SMALL BUSINESS INNOVATION RESEARCH REAUTHORIZATION ON THE 25TH PROGRAM ANNIVERSARY

HEARINGS

BEFORE THE

SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

COMMITTEE ON SCIENCE AND TECHNOLOGY

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

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SMALL BUSINESS INNOVATION RESEARCH REAUTHORIZATION ON THE 25TH PROGRAM ANNIVERSARY

THURSDAY, APRIL 26, 2007

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

The Subcommittee met, pursuant to call, at 1:05 p.m., in Room 2325 of the Rayburn House Office Building, Hon. David Wu [Chairman of the Subcommittee] presiding.

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL, TEXAS
RANKING MEMBER

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The Subcommittee on Technology and Innovation

Hearing on:

"Small Business Innovation Research Reauthorization on the 25th Program Anniversary"

2325 Rayburn House Office Building
Washington, D.C.

Thursday April 26, 2007
1:00 p.m.

WITNESS LIST

Mr. Bruce J. Held
Director of the Force Development and Technology Program
RAND Arroyo Center
The RAND Corporation

Mr. Jon Baron
Executive Director
Coalition for Evidence-Based Policy
Council for Excellence in Government

Mr. Robert N. Schmidt
Founder and Chairman
Cleveland Medical Devices Inc. and Orbital Optical Research Inc.

Dr. Gary McGarrity
Executive Vice President of Scientific and Clinical Affairs
VIRxSYS Corporation

Mr. Anthony R. Ignagni
President and CEO
Synapse Biomedical Inc.

HEARING CHARTER

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

Small Business Innovation Research Reauthorization on the 25th Program Anniversary

THURSDAY, APRIL 26, 2007
1:00 P.M.–3:00 P.M.
2325 RAYBURN HOUSE OFFICE BUILDING

1. Purpose

On Thursday, April 26, the Subcommittee on Technology and Innovation of the Committee on Science and Technology will hold a hearing to review the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Program (STTR) programs.

2. Witnesses

Mr. Bruce J. Held is the Director of the Force Development and Technology Program at the RAND Arroyo Center, The RAND Corporation.

Mr. Jon Baron is the Executive Director of the Coalition for Evidence-Based Policy, a program of the Council for Excellence in Government.

Mr. Robert N. Schmidt is Founder and Chairman of Cleveland Medical Devices Inc, and Orbital Research Inc.

Dr. Gary McGarrity is Executive Vice President of Scientific and Clinical Affairs of VIRxSYS Corporation.

Mr. Anthony R. Ignagni is President and CEO of Synapse Biomedical Inc.

3. Hearing Issues

- **Program Effectiveness:** Are the SBIR and STTR programs meeting program objectives to stimulate and commercialize innovation in support of agency missions through expanded small business participation in extramural federal R&D? How could program efficiency and effectiveness be improved? Does flexibility in program administration contribute to the program effectiveness across agencies with diverse missions?
- **Award Levels.** What are the appropriate award levels in light of typical project costs to support agency missions, the trends in seed and early stage financing, and the fact that there has not been an inflationary adjustment in award levels since 1992?
- **Small Business Participation.** How can the programs increase the participation of innovative small businesses in federal R&D—the total number of small businesses, the geographic distribution, and the participation of minority and disadvantaged firms?
- **Financing and Commercialization.** What common program elements are needed across all agencies to address financing gaps in the Phased award structure, to encourage private equity participation, provide commercialization assistance, and increase small business's share of federal procurement and non-SBIR/STTR federal R&D?
- **Administrative Costs.** How should program administration costs be addressed in reauthorization? Today, costs are paid out of non-SBIR/STTR program funds.
- **Venture Capital Majority Ownership.** Should small businesses be able to participate in the SBIR/STTR programs if multiple venture firms hold some

ownership of the firm at the time of grant award and together hold majority ownership? How would this incrementally support agency missions and project commercialization? Would VCs provide additional project funding beyond SBIR awards and commercialization assistance? Is NIH the only agency that requires this flexibility to address the funding requirements of the biotechnology industry?

4. Background—The SBIR/STTR Programs

SBIR was established in 1982 by the *Small Business Innovation Development Act* [P.L. 97–219] to increase the participation of small, high technology firms in federal research and development (R&D) activities. The Act outlined four broad congressional goals:

- To stimulate technological innovation
- To use small business to meet federal R&D needs
- To foster and encourage participation by minority and disadvantaged persons in technological innovation
- To increase the private sector commercialization of innovations derived from federal R&D.

SBIR has been reauthorized twice in 1992[1] and 2000, with authorization extended through September 30, 2008.

Small businesses are eligible for SBIR awards if they are independently owned and operated for-profit companies, not dominant in the field of research proposed, and employ fewer than 500 people.

Under SBIR, departments and agencies with extramural RDT&E budgets of $100 million or more are required to set aside 2.5 percent of these budgets to sponsor research at small companies through the SBIR program. The award competition is peer reviewed and highly competitive with only 15–20 percent of Phase I (feasibility) stage applicants winning awards. Awards are based on scientific, technical and commercial merit.

Currently, 11 departments and agencies sponsor SBIR programs: the Departments of Defense (DOD), Commerce, Education, Health and Human Services, Housing and Urban Development, Homeland Security, Transportation, Energy, and the Environmental Protection Agency, the National Aeronautics and Space Administration, and the National Science Foundation. DOD, HHS/NIH, DOE, NASA & NSF accounted for 96 percent of SBIR program awards in FY05 (DOD and HHS/NIH alone, 81 percent).

Each agency runs its own SBIR program, emphasizing research areas supporting the mission of the particular agency. There is a great deal of diversity between programs and even within organizations of an agency. For example, DOD has 10 participating components making SBIR awards, and the individual programs differ in how topics are selected and commercialization assistance offered. DOD and NASA, in particular, integrate award winners into their procurement processes. But SBA is supposed to establish broad policy guidelines for the SBIR program. SBA monitors program implementation and reports award statistics to Congress including minority and disadvantaged participation.

From its inception in 1982 to 2005, over $18.9 billion in SBIR awards have been made for more than 88,800 research projects. In fiscal year 2005, SBIR made 6,171 awards, totaling $1.86 billion.

The SBIR program is divided into three phases. Phase I awards (up to $100,000) fund research projects designed to evaluate the feasibility and the scientific and technical merit of an idea. Phase II awards (up to $750,000) provide additional funding for Phase I projects that have demonstrated potential for successful development. Funding covers further development to the prototype stage. Companies are expected to leverage SBIR funding to obtain private or non-SBIR government funding to turn the prototype developed in Phase II into a commercial product or service for sale to government and private sector customers in Phase III. No SIBR funds support Phase III. Phases I and II proposals are evaluated on the scientific and technical merit of the proposed research, the qualification of key personnel, and the potential for transition into a commercial product.

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[1] In 1992, Congress expanded the purposes to include to "emphasize the program's goal of increasing private sector commercialization developed through federal research and development and to improve the Federal Government's dissemination of information concerning the small business innovation, particularly with regard to women-owned business concerns and by socially and economically disadvantaged small business concerns."

STTR was established in 1992 by the *Small Business Research and Development Enhancement Act* (P.L. 102–564) and reauthorized again in 1997 and in 2001 through September 2009. It funds cooperative R&D conducted jointly by small businesses and research institutions (universities, federally funded R&D centers (FFRDCs) or domestic nonprofit research organizations). Like SBIR, the research must support the mission of the funding agency. For STTR the set aside is 0.3 percent for departments that spend over $1 billion per year in extramural R&D. The Departments of Defense, Energy, Health and Human Services, NASA and NSF participate in the STTR program. In FY 2005, there were 832 STTR awards totaling $220.3 million.

History of SBIR Program

The SBIR program was designed to enable innovative small businesses engage in high-risk research and development to compete successfully with large firms and universities for federal R&D grants and contracts. Small companies are at a disadvantage in spite of their great potential to contribute to the Nation's science base. They are also a major source of new jobs. STTR extends the principal to cooperative research with research organization such as universities and federal labs.

In 2001, the most recent reauthorization of SBIR, the *Small Business Reauthorization Act* [P.L. 106–554] required a study by the National Research Council (NRC) to review of the performance of the five largest SBIR programs and semiannual progress reports to the Committee on Science and the House and Senate Committees on Small Business.[2] To date, the NRC has published three reports[3], but results of the individual agency SBIR program assessments and study findings and recommendations have not been released.

The Act also required SBA to establish databases of SBIR activity to help track and assess the performance of the SBIR program, and encouraged SBIR agencies to do a better job of partnering with states via the creation of the Federal and State Technology Partnership (FAST) program and Rural Outreach Program (ROP). FAST is a competitive grants program that allows each state to receive funding in the form of a grant to provide services to promote participation in the SBIR program. ROP provides federal assistance to support statewide outreach to small high-tech business located in 25 states that are under-represented in SBIR/STTR awards.

Effective, January 3, 2005[4], the SBA revised its eligibility criteria for SBIR to allow a wholly-owned subsidiary to participate, providing its parent company, with all its affiliates, still meets the eligibility criteria.

The SBA policy directive requires owners of the SBIR/STTR participant be "individuals" who are "citizens of, or permanent resident aliens in the United States." The regulations do not provide that corporations or other artificial entities may qualify as "individuals."

Other legislative and executive branch actions have shaped the SBIR/STTP program. Section 252 of the *National Defense Authorization Act (NDAA)* of FY 2006 [P.L. 109–163] contains elements to strengthen the SBIR program in DOD, including a stronger focus on cutting-edge R&D, on SBIR Phase III prime contracting and subcontracting opportunities through creation of a Commercialization Pilot Program, and on small high-tech manufacturing by adopting into law, Executive Order 13329, *Encouraging Innovation in Manufacturing.* E.O. 13329 (February 24, 2004) encouraged federal agencies to assist the private sector in its manufacturing innovation efforts through the SBIR and STTR programs.

5. Background—Hearing Issues

Program Effectiveness. Section 108[5] of the *Small Business Reauthorization Act of 2000* mandated the National Research Council "conduct a comprehensive study

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[2] Sec, 108. National Research Council Reports.

[3] The three reports are: *Program Diversity and Assessment Challenge, Project Methodology,* and *Phase III Challenge of Commercialization.*

[4] December 3, 2004, 13CFR121.702

[5] Sec.108(a)(1) says the **comprehensive study should include:** "(A) a review of the value of the federal research agencies of the research projects being conducted under the SBIR program, and of the quality of research being conducted by small businesses participating under the program, including comparison of the value of projects conducted under the SBIR program to those funded by other federal research and development expenditures; (B) to the extent practicable, an evaluation of the economic benefits achieved by the SBIR program, including the economic rate of return, achieved by the SBIR program with the economic benefits, including the economic rate of return, of other federal research and development expenditures; (C) an evaluation of the non-economic benefits achieved by the SBIR program over the live of the program; (D) a comparison of the allocation for fiscal year 2000 of federal research and development funds

Continued

of how the SBIR program has stimulated technological innovation and uses small businesses to meet federal research and development needs." In addition, DOD commissioned the RAND Corporation to evaluate and make recommendations to improve the DOD SBIR program. The results of this report are the subject of the testimony by Bruce Held.

Award Levels. The financing gap for seed and early stage firms, the "valley of death," is still a looming business risk as venture capital firms raise the floor of their investments to several million dollars and focus on investment in business expansion rather than the most risky stages of innovative firms.

Small Business Participation. Outreach programs play a vital role to insure broad geographic distribution of awards and the participation of minority and disadvantaged firms. But, support has not been included in the administration budgets since FY05 for the SBA Federal and State Technology Partnership (FAST) program and Rural Outreach Program (ROP).

Participation could broadly be increased by raising the set-aside above the current 2.5 percent for SBIR. The initial set-aside in 1982 was 1.25 percent of extramural R&D. That was increased to 1.5 percent in 1992 and 2.5 percent in 2000. There have already been significant increases in SBIR funding in the last eight years as a result of the doubling of NIH budget between FY 1999 to FY 2003, and the rise in defense spending since 2001. In addition, the Administration's ACI proposal doubles a portion of NSF, DOE and NIST's budget with associated increases in SBIR program funds.

Financing and Commercialization. As the NRC notes in their study of SBIR, "Commercializing SBIR supported innovation is necessary if the Nation is to capitalize on its SBIR investments. This transition is, however, challenging because it requires a small firm with an innovative idea to **evolve quickly** from a narrow focus on R&D to a much broader understanding of the complex systems and missions of federal agencies as well as the interrelated challenges of managing a larger business, developing sources of finance, and competing in the marketplace."[6]

Since no SBIR/STTR funds support Phase III, firms must begin early in Phase II to plan to cross the "valley of death" where the lack of sufficient funds and commercialization assistance can easily trap a firm. To assist, federal agencies have developed innovative policies to help SBIR and STTP firms address financing gaps inherent in the award cycles, provide incentives to attract third party funds in Phase II and III, to match or showcase SBIR technologies with private companies and government agencies, and encourage insertion of SBIR developed technologies into agency procurement programs.

Administrative Costs. Existing law prohibits the use of SBIR and STTR funds to cover the program's administrative costs, including commercialization assistance, technical assistance beyond $4000 per phase, program evaluation, and salaries. This forces the agencies to pay for these costs out of non-SBIR/STTR program funds. These administrative costs can be critical to program effectiveness.

Venture Capital Majority Ownership. There is a sharp debate in the research and venture capital communities on whether it is appropriate for SBIR awards to be given to small businesses that are majority-owned by venture capital (VC) firms.

SBIR is very attractive to entrepreneurs because the awards are either grants or contracts and do not dilute company ownership. Moreover, companies retain rights to technical data for a four year non-disclosure period following each award. The appeal of SBIR awards extends to private capital when they evaluate investments. An SBIR award provides the firm an imprimatur (a certificate or mark of official ap-

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to small businesses with such allocation for fiscal year 1983, and an analysis of the factors that contributed to such allocation; and (E) an analysis of whether federal agencies, in fulfilling their procurement needs, are making sufficient effort to use small businesses that have completed a second phase award under the SBIR program."

Sec. 108(a)(2) further requires **NRC "make recommendations** with respect to—(A) measures of outcomes for strategic plans submitted. . .of each federal agency participating in the SBIR program; (B) whether companies who can demonstrate project feasibility, but who have not received a first phase award, should be eligible for second phase awards on the competitive selection process of the program; (C) whether the Federal Government should be permitted to recoup some or all of its expenses if a controlling interest in a company receiving an SBIR award is sold to a foreign company or to a company that is not a small business concern; (D) how to increase the use by the Federal Government in its programs and procurements of technology-oriented small businesses; and (E) improvements to the SBIR program, if any are considered appropriate." (emphasis added)

[6] National Research Council, *SBIR and the Phase III Challenge of Commercialization,* 2007, p. 5 (emphasis added).

proval through the peer review process) as an innovative firm, reducing the due diligence required by private investors.

Proponents of changing the current rule argue that VC firms are a major source of financing and that VC support can help a firm continue research and commercialize products beyond the start with SBIR funding. Opponents contend that VC firms control small business firms through the protective covenants of their investments. Therefore, opponents argue, small businesses that are controlled by VC firms are not independent small businesses in need of special research funding and do not merit SBIR support.

Why Now? The current dispute over VC funding began in 2001, when the SBA Office of Hearings and Appeals issued a ruling against the majority ownership of SBIR companies by VC firms in response to an appeal of a rejection of SBIR funding by NIH based upon majority VC ownership.[7] The ruling made by the Administrative Law Judge stated that VC firms were not "individuals," i.e., "natural persons," and therefore SBIR agencies could not give SBIR grants to companies in which VC firms had a controlling interest. BIO and NVCA claimed this was a new interpretation of the VC-small business relationship, but SBA said it was simply a clarification and enforcement of eligibility standards. VCs can take majority ownership after an award is made but the firm would thereafter be denied further awards or enhancements.

Advocates for Expanded VC Participation in SBIR-eligible Companies

The biotechnology industry is the strongest advocate for unrestricted VC affiliation with SBIR-funded companies. Advocates argue that the SBA rule at best creates a meaningless barrier to private-sector investment that inhibits growth of budding companies, and at worst blocks the translation of new discoveries into life-saving products for numerous fatal diseases. They point out that biotechnology R&D is capital-intensive and the involvement of VC money is critical to bring drugs through the development phase to market. BIO and NVCA have taken the official position that eligibility for SBIR awards should be expanded to include small companies that are majority owned by a consortium of VC firms.

Advocates for Limited VC Participation in SBIR

However, the biotechnology industry is not entirely united in its opposition to SBA's policy. Some biotechnology experts and company representatives argue that, if SBA regulations allowed more VC-backed companies to apply for SBIR grants, they would crowd out completely independent small research companies run or owned by individuals who focus on opportunities that do not match VC investment criteria (e.g., more niche markets but are nonetheless medical needs). They also point out that SBIR-eligible companies are currently able to attract VC backing without giving away a majority stake, and therefore it is not necessary to expand the role of VC.

Beyond the biotechnology industry, some companies and small business advocates point out that many large companies, such as Intel, have set up VC funds as a means of investing in, and ultimately buying promising new companies that develop breakthrough technologies. They argue that if the Federal Government funded small businesses backed by such VC funds, the SBIR program could end up subsidizing the acquisition of small businesses by big businesses. This, for example, is the position held by the Small Business Technology Coalition (SBTC), for example.

[7] CBR Laboratories, Inc. of Boston Massachusetts.

Chairman WU. I want to welcome everyone to this afternoon's hearing of the Technology and Innovation Subcommittee on Small Business Innovative Research Authorization. This year represents significant milestones in the history of SBIR as well as the Small Business Technology Transfer Program. July 22nd will be the 25th anniversary of SBIR, and October 28 will be the 15th anniversary of STTR. Indeed, one of our witnesses, Mr. Baron, was counsel on the House Committee on Small Business where he led the effort to secure enactment of legislation establishing the STTR program in 1992.

SBIR is a highly competitive program that encourages small businesses to explore and develop innovative, high-risk technical projects. By including qualified small businesses in the federal R&D arena, high-tech innovation is stimulated, strengthening U.S. innovation and competitiveness.

SBIR and STTR were last authorized in 2000 and 2001 respectively. Today we invite our witnesses to address the overall effectiveness and efficiency of these programs in the intervening years and to recommend changes to improve the programs.

In addition, we have invited federal agencies with both SBIR and STTR Programs to submit written statements for the record with the same objective.

I would like to highlight a few key issues we will consider today. First, award levels. Should award levels be larger for Phase I and Phase II? The "Valley of Death" for seed and early stage companies persists as venture capital firms continue to raise their level of investment and focus on mid- and later-term stage investments where there is less financial and technical risk. Moreover, the SBIR award levels have not been adjusted since 1992.

Second, small business participation. How do we broaden the participation of minority and disadvantaged firms as well as expand the regional participation of innovative small businesses and federal R&D?

Third, financing and commercialization. Agencies are currently prohibited from using SBIR program funds to support administrative costs. Would permitting the use of a percentage of SBIR program funds for technical and commercialization assistance and ongoing program evaluation improve commercialization rates?

Finally, participation of venture capital. There has been debate about SBIR eligibility standards and the program impact of permitting awards to firms when multiple venture capital firms own majority ownership of the firm.

All of these issues are on the table today for comment and discussion with our witnesses. We look forward to hearing your thoughts on how to improve both the effectiveness and efficiency of these programs.

