certainly, I think, is in the interest of the Nation and in the interest of the scientists developing these products. We would welcome the opportunity to think with the Committee about and explore ways in which it might enable our universities, which also are pretty hard hit by this economy and don't have the resources in many cases to assist or the ability to assist in driving this—these developments over this gap.

So there should be, I hope, some way in which we can extend the horizon for development of research advances and new technologies.

Ms. BIGGERT. Do you think that—just to remove the counting of the people that are——

Dr. BERDAHL. I think that is a very important first step. Absolutely.

Ms. BIGGERT. Is there—what would you do further then?

Dr. BERDAHL. Well, possibly an additional program of some sort. I don't favor increasing the set-aside as a means of doing that because I am not sure that we have an indication that there are——

Ms. BIGGERT. Yeah.

Dr. BERDAHL.—enough——

Ms. BIGGERT. Thank you.

Dr. BERDAHL.—able applicants.

Ms. BIGGERT. Mr. Greenwood, what—would you think that that would solve the problem, just not to count the employees or the venture capitalists or their affiliates?

Mr. GREENWOOD. I think that is part of the solution, and I think it would reflect the original intent of the Congress. I think that those affiliation rules really were interpretations made by the bureaucracy at SBA and doesn't reflect—it reflects neither the original Congressional intent nor I would think current Congressional intent.

But certainly changing the rules with regard to the majority-backed VCs is critical. Companies who are doing important biomedical research that will have huge potential to release, relieve human suffering and premature death face the "Valley of Death" whether they are or are not backed by a 50 percent plus venture capital dollars.

And keep in mind that what is important here is that these companies, if you are a drug discovery company, you cannot get very far down the road without VC funds, and what we are talking about there is very rare that one venture capital firm comes in and provides more than half of the funds for one of these companies. It is usually the case that several of them in the aggregate do. So maybe this one is providing ten percent and this one is providing ten percent and so forth.

And none of that alters either the fact that these are still small companies and B, that they are making, as judged by the NIH reviewers, they are making important contributions to research that has great potential for humanity.

Ms. BIGGERT. Thank you. Yield back.

Ms. EDWARDS. [Presiding] Thank you, and thank you to the witnesses.

I want to explore if we could for a bit the implementation of the SBIR Program, because it seems to me that obviously we have one agency in front of us, a big one to be sure, but there are wide variances in the implementation across the agencies of the program, and I understand your testimony with regard to flexibility and nimbleness across the agencies.

But it makes it really tough to gage from one agency to the next whether there is consistency in terms of the implementation of the program and whether we are getting to the targeted need.

And so I wonder if you would comment about the possibility or explore the possibility of some way that we can aggregate data, that we have some way across agencies of analyzing the effective-

ness, the relative effectiveness. I mean, if NIH is doing it in the right way that it makes sense for that agency, what is the cross fertilization with other agencies?

Dr. ROCKEY. So we have, of course, we have a number of ways as you mentioned, Congresswomen Edwards, regarding and analyzing our own data and also through the SBA we have some data available but at least will give you information on firms, and we can do some analysis.

I think the issue about how the SBIR Program is implemented in each agency is an important one, and it becomes particularly important in your reauthorization, because I think it is good to look at best practices and what has worked well for each agency. I will say that the sectors that are being supported by each agency are quite different, and thus ultimately the flexibility that is allowed does help promote the particular type of program that is necessary to support that kind of sector. For example, the biomedical field that NIH would be working with as opposed to some of the more—in the physical sciences there are other small businesses that might be, for example, DOE [Department of Energy] or DOD [Department of Defense].

So I think it is important not only to understand those flexibilities but understand best practices and their relationships to how the programs are managed for the particular sectors.

Ms. EDWARDS. Mr. Glover.

Mr. GLOVER. We have the National Academy of Sciences five-year study that went into this at some length, and it did a very good job of analyzing what the agencies are doing. The conclusions were that the program is remarkable, that it is working very good. This is a data-driven, well-analyzed study. A lot of information is there.

There is flexibility within the programs. A couple of basic things that are important to realize is it has the most remarkable rate of success of any of the federal R&D programs. Approximately half of the technologies make it to the marketplace in some shape or form or fashion, and that is quite successful. NIH just mentioned you are close to 50 percent. The Department of Defense is close to 50 percent. The other agencies are not quite that good but are still in there. So the program is quite good. That is why I say we have to be very careful on how we change it.

Allowing large-size awards, much bigger awards, for example, NIH talks about the number of applicants have dropped. Well, quite frankly, the number of awards dropped, too. Which one came first? Chicken? Egg? I don't know, but they both went down together. So we have to be careful that we don't crowd out good innovations by giving a few large or super, jumbo awards or multiple awards that crowds out a lot of other technologies that may be coming along.

The SBIR Program was designed to fill the earliest stage. One of the things I looked at for each of the states represented on this committee is whether seed and angel financings to your states were bigger than SBIR awards. That answer is they are not. That early stage, the really—the only source of money is SBIR, and that is why I think you have got to be careful about watching what you are doing. It is working remarkably well across all the agencies.

Ms. EDWARDS. But let me just ask this because it gets to the question, I think that there was some suggestion that the changes that essentially screened out the venture capital based programs, backed programs contributed to the decline. I don't know what analytical data we have that suggests that is true, but if we do have it, I would be interested in seeing it.

And what I wonder, the current economic environment that Ms. Biggert talked about, I think, you know, one could make an analysis that perhaps that has contributed as well to the decline in applications. And I come out of doing private sector, non-profit, grant making, and I always know that you always get many more applicants than you can ever fund. At the same time there is always a percentage of those that are just not worth funding at all no matter how much money you ever had.

But my experience is then there is always, you know, a sector of them, maybe even it is above the 2.8 percent that you go, you know, if we just had some more, we actually might want to do that. And so I question, you know, what seems like a really, at least for most of you, a very sort of clear indication that there is no need to increase the set-aside, and then we have testimony from Mr. Glover that, you know, four or five percent set-aside, and I am not even sure why five percent and why not 2.9 percent or three percent, and so there must be, you know, some room in there both from the agency and small business standpoint but also, you know, looking at the percent of set-aside numbers, it says, well, maybe there is at least some room for movement on the set-aside.

Mr. Greenwood or Dr. Rockey.

Mr. GREENWOOD. The first thing I would say is that—and first reflecting on your comment that you get a certain number of applications and not all of them are the best, you know, almost by definition, but if you think about what we are trying to accomplish here in the big picture it is all about advancing the mission of the National Institutes, in terms of our industry, advancing the mission of the National Institutes of Health and making sure that the particular alacrity, the particular level of entrepreneurship and risk taking that small companies can take and be involved in because they don't have large overhead, they don't have large bureaucracies, that those skills are applied to the search for treatments for diseases.

And the best way to make that happen, I think, and to get the greatest number of very qualified applications is to expand the application pool back to just what it was prior to 2004, and that is to re-allow these venture backed companies to participate. You will undoubtedly get a significant number of very qualified applications, making the process more competitive and making—and that competition I am sure will inspire excellence.

Ms. EDWARDS. Thank you, and I will turn the chair back over to Chair Wu.

Chair WU. I thank all the Members and the witnesses for keeping a lively discussion going while I had to step away for another commitment just momentarily. If I rework any territory that has already been explored or thoroughly explored, please apprise me, and we will move on.

I came back in during this discussion of the set-aside, and I very much understand and appreciate that this is a delicate balance, and it is a difficult balance. One can pick 1.0 percent, 2.0 percent, 2.5 percent, 3.5 percent, five percent, and it is basically a value judgment about the appropriate role of tech transfer and tech development versus fundamental research. There is no getting away from that. But that is the line drawing that this institution engages in on a continual basis.

Mr. Glover, I emphatically want to help small business in this endeavor, and it is an effort to help small business that we looked at increasing the set-aside so that although the total amount of funds is going up because of increased research funds, we wanted to grow the pie for everybody so that no one would be left out, as we try to get more people in, applicants in, and at the same time increase the size of grants.

So I am very sensitive to your concerns. I just note that there is some significant resistance to changing set-asides, and I think I understand those concerns also.

Dr. Rockey, there was, what, approximately a 40 percent drop in applications to NIH starting in 2004, and that is roughly correlated with the date of the ALJ [Administrative Law Judge] decision banning venture capital investment, which came down in 2003. Is that correct?

Dr. ROCKEY. That is correct.

Chair WU. Now, we want to work out something that helps this program remain an innovation as well as a small business program, and it is in that spirit, Mr. Glover, that I am asking you to the extent that, you know, would you say that a substantial percentage, perhaps even a majority, of your paying membership, if you have paying membership, are in the defense industry or funded through DOD SBIR funds?

Mr. GLOVER. They are not. Our current chairman has a significant number of NIH awards and is one of the top NIH award——

Chair WU. Right. But that is——

Mr. GLOVER. Many of the other ones, many of the other companies are as well.

Chair WU. Well——

Mr. GLOVER. We are across the whole spectrum.

Chair WU.—Mr. Glover, in looking at some of the data it seems to me that the organizations that you have brought in, when I have dug underneath, every single one of them was on the DOD SBIR.

Mr. GLOVER. Mr. Chair, very few—we have only had one witness appear before this committee from the Small Business Technology Council.

Chair WU. Oh, I mean folks who came to my office.

Mr. GLOVER. Oh. I am not sure who all has come to your office but——

Chair WU. Uh-huh.

Mr. GLOVER.—they are certainly—half of the program is DOD, and so—and many companies that are in other areas are also in DOD.

Chair WU. Well, you know——

Mr. GLOVER. So——

Chair WU.—Mr. Glover, I am asking this as a friendly question.

Mr. GLOVER. I understand that.

Chair WU. And I am trying to find some basis which hopefully gets us away from capital structure as a proxy for either domestic ownership or as a proxy for the character of small business, because I think 500 employees is quite crisp on that front.

It seems to me that a lot of Mr. Greenwood's issues have to do with biotechnology, and there are also software and hardware companies that burn a lot of cash. But if it is the case that DOD uses SBIR in a fundamentally different way as an adjunct to its research, as a spur to innovation by the large defense contractors, then perhaps what we can do if we can't get away with an intellectually pure solution of getting away from capital structure as a proxy for size, at least taking a substantive approach of perhaps exempting DOD from the new statute. And that is the avenue that I am trying to explore with you as an alternative, which may be even more palatable to your membership than the generous concessions which we made in negotiation of the last Congress to take into consideration the very real concerns that your membership has.

Mr. GLOVER. It certainly solves the problem for approximately half of our members. Those members who are in the health sciences and the biotech, there are a lot of very good, important small biotech companies who are working very hard to survive. The only source of funding——

Chair WU. Do any of those small biotech companies not have venture capital investment?

Mr. GLOVER. Absolutely. Many of them do not have venture capital, and they are successful.

Chair WU. And would you characterize those companies currently?

Mr. GLOVER. Well, some are here today. The Maryland, State of Maryland has a wonderful program for angel investors that is making some of our biotech companies in Maryland grow very nicely. You got a 50 percent tax credit for investing in those companies. They have gone to that source. They have been able to raise angel capital to move their companies. There are many successful biotech companies that don't get——

Chair WU. Earlier, Mr. Glover, you said that the HHS SBIR budget would be insufficient to commercialize one pharmaceutical. Are you saying now that these small biotechs can make it on angel investment alone?

Mr. GLOVER. Many have so far.

Chair WU. Then——

Mr. GLOVER. But I am talking, but now when you talk about——

Chair WU. Are you taking back what you said about HHS and its SBIR Program?