[The prepared statement of Chairman Wu follows:]

PREPARED STATEMENT OF CHAIRMAN DAVID WU

I want to welcome everyone to this afternoon's hearing of the Technology and Innovation Subcommittee on Small Business Innovation Research (or SBIR) Authorization.

This year represents significant milestones in the history of SBIR as well as the Small Business Technology Transfer Program (STTR) program. July 22 will be the 25th anniversary of SBIR, and October 28 will be the 15th anniversary of STTR.

Indeed, one of our witnesses, Mr. Baron, was counsel on the House Committee on Small Business where he led the effort to secure enactment of legislation establishing the STTR program in 1992.

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I would like to highlight a few key issues we will consider today:

- **Award Levels.** Should award levels be larger for Phase I and II of the program? The "Valley of Death" for seed and early stage companies persists as venture capital firms continue to raise their minimum level of investment and focus on mid- and later-stage investments where there is less technical risk. Moreover, the SBIR award levels have not been adjusted since 1992.
- **Small Business Participation.** How do we broaden the participation of minority and disadvantaged firms, as well as expand the regional participation of innovative small business in federal R&D?
- **Financing/Commercialization.** Agencies are currently prohibited from using SBIR program funds to support administrative costs. Would permitting the use of a percentage of SBIR program funds for technical and commercialization assistance and ongoing program evaluation improve commercialization rates?
- **Venture Capital.** Finally, there has been debate about SBIR eligibility standards, and the program impact of permitting awards to firms when multiple venture capital firms hold majority ownership of the firm.

All these issues are on the table today for comment and discussion with our witnesses. We look forward to hearing your thoughts on how to improve both the effectiveness and efficiency of these programs.

Chairman WU. Now, I would like to welcome my friend and colleague, the Ranking Member of this subcommittee from Georgia, Dr. Gingrey for his opening remarks.

Mr. GINGREY. Thank you, Mr. Chairman. Good afternoon, everybody, and I want to thank all of your for attending, especially our five witnesses for this hearing on the Technology and Innovation Subcommittee of the Science Committee.

Today we will be looking, as the Chairman said, at the Small Business Innovation Research Program as it goes forward in this, its 25th silver anniversary. This hearing precedes the Subcommittee's markup of reauthorization language, hopefully some time this summer.

The SBIR Program began in 1982 when our government saw a need to increase our national investment in research and development to specifically seek technological innovations in emerging areas. The ultimate goal of the SBIR Program is to bring new products and technologies to commercialization in order to stimulate international competitiveness. This program is an important stepping stone in the overall goal to keep America's competitive advantage in the worldwide marketplace.

Under the SBIR Program, departments and agencies with an R&D budget of $100 million or more are required to actually set aside 2.5 percent of these budgets to sponsor research at small companies. These awards are highly competitive with only the most pioneering and innovative companies receiving any federal money. Currently 11 departments and agencies sponsor SBIR Programs in-

cluding the Department of Defense, Education, Health and Human Services, Homeland Security, Department of Energy, as well as NASA, the National Aeronautics and Space Administration, the National Science Foundation, and the National Institutes of Health.

The SBIR Program is divided into three phases. The initial phase, Phase I, grants awards for the maximum amount of $100,000 for exploration of the technical merit or feasibility of an idea or technology. Phase I awardees may then compete—once again, highly competitive—for Phase II awards which has a maximum award of $750,000 for research that expands upon promising Phase I results. It is during this second phase of the program that the developer evaluates the commercialization potential.

Phase III is that period during which Phase II innovation moves from the laboratory into the marketplace. This of course is the essence of a technology transfer. It is important to note that no SBIR funds support this final phase. The small business must then find funding in the private sector or other non-SBIR federal agency funding in order to complete the technology transition to commercialization.

I am sure there are many people outside of the Federal Government that are not familiar, Mr. Chairman, with the SBIR Program. However, I am here to tell you, and I know you agree with me, that it is a hidden gem. Agencies give a percentage of their major federal R&D budget to support our country's most ground-breaking and pioneering small businesses. I know I do not have to convince anyone here that small businesses truly are the engine that drives this thriving economy, and the SBIR Program is a crucial spark that initiates this success. As a physician five years removed from the practice of OB/GYN, I am keenly interested in the medical breakthroughs and the innovative research headquarters at NIH. The SBIR Program at the Institute has helped spawn new hopes for victims of a variety of diseases such as cancer, HIV/AIDS, Alzheimer's, and of course, especially Type I diabetes.

Neural Signals is an example of one of the many SBIR success stories, and it is located in my home state of Georgia. Neural Signals allows severely paralyzed or locked-in individuals to control their personal computers via a thought control, eliminating completely the need for patient-initiated movement. Amazing.

Another amazing event that's been coming out of the SBIR program is from a company named Abiomed. AbioCor is a product which is a result of three decades of research, development, and testing which produced the world's first completely self-contained replacement heart. This is an outstanding innovation that makes real the day when heart failure, one of our biggest killers, will not mean the end of life or the ability to enjoy life.

We will also hear from Anthony Ignagni of the Synapse company, Synapse Biomedical, and he will discuss their minimally-invasive neuron stimulation devices that will replace or assist mechanical ventilation. Synapse is conducting multi-centered clinical trials at locations across the country, including the Shepherd Center in Atlanta, which is the leading center for treatment of spinal cord injuries in this country. I was—had the opportunity at the start to speak to Mr. Ignagni and let him know that I have a brother who

volunteers there with the feeding of the patients, and I know how important it is to be able to help them with this kind of innovative technology that leads to commercialization.

I am excited to hear the testimony and look forward to the testimony of our five witnesses, as we discuss ways to improve upon this great SBIR Program.

Mr. Chairman, I probably took a little longer than you anticipated, but I thank you for the opportunity to be with you on this subcommittee to serve with you on this subcommittee and on the Science Committee overall. A hearing like this is so, so important, and I am glad to see a good audience in attendance; and with that, I will yield back to you, Mr. Chairman.

[The prepared statement of Mr. Gingrey follows:]

PREPARED STATEMENT OF REPRESENTATIVE PHIL GINGREY

Good Afternoon. I would like to thank everyone for attending today's hearing of the Technology and Innovation Subcommittee.

Today we will be looking at the Small Business Innovation Research (SBIR) program as it goes forward to its Silver Anniversary. This hearing precedes this subcommittee's markup of reauthorization language hopefully sometime this summer.

The SBIR program began in 1982 when our government saw a need to increase our national investment in research and development to specifically seek technological innovations in emerging areas. The ultimate goal of the SBIR program is to bring new products and technologies to commercialization in order to stimulate international competitiveness. This program is an important stepping stone in the overall goal to keep America's competitive advantage in the worldwide marketplace.

Under the SBIR program, departments and agencies with R&D budgets of $100 million or more are required to set aside 2.5 percent of these budgets to sponsor research at small companies. These awards are highly competitive with only the most pioneering and innovative companies receiving these federal monies.

Currently, 11 departments and agencies sponsor SBIR programs including: the Departments of Defense, Education, Health and Human Services, Homeland Security, and Energy, as well as the National Aeronautics and Space Administration, the National Science Foundation and the National Institutes of Health.

The SBIR program is divided up into three phases. The initial phase, Phase I, grants awards with a maximum amount of $100,000 for exploration of the technical merit or feasibility of an idea or technology. Phase I awardees may then compete for a Phase II award which has a maximum award of up to $750,000 for research that expands upon promising Phase I results. It is during this second phase of the program that the developer evaluates commercialization potential.

Phase III is the period during which Phase II innovation moves from the laboratory into the marketplace, this of course is the essence of technology transfer. It is important to note that no SBIR funds support this final phase. The small business must find funding in the private sector or other non-SBIR federal agency funding in order to complete their technology's transition to commercialization.

I'm sure there are many people outside the Federal Government that are not familiar with the SBIR program. However, I am here to tell you it is a hidden gem. Agencies give a percentage of their major federal R&D budget to support our country's most groundbreaking and pioneering small businesses. I know I don't have to convince anyone here that small businesses truly are the engine that drives this thriving economy and the SBIR program is a crucial spark to initiate their success.

As a physician, I am keenly interested in the medical breakthroughs and innovative research headquartered at the NIH. The SBIR program at the Institute has helped spawn new hopes for the victims of a variety of diseases such as cancer, HIV/AIDS, Alzheimer's and diabetes.

Neural Signals is an example of one of the many SBIR success stories and is located in my home state of Georgia. Neural Signals allows severely paralyzed or locked-in individuals to control their personal computers via thought-control—eliminating completely the need for patient-initiated movement.

Another amazing advancement coming out of the SBIR program is from a company named, ABIOMed. AbioCor is a product which is the result of three decades of research, development and testing which produced the world's first completely self-contained replacement heart. AbioCor is an astounding innovation that makes

real the day when heart failure will not mean the end of life or the ability to enjoy life.

We will also hear from Anthony Ignagni (pronounced IG–NA–NI, the second "g" is silent) of Synapse (pronounced SIN–NAP–SIS) Biomedical, Inc. who will discuss their minimally invasive neuron-stimulation devices that will replace or assist mechanical ventilators.

Synapse is conducting multi-centered clinical trials at locations around the country including the Shepherd Center in Atlanta, which is the leading center for treatment of spinal cord injuries in the country.

I am excited to hear the testimony from all of our witnesses here today to discuss ways to improve upon the SBIR program. Mr. Chairman, I am looking forward to working with you as we move forward with reauthorization legislation.

Chairman WU. Thank you very much, Dr. Gingrey. And all the time was very well spent.

And now we turn to our witnesses. As each of you know, oral testimony, we request you keep your oral testimony at approximately five minutes; and if you can, please summarize your written testimony which we will place into the record. Let me provide a brief introduction for the witnesses.

Mr. Bruce Held is the Director of the Force Development and Technology Program at the RAND Arroyo Center, The RAND Corporation. His research is focused on defense acquisition, industrial base, and R&D policy.

Mr. Jon Baron is the Executive Director of the Coalition for Evidenced-Based Policy. That would be a wonderful thing in this institution. He has served as counsel to the House of Representatives' Committee on Small Business and subsequently as Program Manager of the Defense Department's SBIR Program.

Mr. Robert Schmidt is Founder and Chairman of Cleveland Medical Devices, Inc., and Orbital Research. Mr. Schmidt is also on the Board of Directors of the Small Business Technology Council, a council organization of the National Small Business Association.

Dr. Gary McGarrity is Executive Vice-President of Scientific and Clinical Affairs at VIRxSYS Corporation. Prior to joining VIRxSYS, he was CEO of Intronn.

And Dr. Anthony Ignagni is President and CEO of Synapse Biomedical and is responsible for the strategic planning of the company. Tony has developed and commercialized medical devices for over 20 years.

And we will begin with you, Mr. Held.

STATEMENT OF MR. BRUCE J. HELD, DIRECTOR OF THE FORCE DEVELOPMENT AND TECHNOLOGY PROGRAM, RAND ARROYO CENTER, THE RAND CORPORATION

Mr. HELD. Mr. Chairman and Members of the Subcommittee, thank you for the invitation to testify before you today. My testimony today is limited to the Department of Defense's SBIR Program and primarily draws on research that I led in 2004 what is now the DOD's Office of Small Business Programs. While the DOD's SBIR Program is generally accomplishing its broad legislative goal, it is not particularly effective in generating technology and products that are utilized by the Armed Forces. As a result, the DOD may not be taking the best advantage of the program's research result, and the small businesses may not be getting the commercialization opportunities that would turn their innovations into sales and other sources of revenue.

There appear to be two primary reasons for this. First, the DOD's acquisition and R&D leadership emphasis for the program has been on administrative efficiency and process issues associated with executing the thousands of annual SBIR awards.

Second, most of the DOD's program is managed out of its laboratories and research centers. While these centers and organizations conduct and manage important R&D, that work tends to be earlier-stage research that requires a long and difficult develop and transition cycle before being incorporated into the equipment being used by the Armed Forces.

For the program's small business participants, staying with this lengthy and non-transparent process is exceptionally difficult. Efforts in policies to improve the effectiveness of the DOD's programs should therefore have two related goals: first, to emphasize research outcomes and utilization rather than just process efficiency, and second, to increase the participation of the acquisition community in managing SBIR projects.

A key to both of these is to manage the program flexibly, so it can better meet the technology needs of the Department. For example, most of the Armed Services and DOD agencies only have one or two SBIR solicitations a year. More flexible scheduling, however, would include more solicitations to allow acquisition program managers to use SBIR technology development projects according to their own scheduling needs. Once awarded, SBIR project schedules should also be flexible enough to accommodate varying program and technology development requirements. Currently, the tendency is to work all SBIR projects on similar schedules. But this causes delay between phases that hurt both the potential user of the research as well as the small businesses conducting the research.

Funding of projects also needs to be managed more flexibly, since funding guidelines for the program have not changed in the last 15 years; the effective award size has declined by about a third, thus removing a portion of potential research projects as topic candidates. At a minimum, guidelines for the size of SBIR awards should be increased to account for inflation. Phase I awards should be at least $150,000; Phase II awards should be at least $1,125,000. In addition, discretion to exceed these guidelines for important research needs needs to continue in the reauthorization.

Making the program more flexible in terms of project timing and funding should improve its attractiveness to DOD's acquisition program managers, enhancing the probability that SBIR research outcomes will transition into products and services that the small businesses can market to the government and to defense industries.

Another way to increase both flexibility of the program and its attractiveness to the DOD's acquisition program managers is to allow a portion of the SBIR set aside to be used to administer the program. Generally the cost for managing the DOD's programs are borne out of organizational overhead. This not only contributes to the current process orientation of the program, but since the projects are relatively small and are often perceived to be risky, acquisition program managers are not inclined to spend their limited overhead managing them. If administrative resources come with the projects, however, they may find these SBIR programs to be

more attractive as an additional technology source. The amount ultimately allocated for managing the program should be based on an analysis of the cost associated with managing similar R&D and commercialization efforts.

Finally, a few words about increasing innovative small business participation in the program. Since the program has been very successful in attracting new companies to the DOD R&D market and since Phase I competition remains high, the real question should be about increasing the quality of the participation. From the viewpoint of both the small businesses and the DOD, higher quality participation is mostly about transitioning research results into usable technology and products. This means making the program a resource for the DOD's acquisition managers, not just a tax on their R&D budgets. Absent steps to do this, it is unlikely that other commercialization and financing efforts will be very successful. My recommendation for program enhancements thus center around the two main issues I mentioned earlier. The DOD's leadership must move from a process orientation to one that is outcome utilization oriented, and the acquisition community must have more responsibility for the program. Both of these actions require managing the program flexibly and suggest resourcing it in a way that reduces the incentives for minimizing management effort at the expense of technology transition success.

Thank you.

[The prepared statement of Mr. Held follows:]

PREPARED STATEMENT OF BRUCE J. HELD[1]

Improving the Department of Defense's Small Business Innovation Research Program[2]

Mr. Chairman and Members of the Subcommittee, thank you for the invitation to testify before you today. My testimony today draws primarily on research that I led in 2004 for the Department of Defense's Small Business Technology and Industrial Base Office (SBTIBO).[3] The purpose of that research was to provide DOD with insights into the current status of its Small Business Innovation Research (SBIR) program in terms of the department's transformational technology priorities, innovation, and the small-business defense industrial base. Following that initial assessment, the project's objective became the recommendation of policy options for making the DOD SBIR program more responsive to the needs of the department.[4] While my testimony draws on this work, today I speak as an individual.

In my invitation to testify today I was asked to address the following questions:

1. How could program effectiveness be improved? What are appropriate award levels? How should administration costs be funded?
2. How can the programs increase the participation of innovative small businesses in federal R&D?

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[1] The opinions and conclusions expressed in this testimony are the author's alone and should not be interpreted as representing those of RAND or any of the sponsors of its research. This product is part of the RAND Corporation testimony series. RAND testimonies record testimony presented by RAND associates to federal, State, or local legislative committees; government-appointed commissions and panels; and private review and oversight bodies. The RAND Corporation is a nonprofit research organization providing objective analysis and effective solutions that address the challenges facing the public and private sectors around the world. RAND's publications do not necessarily reflect the opinions of its research clients and sponsors.

[2] This testimony is available for free download at *http://www.rand.org/pubs/testimonies/CT280.*

[3] Now in the DOD's Office of Small Business Programs.

[4] Held, Bruce, Thomas Edison, Shari Lawrence Pfleeger, Philip S. Anton, John Clancy, *Evaluation and Recommendations for Improvement of the Department of Defense Small Business Innovation Research Program (SBIR),* Santa Monica, CA: RAND, DB–490–OSD, 2006.

3. What program enhancements do you recommend to address financing and commercialization assistance needs of participants?

Assessing the Current DOD SBIR Program

The DOD's SBIR program appears to be accomplishing the broad goals set out in the program's enabling legislation. The program's resources stimulate innovation by funding R&D contracts with small businesses and, in fact, the DOD SBIR program attracts a large number of small businesses to the DOD R&D market; roughly 250 to 400 new contractors each year. The DOD SBIR program also provides opportunity for minority- and women-owned small businesses to contract with DOD, although it is not as effective as other DOD R&D programs that specifically target these companies. Finally, some commercialization of DOD R&D appears to be linked to the SBIR program. However, the limited information available indicates that commercialization as a result of SBIR-funded research is concentrated in just a few companies.[5]

The effectiveness of the program in generating technology, products, services and process that are utilized by the armed forces is less clear.[6] As a result, the DOD may not be taking the best advantage of the research results that emerge from its SBIR program, and the small-business participants may not be getting the commercialization opportunities that would turn their innovations into sales or other sources of revenue.

There appear to be two primary reasons that the DOD SBIR program has had difficulty transitioning research results. First, the leadership emphasis for the program has been on statutory compliance rather than research outcome and utilization. The result is a management orientation that is more focused on the process issues associated with executing the thousands of SBIR awards than it is with utilizing the results of those awards. Second, most of the DOD's SBIR program is managed out of its laboratories and research centers. Though these organizations conduct and manage important research for the DOD, that work tends to be earlier stage research that requires a long and difficult development and transition cycle before being incorporated into the equipment or processes used by the armed forces. How SBIR research results are managed through this transition process is opaque at best. For the SBIR small business participants, staying with this lengthy and non-transparent process is exceptionally difficult.

Improving the DOD SBIR Program

Efforts and policies to improve the effectiveness of the DOD's SBIR program should, therefore, have two related goals:

1. To move the DOD leadership's emphasis for the program from compliance and process issues to improving research outcomes and utilization.
2. To increase the participation of the DOD's acquisition community in managing SBIR projects.

Emphasizing research outcomes and utilization by the leadership requires emphasizing SBIR program flexibility to meet the technology needs of the DOD. For example, current practice within the DOD limits solicitations for SBIR projects to only one or two per year.[7] This means that if a technology requirement arises shortly after a solicitation has been published, the program will not be able to address that need for six-months or a year.[8] This kind of set schedule is designed for process effi-

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[5] For example, in our research we examined the DOD contracting histories of small companies that first contracted with the DOD through the SBIR program. In 1995 256 companies used the SBIR program as their entrée into the DOD market and in 1999 the number was 227. Of these 483 companies, only six account for 95 percent of the dollar value of subsequent non-SBIR DOD contracts. Additionally, an examination of self-reported commercialization data from DOD SBIR participants indicates just one percent of the companies account for 50 percent of all sales traceable to an SBIR project. The same data base indicates that overall sales success from DOD SBIR projects is relatively low: the sales to SBIR investment ratio is 1.17. This compares to commercial sales to R&D investment ratios of about 25 to one.