Mr. GLOVER. No, sir. There is a very clear distinction. Mr. Greenwood has said many times that it takes $800 million to take one drug through the FDA approval process. There are an awful lot of technologies that don't have to go through that $800 million process. But those that have to go through that process, you couldn't use the whole HHS budget to take one drug through that process.

Chair WU. Mr. Greenwood, I am going to give you an opportunity to respond to this conversation.

Mr. GLOVER. Mr. Chair, I do want to respond to one thing you said earlier about believing the information and data that I provided. I did footnote virtually everything I said so that you can at a time take a chance to look at that. We are very careful about that.

Chair WU. I read your submissions to the Subcommittee with great interest and in detail.

Mr. GLOVER. Thank you, sir, and I—but I did footnote as much as I could because quite frankly that kind of information is shocking to the innovation community.

Chair WU. Thank you very much, Mr. Glover. Mr. Greenwood, would you care to respond.

Mr. GREENWOOD. I would. Thank you, Mr. Chair.

This is a bit of a mystery to me because I think to some extent Mr. Glover's membership and mine are, they are not entirely mutually exclusive, but they seem to be fairly different. The companies in BIO, the companies that I am here to represent, are fundamentally drug discovery companies. They are companies that patented molecules. To some extent they are platform companies, but for the most part they are moving forward trying to get drugs into clinical trials and into the FDA approval process, and that, of course, is a challenge that takes hundreds of millions of dollars. And you cannot get very far down that path without having to rely on venture capital investment. In fact, without having to rely on a majority of your funds coming from venture capital.

So companies that can do well year after year on SBIR grants are not companies that have as their core competency drug discovery and development. I am not frankly quite sure what these companies are doing. I am not suggesting that it is not valuable. Sometimes I wonder if the core competency is succeeding in getting SBIR grants, but they are certainly not companies that are moving down the path towards drug discovery, which is largely what the NIH is trying to accomplish.

Chair WU. Thank you, Mr. Greenwood.

I just want to return for a moment to what are very legitimate concerns of the different parties to this discussion. Mr. Greenwood was addressing small biotechs which I think share some characteristics with software and hardware startups. Frequently they are VC funded. They are looking to hockey puck growth where hopefully if they succeed they will lock it up in size and employment and revenues and the VC investor fundamentally wants his or her money back times 60 if possible.

What I was trying to encourage Mr. Glover to think about and this I only learned recently, that there has been an unfortunate bitterness between the different sides of this debate, and I am familiar with high-tech startups. I was unfamiliar until very recently with an entire industry, which is very, very important, which is primarily concentrated in defense, which does have repeat SBIR grants but for good policy reasons. Frequently there are only a few large defense contractors left in a given field, and not only, as Mr. Glover covered, the small entrepreneur companies have weight for weight more research going on. And the small companies not only innovate new products and in essence by getting contracts repeatedly from the DOD, are forming the backbone of some very impor-

tant research for DOD, but by being small entrepreneur companies, they also spur the big companies because DOD is able to come to the big contractors and say, look. Those guys came up with better body amour. Why can't you?

Now, that is a very legitimate use of repeat SBIR grants. I think I would like to carve something out so that we can all live with this, so that we don't have to live with what in my view is not only a very crude but an erroneous ALJ decision that was made by one person in Boston, ironically, but it has excluded the majority of VC-owned companies or companies that in the aggregate have many minority VC owners but in the aggregate have majority of VC ownership. And the aggregation rules also are a problem for these companies, and as Dr. Rockey points out, there is a problem with a drop off in applications to NIH, and we can't all count on positive outcomes or cures from these many companies, but I believe that they are very, very important, and we should have a crafted balance to bring that process back into harmony.

Mr. Glover, I want to give you another opportunity to talk about the relative weights of your membership versus Mr. Greenwood's.

Mr. GLOVER. Quite frankly, we do have members who are involved in both organizations. Some of our members cannot afford to be in Mr. Greenwood's organization. They simply can't afford the dues, but they share many of the common characteristics and traits.

There is a lot of overlap between the two organizations. I think we feed to his organizations, that as our folks get bigger and grow, they probably do end up in his organization. There are many parts of NIH that are not related to drug development, and I think that you have to be a little careful in that. We are looking at an $800 billion solution to a problem that SBIR is not designed to fix. There is no way that this program is big enough to fund drug approval process through the FDA.

But I think that there is probably some way to shape a compromise that goes along that way, but we have to keep a whole variety of biotech companies that have succeeded and been effective in the program, and we can't allow a few large giant companies with large awards or giant money, lots of money, not giant companies but with lots of backing, to crowd out all the other companies. And what we have seen is NIH—some large awards have, in effect, crowded out the number of awards that could be given.

If you, for example, give a $10 million award, then you have foreclosed a lot of other companies that could have competed. So there is a balance here, and I have to tell you that my membership is far more concerned about competing with well-funded venture capital companies than I was when I first got involved in this process. They are genuinely concerned about the process.

Remember, the company that started this at SBA [Small Business Administration], that decision was the Administrative Law Judge who looked at it and said, AIG's Swiss venture capital company and a Canadian venture capital company owned that company, we don't want money to go to that company. That is what it was. It was not local U.S. venture capital companies. It was AIG, a Swiss company, and a Canadian venture capital company, and he

looked at it and said, this program is designed to help American businesses. No.

Chair WU. Well, Mr. Glover, I see that you have spent some time in this organization and on this Hill. But I recommend to you two things. The next time you want to engage in Canadian bashing, think first about their actions in saving our folks in the Toronto Embassy and the longest undefended border between any two countries the world has ever seen. Secondly, I think that a few organizations get away with no, no, never, never, we are not going to bend one inch. For whatever reason the NRA comes to mind, although I am a loyal firearm owner, but most organizations can't get away with that, and I am glad to hear, Mr. Glover, that your organization is willing to bend and reach reasonable compromises which take care of the legitimate interests of your membership and all the other folks out there as well as the technologic needs and employment needs of this country.

We will return momentarily, but I thank Mr. Luján, the gentleman from New Mexico, for his forbearance, but I might add that we have kept the discussion alive, so Mr. Luján could be next in asking his questions. The gentleman from New Mexico is recognized for five minutes.

Mr. LUJÁN. Mr. Chair, thank you very much, and I won't take long. I think that this is a great conversation, Mr. Chair, and both with what Ms. Edwards and yourself have been able to move forward, and I need to get some answers today as we get some more discussion on those items would be great.

Dr. Rockey, why do you think the number of applicants has dropped?

Dr. ROCKEY. It has been almost like the perfect storm. We really don't understand the entirety of why the applications have dropped. We have mentioned the question about eligibility with the venture capital companies as being perhaps a component. We also had mentioned about the complexity of determining eligibility and whether or not a company is eligible.

There are a number of companies because of the linear fashion of this program which is a Phase I and Phase II, perhaps their model does not fit within the SBIR Phase I and Phase II approach.

And in addition there are just some companies I think feel overwhelmed by the entire process of applying for SBIR grants. So there is a number of things that go on. I can't say that we understand it exactly. I think Chair Wu had pointed out or Congresswoman Edwards about the complexity of this issue, and really if we had any actual data that would support our understanding, we really don't. There are a number of things that have come together, and we really would have to tease out all of those different aspects to be able to understand it.

Mr. LUJÁN. Anything specific with venture capital participation?

Dr. ROCKEY. Well, as we said, the ruling at the same time we saw a drop in applications, whether or not there is a direct correlation we can't say, but we did see that drop.

Mr. LUJÁN. Okay, and Mr. Glover, along the questioning I think that the Chair was pursuing, isn't it true that a small business can be disqualified where multiple venture firms each have a minority stake, but in the aggregate own a majority of the company share?

Mr. GLOVER. That is the current situation.

Mr. LUJÁN. And isn't it true that many small companies in this situation have been excluded from the SBIR Program since the reinterpretation, since '03?

Mr. GLOVER. We looked at some years later—the NIH gave us an analysis, and they said that I think after the first two or three years they looked at it. Only 50 companies had been excluded. A number of those were foreign-owned companies, a number of those had grown beyond 500 employees, and that it turned out to be very few actually had been excluded based on the analysis NIH did at the time. Clearly there are companies that have been excluded. I am not saying they are not. I don't think there is a huge number of them, but I think there certainly have been companies excluded.

Mr. LUJÁN. Okay, and Mr. Glover, you also stated that Congress should renew SBIR without major design changes. Are there any changes in your opinion that should be considered or that would increase the effectiveness of these programs?

Mr. GLOVER. Certainly we have suggested that the award size needs to go up. It hasn't gone up. SBA has proposed raising it. It certainly should be raised for inflation, and we think that there are some additional suggestions.

For example, there needs to be some additional commercialization, and I think everybody recognizes we need to find some way to move the technology readiness level from where it comes out of the SBIR Program closer to commercialization. The founder of the program, Roland Tibbetts—and his paper—analysis is attached to my testimony, very specific. This program is not a commercialization program but moving it closer to commercialization, doing some testing and evaluation, some additional funding. There are good programs like the TIP Program [Technology Innovation Program], the old ATP Program [Advanced Technology Program] that is designed to move technology further down. There clearly needs to be something else done in that area, whether it is part—in addition to the SBIR Program or whether it is something freestanding. We really do have a problem. We are trying to get small business up to the "Valley of Death" to look in. Everybody else says we got to get it across. I am just saying we need to get more up to it, but we also need a bridge across that "Valley of Death."

So there needs to be something extra. I am flexible on how that works, and I—but I think it clearly needs to be something that goes beyond SBIR, but I don't think we want to take away from the base program that we have now——

Mr. LUJÁN. Thank you.

Mr. GLOVER.—to do that.

Mr. LUJÁN. And lastly, Mr. Greenwood, Dr. Rockey gave—mentioned this in the first response to my question. You also brought this to our attention through your testimony with the application process. What can be done to increase the effectiveness or awareness, participation, competition within the program and to get your thoughts on that, Mr. Chair, then I would make sure that we would yield back any excess time that I have consumed today.

Chair WU. That would be fine.

Mr. GREENWOOD. Thank you. I am going to sound like a one-trick pony because I am on this subject, and it has to do—if you want

to get more competition and more excellence in the program, you have to go back to the original Congressional intent and overrule statutorily this ill-found decision by the ALJ that excludes the majority backed venture capital companies.

A couple of points—conjectures that need to be put to rest. This idea that somehow when—allowing these companies to participate crowds out the other applications. The National Research Council study found no evidence that participation of companies with multiple VC ownership was harmful to the program or that small businesses have ever been crowded out by the participation of small businesses that are majority owned by VCs. So that is not a concern at all.

Another thing that is important here is that no one is suggesting that SBIR money is what gets companies through the process, that multiple hundred million dollar process of moving to FDA approval. What really happens is a biotech company will have a molecule that it thinks might cure brain cancer, and venture capitalists will look at that, look at the intellectual property and say, you know what? We think we are right, and we want to invest ten million or $15 million in that. And that program becomes, might become ineligible for an SBIR grant.

Now, meanwhile, back in the laboratory the scientists are saying, you know, this molecule might also cure prostate cancer, breast cancer, have another application, and they want some seed money to get that process started, and the venture capitalists are saying, no, no, no, no. We put our money on the brain cancer application. So then it is—because it is perfectly appropriate for that company to come back with an application and say, this is a secondary project that holds great potential to cure human disease as well. And we think it makes perfect sense, even though that company has venture capital funding to come back to the NIH and say, what about this? Does this look like a good project that you might want to fund as well?

So we think that, again, for all of those reasons that—and particularly going back to the original Congressional intent, and as the Chair said, it was never, never the intent of Congress and nor is it rational to make financial structure a proxy for smallness.

Chair WU. Mr. Greenwood, I would interrupt while you are quoting me with approval. I have a request from the minority to adhere more closely to the five-minute time limit, which is somewhat unusual, but I intend to abide by that request.

So if you could draw your comments to a close and when Mr. Luján is ready to yield back the balance——

Mr. GREENWOOD. I have.

Chair WU. Thank you, Mr. Greenwood.

Mr. LUJÁN. And Mr. Chair, I would just close with, you know, we had a phenomenal conversation with Secretary Chu with his visit to Las Alamos National Laboratories in New Mexico, talking about the importance of R&D science and technology innovation, looking to see what kind of projects we should be supporting, recognizing that eight of the ten may fail, but it is those two that succeed and the breakthroughs that we would yield from them with solving domestic problems and global problems. And that is why we

need to be supporting projects like this so we can get these products to market.

Thank you, Mr. Chair.

Chair WU. Mr. Luján, you had Secretary Chu at a national lab, and you didn't invite me. And all this time I just always talk you up as a very valued contributing Member of the Subcommittee.

Mr. LUJÁN. Mr. Chair, next time we will make sure we invite you, but, Mr. Chair, we had a 24-hour notice, and I am not sure we could have gotten many more people to the laboratories. Thank you, Mr. Chair.

Chair WU. I thank the gentleman, and now the——

Mr. GLOVER. Mr. Chair, could I just mention one thing about national labs?

Chair WU. If Mr. Smith will permit that, I would be happy to.

Mr. SMITH OF NEBRASKA. Briefly.

Mr. GLOVER. The other thing about where innovations come from, the National labs has done remarkably well. That is the biggest increase in innovations, key innovations is the National labs. It is really quite a remarkable success story.

Chair WU. Thank you, Mr. Glover.

The gentleman from Nebraska, five minutes. Thank you very much. Good to see you.

Mr. SMITH OF NEBRASKA. Thank you. I apologize. This might be begging for a long answer, but if you could be as brief as possible.

Could you comment on the National Academies of Sciences' review that—of SBIR that found the program is not sufficiently evidence based and in need of improved data collection on program outcomes and performance matrix to measure its impact? Could you respond to that?

Dr. BERDAHL. In my testimony I mentioned the fact that that is a recommendation of the National Academies and certainly one that we endorse. Indeed, perhaps much of the discussion that has been conducted here in this hearing today could have benefited from some more rigorous data that we might have acquired if we had really done the kind of analysis as between agencies and so forth that would yield some evidence that would help shape policy.

Mr. SMITH OF NEBRASKA. Anyone else wishing to respond?

Mr. Glover.

Mr. GLOVER. I would just comment that there is a lot more information about the SBIR Program than virtually any other federal R&D program. It is quantified, it has been studied by GAO a number of times and the National Academy study is a five-year, $5 million study. There is an awful lot of information about it. We can never get enough information when we are trying to evaluate and make decisions, but there is a lot more here than there is on most other programs.

Mr. SMITH OF NEBRASKA. Okay.

Dr. ROCKEY. I would also say that I would agree with Dr. Berdahl, and I had mentioned earlier that understanding our drop in applications would have been a lot easier had we had some evidence base. We have done a number of studies on the SBIR Program. As you know, the NRC just did theirs. We also have our own PODS [Performance Outcome Database System] database, which is really a way to look at commercialization, what happens.

In addition, the SBA has a database called TechNet which also can help us with some evidence base, but we would agree that there should be and could be more evidence-based analysis of this program.

Mr. SMITH OF NEBRASKA. Okay. Thank you. Mr. Greenwood, if you could give an example of the kind of companies that BIO believes should be made eligible for SBIR funding through a change in eligibility rules and how such a company might compare to others that are currently eligible in terms of employees, revenue, and other things.

Mr. GREENWOOD. Uh-huh. Well, thank you, Mr. Smith. First off, we think it is important that companies who are small, and because they are small, are not burdened by the huge overhead and bureaucracy of, say, large pharmaceutical companies, they are much more willing to take risks and to go into areas that for which there are no cures right now, no treatments. They are into unknown territory, if you will. These are the kind of companies that we think can contribute the most to advancing the science around solving problems related to human disease.

We think that companies that advance the science to the point where the venture capitalists, who are increasingly skeptical, in the beginning when the human genome was first sequenced in about 2000, any biotech company that emerged was pretty quick to get venture capital funds because it was assumed that there was going to be quick solutions. It has turned out that the problem of using the human genetics, understanding of genetics and DNA is more complicated than was first thought.

So venture capitalists are being skeptical. So when the venture capitalists come in and say we are going to bet on this company, it is much more likely than it ever has been that this company is really going somewhere, that this is going to be a new breakthrough invention.

And so the fact of venture capital investment should be—and at times in the program's history, it was an indication that they should merit additional grants, not that they should be turned away. And so we have had a perversion of the original process in which a company that is good enough, the science is good enough, it is smart enough, and making important breakthroughs to the point where the venture capitalists are willing to risk their money, I think those should be the companies that minimally should be able to compete for SBIR funds because they obviously have demonstrated their ability to build the talent pool necessary to advance the science.

Mr. SMITH OF NEBRASKA. Thank you, and what about the impact of the recession? Have you seen change in pattern of application for funds and otherwise?

Mr. GREENWOOD. Well, I don't know that we have had enough time to see that, but we are in trouble. Small—most of our companies don't have any products on the market. They rely entirely on investor capital for their revenues, and they do for a very long period of time, and in this credit crunch right now we are in the position where there is just no money for those. And so we, as I said in my opening statement when you weren't able to be with us, fully a third of our companies are down to their last six months in cap-

ital and something like 40 percent are down to their last—30 down to their last 12 months and 40 percent down to their last six months.

So we are going—our companies whether they are majority VC-backed or not are going to be more in need of help in the next 12 months or so than they ever have before. And much will be lost if these companies dissolve.

Mr. SMITH OF NEBRASKA. Thank you. Thank you, Mr. Chair.

Chair WU. Mr. Smith, you are prompt. I am going to have to mend my ways.

The gentlelady from Maryland, Ms. Edwards, recognized for five minutes.

Ms. EDWARDS. Thank you, Mr. Chair.

I just have one real question, and it has to do with the moving the process towards commercialization, and Dr. Rockey and Mr. Greenwood, when I hear from small businesses, especially these that are nimble technology and research firms and minority-owned business and women-owned business, what they say is they do need that first push. That is why we have the program, but then, you know, a lot of them are not able to get that venture capital at the beginning, but they need something that helps them get there. And so I want to know actually within the context of the program, you know, what ability the program allows to even, you know, sort of see whether it is consultants or some assistance to get the business plan together to then, you know, move into that next phase and then out to real commercialization. Because I think if you are going to go ahead and make an investment in seeding the research and the technology and then you just kind of give it away at the time at which it needs to be spurred on, that is a particular dilemma for small, women, and minority-owned businesses.

Dr. ROCKEY. And while we haven't invested greatly in this, we do have a number of programs at NIH called CAP [Commercialization Assistance Program] and TAP [Technical Assistance Program], which are commercialization assistance programs, and some of them are designed specifically for the smaller programs that really need help in just even understanding the process under which they can commercialize. So we have two programs, one of which supports training for those kinds of businesses to understand the process and one for more actual assistance in the commercialization process further down the road.

But it is an issue. It is an enormous issue that I believe Mr. Greenwood would relate to many companies is getting onto that further step.

Mr. GREENWOOD. If I may, as valuable as the SBIR Program is, and it has been essential to the development of biotechnology in this country, it is not the only source of revenue for early-stage companies, and one of the things that I do is travel from state to state talking to governors and State legislators about what they can do to help these companies as well.

Every state in the union, in fact, virtually every country in the world right now wants to be a big biotech hub because they see both the opportunity to advance the health of their citizens, as well as to advance the economy, because this is a growth industry.

So we encourage states to initiate their own programs. We have in my State of Pennsylvania we took tobacco settlement money and created a greenhouse, incubation centers for small biotechnology companies to get some of the help as you suggest with business plans and that sort of thing.

There are—we have a whole catalog of programs that states, you know, can engage in in order to help all companies, include women-owned, minority companies, to get into this field. And frankly, BIO is taking a leading role in trying to bring minorities into this industry, young people, people of all ages to demonstrate that this a real growth field and an opportunity for diversity.

Ms. EDWARDS. Thank you, and Dr. Rockey, you do feel that in the current structure of the program you have the flexibility to be able to assist with some of that as well, and I would say my own home State of Maryland, you know, does a tremendous job of seeding this because we view like other states, this is definitely a growth industry, at least on the biotech.

Dr. ROCKEY. We have some, and we have, as I pointed out, considered technical assistance in this area for commercialization, very appropriate. I will point out that the SBA did have the Federal and State Partnership Program that ended in 2005. The FSPP Program, I think some of you might have been aware, was an outreach effort, and that was also helpful as was a rural outreach program, which were two programs specifically designed to help bring people in and understand what was happening at a State and federal level.

So while those programs have gone by the wayside, there are—we also have extraordinary efforts in outreach. We attempt to outreach. I would mention that in—we are having our 11th annual SBIR conference in Nebraska this year in Omaha, and so we do think outreach as well as assistance is important in this whole program.

Ms. EDWARDS. Thank you, Mr. Chair, and I will yield.

Chair WU. Thank you very much.

Mr. Smith, do you have any further questions? Okay. I understand that Mr. Luján has a further comment to make.

Mr. LUJÁN. Mr. Chair, yes, and it is to extend an invitation to the Chair to New Mexico. We will make sure we have the appropriate hearing scheduled for that invitation Mr. Chair.

Quickly, Mr. Chair——

Chair WU. I look forward to it.

Mr. LUJÁN.—we reached out to a few businesses in New Mexico, and one of them by the name of Southwest Sciences in Santa Fe, New Mexico, is an example of how this program can work. And another example of a small business that is asking for support from the Congress to be able to support the reauthorization but making sure that the program is made available to their small businesses.

Southwest Sciences has now been issued 28 United States patents, all of them on inventions made through the support of SBIR or STTR Programs. They license many of the patents to manufacturers who are actively making and selling products in the semiconductor industry, natural gas pipeline industry, environmental monitoring, and atmospheric research applications.

And so we just continue to see, Mr. Chair, not only with us reaching out to businesses but them reaching out, back to us that shows the jobs that can be created, progress that can be made, and the importance of making sure the capital is going to be made available to especially a lot of these small companies who need that little boost to be able to make great things happen.

Thank you, Mr. Chair.

Chair WU. Mr. Luján, would you like to enter any of those materials in the record?

Mr. LUJÁN. Mr. Chair, we will request without any objection to submit a letter from Southwest Sciences into the record.

Chair WU. Without objection so ordered.

[The information follows:]

Southwest Sciences
incorporated

1570 Pacheco Street, Suite E-11
Santa Fe, NM 87505
(505) 984-1322
FAX (505) 988-9230

March 9, 2009

Representative Ben Ray Lujan
502 Canon HOB
Washington DC, 20515

Dear Representative Lujan,

I want to alert you about the renewal bill for the Small Business Innovative Research (SBIR) program, which is currently on continuing resolution that is scheduled to expire on March 20. The re-authorization of this bill, with its improved levels of support, is critical to small technology-based companies like mine. Small companies employ more than half of the scientists and engineers in the nation -- more than big business, more than universities, and more than the federal government's own laboratories. Yet, according to the National Science Foundation, small businesses receive only 4.3% of federal R&D funding - while big business, universities and federal labs get over 90%. And the SBIR program accounts for over half of the 4.3%. In the current economy and with the goals of the new Administration for improvements in energy self-sufficiency, combatting global warming and improving energy combustion efficiency, this bill will both generate new jobs in New Mexico as well as lead us to a more secure future.