[6] This is despite an elaborate topic selection and approval process that is designed to insure that the topics align with the DOD's research priorities and are coordinated across the department.

[7] Across the DOD there are three solicitations per year, but most services and agencies in the DOD only participate in one or two per year.

[8] This does not take into account additional time required to process the topic request for inclusion in the solicitation. Additionally, even if a technology requirement is timely addressed in a solicitation, most of the DOD's services and agencies manage the research contracts somewhat inflexibly. Phase I contracts last six months, putting a Phase II contract in place takes several months and the Phase II contract will last about two years.

ciency rather than for meeting the research needs of the DOD. More frequent solicitations will require additional effort, but are likely to be more attractive to program and technology managers who are managing development schedules.

Funding of DOD SBIR projects will also need to be managed more flexibly. Funding guidelines for SBIR projects have not changed in the last fifteen years. This means that the effective size of the award has declined by a third, thus removing a significant portion of the potential research projects from the SBIR program. In order to correct this issue, guidelines for the size of SBIR awards should be increased to account for inflation. Phase I award limits should be at least $150,000 and Phase II award limits should be at least $1,125,000. In addition, flexibility to exceed these guidelines needs to continue to be maintained in the reauthorization, particularly where important DOD technology requirements could be addressed by the SBIR program, but where the project size exceeds the general guidelines.[9] While smaller awards mean that more awards are available, larger awards mean increased flexibility to address the DOD's technology requirements through the SBIR program. That added flexibility has the potential to improve the probability that SBIR research outcomes will transition into products and services that the small-business participants can market to the DOD and to the broader defense industry.

Currently, the administrative costs for managing the DOD SBIR program are generally borne out of the overhead of the organizations within DOD charged with SBIR program responsibility.[10] As a result, the incentive for these organizations is to minimize the effort put into managing the program, contributing to the process orientation that the program exhibits. Allowing a portion of the SBIR set-aside to be used to administer the program would help alleviate this incentive problem.

Perhaps more important, allowing administrative costs to be recovered from the set-aside for the program would make it more attractive to the DOD's acquisition program managers. The DOD's acquisition program managers contribute the majority of the DOD SBIR program's funds because they are primarily responsible for the majority of the DOD's R&D budget from which the set-aside is applied. As noted earlier, however, across most of DOD the SBIR program is managed by the laboratories and research centers. There are likely a number of reasons for this, including explicit policy decisions. However, the disincentive for acquisition program managers to request SBIR projects is also a factor. Program management offices are typically relatively small offices so the resources to manage additional small projects and contracts are at a premium. If resources are provided to manage these projects and contracts, then it is likely that program managers will be more inclined to request access back to some of the resources they provided to the SBIR program. Combining earmarked SBIR administrative resources with increased SBIR program flexibility in terms of solicitation timing, project duration and funding amounts, the SBIR program could be turned into a more sought after resource by DOD's acquisition program managers.

While research is currently on-going to determine the total cost of managing the DOD's SBIR program, previous research suggests that the DOD invests fewer resources into managing its SBIR program than analogous R&D efforts. To meet expectations about commercializing SBIR program results, the amount allocated for managing the SBIR program should be based on an analysis of the costs associated with managing other commercial, governmental and academic R&D and commercialization efforts. The venture capital industry, for example, charges annual management fees of 2.5 to five percent of funds under management and also earns a significant portion of any return on investment.[11]

Increasing Small Business Participation in the DOD SBIR Program

The suggestions already made for increasing the effectiveness of the DOD SBIR program are related to the second question I was asked to address: How can the programs increase the participation of innovative small businesses in federal R&D? As noted earlier, the DOD SBIR program has been very successful in attracting new companies to the DOD R&D market. Moreover, the DOD receives nearly six proposals for every Phase I award it makes. The question should, therefore, be more

[9] Under current legislation, an awarding agency may determine that a particular SBIR award merits greater funding. Such awards require only that, after the fact, a written justification be submitted along with the annual SBIR report to the SBA. This flexibility seems warranted and could even be encouraged in the reauthorization to ensure that program managers feel empowered to make such judgments.

[10] The Navy is an exception. It collects, in addition to the SBIR set-aside, an amount from its R&D budget to manage the SBIR program.

[11] Since the venture capital management fees are assessed annually on funds under management a direct comparison to SBIR overhead rates understates the VC management fee.

about increasing the quality of the participation rather than about the overall number of companies participating.

Over the course of our research we identified four distinct business models for DOD SBIR award winners. The entrepreneurial model is generally a new business created specifically to develop an idea into some product or service. The SBIR program is a source of relatively inexpensive capital for developing these ideas. The mature business model is a business that has been around for some time and that uses the SBIR program as a source of low-cost capital for research. Related to the mature business model are other established small companies who have not previously done business with the DOD and use the SBIR program to enter that market. Finally there is the research house. These companies provide research as a service and use the SBIR to provide their services to the DOD. In all of these models, perhaps with the exception of the research house, the ultimate goal for conducting research is to develop a marketable product or service.[12] In our discussions with the small-business participants, however, one theme seemed fairly constant. While these companies were successfully competing for SBIR awards, they were not successful in marketing and selling the results of their research projects to the DOD for transition into products, processes or services. These interview results reinforce the data cited earlier that any success in transitioning DOD SBIR research is concentrated in a very few companies. Improving the quality of the small business participation in the DOD SBIR program must, therefore, mean improving the likelihood that the research these companies conduct will be marketable to the DOD's acquisition community and will transition into equipment, services and processes used by the armed forces. Making this happen will require much greater participation by the DOD's program managers and program executive officers in the SBIR program. If this can be made to happen, the attractiveness of the DOD SBIR program to the small-business community will be increased and greater participation and competition would result.

Absent steps to increase the willingness and capability of the DOD acquisition community to participate in the SBIR program, it is unlikely that other commercialization and financing efforts will be very successful. My recommendations for SBIR program enhancements, thus, center around the two main issues I mentioned earlier. The DOD leadership must shift the process orientation of its SBIR program to one that is more outcome and utilization oriented. This requires managing the program's flexibly to responsively address the DOD's technology requirements, and it means resourcing the SBIR program in a way that reduces the incentives for minimizing the management effort at the expense of technology transition success. In addition, policies that require and encourage DOD's acquisition program managers to administer SBIR projects as a resource will improve the likelihood that SBIR research results will transition into technologies, products, services and processes used by the soldiers, sailors, airmen and marines of America's armed forces.

BIOGRAPHY FOR BRUCE J. HELD

Bruce J. Held is currently the Director of the Force Development and Technology Program at the RAND Arroyo Center.

Since coming to RAND, Mr. Held has focused his research efforts on defense acquisition, industrial base and R&D policy. He has led projects that examined the use of venture capital as a source of Army R&D, how to best organize the Army's R&D capabilities and how to manage the Army's transformational efforts. He has also participated in a number of other studies, most notably several dealing with improving the efficiency and effectiveness of the defense industrial base.

Prior to joining RAND, Mr. Held worked in private industry as market planner and as a systems engineer. He is a former Army officer, who, in addition to combat unit command and staff positions, spent seven years of his Army career conducting and managing R&D efforts; first as an armor technology manager at the Army Research Laboratory and then in a program management office developing tank guns and ammunition.

Mr. Held holds a BS from the United States Military Academy at West Point, an MS in aerospace engineering from Stanford University and a JD from the University of Maryland School of Law.

Chairman WU. Thank you, Mr. Held. Mr. Baron.

[12] Even for the research house model, gaining additional revenue through mechanisms such as licensing fees is a goal.

STATEMENT OF MR. JON BARON, EXECUTIVE DIRECTOR, COALITION FOR EVIDENCE-BASED POLICY, COUNCIL FOR EXCELLENCE IN GOVERNMENT

Mr. BARON. Thank you, Chairman Wu. Mr. Chairman, Ranking Member Gingrey, and Congressman Mitchell, I appreciate the opportunity to testify on SBIR. My testimony draws on my involvement in the SBIR Program since 1990 in a number of different capacities, first as counsel to the House Small Business Committee where I was the lead staffer for the 1992 reauthorization of SBIR, second as the Program Manager for the Defense Department's SBIR and STTR programs where I introduced and led reforms that were found highly effective in an independent evaluation by the National Academy of Sciences and received the Vice-President's Hammer Award, and third, as a member of the steering committee for the National Academy of Sciences' study the SBIR programs in 2003.

The views I express here are my own, and I want to mention that my organization is not funded by SBIR. And so we have no financial interest in the ideas I'm advocating.

Let me first briefly address the contribution of SBIR to the American economy and then suggest a few ways consistent with your question on how the program might be improved.

The contribution. In several instances, the SBIR has spawned breakthrough technologies that have transformed their field and made a major contribution to the American economy. Let me give you two quick examples. Under SBIR, Science Research Laboratory of Somerville, Massachusetts, developed a set of technologies that greatly improved the performance and reliability of excimer lasers, improvements which for the first time made these lasers a commercially viable tool for writing integrated circuits onto computer chips. These lasers increased by about a third the number of circuits you can fit on a chip. It rapidly became the state-of-the-art technology for chip production around the world and thereby increased the competing power of virtually every commercial and defense system that has been developed since the 1990s. Sales of the excimer lasers now exceed one-fourth of a billion dollars annually. It is an enormous impact.

As a second example from biomedical sciences, Martek Corporation under SBIR developed new technologies for producing omega-3 fatty acids called DHA and ARA which have been approved by the FDA for use in infant formula so that it more closely resembles breast milk. Mark's DHA and RHA are now added to nearly 90 percent of infant formula in the Unites States, sold in more than 65 countries overseas, and have been consumed by an estimated 24 million infants. Importantly, these fatty acids have been shown in randomized clinical trials to increase the height, weight, cognitive development, and motor development of pre-term infants. Martek's technology has thereby contributed in a fundamental way not only to the economy but to the life and health of millions of children around the world.

Moving on to the second part of my testimony, there is good reason to believe that a few modifications to the SBIR Program could substantially increase its success in producing these kind of breakthrough technologies.

Since the program was established 24 years ago, it spawned perhaps 10 to 20 of these breakthroughs which have transformed their field. In addition to these, it has produced a number of smaller but still important technological and commercial successes.

Then in a third category, some SBIR projects have not produced significant technology commercialization. GAO and DOD data suggest that over half of SBIR Phase II's fall into this third category of no significant commercialization. And in part, that's the nature of research and development. One can expect only a fraction of projects will succeed and fewer still become breakthroughs. But there is evidence to suggest that the program could achieve substantially higher success rates in producing such breakthroughs. Specifically the GAO and DOD data show that some SBIR companies, perhaps as many as half of those that have participated long enough to build a track record, consistently are unable to convert their SBIR awards into viable new products sold either to the government, military, or the private sector. These are companies that usually have strong research capabilities, therefore they win SBIR awards, but they lack entrepreneurial capabilities and, in some cases, the motivation to convert their research into successful new products. Many of these companies find the commercialization process unfamiliar, outside their skill set, and daunting. And so modifications to the program that provide strong incentives or assistance for SBIR awardees to strengthen their entrepreneurial capabilities could potentially greatly increase the program's success in spawning these kind of breakthroughs that make an enormous contribution to the economy.

The federal agencies recognize this problem, many of them, and have taken a lot of steps over the last 25 years to try to address it. I'll mention a couple of those in a minute, but what I want to mention is this, that none of these innovations in how the program is managed have ever been evaluated in a study rigorous enough to provide strong evidence of the innovation has an effect on key SBIR outcomes such as commercialization.

And so, despite the program's 24 years in existence, we have many good hypotheses but no scientifically valid evidence about what works in improving the program's performance. That is the central idea I wish to convey in my testimony, that the ideas we are discussing for SBIR improvement today are similar to the ones that were discussed in 2000 during that reauthorization and in the 1992 reauthorization that I participated in. At the agency level, pilots and demonstrations come and go, but without rigorous evaluation of them, little has been learned about what worked.

And so, my recommendation, as a concrete way to address this, is that Congress allocate a small percentage, perhaps one percent of the smaller agencies, less at the larger agencies, of their SBIR funds, to conduct rigorous evaluations of new approaches to building their awardees' entrepreneurial capabilities. Let me just give one quick example, and I will wrap up—of how this might work at modest cost and burden.

In a true randomized control trial, considered the gold standard of study designs for figuring out what works, an agency could randomly assign half of its SBIR awardees to a treatment group that is eligible for a larger Phase II award if it obtains matching funds

from a commercial investor (and that is already done in a pilot basis under the National Science Foundation's Phase II–B process) or assign its other awardees to a control group that participates in the agency's usual SBIR process without this matching fund incentive. And then the evaluation would track commercialization outcomes to the two groups over time to determine whether this Phase II–B incentive made a difference in such outcomes. At agencies which collect good commercialization outcome data like DOD, this kind of rigorous study, producing scientifically valid evidence about whether the darn thing worked, could be conducted at relatively low cost, perhaps $250,000 per year over five years.

That is one approach, the matching funds idea, that I would suggest merits evaluation in a rigorous evaluation. And one other that may merit such evaluation is the idea of using a company's commercialization track record, how well has it done commercializing its previous SBIR awards, as a criterion for evaluating its current SBIR proposals and deciding whether it should get an additional award.

And with that, I conclude. Thank you.

[The prepared statement of Mr. Baron follows:]

PREPARED STATEMENT OF JON BARON

Chairman Wu, Ranking Member Gingrey, and Members of Science and Technology Subcommittee on Technology and Innovation:

I appreciate the opportunity to testify on the reauthorization of the SBIR program. My testimony draws on my involvement in the SBIR program since 1990 in several different capacities—

- First, as Counsel to the House Small Business Committee, where I was the lead staffer for the 1992 reauthorization of SBIR and establishment of the STTR program;
- Second, as the Program Manager for the Defense Department's SBIR and STTR programs from 1995–2000, where I introduced and led program reforms that were found highly effective in an independent evaluation by the National Academy of Sciences, and received the Vice President's Hammer Award for reinventing government; and
- Third, as a member of the Steering Committee for the National Academy of Sciences' study the SBIR program since 2003.

However, the views expressed here are my own.

My testimony will briefly address the contribution of the SBIR program to the American economy, and then suggest ways in which the program might be strengthened, so as to increase that contribution.

In several instances, the SBIR program has spawned breakthrough technologies that have transformed their field and made a major contribution to the American economy.

Here are two illustrative examples. Under the Department of Defense and Department of Energy SBIR programs, Science Research Laboratory of Somerville, Massachusetts developed a set of technologies that greatly improved the performance and reliability of "excimer lasers"—improvements which, for the first time, made these lasers a commercially-viable tool for writing circuits onto computer chips. The lasers increased, by about one-third, the number of circuits one can fit onto a chip, rapidly became the state-of-the-art technology in chip production worldwide, and have thereby increased the computing power of virtually every commercial and military system developed since the late 1990s. Sales of excimer lasers now exceed $250 million annually.

As a second example, under the NIH SBIR program, Martek Biosciences Corporation of Columbia, Maryland developed new technologies for producing omega-3 fatty acids called DHA and ARA, which have been approved by the Food and Drug Administration for use in infant formula, so that it more closely resembles breast milk. Martek's DHA and RHA are now added to nearly 90 percent of infant formula used

in the United States, and are also sold overseas in more than 65 countries. They have been consumed by over 24 million babies worldwide. Importantly, these fatty acids have been shown in randomized clinical trials to increase the height, weight, cognitive development, and motor development of pre-term infants by age two. Martek's SBIR-developed technology has thereby contributed, in a fundamental way, not only to the American economy, but also to the life and health of millions of children worldwide.

There is reason to believe that a few modifications to the SBIR program could substantially increase its success in producing such breakthrough technologies.

Since the SBIR program was launched in 1983, it has spawned perhaps 10–20 "breakthrough" technologies like those I just summarized—that is, technologies which transformed their field and became major commercial successes. In addition to these, the program has produced a number of smaller but still important technological and commercial successes. And then, in a third category, some SBIR projects have not produced significant technology commercialization in either commercial or government markets. GAO studies of the program, as well as the results of DOD's own studies, suggest that over half of SBIR phase II projects fall into this category of no significant commercialization.

In part, that is the nature of high-risk R&D—one can expect that only a fraction of projects will succeed, and fewer still will be breakthrough successes. However, there is evidence to suggest that the program could achieve substantially higher success in producing such breakthroughs. Specifically, the GAO studies and DOD data show that some SBIR companies—perhaps as many as half of those that have participated long enough to build a track record—*consistently* are unable to convert their SBIR awards into viable new products sold to commercial or government customers. These are companies which usually have strong research capabilities—which is why they win SBIR awards—but lack the *entrepreneurial* capabilities, and in some cases the motivation, to convert their research into successful new products. Many of these companies find the commercialization process to be unfamiliar, outside their skill set, and daunting.

Thus, modifications to the SBIR program that provide strong incentives and/or assistance to SBIR awardees to strengthen their entrepreneurial capabilities could potentially correct this source of systematic under-performance, and greatly increase the program's success in spawning commercially-successful technologies that make a major contribution to U.S. economic capabilities.

Many of the federal agencies recognize this problem—that SBIR companies often lack key entrepreneurial capabilities—and have tried innovative approaches to address it.

Illustrative examples of approaches that agencies have tried include:

- Giving a competitive priority, and/or additional funding, to SBIR applicants or awardees that obtain matching funds from a third-party commercial investor;
- Using a company's track record in commercializing its prior SBIR awards as a key criterion for evaluating its current SBIR proposals;
- Providing training to SBIR awardees in commercializing their SBIR technologies;
- Requiring SBIR applicants to include a streamlined business plan in their proposal;
- Including individuals with business experience on the SBIR proposal review panels; and
- Increasing the involvement of potential customers for SBIR products—such as DOD acquisition program offices—in the development of SBIR solicitation topics.

However, none of these innovations in program management has ever been evaluated in a study rigorous enough to provide strong evidence of its effect on key SBIR outcomes—outcomes such as commercialization and contribution to scientific understanding.

And so, even though the SBIR program has been around for nearly a quarter-century, we have many good hypotheses but no scientifically-valid evidence about "what works" in improving program performance. That is the central idea I wish to convey in my testimony. The ideas for SBIR program improvement that we're discussing in the current reauthorization process are similar to the ones that were discussed

in the 2000 reauthorization, and in the 1992 reauthorization before that. At the agency level, pilots and demonstrations come and go, but without rigorous evaluation, little has been learned about what worked.[1]

Thus, I'd recommend that Congress direct the agencies to allocate one percent of their SBIR funds to conduct scientifically-rigorous evaluations of new approaches to building awardees' entrepreneurial abilities.

Wherever possible, these experiments should randomly assign SBIR program applicants, awardees, and/or research topics to the new approach or to a control group that participates in the agency's usual SBIR process. Such randomized experiments are recognized as the gold standard for evaluating the effectiveness of a strategy or approach across many diverse fields because, uniquely, they enable one to determine to a high degree of confidence whether the new approach itself, as opposed to other factors, causes the observed outcomes.[2]

Some SBIR approaches would readily lend themselves to such a randomized evaluation, at modest cost and administrative burden. For example, an agency could randomly assign half of its SBIR awardees to a "treatment" group that is eligible for a larger phase II award if it obtains matching funds from a commercial investor (as is done under the National Science Foundation's "Phase II–B" process), and its other awardees to a control group that participates in the agency's usual SBIR process, without this Phase II–B. The evaluation would then track commercialization outcomes for the two groups over time, to determine whether the Phase II–B incentive made a difference in such outcomes. At agencies such as DOD that already track commercialization outcome data for most of their SBIR awardees, this rigorous study could be conducted at a low cost by using such data—perhaps $250,000 per year over five years as a rough estimate.