It's a program that has just been strongly praised in a landmark, five-year study by the National Academy of Sciences. Increasing the SBIR set-aside would be an effective strategy for tapping into the nation's largest pool of scientists and engineers, as the National Academy of Sciences study noted. Not only has the SBIR Program brought over 376 million dollars into New Mexico, it also has been an integral part of R&D at eleven federal agencies for many years.

For the past 23 years our company, Southwest Sciences, has worked for better understanding and monitoring the environment, improving and developing advanced combustion engines for the military, and improving biological imaging of diseased tissues. The SBIR program has allowed us to inject over 40 million dollars into the economy in New Mexico, as well as generate (from our own commercialization and licensed products) over 55 million dollars in sales. As a result of our work, we have received a **1998 and 2007 Tibbetts Award** from the SBA for our outstanding success in the SBIR program, as well as a **2007 R&D 100 Award** recognizing the innovation of one of our licensed products developed under this program.

While we strongly support reauthorization, there are a number of issues with this bill that need to be addressed. Our concern is that it makes many sharp changes in the SBIR Program, changes that would severely damage the program's integrity, strength and safeguards. Our major concerns include:

1) The bill undermines the scientific basis and taxpayer safeguards of SBIR.

Currently, an SBIR company must prove the scientific validity of its innovation proposal before any additional development funds can be applied for or awarded. This is called "Phase I" of SBIR. Phase I is a transparent and juried competition among SBIR applicants. In Phase I, the basic science of a proposal is proven, the best applicants for further funding ("Phase II funding") are objectively selected, and taxpayers are protected from overspending on concepts that are fundamentally flawed.

The current version, however, allows companies to bypass Phase I. Agencies would be able to award development (or "Phase II") funding to a company with only a representation by the company (without peer review) that its science is sound. Competition, transparency, objective selection, and basic taxpayer safeguards would all go by the boards. Moreover, the bill risks the loss of even greater sums of R&D money by permitting these specially-chosen companies to secure a string of multi-million dollar contract awards.

Currently, Phase I awards are limited to $100,000 and Phase II awards are limited to $750,000. While adjustment in award sizes are necessary for inflation (these haven't changed in over a decade), this bill goes completely overboard by effectively making the maximum unlimited in value. Thus, a single company could be awarded all of the funds in a given year, shutting out everyone else.

2) The bill transforms a highly-successful program to stimulate technological innovation into an old-fashioned pork barrel program.

The changes to the awards process described above would shift SBIR from a program that funds innovations, using the scientific method, to a program that funds companies which privately "persuade" agencies of their need. In other words, millions of dollars in SBIR awards will be made on the basis of lobbying. And deep-pocketed companies that can afford more and better-connected lobbyists will be the winners. Once that process takes hold, true innovations will become increasingly rare.

3) The bill will wipe out many, if not most, of the companies in the SBIR Program. Mine may well be one.

This is pretty much simple mathematics. If you triple the SBIR award sizes, as the bill currently would do, and then give agencies essentially free rein to award as much as they like to certain favored companies as the bill also would do, but you do NOT increase overall size of the SBIR Program, then something has to give. What will give is the number of companies in the program. If you award $8 million to one company in a Phase II award cycle, then ten companies won't get $750,000 awards in that cycle.

That's a huge risk my company and my employees. And it's completely unnecessary. If an agency thinks an innovation idea is that hot, they can use their non-SBIR money to fund it. A proven, effective program of small awards like SBIR should not be raided to pay for it.

4) If the award sizes increase, the program size needs to increase - or many companies will be squeezed out.

The last time Congress increased SBIR award sizes was in 1992, and inflation over the past 16 years has made it nearly impossible for us to keep up. In 1992, Congress avoided decimating the number of companies in the program by increasing the small business set-aside that the program is based on and this balancing act needs to happen again. With only 2½ % of federal R&D, SBIR has proved its worth repeatedly, in every independent study that's ever been made of the program. Today this relatively tiny program produces far more patents per year than all U.S. universities combined. Southwest Sciences, despite its small size, has received 26 U.S. and two foreign patents.

Increasing the SBIR set-aside would not change federal agency R&D budgets. The agencies would still decide their own priorities, publish their own solicitations, establish their own criteria for making awards, and create their own panels for evaluating SBIR applicants and making awards. Not one dime would be "cut" from any agency's R&D budget. However, agencies would award a bit more of their R&D budgets to smaller companies.

Increasing the SBIR set-aside would be an effective strategy for tapping into the nation's largest pool of scientists and engineers, as the National Academy of Sciences study noted. This would be true even if there were no change in award sizes.

5) The current bill opens the door to a big business takeover of the SBIR program.

Big business took little note of SBIR as long as award sizes were $100,000 for Phase I and $750,000 for Phase II. But once agencies began exceeding these caps, as documented in a 2006 GAO study, big business began pushing much harder to access SBIR funding.

Now, with the House agreeing to giant increases in award sizes, easy ways for agencies to waive even these caps, multiple awards per cycle to individual companies, and elimination of the Phase I "proof of concept" requirement, big business has agitating even more strongly to get into this small business program. It is noteworthy that the House sponsors of the bill named only the Biotechnology Industry Organization, which is dominated by big pharma, and the National Venture Capital Association, which is similarly dominated by high rollers, as the endorsing organizations for the bill. Not one small business organization has endorsed the bill. Many, like SBTC and the National Small Business Association, are strongly opposed to it.

To enable large businesses to access SBIR, this bill allows venture capital companies that are

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large businesses by SBA standards, and that are owned by other companies, to set up syndicates that control SBIR awardees. In other words, SBIR applicants with access to the vast financial and technical expertise of large businesses would be competing with genuinely small companies for SBIR awards.

The original intent of the SBIR program was to provide a transition to take the technological advances made in basic research by small businesses and translate that into tax-generating commercial products that spur economic growth. Because venture capitalists were not interested in these less mature, but potentially useful, research ideas, the Government stepped in to assist in the transition from a research program to something that would be seen as commercially viable to a VC or licensee. As evidences by GAO and National Academy of Science studies, this program has been wildly successful. To change the rules in the middle of the game so that VC's can access unlimited amounts of the funds is unfair and self-defeating. In particular to New Mexico, I note that if the VC's get access to this funding the money will flow to New York, Massachusetts and California, where the majority of VC's reside, not to our state!

In summary I ask you to:

1) Retain the provisions limiting each funding cycle to a single, peer-reviewed Phase I and Phase II component.
2) Increase the overall percentage from 2½ % to 4% or 5%.
3) Increase the average award size to $150,000- $200,00 in Phase I and $1-1.25 M in Phase II, to make up for inflation losses in the past 12 years.
4) Tie future award levels to the cost of living.
5) Do not let large businesses and venture capitalists to take control of the program.
6) Please see that an SBIR reauthorization bill is ultimately passed this session. A dropout will put us and many other small scientific R&D firms out of business.

I ask you, as a Representative for me and my company's employees, and who should be thinking of the welfare of our country as a whole, and the economy of New Mexico in particular, to insist upon major improvements in the SBIR program and get this bill passed this year.

Thank you very much.

Sincerely,

Joel A. Silver
Executive Vice President
Southwest Sciences, Inc.

Chair WU. As I said, the gentleman from New Mexico is a valued Member of the Committee and has now—works diligently and now has also invited me to New Mexico. I thank the gentleman.

Well, the Chair recognizes himself. Ms. Edwards, I am about to get to your fine State of Maryland. We count on the NIH for innovation, and it has not gone unnoted that in the very thorough materials prepared by Mr. Glover that there is a tremendous concentration of SBIR companies and employees in the lovely State of Maryland, and we suspect that that may have something to do with NIH innovation. Another arena in which you all have been innovating is Phase II competition re-awards I would call it.

Dr. Rockey, could you describe that program to us, because I think we share an interest in getting folks over the "Valley of Death" in promoting innovation, in protecting legitimate small business interests, and this may be an interesting tool for us to fol-

low up on as a method of getting over the "Valley of Death," although there are some downsides to it, too, perhaps.

Dr. ROCKEY. So the competitive renewal of Phase II is really a phase 2.5, which allows us to support companies that have successfully completed their phase or are in the midst of their Phase II and come back in for competition to further their project towards the ultimate goal of commercialization.

I would say that in the case of clinical research, we are still pre-clinical at that stage, but it is taking the projects further down the line. We do support these projects for three years at $1 million per year. So it is substantial support, and we do think it has been effective at getting closer to the "Valley of Death," although as I said, it is usually still pre-clinical. But we find this is a way to successfully try to navigate this next step, which they otherwise would not have funding for.

But I do want to point out that it is competitive renewal. They are not guaranteed the renewal. They must come in and compete for it, and so they are judged against others who are competing for this as well.

But we found it to be a very effective way of promoting the development further along.

Chair WU. Thank you very much, Dr. Rockey. We very much value NIH's innovation in Phase II competitive re-awards, its innovation with respect to flexibility and grant sizes. I would just like to underscore in a very friendly way that there are those of us who prefer NIH to innovate with a more clear statutory basis, and that is up for discussion.

Mr. Glover, would you like to comment on the Phase II competitive re-award efforts that NIH has engaged in? Is that something that you view as a positive negative or a sideway slam?

Mr. GLOVER. We think that is a positive. We think that because it is a gaited process where they have to compete again for the additional money, that is important. We also think that it can't be too big, because if you get too much money going into that phase, you are crowding out, you are eating your seed corn. You are not getting enough new ideas coming forward, but we think that so far that seems to be to be balanced at NIH, and it is a positive.

And I think that as long as Congress puts a gaited process in and provides some additional funding for this kind of activity, it is a great idea.

Chair WU. Well, Mr. Glover, I just want to point out that you and your organization might feel that our $2.2 million Phase II award was way too high last go-round, but I think that in view of your support of a Phase II competitive re-award, there is flexibility on these numbers.

Mr. Greenwood, would you care to comment on this Phase II recompetition?

Mr. GREENWOOD. I would like to, but I can't. I don't know enough about it to give you good information.

Chair WU. Hopefully we will have the benefit of your organization's thoughts.

Mr. GREENWOOD. We will submit it in writing if the Chair would like.

Chair WU. Thank you very much. I appreciate that.

And with that I guess there are not going to be comments from any other Members of the Subcommittee. If our witnesses are not going to volunteer anything for the good of the order, then I want to thank you all for being here this afternoon and spending a decent chunk of time with us. It has been I think edifying for all Members, and I hope that it is part of a collaborative process as we go forward to have an SBIR Program that helps stimulate innovation, stimulate small business and employment and the production of new products, new services, and life-saving therapies and also helps keep our defense and other industries strong.

The record will remain open for additional statements from Members and for answers to any follow-up questions that the Committee may ask of the witnesses.

Again, I want to thank the witnesses and you are excused, and thanks profusely for your participation. The meeting is adjourned.

[Whereupon, at 4:15 p.m., the Subcommittee was adjourned.]

Appendix:

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Robert M. Berdahl, President, Association of American Universities

Question submitted by Representative Adrian Smith

Program evaluation, performance measures.

Q1. The recent National Research Council review of SBIR found that the program is "not sufficiently evidence-based" and is in need of improved data collection and tracking of program outcomes, as well as clear performance metrics for assessing the success or failure of a given initiative. Do you agree with this finding and recommendation?

A1. In response to your question about the need for "improved data collection and tracking of program outcomes," I would commend to you the comments made in my written testimony, as well as the recommendations made by the National Research Council in its 2008 report, "An Assessment of the SBIR Program." As stated in my written and oral testimonies, it is difficult to truly assess the economic and innovative impact of the SBIR and STTR programs when there has not been systematic data-gathering by sponsoring federal agencies. To this point, the NRC report includes an example in which a sponsoring agency suggested the need to increase in the median Phase I and Phase II award sizes. However, due to the lack of data-collection, the sponsoring agency was unable to provide a systematic, data-driven justification for increasing the award sizes. Simply put, limited use of metrics, data-collection, and analysis hinders our ability to assess and improve these programs. In addition to providing for better assessment of these programs, it is also important that the specific missions and goals of each federal research agencies be taken into account when assessing these programs effectiveness. This was a point that was also highlighted in Chapter 4 of the NRC report.

Questions submitted by Representative Daniel Lipinski

Q1. If the SBIR and STTR award amounts are increased and the set-asides are not, thus resulting in fewer awards, what do you think the impact will be on the number of successful commercializations? Will we see more successes because we cull out more marginal companies and increase award sizes, or will it diminish the overall impact of the program because it eliminates research on promising ideas?

A1. If federal funding for research stays flat, then indeed increased award sizes in the absence of an increased set-aside will lead to fewer awards. On whether fewer awards lead to fewer commercializations, we can only echo the recommendations of the National Research Council in suggesting that accurate data collection about the performance of agency SBIR/STTR awards—and indeed the results of individual SBIR/STTR awards—is needed. The National Institutes of Health's experience seems to suggest that, where NIH has been able to be more flexible in the size of grants awarded, the agency has been able to attract and fund higher quality proposals. In addition to the recommendations made by the NRC and contained in my testimony, I would underscore the importance of sustained increases for federally funded research. Such increases will not only allow us to maintain our global scientific leadership, they will also assure that the SBIR/STTR programs grow in tandem with our nation's research enterprise.

Q2. The STRR in particular program looks to promote cooperation between a small firm and a scientist in a University or National Lab. But starting a company from the ground up can be a full-time job for a scientist. Do you have any sense about the extent to which University or Lab scientists can actually participate in a startup? How flexible are Universities and Labs, respectively, with policies to allow their researchers this opportunity?

A2. Many universities have policies that will allow faculty leaves of absence or reduction in appointments to assist in the formation of a start-up, with appropriate conflict of interest oversight. They also have policies that permit faculty to devote a certain percentage of their time to consulting outside of the university. Having said that, many faculty members want to continue their research and don't want or don't have the time to start a new company. As a result, most university spin-offs are created by a faculty member in partnership with an entrepreneur outside of academia who actually guides the formation of the start-up. The faculty inventor serves as a consultant, the Chief Scientist or Chair of the Science Advisory Board

to the start up, where their knowledge of the new technology is their primary contribution. It is precisely this partnership that STTRs seek to enhance—the transition from academic lab to a company lab. This less time-consuming role can be handled by most faculty within the time allotted by many institutions for consulting activities. The transition is often facilitated by a graduate student, post-doc or research associate leaving the university to help start-up the research and development effort at the new company.

Questions submitted by Representative Gary C. Peters

Q1. When I talk with my constituents back home, they echo much of what has already been said here: that the SBIR/STTR programs are often the life blood for small firms, and that small firms are a crucial driver of innovation. However, they also mention the "Valley of Death" that occurs for technologies after the prototype has been developed. The companies do not have the dollars for marketing and commercialization of the product. To truly support economic development, we need for these small firms to have the support to make the jump from development to commercialization. How can SBIR/STTR support companies in making this leap and avoid the "Valley of Death"? Wouldn't we see a greater return on our tax dollar investment if the SBIR/STTR program dollars helped companies through the commercialization phase?

A1. In response to your question about "traversing the Valley of Death," I refer you to the comments made in my written testimony. As addressed in the NRC report, and as discussed during the hearing, some agencies are currently providing "beyond Phase II" support in order to improve the commercialization potential for SBIR-funded technologies. For example, National Institutes of Health has improvised a system to provide such funding with its "competing renewal" program for especially promising projects. Likewise, the Department of Defense's Navy Technology Assistance Program has developed a system for companies entering Phase III.

The AAU agrees with the NRC's recommendation—"beyond Phase II" funds are important and an essential step in helping companies traverse the "Valley of Death." Embedded within this discussion of "beyond Phase II" is the notion of agency flexibility. Indeed agencies should be given the flexibility to develop their own, agency-specific "beyond Phase II systems"; systems that lend themselves to the overall mission of the agency and the needs of the specific SBIR/STTR project.

Q2. New companies in my district find the Fast Track program extremely valuable, and have even been launched based on a fast-track Phase II award. The National Academies have also found that experimentation by the agencies, such as the Fast Track program should be encouraged. Can you expand on how we can further promote the Fast Track program within SBIR/STTR?

A2. In response to your question concerning the Fast Track program, I would commend to you the recommendations made in the NRC SBIR report, as well as my own testimony before the Subcommittee in endorsing experimentation in the SBIR/STTR programs.

Research agencies should have the flexibility to adapt SBIR/STTR awards to suit their programmatic objectives, address the needs of the companies competing, and ensure that additional commercialization arises from SBIR/STTR awards. To this point, the National Research Council's report, "An Assessment of the Department of Defense Fast Track Initiative" found that agency experimentation and flexibility at DOD increased the effectiveness of the SBIR program by encouraging the commercialization of new technologies.

Similarly, the NRC's SBIR report notes that NIH's Fast Track program operates differently than DOD's and functions more as a complete Phase I and II award without matching funding. The NRC report further states that "to date, there is little evidence about the impact of the program," but we are confident that, with the additional data collection and analyses, the relative merits of such expedited or flexible approaches should be revealed.

Q3. Do you see a need to encourage larger companies to participate in the SBIR/STTR program at an earlier stage? Would extending R&D tax credits on a limited basis to larger commercial partners provide more of an incentive for large companies to partner with a small firm that may be operating at a zero net profit?

A3. A program that required pairing of small and large companies would be a great boon to emerging start-ups. The "first customer" barrier is a critical stage in the life of a start up and the large company partner could provide that entree to the

market for a small business. Additionally, the networks, facilities, technical and business assistance that might be available from a larger company would be invaluable to a small company. Start-ups are often able to develop products and processes as a function of their agility and flexibility that larger companies are unable to incubate, so the partnerships may be productive to both, especially in these days when access to investment capital is so difficult to come by.

ANSWERS TO POST-HEARING QUESTIONS

Responses by James C. Greenwood, President and CEO, Biotechnology Industry Organization (BIO)

Question submitted by Representative Adrian Smith

Program evaluation, performance measures.

Q1. The recent National Council review of SBIR found that the program is "not sufficiently evidence-based" and is in need of improved data collection and tracking program outcomes, as well as clear performance metrics for assessing the success or failure of a given initiative. Do you agree with this finding and recommendation?

A1. BIO supports efforts to ensure that the SBIR program is able to track outcomes. We would recommend that metrics used to assess the success or failure of a given initiative are discussed with each individual agency, as the measures of success or failure will be unique to each agency's goals and missions. We would also recommend that the metrics focus on tracking the potential benefit to the public of projects being funded and whether those projects are commercialized over time. It is important to note that in some industries, such as biotechnology, it can take longer than a decade for a research project to reach commercialization. As such, any analysis of data collected must take this time horizon into consideration when evaluating success. Examining the potential for public benefit is equally important, as early stage research can often evolve into discoveries beyond the scope of the initial research project, based on scientific findings in the early stage research projects.

Questions submitted by Representative Daniel Lipinski

Q1. If the SBIR and STTR award amounts are increased and the set-asides are not, thus resulting in fewer awards, what do you think the impact will be on the number of successful commercializations? Will we see more successes because we cull out more marginal companies and increase award sizes, or will it diminish the overall impact of the program because it eliminates research on promising ideas?

A1. It is important that the award amounts are reflective of inflation and the increased costs associated with scientific research. The award amounts need to be meaningful in order for the funded research to be able to meet designated milestones in the funded project. This will increase the ability of these projects to move forward towards commercialization.

As discussed in my testimony, it also important that agencies maintain flexibility in how they fund SBIR projects. This was supported by the National Research Council's 2007 report which stated ". . . 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." BIO believes that agencies are the best judge of how to use their SBIR funds to advance science and commercialization of new innovations.

The number of awards each agency is able to give is also dependent on the research and development budget of that agency. BIO has consistently communicated to Congress the importance of having a properly funded NIH. More research and development funding at NIH equals more funding that will go to the SBIR program.

Thus, the combination of a properly funded NIH, meaningful award amounts, and the ability of the agencies to have flexibility in exceeding those award amounts will help maximize the impact of the SBIR program.

Q2. During the hearing Dr. Rockey discussed the NIH "Phase 2.5" competitive re-awards. The NSF has a similar "Phase II supplement" program. Is either of these programs, or are there similar efforts at other agencies, that are particularly effective at commercializing products toward the end of their Phase II grant?

A2. The competitive re-award programs at NIH are critical to ensuring research projects that have great scientific and commercialization potential are able to receive more funding, when warranted, to meet early-stage research milestones. This program is vital to small companies' ability to traverse the oft-discussed "Valley of Death," where funding is difficult to find for early-stage high-risk but promising research projects.

Q2a. Does the current approach to Phase III funding for commercializing products, which precludes using any SBIR or STTR funds, work for companies and products that are trying to move beyond their Phase II grant? Are there changes that you would recommend?

A2a. As mentioned previously, NIH's Phase 2.5 awards and ability to exceed award caps, when warranted, are key to maximizing commercialization of SBIR-funded research projects. BIO would also recommend that Congress look to the successes of NIH's Commercialization Assistance Program (CAP), which has been very successful in helping small businesses develop a sound strategy for commercialization, as an example of how to help small businesses move beyond their Phase II grants towards commercialization. The success of this program is dependent on the ability of the agency to have flexibility in awarding SBIR dollars. Caps on SBIR grants, if imposed, should not apply to the entire amount that the agency spends on a particular project. The NIH CAP program provides commercialization assistance to those companies who may need extra funding before they can attract private dollars to further develop early-stage research projects.

BIO also supported provisions in H.R. 5819, the *Small Business Innovation Research Program Reauthorization Act,* as passed by the House in 2008, that would help small businesses develop a commercially-available product. These included establishing the Partnerships, Resources, Investors, and Market Entry Research Program (PRIMER) [Sec. 302]; increasing partnerships between SBIR awardees and Prime contractors, VC and larger businesses [Sec. 404]; and providing funds to all agencies to develop commercialization programs [Sec. 406].

Q3. The STRR in particular program looks to promote cooperation between a small firm and a scientist in a University or National Lab. But starting a company from the ground up can be a full-time job for a scientist. Do you have any sense about the extent to which University or Lab scientist can actually participate in a startup? How flexible are Universities and Labs, respectively, with policies to allow their researchers this opportunity?

A3. I agree that founding a start-up company can be time-consuming and challenging, yet it is essential to the commercialization of new technologies in areas such as biotechnology. I would defer to my fellow witness, Dr. Berdahl of the Association of American Universities (AAU), to comment on the specific policies of Universities with respect to their researchers' involvement in start-up firms.

Q4. Some of the nanotech businesses I've spoken with in Chicago have pointed to inconsistent paperwork as an obstacle encountered by people who are trying to turn their idea from a laboratory success into a small business. Can you comment on the consistency of SBIR and STTR program and application procedures across and within agencies? Is this something that discourages first-time SBIR applicants?