Based on existing evidence, I'd suggest two approaches to improving the SBIR program that may merit particular consideration for these rigorous evaluations.

The first of these is the approach of providing a larger phase II award, and/or a competitive priority in the phase II proposal evaluation process, to SBIR companies that obtain at least a partial match of funds from a third-party investor. The National Science Foundation's "Phase II–B" award, and DOD's "Fast Track" and "Phase II Enhancement" policies, are specific versions of this approach. The rationale for this approach is that an investor's hard commitment of matching funds is a strong endorsement of the SBIR company's entrepreneurial capabilities and the market size (commercial or military) for its technology. The National Academy of Sciences' study of DOD's Fast Track provides initial evidence that this approach yields much higher commercialization and research outcomes—evidence which, I'd suggest, merits confirmation in a randomized evaluation.

The second approach I'd recommend testing in a rigorous evaluation is that of using a company's track record in commercializing its prior SBIR awards as a key

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[1] The one partial exception is the National Academy of Sciences' 1999 study of the DOD "Fast Track," which is the most rigorous and impartial evaluation to date of a new approach to implementing the SBIR program. That study compared research and commercialization outcomes for DOD Fast Track SBIR projects to outcomes for a statistically-matched comparison group of non-Fast Track projects. The study found that the Fast Track projects achieved much higher levels of commercialization and made a larger contribution to the agency's research program than projects in the comparison group. These results, although highly valuable, should nevertheless be interpreted with caution because SBIR companies self-selected themselves into the Fast Track versus the comparison group, raising the possibility that any difference in outcomes between the two groups is due to inherent differences in their motivation or capabilities, rather than the Fast Track approach itself. There is consistent evidence from many different policy areas that such comparison-group studies, although extremely useful in generating good hypotheses about what works, may sometimes produce erroneous conclusions about an approach's effectiveness (for a summary of this evidence, see Office of Management and Budget, What Constitutes Strong Evidence of Program Effectiveness, *http://www.whitehouse.gov/omb/part/2004_program_eval.pdf,* 2004, pp. 4–8).

[2] See, for example, U.S. Department of Education, "Scientifically-Based Evaluation Methods: Notice of Final Priority," *Federal Register,* vol. 70, no. 15, January 25, 2005, pp. 3586–3589; the Food and Drug Administration's standard for assessing the effectiveness of pharmaceutical drugs and medical devices, at 21 C.F.R. §314.12; "The Urgent Need to Improve Health Care Quality," Consensus statement of the Institute of Medicine National Roundtable on Health Care Quality, *Journal of the American Medical Association,* vol. 280, no. 11, September 16, 1998, p. 1003; "Criteria for Evaluating Treatment Guidelines," American Psychological Association, *American Psychologist,* vol. 57, no. 12, December 2002, pp. 1052–1059; *Standards of Evidence: Criteria for Efficacy, Effectiveness and Dissemination,* Society for Prevention Research, April 12, 2004, at *http://www.preventionresearch.org/sofetext.php;* Office of Management and Budget, *What Constitutes Strong Evidence of Program Effectiveness,* op. cit., no. 1.

criterion for evaluating its current SBIR proposals. As noted earlier, some agencies such as DOD collect excellent data on companies' commercialization track records. These agencies could readily use this data in their proposal evaluation process to focus funds on companies that either have a strong SBIR commercialization track record or are new to the SBIR program, and away from companies that have repeatedly won SBIR awards but not commercialized. A rigorous evaluation could determine whether this promising idea does in fact improve the SBIR program's overall research and commercialization outcomes.

Conclusion: Over time, these rigorous studies could produce scientifically-valid, actionable evidence about "what works" to increase SBIR's success in spawning breakthrough technologies—evidence which, I'd suggest, is the critical missing piece that the agencies and Congress need to turn SBIR into a more powerful engine for American innovation and economic growth.

BIOGRAPHY FOR JON BARON

Jon Baron founded the nonprofit, nonpartisan Coalition for Evidence-Based Policy in fall 2001, and currently serves as its Executive Director. The Coalition is sponsored by the Council for Excellence in Government. Since its founding, the Coalition has built a strong track record of success in working with top Executive Branch and Congressional policy-makers to advance evidence-based reforms in major federal programs. A recent independent evaluation of the Coalition's work, conducted for the William T. Grant Foundation, found that the Coalition has been "instrumental in transforming a theoretical advocacy of evidence-based policy among certain [federal] agencies into an operational reality."

Based on this work, Mr. Baron was nominated by the President, and confirmed by the Senate in 2004, to serve on the National Board for Education Sciences, which helps set the research priorities and agenda for the U.S. Education Department's Institute of Education Sciences.

Prior to establishing the Coalition, Mr. Baron served as the Executive Director of the Presidential Commission on Offsets in International Trade (2000–2001).

Experience with the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs (1989–2007):

- Since 2003, Mr. Baron has served as a member of the Steering Committee for the National Academy of Sciences' study the SBIR program.
- From 1995–2000, Mr. Baron served as the Program Manager for the Defense Department's SBIR and STTR programs, where he spearheaded program reforms that:
  - — Were found highly effective in an independent evaluation by the National Academy of Sciences;
  - — Were selected by Harvard University's Innovations Award Program as one of the top government innovations in the United States (2000); and
  - — Received the Vice President's Hammer Award for reinventing government (1999).
- From 1989–1994, Mr. Baron served as Counsel to the House Small Business Committee, where he was the lead staffer for the 1992 reauthorization of the SBIR program and establishment of the STTR program.

Chairman WU. Thank you very much, Mr. Baron. Mr. Schmidt.

STATEMENT OF MR. ROBERT N. SCHMIDT, FOUNDER AND PRESIDENT, CLEVELAND MEDICAL DEVICES, INC., AND ORBITAL RESEARCH, INC.

Mr. SCHMIDT. Chairman Wu, Representative Gingrey, Congressmen Mitchell and Smith, thank you very much for inviting me here today.

I am Bob Schmidt, Founder and Chairman of Cleveland Medical Devices and Orbital Research. I am here on behalf of the Small Business Technology Council and the National Small Business Association. Cleveland Medical Devices makes brain monitoring devices that we sell around the world. Orbital Research focuses on

making tiny MEMS devices and creating third generation flight controls which we are developing for the military. My two companies have 70 full-time employees, and we train about a dozen college interns each semester. Harvard and *Inc. Magazine* have both recognized our rapid growth.

I have four major points today. First, the United States will have to push very hard to keep up with global technological competition. In many respects, we are already behind. The United States accounts for just 16 percent of the world's high-tech imports, half of what it was in 1980. What is worse, we went from a $30 billion trade surplus in technology exports ten years ago to a $45 billion deficit in 2005.

Second, wealth today correlates with the ownership of knowledge. A Federal Reserve Bank study showed the most important factor for economic growth in the country is patents. That is right, patents, bigger than education which was in second place, bigger by far than industry structure, public finance, taxation, business failure rates and a host of other variables. Where are American patents coming from today? The SBIR Program generates 55 percent more patents than all of our universities combined. That is on one-twelfth as many federal R&D dollars. 55 percent more patents for one-twelfth of the cost.

Third, SBIR and STTR Programs are good for universities, and we are important partners with them. SBIR researchers often have ties to universities, and STTR research always do. Together they help universities strengthen the commercialization of innovations and focus the research leading to new income streams for the schools and valuable technology transfer for the Nation. Most important, SBIR companies provide job opportunities that attract students into science and technology.

Fourth, today more scientists and engineers work for small companies than for large companies and for universities and federal labs combined. Small companies employ 32 percent of all the Nation's scientists and engineers, yet we receive only 4.3 percent of the federal R&D dollars, and SBIR and STTR account for most of that. Small businesses produce 20 times more patents per R&D dollars than universities and five times more than large businesses. Small businesses are America's golden goose. The very group that is most productive for wealth creation and job creation receives only about one-eighth of its fair share.

Federal R&D expenditures are far too concentrated. For example, at DOD one company receives seven times more R&D dollars than all SBIR companies combined. The top three companies at DOD have received more R&D dollars in one year than all SBIR companies have received government-wide in the entire 25-year history of the program.

What should Congress do now? We believe it is time to unleash American innovation and gradually double the SBIR and STTR programs and make them permanent. A number of current proposals would require SBIR to hire more consultants, give money to large, multi-national companies, allow venture—large venture capital companies rather than only small venture capital companies control in SBIR companies and pay more federal agency administrative expenses.

What all of these proposals have in common is reducing the investment that actually goes to the small companies and blurring SBIR's focus on developing innovations. Without additional funds to support those proposals, we will have fewer jobs and patents, not more in the future. The SBIR Program has shown that it will help America catch up and stay ahead globally. If you agree that growing new companies and jobs for scientists and engineers and creating patents and new technologies are crucial, then SBIR needs to be larger, not smaller. Even the smallest cuts in dollars actually going to the innovative small companies, however well-intentioned, will cost us internationally. Let us build on our SBIR success.

Thank you.

[The prepared statement of Mr. Schmidt follows:]

PREPARED STATEMENT OF ROBERT N. SCHMIDT

Chairman Wu, Representative Gingrey, Members of the Subcommittee, good afternoon. Thank you for inviting me to appear here today. I am Bob Schmidt, founder and President of Cleveland Medical Devices, Inc. and of Orbital Research, Inc. CleveMed makes brain monitoring devices that we sell all over the world. Orbital Research makes microelectomechanical (MEMS) systems and is developing third-generation flight control technologies for the U.S. military. My two companies employ about 70 people, and we train about a dozen students each semester. We have researched, developed, and commercialized new technologies through the Small Business Innovation Research (SBIR) Program.

Harvard University and *Inc.* Magazine, among others, have recognized the companies' rapid growth. And we have received two Tibbetts Awards, which are given annually to outstanding companies in the SBIR Program.

I am also here today on behalf of the Small Business Technology Council, the Nation's largest organization of small, technology-based companies in diverse fields. Over 250 SBTC companies have won SBIR contract awards, from all eleven issuing agencies, making SBTC also the largest concentration of SBIR award winners from across the government.

SBTC serves as the Technology Council of the National Small Business Association, and I am appearing here today on NSBA's behalf as well. NSBA is a nonprofit small business organization that serves over 150,000 companies. NSBA is the Nation's oldest small business advocacy group and was the founder of the "small business movement" in the United States. It celebrates its 70th anniversary in two weeks.

Two months ago, NSBA's biennial "Small Business Congress" selected the reauthorization of the SBIR Program as one of the top four small business legislative priorities for the 110th Congress—right behind taxes and health care.

Today, as the Subcommittee considers reauthorizing the SBIR Program, we would like to offer our views and address the questions that the Subcommittee posed of us.

I. THE U.S. AS A GLOBAL TECHNOLOGY COMPETITOR

This subcommittee, as well as the Full Science and Technology Committee, have had longstanding concerns about our nation's standing as a global leader in technology. While the U.S. currently remains the acknowledged front-runner in technological innovation, there are a number of indications that our global leadership is in jeopardy.

Consider the status of U.S. technology products in international trade.[1]

[1] This table is taken from *Measuring the Moment: Innovation, National Security and Economic Competitiveness,* a report of the Task Force on the Future of American Innovation, November 2006, p. 14. The Task Force members included: Agilent Technologies, Alliance for Science & Technology Research in America, American Chemical Society, American Chemical Society, American Electronics Association, American Institute of Physics, American Mathematical Society, American Physical Society, American Society for Engineering Education, Association for Computing Machinery, Association of American Universities, Battelle, Business Roundtable, Computing Research Association, Computing Technology Industry Association, Council on Competitiveness, Electronic Industries Alliance, Google, Inc., Intel Corp., Luna Innovations, Inc., Microsoft Corp., National Association of Manufacturers, National Association of State Universities and Land-Grant Colleges, Northrop Grumman Corp., The Science Coalition, Semicon-

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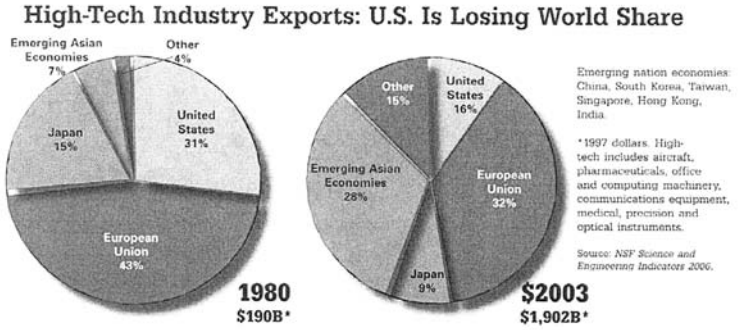
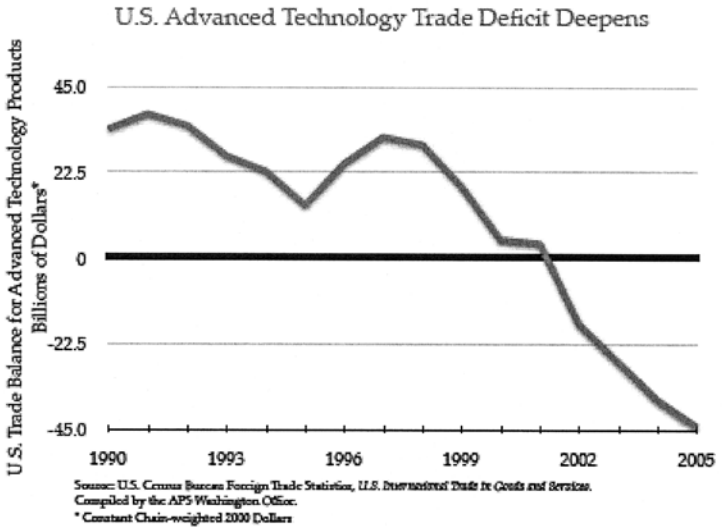


While the overall pie has gotten bigger, the U.S. share has been cut in half.

A parallel development has been the shift of the United States from a technology-exporting nation to an importing one.

Ten years ago, the U.S. had about a $30 billion trade surplus in high technology exports. By 2005, as the chart below shows, that had fallen precipitously to a $45 billion trade **deficit**.[2]



These trends are in part due to the success of some of our global competitors in copying U.S. innovation-promotion programs like SBIR, the Advanced Technology Program (ATP) and the Manufacturing Extension Program (MEP). SBIR variants are now in use in at least twenty countries. SBA reports that delegations from other countries appear regularly to inquire about how SBIR is organized and administered.

Overall, many countries are more active than our own in targeting and promoting innovation as a national economic strategy. So in addition to improving and expand-

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ductor Industry Association, Southeastern Universities Research Association, Technology CEO Council, Telecommunications Industry Association, Texas Instruments Incorporated. *http://futureofinnovation.org/PDF/BII-FINAL-HighRes-11-14-06_nocover.pdf*

[2] *Ibid.,* p. 13.

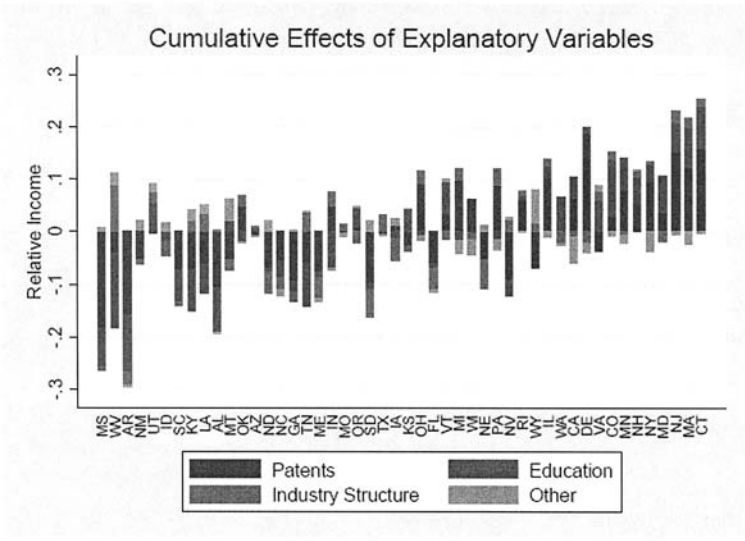
ing the SBIR program, Congress should consider strengthening ATP and MEP. Science and engineering studies at our high schools and universities should be enhanced, as well.

The declining shares of technology exports—and rising technology imports—by the U.S. also represent a threat to economic growth at the *regional and local level,* where wealth creation is increasingly linked to the ownership of knowledge.

For a striking illustration of this relationship, we can turn to a recent economic study by Paul Bauer, Mark Schweitzer and Scott Shane.[3] The authors measured eight determinants of personal income growth per capita, in the 48 contiguous states of U.S., from 1939 to 2004. (Each determinant had been highlighted in previous studies.) Among these were: the size of private financial markets, tax burdens, public infrastructure, business failure rates, industry structure, climate, bank deposits, and knowledge stocks.

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.*

The chart[4] 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 are on the left; those with higher growth, on the right. The remarkable aspect of the patent indicator is that it correlates strongly with *both* the poorer states and the wealthier ones—and does so more than any other indicator. A lack of patents per capita is a leading indicator of relative poverty; a profusion is strongly associated with relative affluence.

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

The importance of patents is also well understood globally.[5]

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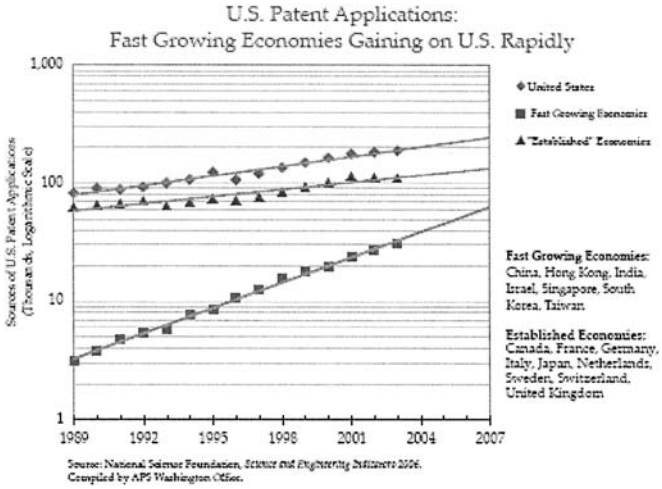
[3] See Federal Reserve Bank of Cleveland, "Altered States: A Perspective on 75 Years of State Income Growth," *Annual Report 2005.* For more detail, see Paul Bauer, Mark Schweitzer, Scott Shane, *State Growth Empirics: The Long-Term Determinants of State Income Growth,* Working Paper 06–06, Federal Reserve Bank of Cleveland, May 2006, *www.clevelandfed.org/research/Workpaper/2006/wp0606.pdf*

[4] *Ibid.,* p. 46

[5] *Measuring the Moment, op. cit.,* p. 15.



II. CONSIDERATIONS FOR POLICY–MAKERS

All of this leads to an obvious question: what can policy-makers do to encourage a climate conducive to patenting?

The surprising answer is that Congress has already taken two of the most important steps possible in promoting the growth of patents: First, by means of the Bayh-Dole Act,[6] Congress assured innovators that they could maintain control of the intellectual property that they developed while working in conjunction with the Federal Government.

Second, and perhaps most important, *Congress enacted the Small Business Innovation Research Program in 1982, and has since reauthorized it five times.*

SBIR—and the subsequent Small Business Technology Transfer (STTR) Program—put the creativity of technology-based small businesses to work in supplying the Federal Government's technology innovation needs. This was the first step in "Unleashing American Innovation."

Competitive, transparent, and focused, SBIR established a three-step process for stimulating innovation that was aligned with the natural evolution of an innovation through research and development to commercialization.

SBIR Program explicitly recognizes the different research styles and capabilities of large and small businesses.[7] Phases I and II of SBIR are reserved for small business. In the commercialization phase of SBIR, Phase III, where large company financial support, manufacturing expertise and marketing muscle is vital, such companies are welcomed into the Program. Indeed, they are indispensable to its success.

No innovation stimulation program in our nation's history has received such high marks from independent, third-party assessments.[8]

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[6] 35 USC 200–212

[7] See William J. Baumol "Entrepreneurship, Innovation and Growth: the David-Goliath Symbiosis," *Journal of Entrepreneurial Finance and Business Ventures,* Vol. 7, Issue 2, Fall 2002, pp. 1–10.

[8] See for example the various GAO assessments: *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; *Federal Research: Observations on the Small Business Innovation Research Program,* GAO Report GAO–05–861–T, June 28,2005. See also: *Small Business Innovation Research Program: Challenges and Opportunities,* Board on Science, Technology and Economic Policy, National Academies of Science and Engineering, 1999, *Conflict and Cooperation in the National Competition for High Technology Industry,* National Academy of Sciences, 1996;

And none can point to such a stellar list of "graduates," including: Qualcomm, Symantec, Amgen, Biogen, Genzyme, Chiron, Titan, Nanosys, American Biophysics, Luna Innovations, JDS Uniphase, iRobot, and Armorworks, to name but a few.

SBIR has delivered not only innovations and new companies—but also *patents.*

Throughout the 1980's and early 1990's the volume of patents produced by SBIR rose steadily. A tipping point came in 1997. For the first time, the number of SBIR-related patents exceeded the number of university-related patents. Since then, SBIR's lead has widened.

Today, the SBIR program is delivering about 50 percent more patents than all U.S. universities combined. In 2006, for example, there were 4,588 patents issued to SBIR-related companies. Just over 2,900 patents were issued to Universities.[9]

Not only are SBIR's patents plentiful. They are also produced very efficiently and are exceptionally valuable.

- SBIR's vast output of patents—which now exceeds an average of seven patents a day, and has surpassed 60,000 patents over the life of the program, with about 8,000 patents pending—is being generated on **one-twelfth** the federal R&D funding that U.S. universities receive.[10]
- Overall, smaller companies produce about **13 times** more patents per employee than large patenting firms.[11]
- These small company patents are twice as likely as large firm patents to be among the one percent most cited in scientific and technical literature and in subsequent patent applications.[12]
- And small firm innovation is twice as closely linked to current scientific research as large company research, on average, and is thus substantially more "high tech" or "leading edge."[13]

For scientists and engineers, the opportunity to own this valuable intellectual property has been one of the principal attractions of working in a small company setting. Indeed, so many scientists and engineers have migrated into smaller companies in recent years that these companies now have the Nation's largest concentration of science and engineering talent.[14]

SBIR: Assessment of the Department of Defense Fast Track Initiative, STEP Board, National Academies of Science and Engineering, 2000. Another National Academy of Sciences study of the SBIR Program is ongoing, with a final report expected later in 2007.

[9] Source: SBIR patent database, Innovation Development Institute, *www.inknowvation.com*

[10] *Science and Engineering Indicators 2006,* National Science Foundation.

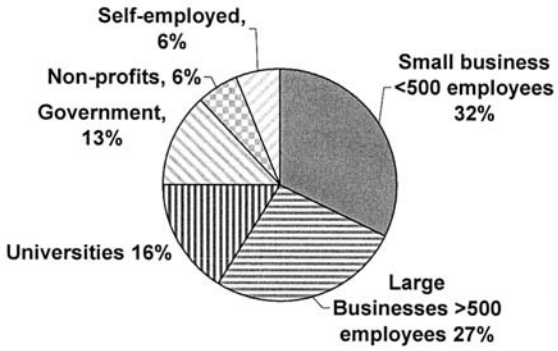
[11] *Small Serial Innovators: The Small Firm Contribution To Technical Change,* CHI Research, Inc, under contract to the U.S. Small Business Administration, March 2003, *www.sba.gov/advo/research/rs225tot.pdf*

[12] *Ibid.*

[13] *Ibid.*

[14] *Science and Engineering Indicators 2006, op. cit.*

Figure 1. Percentage of Scientists and Engineers Employed In Government, Academia and Business (NSF 2003)



Put differently, *over half* the scientists and engineers in the private sector now work for smaller companies.

Together, these statistics tell an important story. It's this:

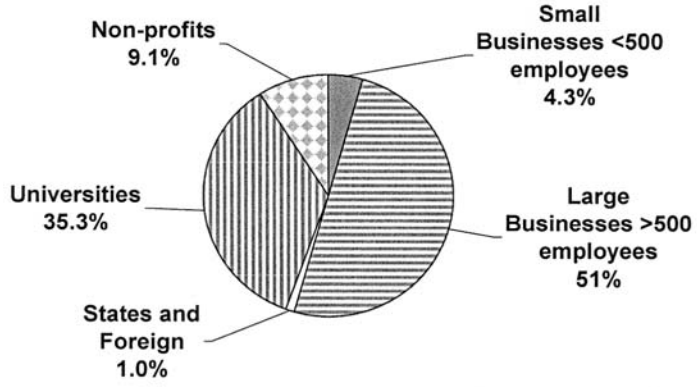
- Patents, and the technologies they represent, are strongly linked to both local economic growth and global competitiveness.
- Awarding competitive federal R&D contracts to small, technology-based businesses, in a rigorous and disciplined manner like that used by the SBIR Program, produces a very large number of high-quality patents.

But there's one problem.

Only 4.3 percent of federal R&D dollars go to small companies—and the SBIR and STTR Programs account for most of that.[15]

[15] *Ibid.*

Figure 2. Percentage of Total Extramural Federal R&D Expenditures Received by Academia and Businesses $81.7 Billion (NSF FY-2005)



Thus, with one-third of the nation's scientists and engineers,

with a set of companies that is already producing 50% more patents than all the nation's universities combined – at one-twelfth the cost in federal R&D dollars –

with a track record of leading-edge patents and technologies,

and with the nation in need of accelerated technological advances to compete globally,

small technology-based companies still are obtaining less than one dollar out of every twenty that the federal government spends on extramural R&D.

Overall, extramural federal R&D spending is highly concentrated. In FY 2005, at the National Institutes of Health, one university received 1299 awards, valued at more than $600 million.[16] This exceeds all SBIR awards at NIH in FY 2005.

The same situation prevailed at DOD, where one company's RDT&E awards greatly exceeded all SBIR awards.

In fact, RDT&E awards to the top **three** companies at DOD, in FY 2005 alone, exceeded every dollar that has been spent on the SBIR Program—government-wide—in the entire 25 year history of the Program.[17]

III. SBIR AND THE UNIVERSITIES

SBIR and STTR make an important contribution in another way, too. The Programs offer an especially important venue for public-private, and nonprofit-private, partnerships with Universities. SBIR researchers often have ties to universities, and STTR researchers always do. In my own two companies, I have used researchers from **Case Western Reserve, Cleveland State, Johns Hopkins, Michigan**

[16] See: *http://grants2.nih.gov/grants/award/trends/Rnk_05_All.xls*

[17] See: *http://siadapp.dior.whs.mil/procurement/historical_reports/statistics/p02/fy2005/P02_05.pdf*

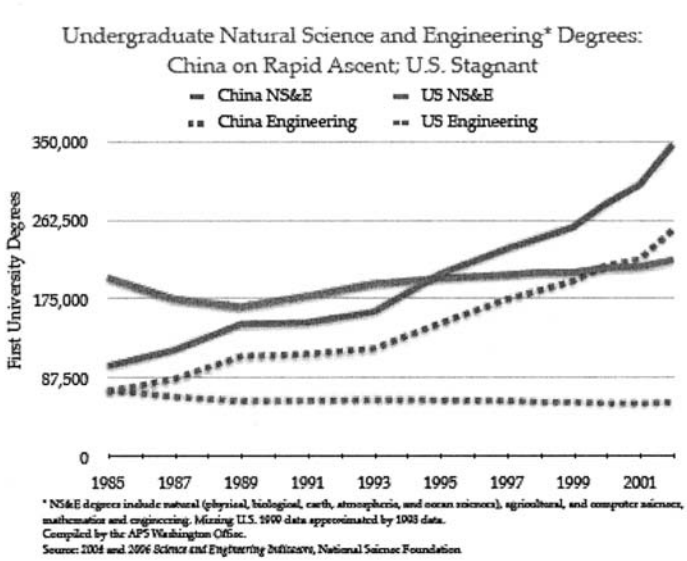
Tech, Notre Dame, Ohio State, University of Alabama-Huntsville, University of California Los Angeles, University of Michigan, University of Southern Florida, University of Toledo, and Washington University in St. Louis. We have also partnered on projects with a number of universities, such as **Colorado State, the University of Utah and the University of Idaho.** And we provide internships for about a dozen university students every year.

Together, SBIR/STTR companies and the Universities can:

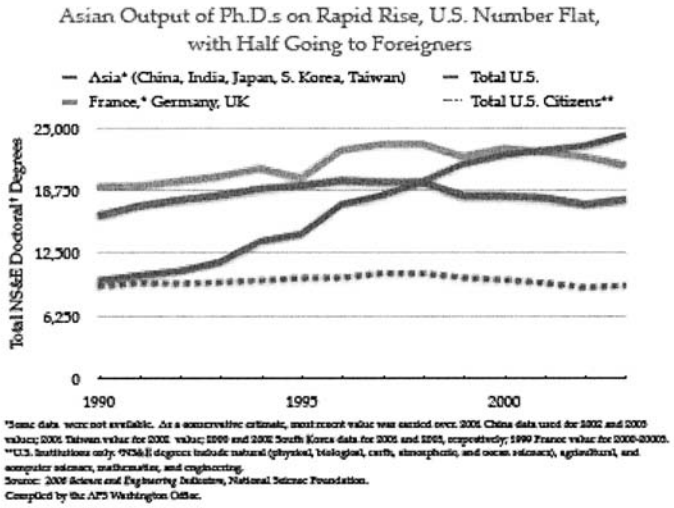
- Identify University R&D with potential downstream commercial applications, strengthening this awareness and focus,
- Develop new revenue streams for the Universities through R&D sales and licensing,
- Supplement the income of University-based researchers that work on SBIR and STTR projects, thus aiding 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.

But there is an even more important reason why Universities and SBIR/STTR companies are natural partners. *Just as SBIR/STTR companies need the flow of scientific and engineering graduates from the schools, so also Universities need the availability of attractive yet realistic private sector job opportunities to attract students in the first place.* For many prospective science and engineering students, the challenges, relative freedom, and upside income potential of working in a leading-edge small company will be exactly what they are seeking.

With numerous studies suggesting that the Nation urgently needs to graduate more scientists and engineers, Congress should enhance this important symbiosis between Universities and SBIR/STTR companies.[18]



[18] The two charts which follow are taken from *Measuring the Moment, op. cit.,* pages 24 and 26.



*Some data were not available. As a conservative estimate, most recent value was carried over. 2005 China data used for 2002 and 2005 values; 2005 Taiwan value for 2005 value; 2000 and 2005 South Korea data for 2005 and 2005, respectively; 1999 France value for 2000-20005.
**U.S. institutions only. †NS&E degrees include natural (physical, biological, earth, atmospheric, and ocean sciences), agricultural, and computer sciences, mathematics, and engineering.
Source: 2006 Science and Engineering Indicators, National Science Foundation.
Compiled by the APS Washington Office.

The trend shown below is especially disturbing. In the past four years, the number of degreed scientist and engineers in the U.S. increased by less than 20,000 graduates per year. India, by contrast, is graduating 78,000 more scientist and engineers than four years ago—almost doubling their output.

Four-Year Bachelor's Degrees in Engineering, Computer Science, and Information Technology Awarded in the United States, India, and China[19]

Country	2000-1	2001-2	2002-3	2003-4	2004-5	2005-6
United States	108,750	114,241	121,263	134,406	137,437	133,854
India		82,107	109,376	129,000	139,000	170,000
China				282,610	361,270	

IV. COMMERCIALIZATION OF SBIR TECHNOLOGIES

The SBIR Program is divided into three Phases that correspond to the *research, development,* and *commercialization* of an innovation. Since the Program's inception, Phase I (initial research) and Phase II (development of prototypes) in general have been handled well by the participating federal agencies.[19,20]

Where SBIR has needed improvement is in the commercialization phase (Phase III). Since it requires agencies to either find outside funding to commercialize an innovation, or to use non-SBIR agency funds to acquire the innovation for the agency itself, Phase III has been more challenging for agencies than simply using SBIR Phase I and Phase II to obtain desired R&D work.

Congress focused considerable attention on SBIR commercialization in the 2000 reauthorization. Since that time the rate of commercialization has steadily increased. As part of the SBIR solicitation process, companies must report their rate of success in commercialization, using published agency criteria. Today over 40 per-

[19] Vivek Wadhwa, Gary Gereffi, Ben Rissing, Ryan Ong. *Where the Engineers Are, Part 2,* Duke University School of Engineering Management, 2006

[20] See the studies cited in endnote 8, above.

cent of all SBIR technologies reach the marketplace. This is truly a remarkable result.

And thanks to commercialization successes in some units within the Department of Defense,[21] Congress was able to advance Phase III broadly within DOD under legislation that was approved in 2006.

Called the Commercialization Pilot Program (CPP), the new law[22] is helping bridge a gap between promising defense R&D and the mainstream DOD acquisition system that has long been known colloquially as "the Valley of Death."

The new CPP Program suggests ways that commercialization might be improved across the government.

While the CPP has only been in place at DOD only since 2006, it has greatly increased the focus on SBIR insertion in the DOD procurement process. Actions taken by key officials during the past six months strongly suggest that a surge of SBIR technology insertion is ahead in the next one to two years.

V. REPLIES TO QUESTIONS POSED BY THE SUBCOMMITTEE.

1. SBIR Program effectiveness and recommendations.

The SBIR/STTR Programs have succeeded in the goal of recruiting smaller technology-based companies to help address federal R&D needs. Over 16,000 companies have participated in the SBIR program, and over 6,000 are currently active in it.[23] All available evidence indicates that the SBIR/STTR Programs are working as well as, if not better than, other federal R&D programs. As noted above, although the SBIR/STTR programs receive about one-twelfth as much federal R&D funding as that allocated to universities,[24] SBIR and STTR companies generate about 50 percent more patents annually than all U.S. universities combined.[25]

It would be hard to overstate the financial significance of SBIR / STTR to small, technology-based businesses. The Programs are *by far the Nation's largest source of capital for early-stage R&D, particularly for high-risk projects.*

It is not at all clear what would replace these Programs if they were to disappear.

- Banks typically will not lend to early-stage technology companies, especially over the time horizons that the companies would need for repayment.
- Smaller technology companies tend to be fueled by the dreams of their initial owners and investors. These individuals resist yielding equity—especially controlling equity—to venture capitalists and other "outsiders." Even if the companies welcomed such equity participation, it would be hard to find.
- Venture capital tends to cluster in specific sectors and specific geographical areas; relatively little of it is available for early-stage technology firms like most SBIR/STTR firms, particularly those outside of the Boston and San Francisco Bay areas.

The core issue in SBIR/STTR reauthorization is that ***historically, nothing else has worked*** in drawing small, technology-based companies into the task of addressing federal R&D priorities.

Untapped small business technology capabilities are growing, as evidenced by their quantity and quality of patents as well as by the increased concentration of R&D talent in the sector.

The only ***proven, effective*** way to bring more of this capability to bear on the federal government's R&D needs is to gradually increase the percentage of federal R&D allocated to the SBIR and STTR Programs.

[21] SBTC White paper, "Mining the Small Business Resource: Issues and Recommendations" vol. 1, No. 4. *www.nsba.biz/docs/sbir_white_paper_iv_final_11_jan_07.pdf*

[22] *National Defense Authorization Act of FY 2006,* P.L. 109–163, Sec. 252.

[23] Source: SBIR patent databases, Innovation Development Institute, *www.inknowvation.com,* and U.S. Small Business Administration Office of Technology.

[24] Source: National Science Foundation, *Science Indicators, 2006.*

[25] See: *www.inknowvation.com/PatentGraphsShow.html?graph=SBIRvsUnivPatents.gif*

Agency flexibility. Agencies in the SBIR/STTR programs have diverse missions, and have been given considerable flexibility by Congress in administering their programs. SBTC agrees with this general orientation. However, certain basic rules do need to be observed and SBA does need to function effectively as an effective Program coordinator and impartial adjudicator.

Definition of a small business. The most important rule for the program is that participation is statutorily limited to companies with fewer that 500 employees, including affiliates and subsidiaries. This requirement is derived not only from Congress's long-standing mandate that a small business must be one that is "independently owned and operated,"[26] but also from the need to avoid the "capture" by larger enterprises of the resources that Congress intended for small business.

There are occasional efforts to breach SBIR's statutory maximum of 500 employees; doing so would undermine both the central purpose of the program and the key ingredient of its success.

It is also appears totally unnecessary. If SBIR accounts for two and one-half percent of extramural federal R&D, then the other ninety-seven and one-half percent is available for entities that are **not** small businesses.

Technologies developed by other agencies. An area where agency flexibility should be continued and expanded is encouraging agencies to fund Phase II awards, or promote the Phase III commercializations of technology initially developed by other agencies in the SBIR/STTR Programs. Overlapping agency missions in fields like defense and homeland security, and science and life sciences, suggest that agencies should be able to take advantage of technological breakthroughs in any part of the SBIR/STTR Programs. This type of sharing is in the public interest and has been occurring for several years. Congress should encourage it.

SBA management. SBIR and STTR are critical national R&D programs providing scarce dollars for early stage technologies of potentially great importance. The interests of the taxpayers in assuring the effective management and oversight of these programs and these dollars must be respected. SBA needs to strengthen its Office of Technology to provide this guidance and leadership to the participating agencies.[27]

Award levels. SBIR Phase I and Phase II award level sizes have not been adjusted since 1992. Inflation and other cost factors in the intervening years have made an upward revision necessary. At the same time, some agencies have simply "taken the law in their own hands." A GAO Report in 2005 found that more than half of NIH's SBIR awards in recent years exceeded the Program Guidelines agreed upon by Congress, SBA and OMB and published in the *Federal Register.*[28] The 2006 Senate Small Business and Entrepreneurship Committee report on SBIR reauthorization cites a $6.5 million Phase II award by NIH.[29] Such an award displaces almost seven Phase II contracts that could have been awarded if the Congressionally mandated cap of $750,000 had been observed.

Congress must be clear about this. Either SBIR/STTR Programs should grow by several orders of magnitude, or agencies must stop using the Programs as "piggy banks" to finance projects that should be funded from other agency sources.