A4. BIO member companies have not indicated they are discouraged from applying to the SBIR program due to inconsistent application procedures. The two main obstacles hampering the ability of small biotechnology companies' to apply to the SBIR program are the SBA rules excluding small companies that are majority venture capital-backed and the overly-broad application of SBA's affiliation rules. In certain instances, if the SBA determines that a venture capital company is affiliated with the SBIR applicant, they will then make determinations that a venture capital company's other portfolio businesses are also affiliated to the SBIR applicant, even though the only thing they share in common is an investor. These complex and broadly-applied affiliations rules are an application barrier to many small biotechnology companies that rely on funding from multiple sources and investors to continue their capital-intensive research and development projects. The rules, as currently applied, create an enormous amount of uncertainty for many life sciences entrepreneurs as to whether or not their company is eligible for an SBIR grant award.

Questions submitted by Representative Gary C. Peters

Q1. When I talk with my constituents back home, they echo much of what has already been said here: that the SBIR/STTR programs are often the life blood for small firms, and that small firms are a crucial driver of innovation. However, they also mention the "Valley of Death" that occurs for technologies after the prototype has been developed. The companies do not have the dollars for marketing and commercialization of the product. To truly support economic development, we need for these small firms to have the support to make the jump from devel-

opment to commercialization. How can SBIR/STTR support companies in making this leap and avoid the "Valley of Death"? Wouldn't we see a greater return on our tax dollar investment if the SBIR/STTR program dollars helped companies through the commercialization phase?

A1. The development of biotechnology treatments and therapies requires several avenues of funding working in a cohesive manner. As stated in my testimony, it takes between eight and twelve years to bring a biologic therapy to the market and costs between $800 million and $1.2 billion. A small biotechnology company generally has between one and five research projects in development. Small biotechnology companies rely on grant funds, angel investors and venture capital companies to develop their biotechnology innovations into commercially available products. Since 2003, the majority of small biotechnology companies have been unable to access critical SBIR dollars because they are "majority owned" by venture capital companies. This ruling has prevented small companies who generally have fewer than 75 employees and no product revenue from competing.

It is important to understand that small biotechnology companies often exceed the majority owned restriction in the very early stages of the company because they usually have multiple venture capital companies who each have minority ownership stakes in the company for the company's lead product, that collectively trigger the 51 percent ownership restriction. As such, these small biotechnology companies are now unable to compete for SBIR dollars that can help fund their early-stage projects and have a very difficult path to develop those projects to the point where it is attractive to private-sector investors.

Allowing small businesses that happen to be majority venture-backed once again compete for SBIR funds is the best way for the SBIR/STTR programs to better support companies through the "Valley of Death." Additionally, we support agency flexibility within SBIR so that commercialization programs, such as NIH's Commercialization Assistance Program, can continue to provide valuable funding for small companies that need further assistance in the commercialization process.

Q2. New companies in my district find the Fast Track program extremely valuable, and have even been launched based on a fast-track Phase II award. The National Academies have also found that experimentation by the agencies, such as the Fast Track program should be encouraged. Can you expand on how we can further promote the Fast Track program within SBIR/STTR?

A2. I would agree that experimentation by the SBIR-participating agencies is an important component of an effective and successful SBIR program. Maintaining agency flexibility as part of the SBIR reauthorization process will enable each agency to pursue programs, such as Fast Track, that the agency determines is necessary to improve that agency's SBIR program. While it is Congress's job to set the broad parameters of the SBIR and STTR programs, we should not forget that it is the individual agencies that are in the best position to implement these programs effectively.

Q3. Do you see a need to encourage larger companies to participate in the SBIR/STTR program at an earlier stage? Would extending R&D tax credits on a limited basis to larger commercial partners provide more of an incentive for larger companies to partner with a small firm that may be operating at a zero net profit?

A3. The SBIR program should be reserved for small businesses, so long as this determination is made using an objective and technology-neutral metric such as employee count. The current restriction on venture capital investment does not relate to the size of the company and it effectively discriminates against more capital-intensive sectors, such as biotechnology, relative to less capital-intensive technologies. This restriction does nothing to preserve the small business element of the SBIR program that could not be just as effectively preserved through the 500 employee count limitation. It does, however, serve to exclude many worthy small businesses from the SBIR program.

With respect to the R&D tax credit, I agree that a major issue facing many small businesses is their inability to utilize many of the tax incentives that Congress has seen fit to enact over the years. These not-yet-profitable small companies are able to carry-forward their tax credits, but this carry-forward does nothing to inject investment capital into the small company at the point when it is most needed. I would be pleased to work with you and other Members of Congress to enact tax policies that more effectively support U.S. innovation and global competitiveness.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Sally J. Rockey, Acting NIH Deputy Director, Extramural Research, National Institutes of Health, U.S. Department of Health and Human Services

Questions submitted by Chair David Wu

Q1. In the American Recovery Act, the additional $8.2 billion that NIH is set to receive for extramural research was specifically exempted from the SBIR/STTR set aside requirement. Who at NIH asked for this set aside and what was the justification for the specific exemption from the SBIR/STTR statutory requirement?

A1. Due to the unique nature of the *American Recovery and Reinvestment Act of 2009* (ARRA) funding requirements, NIH originally planned that most of the NIH's funding would be distributed by supplements to existing grants, or applications that had already been reviewed/scored and deemed to have scientific merit.

NIH was concerned that because of the decreasing number of SBIR applications (we saw a near 40 percent decrease in fiscal years 2004 through 2008), that a lack of flexibility on how to expend the funds would make it difficult to continue funding scientifically meritorious projects under the ARRA requirements. I have no specific details of how this exemption was put into ARRA.

Although the NIH is not required by this law to provide a set amount of the funds toward the SBIR/STTR programs, it is important to note that small businesses are able to receive such funds. NIH is committed to the small business community and has been encouraging small businesses to apply for stimulus funds through the Challenge Grant and Grand Opportunity "GO" grant funding opportunities. Additionally, new funding mechanisms will be coming out soon under which NIH plans to set-aside some ARRA funds for small businesses.

Question submitted by Representative Adrian Smith

Program evaluation, performance measures.

Q1. The recent National Research Council review of SBIR found that the program is "not sufficiently evidence-based" and is in need of improved data collection and tracking of program outcomes, as well as clear performance metrics for assessing the success or failure of a given initiative. Do you agree with this finding and recommendation?

A1. While the National Research Council (NRC) may highlight certain inherent challenges to measuring the program success and impact, the NIH has conducted two evaluations of its SBIR program and other groups, such as the General Accountability Office have also assessed the program. The NRC correctly observed that factors such as firms obtaining SBIR funds from several agencies, firms changing names and/or locations, key individuals moving on and taking their knowledge of the project with them pose real challenge to data collection. However, program decisions and management are evidence-based. Regular data collection and tracking of program outcomes helps to keep the SBIR program up to date on program performance and are useful in assessing the success or failure of a specific pilot program an agency may initiate.

NIH has conducted two evaluations of its SBIR program and other groups, such as the National Research Council of the National Academies of Sciences and the General Accountability Office have also conducted studies. Regular data collection and tracking of program outcomes helps to keep the SBIR program up to date on program performance and can be useful in assessing the success or failure of a specific pilot program an agency may initiate. Therefore, the NIH developed an evaluation framework that includes performance measures and indices and conducts regular evaluations of its SBIR program. In addition, NIH established a dynamic monitoring system, called Performance Outcomes and Data System (PODS), which enables NIH to document the continued achievements of SBIR awardees over time. For example, through surveys and regular updates on SBIR awardees, NIH has found that about 50 percent of its SBIR awardees funded from 1992 to 2001 have achieved commercial sales.

It is important to note that some products take much longer to reach the market than others. For example, the drug development process is a complex, long, and expensive one. The cost of bringing a drug to market is estimated to be over $1 billion with a timeframe of eight to twelve years before availability of the drug. Therefore, it is important when analyzing the success of the program to consider the trajectory

a product takes to reach the market, and to consider other metrics equally valuable in demonstrating success of SBIR projects. These include published papers, patents, conduct of FDA-regulated trials, FDA approval/clearance of drugs and devices, Initial Public Offerings, the use of the technology in other research projects, and increasing the knowledge base in a scientific field. In addition to sales, these other metrics provide the much-needed evidence based data for tracking program outcomes.

Questions submitted by Representative Daniel Lipinski

Q1. If the SBIR and STTR award amounts are increased and the set-asides are not, thus resulting in fewer awards, what do you think the impact will be on the number of successful commercializations? Will we see more successes because we cull out more marginal companies and increase award sizes, or will it diminish the overall impact of the program because it eliminates research on promising ideas?

A1. The SBIR and STTR award amounts have remained at their current levels since 1992. Although agencies have the discretion and flexibility to exceed those award amounts where appropriate for a particular project, formally increasing the Phase I and Phase II award amounts to reflect economic adjustments and programmatic considerations may be viewed by small businesses as financial incentives for participating in the program, especially new start-ups who may not be aware of the program nuances. Larger award amounts may incentivize startups that have no other resources on which to draw, while being required to present feasible and exciting projects. Further, larger award sizes may enable small businesses to hire or retain strong talent that can help a project succeed. We believe that there could be a positive correlation between program incentives and successful outcomes. While we believe that the SBIR legislation should contain purposeful guidelines on award amounts and project periods, we believe that agencies should also have the flexibility to provide support for meritorious SBIR research projects at a funding level that is considered appropriate to achieve success in these projects. Our experience is that the conduct of some types of biomedical and behavioral research projects, such as clinically-related studies, vaccine development, drug discovery or certain technology development, does not routinely lend itself to prescribed maximum dollar levels.

The commercialization success rate for NIH SBIR projects is now over 50 percent. While award amounts is likely not the only reason for success, we believe that the flexibility to make awards of sufficient size to accomplish the meritorious proposals, stimulates research on truly promising ideas with commercial potential. Further, what has made our program so appealing are the opportunities for firms to propose investigator-initiated, research projects in the fields that have the most biological promise, rather than to restrict their ideas to projects that can only be conducted under a prescribed amount of time and money. Such projects can be important steps in integrally involving small businesses in some of the most exciting, cutting-edge research with the potential to benefit health related outcomes.

Q2. During the hearing, Dr. Rockey discussed the NIH "Phase 2.5" competitive re-awards. The NSF has a similar "Phase II supplement" program. Is either of these programs, or are there similar efforts at other agencies, that are particularly effective at commercializing products toward the end of their Phase II grant?

A2. Small businesses are playing an increasingly important role in drug discovery and development, typically, but not entirely, focusing their efforts on the earlier stages of this process rather than clinical trial evaluation. SBIR support has heretofore only allowed for a Phase I and single Phase II grant for such research. A recipient of an NIH SBIR Phase I and Phase II award normally receives no more than $1 million and less than three years of support. Although Phase I and Phase II SBIR support is sufficient for initial discovery efforts, it is often not adequate to support either the kind of developmental work needed for compliance with the FDA's requirements for an investigational new drug (IND), or for clinical trials. If the intended commercialization product is a drug or biologic, the SBIR funds are often a small percentage of the funds necessary to complete the studies required for licensing by the Food and Drug Administration (FDA). Further, the process of moving promising new products from bench to bedside typically takes more than a decade.

The NIH "Phase 2.5" competitive re-awards, which at the NIH are called Phase II Competing Renewal awards, provide up to three additional years of support to

small businesses for promising drug research and development through the award of a Phase II Competing Renewal grant. It is recognized that even with a competing renewal grant, the entire development timeline will not be supported by the SBIR Program for any given drug. The competing renewal grant will, however, allow small businesses to carry further the fruits of their research to advance science and to attract interest and investment in their research programs by third parties.