SBTC generally agrees with the award size revisions contained in S. 3778 from the last Congress, which was approved by the Senate Small Business and Entrepreneurship Committee. The Committee bill raised Phase I awards caps from $100,000 to $150,000 and Phase II award caps from $750,000 to $1,250,000. However, SBTC would caution Congress that such increases in the caps will result in a significant reduction in the number of total SBIR awards (and therefore the number of companies participating in the Program) if overall SBIR dollars remain constant.

Depending on how awards were distributed between Phase I's and Phase II's within each agency, as many as 40 percent fewer companies could end up in the SBIR Program. This could represent a devastating loss of technological talent to the government. It is another compelling reason for increasing the percentage of federal R&D allocated to SBIR/STTR.

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[26] This legal stipulation has been included in the *Small Business Act* (15 USC 632) since the Act was passed in 1953. It is the foundation of much subsequent small business law and a large body of federal rules.

[27] For a more complete discussion of this point, see the Small Business and Entrepreneurship Committee, U.S. Senate, *Small Business Reauthorization and improvements Act of 2006,* Report Number 109–361, p.46.

[28] *Small Business Innovation Research: Information on Awards Made by NIH and DOD in Fiscal Years 2001 through 2004,* GAO Report GAO–06–565.

[29] Small Business and Entrepreneurship Committee, U.S. Senate, *Small Business Reauthorization, op. cit.,* p.45.

Of course, the SBIR/STTR dollar level might not remain constant. If the higher levels of R&D funding recommended by the President's Competitiveness Initiative were to be so allocated by Congress, the dollar size of the SBIR/STTR Programs would grow in tandem. But this is difficult to predict, and, in any event, future years could just as easily witness a *decline* in federal R&D spending.

The Senate bill also anticipates an opportunity for agencies to "override" the caps by 50 percent. The Phase I "override" would be $225,000; the Phase II, $1,875,000. This would obviously exacerbate the foregoing problem. SBTC would like to see clear conditions imposed on the agencies for any such "overrides." But again, those conditions could become more flexible if the allocation of funds going to the SBIR and STTR Programs is increased in the manner that we have recommended.

Commercialization funding gaps. Perhaps no subject is more important for this reauthorization than the effective transitioning of technology from the working prototype stage to production and utilization by the agencies or the private sector. Agency efforts like NIH's Phase IIB, NSF's Phase II+, and DOD's Commercialization Pilot Program are pointing the way. Successes like those experienced by the Navy show that such transitioning can be accomplished in ways that benefit the government and the taxpayers. SBTC urges Congress to incentivize agencies to match the successes of SBIR Phases I and II in SBIR Phase III. One key to this will be the expenditure of additional dollars on testing and evaluation.

Program administrative costs. SBTC is aware that strengthening the SBIR and STTR Programs in the ways we recommend will place additional administrative responsibilities on the participating agencies. Although SBTC has long opposed the transfer of dollars from contract awards to administrative overhead, we would, as we told the Senate last year, consider re-allocating no more than one percent of SBIR's total dollars to **new** agency administrative costs. We recommend that this funding increment be used strictly for strengthening commercialization of SBIR technologies, and that agencies be required to report on how any expenditure of these funds directly supports this objective.

Venture capital company participation in the SBIR Program.

Background. Since the SBIR Program is intended for small businesses, Congress made it a part of the Small Business Act and set a statutory cap of 500 employees for participating companies.

The Small Business Act defines a small business as one that is "independently owned and operated."[30]

Charged with implementing this mandate,[31] SBA promulgated the "affiliation rule,"[32] which states that in determining whether a business is small, all of the business's subsidiaries and affiliates will be counted, including any company controlling, controlled by, or under the mutual control of, the business claiming to be small. (Likewise, under the commercial codes of all 50 states, a firm that controls more than 50 percent of another company is treated as owning the company.)

This legal framework has not been challenged in over half a century. Tampering with it would set legal precedents affecting a large body of laws and regulations, ranging from tax laws to small business lending to the regulations and procurement policies affecting small businesses at dozens of federal agencies.

Under the SBIR rules, a venture capital company that is **small** by SBA's standards *may hold a controlling interest in an SBIR company,* as long as the combined entity is still small and is owned by individuals. A venture capital company that is **large** by that standard *may hold a minority (less than 50 percent) interest* in an SBIR company. The only prohibition is on **control** of an SBIR company by a **large** VC.

Current controversy. We are now in the fifth year, and third consecutive Congress, that elements of the biotechnology and venture capital industries have petitioned Congress and the Small Business Administration to override the SBA's legal framework for determining what is a small business.

The focal point of this dispute is a small group of large-VC-controlled firms that are seeking access to SBIR awards at the National Institutes of Health and perhaps other agencies.

The fact that the firms involved, and their VC backers, have spent this long unsuccessfully promoting these changes in Congress and at SBA should suggest that their arguments are far from persuasive when closely examined.

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[30] 15 USC 632(a) (1)
[31] 15 USC 623(a)(2)
[32] 15 CFR 121.103

The fact that the firms and the VCs are back again in this Congress is linked, in SBTC's view, to a number of misleading or incorrect assertions about the issue.

We looked at these assertions very carefully in our Senate testimony last year;[33] here we will simply summarize some of them.

1) Let us start with the most emotional assertion. It is sometimes stated that the prohibition on SBIR access by large VC-controlled firms is denying patients with life-threatening diseases the "important, life-saving" medications they need. Various patient groups, among others, have been told this.

The simplest and most logical response is that if NIH funds proposals by these large venture-backed companies, then other "important, life-saving" proposals will *not* be funded.

Most proposals that NIH considers have life-saving implications. Until the NIH budget is large enough to fund every proposal, the competitive awards process will always yield winners and losers. For their part, SBTC members that are active in the NIH SBIR Program *also* fear that their "important, life saving" innovations will lose out—to the large venture-backed companies.

They may well have more to fear.

Thanks to their deep-pocket backing, the companies that the VCs fund will be able to submit *multiple* proposals per solicitation. They won't necessarily be more life-saving, but they will be more polished. They will also have features that do well under NIH's scoring system—like impressive looking "teams" and extensive preliminary research. It costs money to submit multiple proposals, to make them polished, to keep impressive teams on hold until an award decision is reached, and to conduct preliminary research. That is exactly where large VC-backed companies will have the edge.

Proposals that won't have that edge will be those from companies whose research interests don't fit the large VC business model, and who therefore don't have that backing. Examples of research that generally doesn't fit the model are treatments for orphan diseases, (which don't generate a lot of cash flow), bioterrorism defenses (only one buyer, the Federal Government), and vaccines (patients only take the drug once, not daily). Yet a key reason for *creating* NIH was to address public health challenges such as these—challenges that are often outside the normal commercial nexus of medicine. SBIR should support that mission, not attempt to distract the agency from it.

Whether or not large VCs are interested in such areas, small companies are.

2) For some reason, the VCs and their allies continue to state that "SBA changed the rules" on them. As noted, the Small Business Act and the affiliation rule are more than 50 years old. GAO looked at this "changed the rules" allegation in 2006 and correctly stated that SBA had *clarified* long-standing rules.[34] It may well be true that some large VC backed firms were obtaining SBIR awards prior to the clarification; it does not mean that SBA, having had that fact drawn to its attention, should have allowed it to continue. Nor does it mean that the large VCs now have some "right" to demand such treatment.

3) Companies and associations seeking this change say that the SBIR Program at NIH will be strengthened by having the big VC backed companies in it.

The problem with this assertion is the disconnect between Phases I & II as they are intended to work in the SBIR Program and what VCs prefer to fund. In VC terminology, Phase I represents "seed or startup" R&D and Phase II "early stage" R&D. Neither is much of a focus of VCs.

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[33] Accessible at:
www.nsba.biz/docs/squillante_testimony__ssbec__july_12__2006_final.pdf

[34] *Small Business Innovation Research. . ., op. cit.,* p. 1.

Trends in Institutional Venture Investing by Stage of Development

	Startup/Seed		Early Stage		Expansion		Later Stage		Total*
1995	$1,313	17%	$ 1,684	21%	$ 3,681	47%	$ 1,198	15%	$ 7,879
1996	$1,492	14%	$ 2,744	25%	$ 5,143	47%	$ 1,632	15%	$ 11,014
1997	$1,310	9%	$ 3,450	24%	$ 7,592	52%	$ 2,259	15%	$ 14,612
1998	$1,751	8%	$ 5,421	26%	$ 10,434	50%	$ 3,194	15%	$ 20,811
1999	$3,275	6%	$ 11,701	22%	$ 29,848	56%	$ 8,652	16%	$ 53,476
2000	$3,094	3%	$ 25,573	24%	$ 59,979	57%	$ 16,054	15%	$104,701
2001	$ 730	2%	$ 8,961	22%	$ 23,024	57%	$ 7,989	20%	$ 40,703
2002	$ 290	1%	$ 3,927	18%	$ 12,320	57%	$ 5,160	24%	$ 21,697
2003	$ 357	2%	$ 3,454	18%	$ 10,100	52%	$ 5,674	29%	$ 19,585
2004	$ 407	2%	$ 3,987	18%	$ 9,257	43%	$ 7,985	37%	$ 21,639
2005	$ 736	3%	$ 3,396	16%	$ 7,821	36%	$ 9,727	45%	$ 21,680

* in millions of dollars

source: Venture Economic/NVCA/Pricewaterhouse Coopers 'Money Tree'

Seed capital currently accounts for a minuscule $3 out of every 100 that large VCs invest, and early stage capital only 16 percent. A large VC presence in the NIH SBIR Program seems likely to inexorably draw the Program away from its mission to provide scarce R&D dollars for high-risk, early stage R&D.

There is another problem as well. Congress intended for the SBIR Program to harvest innovations from across the country, even in areas not known as technology centers. That is why the Federal and State Technology (FAST) Program and Rural Outreach (RO) Program were developed by Congress as adjuncts to SBIR. They have been fairly successful. In the "best practice" FAST and RO state programs, more than one out of every three companies receiving the training goes on to obtain an SBIR award.

By contrast, venture capital investors generally operate out of a headquarters in a technology center and try to invest in companies that they can personally visit on a regular basis. This is perfectly reasonable, but it is a far different model than SBIR. The different outcomes can be seen in the contrasting distribution of dollars, in the chart below.

SBIR Program Compared to Venture Capital Investment

Concentration of Dollars By State, 2004

Measure	SBIR Contract Awards	Venture Capital Disbursed
Total dollars	$2.0 billion	$20.9 billion (10 x SBIR)
Percentage of dollars going to top 5 states	45%	70%
Percentage of dollars going to "middle 20" states (ranked 15-35)	24.3%	5.9%
Percentage of dollars going to bottom 5 states	2.1%	.002%
States receiving ***less than*** $1 million	4	7
States receiving ***less than*** $4 million	9	15
States receiving $10 million to $100 million	26	13
States receiving ***more than*** $1 billion	0	3

Sources: SBIR, U.S. Small Business Administration, www.sba.gov/sbir/2004SBIRStateChart.xls
Venture capital, National Science Foundation, *Science and Engineering Indicators, 2006*, Table 8-42.

Note: both sets of figures include the District of Columbia and Puerto Rico

So apart from the damage that the intrusion of large companies would do to the integrity of SBIR as a *small business* program focused on *very early-stage* R&D, *the rise of large VCs in the SBIR Program will shift the distribution of SBIR's dollars more toward the relative handful of cities and states that the VCs focus on.*

> Recall the chart on patents and wealth creation at the beginning of my testimony. Then reflect on what a shift in SBIR toward the VC model would mean for large swaths of the nation.

A SBIR Program that is not truly a small business program, and not truly national, would soon be curtailed by Congress, and deservedly so.

There is a vital and necessary place for large VCs in the SBIR Program. It is in Phase III.

Companies entering the commercialization phase of SBIR urgently need to partner with outside investors—and this is precisely the stage of R&D development that VCs prefer in the first place. Thus neither Congress nor SBA sets any restrictions on the size of companies that can participate in Phase III of SBIR. If this does not meet the needs of large VCs, SBTC would be willing to work them to craft another program that does—an offer we have made repeatedly over the years.

Now would be a good opportunity to create such a program. It could be tied in to the strengthening of ATP and MEP, two important innovation programs for companies of all sizes that SBTC strongly supports.

But SBIR needs to stay focused on the core issue that we have outlined—that the Nation still is receiving only a fraction of the innovation benefits it could—if the growing number and capabilities of small technology companies were better utilized. Efforts to correct this problem should not lose their focus or become diluted.

VI. SBTC'S RECOMMENDATIONS TO CONGRESS

In my opinion, SBIR appears to be the most successful program that Congress has ever devised to stimulate innovations; now is the time to expand the Program and make it permanent.

SBTC recommends that Congress:

1. Make the Program permanent. SBIR is the largest single source of patents in the United States. 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. It should not have to justify its existence every few years. Delays in Congressional approval of reauthorization, 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 permanent, 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 one-half percent 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*.

To further 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 on FY 2008 and 0.9 percent in FY 2009 and thereafter.

3. Strengthen commercialization of SBIR. SBTC suggests that Congress take several new actions that will help "Unleash American Innovation."

First, if the funding for SBIR and STTR is increased as suggested above, allowable Phase I and Phase II SBIR and STTR funding should be increased during 2008 and 2009 to $150,000 for Phase I and $1,250,000 in Phase II, and indexed to inflation, to allow more work to be performed under the initial two phases of the program.

Second, starting in 2009, one third of the increased funding in the SBIR and STTR programs over the 2007 funding levels should be set aside for funding "Phase 2c" type initial manufacturing prototypes and testing by the agency and other commercial clients or for clinical trials deemed important to the agency's mission.

Third, a "CPP" **type** program should be formed in the NIH, NASA, and DOE. Additional funding should be provided, and the Program opened up to companies that have received VC funding from all sources.

4. Reinforce the intellectual property rights of SBIR companies. In a recent decision involving the intellectual property rights of an SBIR company, the court appeared to misinterpret longstanding Congressional intent on the issue.[35] SBTC would like to work with Congress in rectifying this problem.

We believe that these actions will allow more new companies to be formed, SBIR and STTR companies to grow faster and larger, and encourage venture capital flows to those SBIR companies that are ready to enter the next stage of their growth.

The gap in funding the growing number of innovative small companies, and the scientific and technological innovators who work for them, has potentially important consequences for the Nation. As Harvard economist Dale Jorgenson has noted about IT companies:

> *Since 1995, information technology industries have accounted for 25 percent of overall economic growth, while making up only three percent of GDP. As a group, these industries contribute more to economy-wide productivity than all other industries combined.*[36]

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[35] United States Court of Appeals for the Federal Circuit. Opinions, Decisions & Orders. . . 2006/11/22, 06–5048.pdf, CFC, Night Vision Corp. v. U.S.

[36] Dale Jorgenson, *Moore's Law and the Emergence of the New Economy,* Semiconductor Industry Association, 2005.

BIOGRAPHY FOR ROBERT N. SCHMIDT

Mr. Robert N. Schmidt is the founder and Chairman of Cleveland Medical Devices Inc. and of Orbital Research Inc., both of which were started in 1990. He received his BS degree in Mechanical Engineering (70) and his MS (71) from Rensselaer Polytechnic Institute in Troy, NY; his MBA (75) from the Univ. of Utah, and his Juris Doctor (80) from Cleveland State University. He is a licensed professional engineer (Ohio, 76) and an attorney (Ohio, 81 and U.S. Patent and Trademark Office, 82).

Both Orbital Research and Cleveland Medical Devices have experienced extraordinary growth over the last decade; both being named to the Inc. 500 list, and both being on NE Ohio's Weatherhead 100 list at least seven times. Mr. Schmidt is the only person in America to have two companies named on the Inc. Inner City 100 list, and both companies have made the list at least three years in a row. Mr. Schmidt is the only entrepreneur to have received this Inc. Inner City 100 Award from Harvard seven times in the seven years of its existence. Both companies have been bootstrapped with sales generated funding. He was on the Inc. 500 Advisory Board in 2002.

Both Mr. Schmidt and his companies have also been recognized for their innovative technologies: Cleveland Medical Devices has received the NORTECH/EDI Innovation Award four times, and Orbital Research has received this award twice. As a principal investigator, Mr. Schmidt has supervised programs for the U.S. Army, Navy, and Air Force, DARPA, the National Institutes of Health, NASA, Dept. of Education, Dept. of Transportation, and the National Science Foundation. The companies have performed over $50 million of research for the U.S. Government.

Prior to starting his companies, Mr. Schmidt was a consultant to the Center for Materials for Space Structures, a NASA Center at Case Western Reserve University. He coordinated materials space flight experiments to fly on the Space Shuttle and on the Wakeshield, evaluating the effects of atomic oxygen and the low Earth environment on lighter weight polymers and "self-healing" materials. From 1984 to 1990, Mr. Schmidt served as Director of Technology and Program Development at Life Systems, Inc. He managed Functional Electrical Stimulation (FES) programs, helping paraplegics to walk, and other medical programs; an "Advanced Collective Protection Chemical Defense System," and several other Army chemical defense programs; and the "Zero-Gravity Shower" program and several other hygiene and regenerable life support programs for the Space Station Freedom; as well as working on water recycling and regenerative fuel cell programs.

From 1976 to 1983, Mr. Schmidt was Manager of Licensing and Technology Development, an Engineering Manager, a Project Control Manager, and a Project Engineer for Davy McKee Corporation. He was responsible for technology transfer for the 4,000-person engineering firm. As the project engineer for three petrochemical plants, he directed engineering efforts and controlled programs worth up to $200 million for ARCO, Exxon, and Shell Oil. He was the chief engineer for the design of the world's largest single train methanol plant, and built a coal liquifaction plant for Exxon. From 1972 to 1976, he was Chief of Engineering Plans for the U.S. Army Corps of Engineers in Stuttgart, West Germany, managing engineering efforts at 48 U.S. Military installations in southern Germany supervising over 800 projects.

Mr. Schmidt has received the Edison Biotechnology Center Award for Outstanding Contribution to Biotechnology in Ohio in 1993, is a Founding member of the FES Society, and a member of the AIAA, IEEE, and SAE. He has published over 30 papers, and has 23 U.S. patents in the areas of medical devices, flight control, radio design, electrophysiology, pressure measurement, chemical defense, and Braille displays.

In his newest ventures, Mr. Schmidt serves as the Chairman of several other companies including iACTIV Corporation and ComSense Technology Inc., both MEMS companies; and of RadioStorm Inc., Flocel Inc., and CleveMed NeuroWave Inc. He is also the founder of the Americas' Arts and Sciences Foundation and of NEOBio; and is an angel investor in several non-related Cleveland area companies. He is on the Federal Reserve Bank of Cleveland Business Advisory Council, and has been the Keynote speaker for the Society of Manufacturing Engineers and an invited Speaker to the American Institute for Medical and Biological Engineering. He was named by The National Small Business Association (NSBA) as the 2006 Small Business Advocate of the Year for his national and state work promoting policies to help small business prosper (Money Magazine, p.50 12/05, and p.136 5/06); and is one of only of handful of individuals in America to have received the Inc. 500 Award as one of the 500 fastest growing companies in the U.S. as CEO for more than one company (CleveMed 2000 and Orbital Research 2001).

Chairman WU. Thank you very much, Mr. Schmidt. Dr. McGarrity.

STATEMENT OF DR. GERARD J. McGARRITY, EXECUTIVE VICE PRESIDENT OF SCIENTIFIC AND CLINICAL AFFAIRS, VIRxSYS CORPORATION

Dr. MCGARRITY. Chairman Wu, Ranking Member Gingrey, and Members of the Subcommittee, my name is Dr. Gary McGarrity, Executive Vice President at VIRxSYS, a private biotechnology company developing treatment for HIV and for vaccines. Our lead product is a cutting-edge gene therapy technology against HIV and has completed Phase I safety trials and is presently in Phase II efficacy trials.

Previously I was CEO of Intronn, Inc., and I have 30 years of experience in biotechnology companies and biomedical research, including chairing the recompetent DNA Advisory Committee at the NIH.

I am testifying today for BIO, the Biotechnology Industry Association which represents more than 1,100 biotechnology companies, academic institutions and other organizations in all 50 states. The vast majority of BIO members are small, early-stage R&D companies just like mine. BIO has over 600 emerging technology companies, most with fewer than 50 employees that do not have a marketed product.

Biotechnology research follows a long, unpredictable road from pre-clinical research to FDA approval, an average about eight years and upwards of $800 million to $1.2 billion. Without product revenues, companies must undertake fundraising from angel investors and venture capital firms. Private equity fundraising is absolutely critical to the development of new therapies.

My company started in 1998 using technology out of Johns Hopkins. We began our clinical trials five years later, and if we get all of this correct, we will have a marketable product in 2010 or 2011. In addition, we, like most companies, are working on three to four other products that are at a very, very early stage of development.

A biotechnology company requires extensive fundraising for its lead product, and these funds are tied to very specific milestones for their product, not for other programs that may be at earlier stages. Researching other therapies typically requires different funding sources which is particularly challenging at the very earliest stages of development as you have stated today, Chairman Wu.

Congress created the SBIR Program to utilize the capabilities of innovative companies to fulfill federal R&D needs, and they provided discretion to the SBA to determine eligibility of small domestic companies. SBIR grants were never intended to prop up small businesses through corporate welfare but instead represent a competitive grant program stressing innovation.

For 20 years, small domestic biotechnology companies competed for SBIR grants based on scientific merit through a peer review process. Obtaining these grants was a powerful signal to the private sector that the company's research was compelling.

The SBIR Program has played a pivotal role in advancing new treatments. For example, of the 163 companies and their affiliates

that have been involved in the development of 252 FDA-approved biologics, 32 percent, one in three, have received at least one SBIR STTR grant. That is an impressive statistic. I mean, the system was working. Now, however, many biotech companies are excluded from competing for SBIR's. In 2003, the SBA ruled that a biotechnology firm was not eligible for the SBIR program because of its capital structure based on a new view of SBA regulations but not a change in underlying statute or Congressional intent. SBA has stated that the so-called ownership rule is meant to be a proxy for determining that a company is domestic. However, this has had the unintentional consequence of excluding many small domestic biotech companies from the SBIR program.

My company, VIRxSYS, is actually eligible to compete for SBIR grants. So I have led companies that have been eligible and companies that have not been eligible.

When I was CEO of Intronn, we successfully competed for Phase I and Phase II SBIR grants in cystic fibrosis. In the summer of 2003, after being awarded the second Phase II SBIR grant in cystic fibrosis that ultimately would have led to clinical trials, our grant was rescinded because of the SBA rule change. The company's previous SBIR grant resulted in getting venture capital investment into the company which made us no longer eligible for SBIR's. We had 20 employees at the time. We terminated promising research in cystic fibrosis, and we laid off employees. And this is not an isolated incident.

Excluding companies from the SBIR program because of their capital structure could benefit still eligible companies like VIRxSYS by reducing highly qualified applicants. But the SBIR program would be less competitive, and science itself would suffer.

Since the new rule was implemented, applications for SBIR grants declined by almost 12 percent at the NIH in 2005 and by 14.6 percent in 2006. NIH director, Dr. Zerhouni, stated in a letter to the SBA, "NIH believes the current rule undermines the statutory purposes of the SBIR program. It undermines NIH's ability to award SBIR funds to those applicants whom we believe are most likely to improve human health." And I would like to submit this letter for the record.

I am perfectly willing to compete with small domestic biotech companies regardless of their capital structure based on the scientific and the technical merit of our research. That is the American way. I respectfully request that the Committee act to allow small domestic companies to compete for SBIR grants regardless of capital structure. SBIR should be a competitive program that fulfills federal R&D needs. Funding highly qualified research should be the priority, not corporate welfare.

Again, thank you for providing me the opportunity to testify here this afternoon.

[The prepared statement of Dr. McGarrity follows:]

PREPARED STATEMENT OF GERARD J. MCGARRITY

Chairman Wu, Ranking Member Gingrey, and Members of Science and Technology Subcommittee on Technology and Innovation:

I appreciate the opportunity to testify before the Subcommittee today regarding the Small Business Innovation Research (SBIR) grant program. For more than

twenty years the SBIR program has served as a platform by which innovative, small companies can compete to participate in federal research and development.

My name is Dr. Gary McGarrity, I am the Executive Vice President of Scientific and Clinical Affairs at VIRxSYS. VIRxSYS is a private biotech company whose mission is to develop gene therapies using its proprietary lentiviral vector delivery system. We have completed Phase I safety testing and are now in Phase II clinical trials testing the first application of our gene therapy technology against HIV. I have 16 years experience with biotech companies and an additional 14 years of in-depth scientific experience. Prior to joining VIRxSYS, I was the CEO of Intronn, Inc., which developed products to fight cystic fibrosis.

I am testifying today on behalf of the Biotechnology Industry Organization (BIO), an organization representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in 50 U.S. states and 31 other nations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The overwhelming majority of BIO member companies are small, early stage research and development oriented companies pursuing innovations that have the potential to improve human health, expand our food supply, and provide new sources of energy.

Biotechnology Companies' Aggressive Capital Needs

The largest obstacle to delivering on the scientific promise of biotechnology is accessing sufficient capital to fund research and development. BIO has over 600 emerging companies in its membership that have fewer than 350 employees and do not yet have a product on the market. In the absence of product revenue, biotechnology companies are almost entirely reliant on the capital markets or other sources of non-dilutive financing to fund research and development. This is particularly challenging at the earliest, highest-risk stages of research and development.

Promising biotechnology research has a long, arduous road from preclinical research, through Phase I, safety, Phase II, efficacy, and Phase III broader population clinical trials, and ultimately to FDA approval of a therapy. It is estimated that it takes 97.7 months, or eight years to bring a biotechnology therapy to market and costs between $800 million and $1.2 billion.[1] For the majority of biotechnology companies that are without any product revenue, the significant capital requirements necessitate fund-raising through a combination of angel investors and venture capital firms. The role and importance of private equity fund-raising in the biotechnology industry cannot be understated.

Typically, a biotechnology company will begin by fund-raising for its lead product in development. The lead product is the one that is furthest along in clinical development, in the case of VIRxSYS our lead product is VRX496, which as I previously stated, is in Phase II clinical trials. To get to this point we undertook five rounds of private fund-raising.

Biotechnology companies are generally a collection of research projects that range from early to very-early stage development. In addition to the lead therapy biotechnology companies have, on average, five other therapies or candidates in development, which are often at the very earliest stage of pre-clinical research. These candidates may be an outgrowth of research on the lead product or a result of utilizing a particular technology to address a different disease with a completely different set of intellectual property.

Despite the extensive fund-raising that a biotechnology company undertakes for the lead product, these funds are not interchangeable, that is they are often tied to very specific milestones to support the lead the product's development. As such, in order to develop secondary or tertiary candidates/therapies a company has to find secondary sources of fund-raising capital. At the very earliest stages of development this is particularly challenging, and it is often times in this capacity that the SBIR grants were instrumental in advancing research and development in biotechnology for over twenty years.

Critical Role of the SBIR Program

Congress created the SBIR grant program in order to utilize the capabilities of small, innovative, domestic companies to fulfill federal research and development needs. In the early 1980's there was growing concern that the United States federal research and development spending was not improving the health and well being of the citizenry through the development and commercialization of new products and therapies. Furthermore, it was recognized that some early stage, promising scientific

[1] Tufts Center for the Study of Drug Development. *http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69*

research 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." In biotechnology, the "valley of death" delays potential therapies for HIV, cancer, and infectious diseases from reaching patients, who often lack other comparable alternatives.

For these reasons, in 1983 Congress authorized the SBIR grant program. These grants set aside 2.5 percent of certain departments' and agencies' extramural research budgets for innovative research grants with an aim towards commercialization. One of the great strengths of the SBIR program is that Congress provided the affected departments and agencies with flexibility in establishing the program. As a result, the SBIR program both assists the Department of Defense in its procurement needs and furthers the National Institutes of Health's (NIH's) mission of advancing science and improving health.

In order to participate in the program, Congress provided discretion to the Small Business Administration (SBA) to determine the definition of a qualifying small business concern (SBC). However, the Congress did make clear that the program should be open only to domestic, small companies. In order to be awarded an SBIR grant, an applicant's research is thoroughly examined through peer reviewed research groups that are comprised of experts in the particular field. It should be made clear that the SBIR program was never intended to prop up small businesses through corporate welfare, but instead its mission is to fund competitive and innovative research in small, domestic companies with the goal of commercializing a product.

There are two SBIR grant phases. Phase I grants are for proof of concept or technical merit. These grants are typically no greater than $100,000 although the granting agency does have some flexibility to fund awards that exceed this amount. Companies that successfully complete a Phase I grant can apply for a Phase II grant. A Phase II application is evaluated again on the science and technical merit and feasibility as well as the commercialization potential, as evidenced by private sector, non-SBIR funding commitments. Phase II awards are typically no greater than $750,000, but again, agencies have some flexibility to fund awards at a higher amount. This flexibility should be maintained because it allows expert peer review groups to adequately fund awards where merited by the science.

Unintended Consequences of the SBA's Domestic Company Proxy

For twenty years small, domestic biotechnology companies competed for SBIR grants. In addition to providing non-equity diluting funding, these grants were a powerful signal to the private sector that a company's research was compelling and possessed scientific and technical merit. In biotechnology, the SBIR program has played a role in advancing the science and research of companies that have ultimately brought a product to market. For example, there are 163 companies and affiliates involved in the development of the 252 FDA approved biologics, 32 percent of those companies and affiliates have received at least one SBIR/STTR award.

However, today most biotechnology companies are excluded from participating in the SBIR program as a result of a SBA Office of Hearings and Appeals (OHA) ruling. On April 7, 2003, the SBA arbitrarily ruled that a biotechnology firm, Cognetix, did not meet the SBIR size standard because it had venture capital investment in excess of 50 percent. This ruling is based upon SBA regulations, not underlying statue, by which a small business concern (SBC) for the SBIR program is defined as having fewer than 500 employees, including affiliates, and is at least 51 percent owned by U.S. citizens.

SBA has stated that the ownership rule is meant to be a proxy for determining that a company is domestic.[2] However, the use of capital structure as proxy for determining domesticity and the subsequent OHA ruling has the unintentional consequence of excluding a sizable portion of the biotechnology industry that would be otherwise eligible to participate in the program. These are companies that are solely based in the United States and are majority funded through a combination of U.S. based venture capital companies and citizens.

VIRxSYS is a unique biotechnology company because the five rounds of fund-raising that the company has undergone have been financed through more than 600 private individuals. VIRxSYS is eligible for applying for an SBIR grant. However, I have led both an SBIR-eligible and a non-eligible biotechnology company.

Intronn, Inc., where I was formerly CEO, successfully applied for a Phase I SBIR grant in the area of cystic fibrosis. After meeting the objectives of the Phase I grant, Intronn, Inc. applied for and was granted a Phase II grant. This funding continued

[2] 54 Fed. Reg. 52634 (Dec. 21, 1989) Interim Final Rule on defining a business concern for the purposes of the SBIR program.

to advance the research in cystic fibrosis and as a result Intronn, Inc.'s work was published on the cover of the *Nature Biotechnology* journal. In the summer of 2003, Intronn, Inc. successfully applied for a second Phase II SBIR grant to determine if the candidate was appropriate for Phase I clinical trials.

However, Intronn, Inc. never was able to use this award because several months later NIH requested information on the capital structure of the company. As a result of the previous success with SBIR awards, the company had attracted venture capital investment, which made us no longer eligible, despite the fact that we were clearly a small, domestic company at the time of the award. The award was rescinded; we closed down this promising research into Cystic Fibrosis, which was also funded by the Cystic Fibrosis Foundation, and laid off employees. Based upon the reports of other small biotechnology companies, Intronn, Inc.'s experience of having to abandon promising science is, by no means, an isolated incidence.

Arguably, excluding companies from the SBIR program solely on the basis of their capital structure could benefit still eligible companies like VIRxSYS. Yet it does so by making the program less competitive. As evidence of the impact of the new rules on biotech and medical device companies, applications for SBIR grants at the NIH declined by 11.9 percent in 2005 and by 14.6 percent in 2006.[3] As the Director of the National Institutes of Health (NIH), Dr. Elias Zerhouni, wrote in a letter to SBA Administrator Barreto dated June 28, 2005: *"NIH believes that the current rule* undermines the statutory purposes *of the SBIR program. . . It undermines NIH's ability to award SBIR funds to those applicants whom we believe are* most likely to improve human health." (emphasis added) I would like to submit this letter for the record.

A recent survey of small biotech companies found that 50 percent are ineligible for the SBIR program because of their capital structure. Additionally, 85 percent of the companies surveyed said that if the rules were changed to allow them to apply for these grants they would do so.[4] These companies are researching and developing therapies for diabetes, Alzheimer's, lupus and leukemia, among others diseases.

I am willing to compete with small, domestic, majority-backed venture capital companies for SBIR grants based on the scientific and technical merit of VIRxSYS research. That's the American way. I respectfully request that should the Subcommittee reauthorize the SBIR program, that it allow domestic, small companies to compete for SBIR grants regardless of its capital structure. SBIR should be a competitive program that fulfills federal research and development needs while addressing a failure in the market system. It is not meant to repeatedly be a source of corporate welfare but instead should fund highly qualified research.

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

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[3] The National Institutes of Health.

[4] Survey of 144 BIO emerging companies' Chief Executive Officers and Chief Financial Officers, March-April, 2007.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

JUN 2 8 2005

The Honorable Hector V. Barreto
Administrator
United States Small Business Administration
409 Third Street, S.W.
Washington, DC 20416-0001

Dear Administrator Barreto:

I am writing to express concern that current Small Business Administration (SBA) limits on eligibility for Small Business Innovation Research (SBIR) awards, in the context of biomedical and public health research, unduly restrict the ability of the National Institutes of Health (NIH) to fund high quality, small companies that receive venture capital (VC) investment. As a result, NIH must turn away many deserving applicants, and the goals of the SBIR program are being undermined. I ask that you consider a waiver to enable NIH to remedy this problem and look forward to discussing it with you.

The legislation establishing the SBIR program was signed into law on July 22, 1982, by President Reagan. As stated in the SBA's *SBIR Program Policy Directive*, "the statutory purpose of the SBIR program is to strengthen the role of innovative small business concerns (SBCs) in federally-funded research or research and development (R/R&D). Specific program purposes are to:

(1) stimulate technological innovation;
(2) use small business to meet Federal R/R&D needs,
(3) foster and encourage participation by socially and economically disadvantaged SBCs, and by SBCs that are 51 percent owned and controlled by women, in technological innovation; and
(4) increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity and economic growth."

Consistent with these goals, the NIH SBIR program supports a wide array of biomedical and public health R/R&D activities of small, innovative firms. But, in today's high risk biomedical research environment, in areas such as drug development, drug discovery, and therapeutics, fewer than one percent of the innovative, promising projects reach the marketplace. Research in public health and biotechnology is characterized by the following features:

- High and intense capital needs (i.e., up to $1 billion) to see a product from idea to market;
- Unusually long development time (i.e., 5-12 years);

- Exceptionally high "burn rate" for investment funds;
- Significant investment by venture capital companies (VCCs), many of whom are not owned at least 51 percent by natural persons;
- Multiple rounds of venture capital financing required; and
- Except for the smallest service-oriented entities, majority ownership and control by natural persons or business concerns majority owned by natural persons is extremely unlikely for R&D companies with significant market potential.

Given that the landscape for small business entities in the public health and biotechnology sector presents unique challenges, NIH is concerned that SBA's new eligibility rule, while opening the field somewhat, leaves out many small concerns, and, in turn, substantially damages the NIH's SBIR program. By limiting eligibility to concerns that are owned at least 51 percent by natural persons, or another concern that is itself owned 51 percent by natural persons, the rule disqualifies many highly-deserving small entities. Perversely, this rule dries up Federal funding for early-stage ideas from small concerns that, by attracting substantial VCC funding, show strong signs of likely success. Many of these concerns are the very entities that, with SBIR funding, offer significant promise for progress in improving public health. NIH believes that the current rule undermines the statutory purposes of the SBIR program to "*stimulate technological innovation*" and to "*increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity and economic growth.*" Furthermore, it undermines NIH's ability to award SBIR funds to those applicants whom we believe are most likely to improve human health, which is the mission of NIH.

NIH shares SBA's commitment to ensuring that only small business concerns receive SBIR awards. To advance this goal, and ensure that NIH also meets its need to support deserving R/R&D in the biotechnology field, I ask SBA to consider a waiver from certain eligibility standards for some concerns. Specifically, in addition to applicants eligible under current rules, the NIH requests that SBA permit it to award funds to small businesses when:

> *A concern is owned and controlled, at least in part, by a single VCC or multiple VCCs, provided that at least 51 percent of the concern is owned by U.S. individuals and/or VCC(s) that are owned no more than 49 percent by foreign business entities or individuals, and, provided further, that applicable small business affiliation standards are satisfied.*

While many details of this proposal remain to be discussed between our two agencies, and its precise formulation may change as we work together, please understand that NIH aims to ensure that small business concerns with substantial VCC support in the biotechnology and public health R/R&D arena are able to receive SBIR awards from NIH. We do not aim to include concerns that are owned and controlled by large companies and believe that adherence to existing affiliation rules will limit this risk.

As additional background, I note that this request is not unprecedented. In the past, SBA waived SBIR program parameters and granted NIH the opportunity to make SBIR awards for certain

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types of biomedical R&D projects requiring time and dollars above the amounts specified in applicable Policy Directives.

In signing into law the legislation that established the SBIR program, President Reagan stated, "*We in government must work in partnership with small businesses to ensure that technologies and processes are readily transferred to commercial applications.*" The program was designed "*to strengthen the role of the small, innovative firms in federally funded research and development, and to utilize Federal research and development as a base for technological innovation to meet agency needs and to contribute to the growth and strength of the Nation's economy.*"

In keeping with President Reagan's directive, NIH believes that it must be able to make SBIR awards to many small biotechnology concerns currently excluded from participation. We look forward to working with you on this important issue.