NIH started issuing Phase II Competing Renewal awards in 2005. Therefore, some of the earlier projects just finished last year and many of the projects are still ongoing. To date, 56 Competing Renewal awards have been awarded. We are tracking the companies closely and plan to evaluate the Phase II Competing Renewal award program to assess the extent to which it is effective at helping small businesses bridge the "Valley of Death" by contributing to the critical funding needed by companies to carry out R&D activities necessary to move a product or technology along the commercialization pathway.

Q2a. Does the current approach to Phase III funding for commercializing products, which precludes using any SBIR or STTR funds, work for companies and products that are trying to move beyond their Phase II grant? Are there changes that you would recommend?

A2a. NIH does not provide Phase III funding. However, the current approach NIH uses to assist SBIR/STTR awardees in their transition to the marketplace does seem to work well. The NIH SBIR program commercialization success rate is now about 50 percent, the current approach to Phase III funding for commercializing products seems to work well. It is important to not lose sight of the fact that, given the "I" in the SBIR program, some projects will fail.

Increasing the commercialization of products and services derived from Phase I and Phase II SBIR/STTR awards is one of the four Congressional goals of the Program and also a high priority of the agency. An interesting approach might be to consider revising the SBIR provisions of the Discretionary Technical Assistance to SBIR Awardees clause (and consider applying the clause to the STTR program) to permit a larger portion of the SBIR dollars to be used to provide small business concerns engaged in SBIR projects with technical assistance services. The $4,000 level has not been amended since 1992. The increase in Technical Assistance funds would be more aligned with the current market for such services. The increase will also allow federal agencies to establish more robust technical assistance programs that will permit more effective translational research.

Currently, NIH's Technical Assistance Program (TAP), serves to enhance the current phased award structure, provides commercialization assistance, facilitates partnering opportunities, and helps small businesses cross what is so often called the "Valley of Death," that gap between innovative promising research and development (R&D) and transitioning those innovations to the market. One program within the NIH TAP, called the "Niche Assessment Program" helps Phase I awardees assess the market opportunities as well as the needs and concerns of end-users and assists them in discovering potential new markets. This program has been helpful to researchers who often lack the entrepreneurial skills to assess whether there are other applications or niches for their SBIR-developed technology. Another TAP program, the NIH "Commercialization Assistance Program" (CAP) provides entrepreneurial training assistance and one-on-one business counseling to Phase II SBIR awardees in order to develop and implement an appropriate business strategy aimed at commercializing the products resulting from their SBIR research projects. CAP culminates with an investment event at which the participants present their business opportunities to a targeted group of potential investors and/or strategic partners. A recent enhancement to the CAP makes available publicly the abstracts and company presentations upon completion of the CAP to facilitate the identification of commercialization partners after the opportunity forum. NIH is tracking each participating company's commercialization progress for 18 months following completion of the program. Although investments and deals take time to mature, we believe the CAP is having positive impacts on SBIR companies seeking investments and partnerships. For example, one company is developing a technology to create a living blood vessel. This exciting medical advancement holds promise for coronary bypass candidates, lower limb amputation candidates, and hemodialysis patients. As a CAP participant, the company has raised more than $30 million in private equity financing to fund some of their clinical studies.

Since the program's inception in 2004 through June of 2008, we have found that 91 NIH–CAP companies have been able to raise over $326.5M in funding. In addition, NIH–CAP participants have experienced over 3,900 contacts with investors, over 2,800 meetings with investors and partners, 1,500 Confidentiality Disclosure

Agreements signed, 800 negotiations with investors and partners, 400 initial proposals and term sheets, and 235 deals.

Finally, understanding that negotiations and deals take time, NIH has established the NIH Pipeline to Partnerships (P2P), a virtual space for NIH SBIR/STTR awardees and NIH licensees to showcase technology and product development for an audience of potential strategic partners, licensing partners and investors. P2P helps NIH in advancing its mission by furthering the development of its own licensed technologies or those for which it has provided SBIR/STTR funding. Currently, there are over 150 technologies in the searchable/indexed database.

NIH is hopeful that this type of approach will help SBIR/STTR awardees attract funding and partners that will help to commercialize products and services supported by Phase I and Phase II.

Questions submitted by Representative Gary C. Peters

Q1. When I talk with my constituents back home, they echo much of what has already been said here: that the SBIR/STTR programs are often the life blood for small firms, and that small firms are a crucial driver of innovation. However, they also mention the "Valley of Death" that occurs for technologies after the prototype has been developed. The companies do not have the dollars for marketing and commercialization of the product. To truly support economic development, we need for these small firms to have the support to make the jump from development to commercialization. How can SBIR/STTR support companies in making this leap and avoid the "Valley of Death"? Wouldn't we see a greater return on our tax dollar investment if the SBIR/STTR program dollars helped companies through the commercialization phase?

A1. For the past five years, the NIH focused on ways that can assist SBIR awardees cross the "Valley of Death." NIH has one of the highest success rates, and we attribute this to several factors. First, we recognize that the three-phase program progression is more a cyclical, rather than linear, uniform one. Thus, it may take multiple Phase I and Phase II projects to ultimately reach the Phase III stage. In addition, NIH offers gap-funding between Phase I and Phase II (e.g., Fast-Track awards, Phase I administrative and competitive supplement funding) and between Phase II and Phase III (e.g., Phase II Competing Renewal awards, Phase I administrative and competitive supplement funding; Commercialization Assistance Program; NIH Pipeline to Partnerships).

The funding a company receives can serve as leverage for attracting additional resources that are critical in helping a company cross the "Valley of Death." SBIR and venture capital or strategic partner investments act in synergy with all three phases of the SBIR and in accord with two broad legislated goals of the SBIR program:

- "To more effectively meet R&D needs brought on by the utilization of small innovative firms (which have been consistently shown to be the most prolific sources of new technologies) and
- To attract private capital investment to commercialize the results of federal research."

When the SBIR program was reauthorized in 2000, the authorizing legislation included a provision for the establishment of the Federal and State Technology Partnership (FAST) program, which was intended, in part, to strengthen the technological competitiveness of small business concerns in states. The types of services that States offered through the FAST program (e.g., technology deployment; establishing a mentoring network; commercialization assistance) are one approach that could help SBIR/STTR awardees "make the leap" to the marketplace.

A primary goal of the SBIR program is the commercialization of the outcome(s) of the research, leading to job creation and the significant attendant economic benefits to the Nation attached thereto. Phase II is the in-depth continuation of the project that has met the requirements of Phase I for scientific and technical feasibility. Thus, Phase II provides the greatest opportunity for achieving Phase III commercialization. Another approach, particularly given non-SBIR/STTR funding opportunities for which small businesses are competing, is to consider is an alternative to the current phased structure of the program where small businesses would not be restricted to having received an SBIR- or STTR-funded Phase I in order to obtain Phase II SBIR or STTR support.

Q2. New companies in my district find the Fast Track program extremely valuable, and have even been launched based on a fast-track Phase II award. The National Academies have also found that experimentation by the agencies, such as

the Fast Track program should be encouraged. Can you expand on how we can further promote the Fast Track program within SBIR/STTR?

A2. NIH has heard repeatedly, and the case studies gathered by the NRC in its recent assessment of the SBIR program at the NIH underscored, that one of the most difficult issues faced by small businesses and entrepreneurs is the funding gap between Phase I and Phase II. As one company noted, "The funding gap, which can be six months or more, creates an unstable employment environment. The funding gap can induce key scientific personnel to leave the firm and force the firm to abandon that line of research."

Current efforts to address this lull in funding include a Phase I/Phase II Fast-Track review option in which applicants submit a Phase I and Phase II simultaneously for concurrent review. The Fast Track program is intended for companies that have some preliminary data as well as measurable and realistic milestones for transitioning to Phase II seamlessly, and who may be able to obtain letters of interest from investors or strategic partners for carrying the R&D further along the commercialization pathway. In NIH's experience, encouraging but not requiring third-party support is very important given how early-stage some of the projects may be in the eyes of an investor or strategic partner. NIH has exercised caution to not create unrealistic expectations or put a company in a position that might compromise future partnerships.

We realize that the Fast-Track mechanism is not appropriate for all applicants or for all types of research, and in some cases, fully eliminating the funding gap is not possible. Therefore, NIH offers alternative gap-funding avenues such as no-cost award extensions, supplemental awards, and Phase II Competing Renewal awards.

One approach to promote the Fast-Track program within SBIR/STTR is to consider longer Phase I project periods such that the Phase II could be submitted in the second year of Phase I.

Q3. Do you see a need to encourage larger companies to participate in the SBIR/STTR program at an earlier stage? Would extending R&D tax credits on a limited basis to larger commercial partners provide more of an incentive for large companies to partner with a small firm that may be operating at a zero net profit?

A3. This is an interesting approach to consider and would add a new dimension to the SBIR and STTR programs. Extending R&D tax credits to larger commercial partners may provide more of an incentive to become involved with small companies at an earlier stage. Small companies may benefit from their involvement if the partners can bring resources that would supplement SBIR/STTR R&D activities and that would further the R&D toward commercialization.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Jere N. Glover, Attorney and Executive Director, Small Business Technology Council, Washington, DC

Question submitted by Representative Adrian Smith

Program evaluation, performance measures.

Q1. The recent National Research Council review of SBIR found that the program is "not sufficiently evidence-based" and is in need of improved data collection and tracking of program outcomes, as well as clear performance metrics for assessing the success or failure of a given initiative. Do you agree with this finding and recommendation?

A1. The National Research Council/National Academy of Sciences study of the SBIR Program[1] offered high praise for the Program, both in individual agencies and government-wide. Calling SBIR "an effective program" that "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" (p. 88 of the summary of the final report), the report also recommended improved data collection and tracking of program outcomes, as well as an enhanced culture of evaluation (pp. 73–4). The NRC/NAS identified "inadequate management funding" (p. 74) as the underlying cause of these needs and stated that "additional management resources are needed" (p. 76). The report weighed various approaches to financing these recommended steps. It noted that diverting funds from existing program dollars would "limit funds for awards to small companies, the program's core objective" (fn 68, p. 76). But a new funding set-aside, dedicated to these data collection and evaluation initiatives, and structured within an overall increase in the SBIR Program set-aside, would "perhaps be more easily achievable" (fn 68, p. 76), the report observed. The report recommended a management funding increase of 0.03 percent to 0.05 percent, and noted that even the upper end of this range (0.05 percent) would still only bring the total SBIR set-aside "to 2.55 percent, providing modest resources to assess and manage a program that is approaching an annual spend of some $2 billion" (fn 68, pp. 76–7).

SBTC agrees with both the need and the solution identified by the NAS study. There *is* a need for better data collection and evaluation, and enhanced funding for program management *would best address* the need. We urge Congress to increase the management funding for SBIR as part of an overall increase in the SBIR set-aside, as described further in our testimony.

Questions submitted by Representative Daniel Lipinski

Q1. If the SBIR and STTR award amounts are increased and the set-asides are not, thus resulting in fewer awards, what do you think the impact will be on the number of successful commercializations? Will we see more successes because we cull out more marginal companies and increase award sizes, or will it diminish the overall impact of the program because it eliminates research on promising ideas?

A1. In assessing commercialization strategies, it must be remembered that the primary goal of the SBIR Program, and indeed most federal R&D, is to conduct research that *the government needs.* Thus the R&D topics chosen by the government for SBIR solicitations often do not lend themselves to private sector commercialization. Yet, as the NRC/NAS studies show, the SBIR Program still manages to move some 40–50 percent of its innovations close to the point that they are commercially feasible. This is an impressive feat, but it is due in large part to the current design of the SBIR Program. Crucially, SBIR and STTR sets relatively low award maximums for Phase II, and particularly for Phase I. This makes the Program dollars go further, because technological approaches that turn out to be unworkable or highly unpromising are cut off quickly, before much money has been spent on them.

SBTC regards it as very unlikely that a major increase in the SBIR and STTR award maximums would lead to more commercialization. In the first place, the R&D that SBIR and STTR fund is very high-risk, meaning most Phase I innovations will not reach Phase II. In the second place, SBIR and STTR are intended to address

[1] National Research Council, Chuck Wessner, editor, *An Assessment of the SBIR Program,* National Academies Press, 2008.

Federal Government R&D priorities. Thus, quite a few Phase I's will lose out in competition with better technologies and never get to Phase II. Then, quite a few Phase II's will do just fine addressing the government's needs, but won't interest the private sector. *The more robust the SBIR Program is, in terms of the number of science and technology ideas that it can choose from, the more likely the Program is to identify breakthrough innovations, for both the government and, subsequently, the private sector.*

Fewer and larger awards would not only reduce the options for later development and commercialization. They would also significantly increase the odds against a company winning an SBIR award, particularly a Phase II SBIR award. This would discourage many companies from making the effort to apply. As SBIR Founder Roland Tibbetts wrote, in a White Paper that SBTC included with its testimony:

> *"With the high risk involved in early-stage R&D, there is a need to diversify the federal investment by betting on many, rather than fewer, technologies and ideas . . .. Most of those I worked with in developing SBIR agreed that the technologies involved were such inherently high-risks that smaller bets should be made on many projects before making a few larger bets . . .. My own 20-year experience as an SBIR Program Manager subsequently confirmed that the economic payoffs would be higher this way. Many smaller awards mean that more ideas can be evaluated for their potential. More and better choices for further development become available . . .. If there are fewer SBIR awards in the future, not only will fewer technologies get evaluated and funded. Fewer companies will compete, because the odds against winning will get even higher . . .. There will be no shortage of great new innovations to invest in if we allow SBIR to do its work in supporting truly innovative small companies by objectively assessing which ideas are wheat and which ones chaff."*

Q2. During the hearing, Dr. Rockey discussed the NIH "Phase 2.5" competitive reawards. The NSF has a similar "Phase II supplement" program. Is either of these programs, or are there similar efforts at other agencies, that are particularly effective at commercializing products toward the end of their Phase II grant?

a. Does the current approach to Phase III funding for commercializing products, which precludes using any SBIR or STTR funds, work for companies and products that are trying to move beyond their Phase II grant? Are there changes that you would recommend?

A2. The NIH "Phase 2.5" NSF Phase II supplement" programs have helped many companies move their technology closer to ripeness for commercialization. SBTC believes that these programs have been largely successful. The structure and cost of these programs must be continually evaluated, however. They, and similar programs elsewhere in the government, must not drain away funding needed for the Phase I and Phase II core of the SBIR Program, the seed bed of its innovations.

Q3. Some of the nanotech businesses I've spoken with in Chicago have pointed to inconsistent paperwork as an obstacle encountered by people who are trying to turn their idea from a laboratory success into a small business. Can you comment on the consistency of SBIR and STRR program and application procedures across and within agencies? Is this something that discourages first-time SBIR applicants?

A3. DOD, the agency with the largest SBIR budget, has consolidated and standardized its application process across the twelve diverse operational units that participate in its SBIR Program.[2] That change is working well. The DOD example shows that more standardization is possible. So Representative Lipinski and his constituents have good point: agencies in the SBIR Program ought to do more to standardize. Generally the SBIR law requires the agencies to use the same awards process, but the agencies have evolved different application processes and to some extent different proposal evaluation processes. Much more standardization could be achieved. At the very least, SBIR applications could be divided into two parts, one of which is common to all agencies in the Program, and the other of which meets more specific agency needs. We would note, for example, that the "Grants.gov" process used by NIH is extremely hard for first-time applicants to master. By contrast,

[2] These include the Departments of the Air Force, Army and Navy, Chemical and Biological Defenses Program, Defense Advanced Research Projects Agency, Defense Logistics Agency, Defense Media Activity, Defense Threat Reduction Agency, Missile Defense Agency, National Geospatial Intelligence Agency, Office of the Secretary of Defense, and United States Special Operations Command.

the NSF application procedure is far more user-friendly, especially for first time users.

As the agency that administers SBIR, SBA should play a role in this, perhaps by bringing in a specialized management consulting firm to move the process forward.

Questions submitted by Representative Gary C. Peters

Q1. When I talk with my constituents back home, they echo much of what has already been said here: that the SBIR/STTR programs are often the life blood for small firms, and that small firms are a crucial driver of innovation. However, they also mention the "Valley of Death" that occurs for technologies after the prototype has been developed. The companies do not have the dollars for marketing and commercialization of the product. To truly support economic development, we need for these small firms to have the support to make the jump from development to commercialization. How can SBIR/STTR support companies in making this leap and avoid the "Valley of Death"? Wouldn't we see a greater return on our tax dollar investment if the SBIR/STTR program dollars helped companies through the commercialization phase?

A1. The "Valley of Death" problem exists for every new technology-based business. And our country hasn't yet found a way to solve it. Consider venture capital investments. They succeed in roughly *one case out of every eight.* Thus even a large majority of those companies that attract VC investment never exit the "Valley of Death." The SBIR success rate for moving early-stage R&D to a later stage of development—defined as sales or investments in excess of SBIR awards—is in the 40–50 percent range. While this is a remarkable achievement, as the NRC/NAS report often emphasizes, it still falls short of the commercialization that's needed. Ironically, it has been the amazing success of SBIR as a nurturer of technology that has increased the calls to shift its limited funds to commercialization.

In assessing SBIR, then, it is important to keep in mind that the Program was never designed to bridge the "Valley of Death." Rather, it was designed as a competitive, science-based source of early-stage R&D investments. It is supposed to stimulate the creation of innovative technologies and then move these technologies on to later stage development.

For more than twenty years, SBIR has been the Nation's largest source of early and seed-stage R&D funding. Today *SBIR provides more than ten times as much early-stage and seed capital as venture capital investments,* even though VC investments overall are orders of magnitude larger than the entire SBIR and STTR Programs. Diverting the scarce early-stage funding that SBIR currently provides, and shifting it to much later-stage commercialization funding, would be bad policy for several reasons. First, it would duplicate funding that is already available from many sources, including "angel" funding, bank lending, IPOs, and venture capital financing. Second, and much more destructively, it would dry up a vital stream of innovations before they can *reach the potential* for commercialization.

Instead of consuming the SBIR seed-corn by diverting precious early-stage R&D funding to commercialization, we should find new ways to grow the plants.

Programs such as the former Advanced Technology Program (ATP), now the Technology Innovation Program (TIP) at the National Institute of Standards and Technology have shown great promise in helping companies cross the "Valley of Death." These programs should be expanded. Other new programs outside SBIR should be devised and tested.

Within the SBIR program, the SBIR Commercialization Pilot Program at DOD has been successful in moving technology to a later stage of development where Phase III mainstream procurement funding may be available.[3] (The program's title is something of a misnomer, though, since it does not actually commercialize technologies.).According to the Defense Department, the CPP has provided about 100 SBIR companies (50 in the Navy and 25 each in the Air Force and Army) with about $100 million in development funding.[4]

While it is early to know with certainty, the CPP appears to be successful in advancing some defense technologies to a higher level of development. Programs such as CPP should be expanded to agencies such as DOE and NASA, where technological innovations can be similarly channeled toward consumption by the government itself, via the mainstream procurement system.

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[3] See National Research Council, *SBIR and the Phase III Challenge of Commercialization,* National Academies Press, 2007.

[4] U.S. Department of Defense, Small Business Innovation Research Program, Commercialization Pilot Program (CPP), Report for Fiscal Year 2008, April 2009.

The challenge remains, however, to balance early and later stages of development funding within SBIR's finite budget. Selection processes for later stage funding need to be rigorous, transparent, and competitive. And the tradeoffs between enhanced funding for later stage development and reduced funding for early stage development need to be explicitly acknowledged.

Q2. New companies in my district find the Fast Track program extremely valuable, and have even been launched based on a fast-track Phase II award. The National Academies have also found that experimentation by the agencies, such as the Fast Track program should be encouraged. Can you expand on how we can further promote the Fast Track program within SBIR/STTR?

A2. SBTC agrees with the NRC/NAS finding that agency experimentation in pushing SBIR technologies forward should be encouraged. Fast Track, Phase IlB, and CPP have indeed proven helpful. But, as noted above, these and other such programs should not be expanded at the cost of significantly reducing the number of Phase I and Phase II SBIR awards that can be made.

Q3. Do you see a need to encourage larger companies to participate in the SBIR/STTR program at an earlier stage? Would extending R&D tax credits on a limited basis to larger commercial partners provide more of an incentive for large companies to partner with a small firm that may be operating at a zero net profit?

A3. As shown in the NRC/NAS reports, the SBIR program has been remarkably successful in creating technologies that larger companies want to access. Nearly 1,300 SBIR companies have been acquired by larger firms. Partnerships between larger firms and SBIR companies now number in the thousands, and hundreds of licenses have been sold by SBIR companies to such larger firms. Indeed, the original design for the SBIR Program depends on larger companies coming in at Phase III—as buyers, investors and partners—in order for SBIR companies to successfully commercialize innovations. Likewise, the STTR Program partners small companies with universities, who may in turn seek to link up with large companies to foster commercialization at the Phase III stage of that Program.

But neither SBIR nor STTR should invite large companies in at an earlier stage, in SBTC's view. There are several reasons for this.

First, SBIR has been described to the public as a small business program for 25 years. Much of the Program's public support is rooted in that still quite accurate characterization. Devaluing the "SB" of "SBIR" would not only endanger the empirical basis of the Program's success, as has been shown in the NAS studies. It would also gravely endanger public support for the Program.

Second, large companies already have access to other sources of federal R&D funding—the 97.2 percent that *isn't* allocated to small business through the SBIR and STTR Programs. Small companies don't have that access. Even though small companies today employ six million scientists and engineers—significantly more scientists and engineers than either large companies or universities—and are producing more of the top innovations than either of them (see pp. 7–8 of our Subcommittee testimony), small companies still obtain only 4.3 percent of federal R&D dollars. And SBIR/STTR accounts for over half of that. If a group of SBIR applicants were to be backed by large companies, they would be able to generate far more polished-appearing applications, in far greater numbers, than smaller companies. This would soon swamp many smaller companies. Deserving technological ideas would lose out, as these deep-pocketed companies with large business backing took over more and more of the Program.

Third, large companies have fundamentally different attitudes toward innovation than smaller companies. Large companies have product lines, sales channels, and customer bases to protect. Small companies are looking for the breakthroughs that will generate entirely new products and lines of business. Insert large companies into Phase I and II of the SBIR Program, and they will inevitably imbue their SBIR apprentices with far narrower and more guarded attitudes toward R&D. Here again SBIR Founder Roland Tibbetts is eloquent:

> *"(The large company looks for] incremental innovations that make its existing products a little better and a little cheaper to produce. It looks for new products that are familiar and comfortable. For large companies, "re-defining" types of innovations are frightening. They upset settled ways of doing business. The Nation needs both incremental innovations and quantum-leap innovations, but right now and for the foreseeable economic future, it needs those out-sized innovations the most. SBIR can deliver sweeping innovations, but to do so it must avoid taking on the coloration and biases of large companies."*

The question of R&D tax credits for larger companies requires a careful balancing of tax, innovation, and budget priorities. But in general SBTC would favor any reasonable incentive to promote the post-Phase II commercialization of SBIR technologies that does not diminish SBIR funds.

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