Sincerely,

Elias A. Zerhouni, M.D.
Director

BIOGRAPHY FOR GERARD J. MCGARRITY

Gerard McGarrity has been Executive Vice president of Scientific and Clinical Affairs of VIRxSYS since November, 2006. VIRxSYS is his fifth biotechnology company. Previously, he was President and CEO of Intronn Inc. from 2000 to 2006. Prior to Intronn, Dr. McGarrity was Founding Chief Scientific Officer of Cambridge Genetics Ltd. in Cambridge, UK which purchased Cambridge Drug Discovery and sold to Biofocus plc. He was Senior Vice President of Genetic Therapy Inc./Novartis and was an ad hoc member of the Research Management Board of Novartis. Novartis purchased Genetic Therapy Inc. for $310M. Dr. McGarrity was Chief Executive Officer of the Coriell Institute and was Adjunct Professor at Thomas Jefferson University and the Robert Wood Johnson School of Medicine. In his academic career, he served as consultant to a number of biotechnology and pharmaceutical companies including Genentech, Abbott, Celltech, among others. He served two terms on the NIH's Recombinant Advisory Committee (RAC) and was Chair of the RAC when the Committee formulated policies for human trials in gene therapy. He received his BS degree from Saint Joseph's University and his Ph.D. from Thomas Jefferson University, both in Philadelphia. He was a member of the Board of Trustees of Thomas Jefferson University and received the Distinguished Alumnus Award from the University's College of Graduate Studies. He has authored more than 160 publications and holds five U.S. patents. Additional patents are pending. He had led delegations of U.S. scientists on visits to the United Kingdom, Germany, Japan, China and the Czech Republic. He has participated widely in public policy forums, speaking at academic centers for the NIH on gene therapy; on gene therapy and transport of genetically modified organisms for Novartis; and has spoken on behalf of the Biotechnology Industry Organization a variety of issues.

Chairman WU. Thank you, Dr. McGarrity. Mr. Ignagni.

STATEMENT OF MR. ANTHONY R. IGNAGNI, PRESIDENT AND CEO, SYNAPSE BIOMEDICAL, INC.

Mr. IGNAGNI. Chairman Wu, Ranking Member Gingrey, and Mr. Mitchell, thank you for inviting me to testify before you today on SBIR grants and the reauthorization of the program.

My name is Anthony Ignagni, and I am the Founder and President and CEO of Synapse Biomedical, a start-up medical device company located in Oberlin, Ohio, established with the mission for commercializing life-changing, minimally-invasive, neuro-stimulating devices.

Today I am here to testify on behalf of the Medical Device Manufacturers Association, a national organization representing the innovative entrepreneurial sector of the medical technology industry. Our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small research-driven medical device companies such as Synapse.

Synapse was founded four and one-half years ago based on technology developed at Case Western Reserve University and University Hospitals of Cleveland. We have pioneered the innovative use of standard laparoscopic techniques to provide a low-risk alternative to mechanical ventilation, and people with spinal cord injuries, such as our third patient, Christopher Reeve. We have also applied this technology in people with a devastating disease such as ALS, also known as Lou Gehrig's disease. With our 56th patient just implanted yesterday, we have a 97 percent success rate in the spinal cord population.

We have evidence that this technology not only works but saves healthcare costs and is life saving. One of our patients was able to save $13,000 per month in Ohio Medicaid costs by weaning off of a ventilator and moving from the vent support ward to a non-vent support ward one hallway over. He was recently married and is an advocate for people now living with spinal cord injury.

Synapse is a small business. We have nine employees and the sponsor of two pivotal device trials. I have raised $6.5 million to fund these activities, and most importantly, those dollars enable us to commit the resources necessary for 100 patient ALS pivotal trial.

As indicated in my disclosure statement, we currently exchanged almost 49 percent of the company's equity to venture and other institutional investors to raise that money. We have retained just a little over 51 percent of the ownership with the founders, employees, initial, individual angel investors.

As you have heard today, the SBIR program was established in 1982 to offer competition-based awards to small private-sector businesses such as mine to stimulate technological innovation with the intention that the small business will take the product through to commercialization. Synapse's involvement in the SBIR Program has provided important support for continued innovation of our technology platform. Our ability to participate in the program provides the R&D funds to continue these efforts. Without these funds, we could not support the manpower to apply the continuing advancement of our platform in these areas.

I am here today because the Committee has asked me to address ways in which the SBIR program could be improved. As I noted before, under the strict eligibility rules, Synapse is on the cusp of be-

coming ineligible to apply for a SBIR grant due to the fact that additional institutional investments would put us below the 51 percent individual ownership. Our situation is one that is also faced by a majority of companies in the medical device industry as evidenced in part by the decline of applications that have been received since the 2003 rule change.

Some suggestions that I believe would make the program more effective in achieving its goals and therefore be improved include first, increasing the dollar amount of the Phase I and II awards as they have not changed since 1992 but maintain these as guidelines, not as caps. Two, providing the agencies with more flexibility in administering the SBIR Program, and third, returning to the previous policy before the 2003 rule change so that all companies can have an equal chance at participating in the federal grant process. This would mean that allowing some companies that are majority owned by multiple VCs to participate in the program.

To elaborate on these recommendations, I believe that it would benefit the small businesses that apply for the grants if the Phase I award could be raised to $150,000 and Phase II increased to $1.25 million. I also believe there are opportunities to improve the program by providing agencies with more administrative flexibility. MDMA and those of us in the industry would agree that it would be appropriate to allow two to four percent of the funds to pay for administrative and assistance activities.

Further, it would be beneficial to remove the requirement that a company must have applied for a Phase I grant in order to apply for Phase II. Under the current rules, only companies that have applied for and received Phase I SBIR grants are eligible to apply for Phase II. If this rule were changed, I believe more small business participation in the SBIR program would occur.

Finally, my greatest concern pertaining to the viability of the program is the need to increase participation of all innovative small businesses in federal research and development, including those with venture backing. The SBIR Program as originally designed did this, but its effectiveness is being hampered by the fact that many small businesses are deemed ineligible to participate based on their financing structure. The stimulation and sustaining of technological innovation will only be met if all companies, regardless of how they are financed, are able to apply for SBIR grants. If agencies have the flexibility they need to administer the program according to their needs and the needs of the small business community and the dollar amount of the individual awards are increased to reflect inflationary adjustment.

Thank you for providing me this opportunity to testify.

[The prepared statement of Mr. Ignagni follows:]

PREPARED STATEMENT OF ANTHONY R. IGNAGNI

Chairman Wu, Ranking Member Gingrey and Members of the Technology and Innovation Subcommittee:

Thank you for inviting me to testify before you today on Small Business Innovation Research (SBIR) grants and the reauthorization of the program.

My name is Anthony Ignagni and I am the President and Chief Executive Officer of Synapse Biomedical, Inc. Synapse Biomedical is a privately-held medical device company located in Oberlin, Ohio. We are a startup company established with the mission of developing, manufacturing, selling and supporting life changing mini-

mally invasive neurostimulation devices used in the diagnosis and treatment of persons with neurological impairment.

Founded in September 2002, Synapse's product portfolio is focused on neurostimulation devices for minimally invasive surgical interventions and respiratory assist. These two areas of medical specialization have come together in our first product, the $NeuR_X$ Diaphragm Pacing Stimulation (DPS) System. The founders of the Company have pioneered the innovative use of standard minimally invasive laparoscopic techniques to provide ventilation in persons with respiratory muscle paralysis. This technological advance provides a device that is a low-risk, low-cost alternative to a very invasive procedure that has been performed for thirty-five years.

I am pleased to tell you that our current percutaneous technology has been successful in over fifty patients including the late Christopher Reeve (our third implanted patient). Our technology has demonstrated clinical promise in the pilot series of Amyotrophic Lateral Sclerosis (ALS, commonly known as Lou Gehrig's disease) patients. The longest implanted patient has used the device for full-time respiratory support for over six years. We additionally have evidence of this technology saving health care costs and potentially saving lives. Our fourth patient implanted was able to save $13,000 per month in Ohio Medicaid costs by weaning off of a ventilator, moving to a non-ventilator support ward in the nursing home he was in, and then was able to move back home with his elderly mother. He has recently married and is an advocate for people with spinal cord injury on the board of local hospitals.

We also have had several implanted patients in the hurricane affected areas of the South. One young woman specifically lost her home in Hurricane Rita and had to go to a shelter. Fortunately she had been already fully weaned off of her ventilator and was able to sustain extended periods without power as our device lasts several weeks on a single replaceable battery. These are just two of the many stories that demonstrate the compelling benefit of our technology.

The $NeuR_X$ DPS System is currently being studied in two human clinical trials. The first trial of *chronic diaphragm pacing* has demonstrated clinical efficacy as a ventilator replacement in chronic respiratory insufficiency with a 97 percent success rate in providing ventilatory support. The second ongoing clinical trial is for *diaphragm conditioning* stimulation to improve the survival time in ALS, which has shown a preliminary 15 to 20 month survival benefit in the pilot series. Additional feasibility studies have begun to demonstrate the therapeutic implementation of diaphragm stimulation in an *acute ventilatory assist* trial intended to demonstrate reduction in ventilator associated risks, improvements in cardiovascular function, and reduced length of stay in intensive care units. Synapse is at the forefront of the pioneering use of Natural Orifice Translumenal Endoscopic Surgery (*NOTES*) for our clinically recognized efforts as the seminal application for acute ventilatory assist. Additional trials are planned, beyond the diaphragm, to demonstrate the feasibility of the technology platform in two active research areas of Synapse's founders: *chronic abdominal pain* and *gastroesophageal reflux disease.* So, as you can see we are working on very promising and life enhancing technology which serves a very narrow patient population.

Today, I am here to testify on behalf of the Medical Device Manufacturers Association (MDMA), a national organization representing the innovative, entrepreneurial sector of the medical technology industry. MDMA's mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

As a representative of the medical device industry, I thank you for allowing me to share with you my experience in applying for and obtaining a SBIR grant. As you know, the SBIR program was established in 1982 to offer competition-based awards to small private-sector businesses (such as mine) to stimulate technological innovation with the intention that the small business will take the product through to commercialization, all the while helping to stimulate U.S. economic growth and international competitiveness. The grant making process is structured into three phases:

- Phase I is the feasibility study in which award winners undertake a limited amount of research aimed at establishing an idea's scientific and commercial promise. These grants typically range up to $100,000.
- Phase II funds are used to finance more extensive research and development and the grant awards are usually around $750,000–$1 million.
- Phase III is the commercialization stage and companies are expected to use non-SBIR funds to get their product into the marketplace.

The Small Business Administration establishes the eligibility criteria for participation in the SBIR program. As such, only United States small business concerns (SBCs) are eligible for an SBIR award. The SBC must be organized for-profit with its place of business in the United States. It must be independently owned and operated, and it must meet one of two ownership criteria: it must be at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, or, it must be a for-profit business concern that is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. Finally, the SBC must be small in that it must have no more than 500 employees including affiliates.

Synapse's involvement in the SBIR program has provided important support for continued innovation of our technology platform. Our current grants extend the potential use and market potential for our diaphragm stimulation technology in compelling need orphan clinical diseases of spinal cord injury and ALS. Our ability to participate in the SBIR program provides the R&D funds to continue these efforts. Without the SBIR funds we could not support the manpower to apply to continuing the advancement of our platform in these areas.

Synapse is a small business. We have eight full-time employees and one part-time employee. We are actively sponsoring/conducting two pivotal device trials for application of our DPS System in spinal cord injury and ALS. We have recently made our first market application to the FDA for use of the device in spinal cord injury. We have setup a complete clean-room, manufacturing facility, and quality system with ISO 13485 certification and also anticipate submitting for European market approval within approximately one month. To accomplish this we run a very lean and efficient shop. We have spent $2.5MM since the inception of Synapse to achieve these accomplishments with a very dedicated and motivated staff. Our vision is to build a profitable company based on the sound science of our initial clinical applications. To continue these accomplishments and establish a sound foundation for the company to further build upon, we anticipate spending another $4MM. To be able to fund these activities and most importantly be able to commit the resources necessary for a 100 patient pivotal trial in ALS to the patients and clinical community, we have had to raise significant venture investments. As indicated in my disclosure statement, we have currently exchanged 49 percent of the company equity to venture and other institutional investors to raise this money. We have retained just over 51 percent of the ownership with the company founders and initial individual angel investors.

Since our device has a Category B1 designation by the FDA and CMS we have been able to charge for the device during clinical trials and have therefore been able to realize total income since our inception of almost $1MM. This includes awards (for our business plan), SBIR grants, contract manufacturing efforts and reimbursement for clinical study devices. The SBIR program grant funds that we have drawn down to date have been approximately 14 percent of this total. We additionally have another $200K in current SBIR grants funds available and pending award.

The Committee has asked me to address ways in which the SBIR program could be improved. As I noted before, under the 2003 rule change, Synapse is on the cusp of no longer being eligible to apply for the SBIR grant due to the fact that additional institutional investments would put us below the 51 percent owned by individuals' qualification. Our situation is one that is also faced by a majority of companies in the medical device industry as evidenced in part by the decline in applications for SBIR grants since the 2003 rule change. Based on the awards statistics located on the National Institutes of Health's (NIH) website, there has been a significant decline in applications for SBIR grants. In the first year (2004–2005), post the rule change, there was a 12 percent decrease in applications followed by an almost 15 percent decrease this past year (2005–2006). This after double digit increases in the two years leading up to 2003.

Some suggestions that I believe would make the program more effective in achieving its goals and therefore improved include:

- Increasing the dollar amount of the awards as they have not changed since 1992;
- Providing NIH with more flexibility in administering the SBIR program; and
- Returning to the previous policy before the 2003 rule change so that all companies can have an equal chance in participating in the federal grant process. This would mean allowing companies that are majority venture backed to participate in the program. This would mean allowing some companies that are majority owned—in the aggregate—by multiple VCs to participate in the program.

To elaborate on my recommendations, I believe that it would benefit the small businesses that apply for the grants if the Phase I award could be increased to $150,000 and the Phase II award increased to $1.25 million. This could potentially encourage companies that are currently not applying for the grants because they think the awards are too low and therefore not worth the time and effort required to submit a successful SBIR application.

I also believe there are opportunities to improve the SBIR program by providing NIH with more administration flexibility. Specifically, I think it would be helpful to the NIH if the costs of administering the program (three percent) could be paid out of the SBIR funds. MDMA and those of us in the industry agree that it would be appropriate to allow three percent of the SBIR funds to pay for administrative costs. These resources will help to administer the SBIR program without diverting funds from other areas within NIH. Second, it would be beneficial to remove the requirement that a company must have applied for a Phase I grant in order to apply for a Phase II grant. Under the current rules, only companies that have applied and received a Phase I SBIR grant are eligible to apply for a Phase II grant. If this rule were changed, I believe many more small businesses would submit applications for SBIR grants.

Finally, my greatest concern pertaining to the viability of the SBIR program is the need to increase participation of all innovative small businesses in federal research and development including those with venture backing. A key purpose of the SBIR program, a public-private partnership, is to help entrepreneurs overcome many of the obstacles they face in developing new technologies. The SBIR program as originally designed does this, but its effectiveness is being hampered by the fact that many small businesses are deemed ineligible to participate in the SBIR program based on their financing structure. Further, the program is not meeting its entire goal to stimulate and sustain technological innovation. The stimulation and sustaining of technological innovation will only be met if all companies regardless of how they are financed are able to apply for SBIR grants; if NIH has the flexibility it needs to administer the awards and the dollar amount of the individual awards are increased.

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

BIOGRAPHY FOR ANTHONY R. IGNAGNI

As co-founder, President and CEO of Synapse Biomedical, Inc., Mr. Ignagni (“Tony”) is responsible for the strategic planning for the company. Tony has developed and commercialized medical devices for over 20 years. He received his undergraduate and graduate degrees from Case Western Reserve University in the area of Biomedical Engineering specializing in applied neural control. As a research engineer, at the Cleveland FES Center, he has designed neurostimulation software and instrumentation and applied these efforts clinically. As part of the efforts that led to the formation of NeuroControl Corporation, Tony has had direct experience in transferring this technology from the university environment to commercially viable products. As an original member and Vice President of NeuroControl he established many of the base systems required for operations within the scope of the regulated medical device industry and led the product development efforts that brought neurostimulation devices to the U.S. and European markets.

About Synapse

Synapse Biomedical Inc. (SBI) is established with the mission to develop, manufacture, market and support life changing minimally invasive neurostimulation devices used in the diagnosis and treatment of persons with neurological impairment. Founded in September 2002, to support the ongoing clinical study of the DPS System for Chronic Respiratory Insufficiency at University Hospitals of Cleveland, SBI has licensed the core patents from Case Western Reserve University and is comprised of investigators from University Hospitals (Cleveland, OH), MetroHealth Medical Center (Cleveland, OH) and Case Western Reserve University. The current percutaneous technology has been successful in spinal cord patients for over fifty cumulative patient years and demonstrated clinical promise in the pilot series of Amyotrophic Lateral Sclerosis (ALS, commonly known as Lou Gehrig’s disease) patients. The longest implanted patient has used the device for full-time respiratory support for over six years.

SBI’s product portfolio is focused on neurostimulation devices for minimally invasive surgical interventions and respiratory assist. These two areas of medical specialization have come together in our first product, the NeuRX DPS System. The founders of the Company have pioneered the innovative use of standard minimally

invasive laparoscopic techniques to provide ventilation in persons with respiratory muscle paralysis. This technological advance provides a device that is a low-risk, low-cost alternative to a very invasive procedure that has been performed for thirty-five years. The media awareness that has come, as a result of Christopher Reeve, our third implanted patient, has reached over 13 million households through print circulation and many more through his appearances on national and international television broadcasts. As a result of this, we have been able to reach a large population of patients, with over 50 patient implants.

The $NeuR_X$ Diaphragm Pacing Stimulation (DPS) System is currently being studied in two human clinical trials. The first trial of *chronic diaphragm pacing* has demonstrated clinical efficacy as a ventilator replacement in chronic respiratory insufficiency with a 97 percent success rate in providing ventilatory support. The second ongoing clinical trial is for *diaphragm conditioning* stimulation to improve the survival time in ALS, which has shown a preliminary 20 month survival benefit in the pilot series. Additional feasibility studies have begun to demonstrate the therapeutic implementation of diaphragm stimulation in an *acute ventilatory assist* trial intended to demonstrate reduction in ventilator associated risks, improvements in cardiovascular function, and maintenance of diaphragm contractile properties in intensive care units. SBI is at the forefront of the pioneering use of Natural Orifice Translumenal Endoscopic Surgery (*NOTES*) for the clinically recognized efforts as the seminal application for acute ventilatory assist. Additional trials are planned, beyond the diaphragm, to demonstrate the feasibility of the technology platform in two active research areas of SBI's founders: *chronic abdominal pain* and *gastroesophageal reflux disease.*

DISCUSSION

Chairman WU. Thank you very much, Mr. Ignagni. And now we move onto the question phase of our hearing, and The Chair recognizes himself for five minutes.

Dr. McGarrity, you characterized both in your written and your oral testimony that SBA has stated the ownership rule is a proxy for determining that a company is domestic, and Mr. Schmidt has stated that what is at issue is size. And I wanted to give both you, Dr. McGarrity, an opportunity to comment on that and Mr. Ignagni and Mr. Schmidt to reply to that discussion about whether looking at the capital structure, that is, whether venture capital is owned 50 percent plus one share of an enterprise is an appropriate dividing line for SBIR or not.

Dr. MCGARRITY. No, I don't think there is at all. The regulations say that a company, a small company, should be less than 500 employees. So if you use that as the guideline, technically my company, Intronn at the time had 20 employees, no revenue stream, and we were declared ineligible. In other words, we were not an appropriate small business. On the other hand, you could have a company with 450 employees and making revenues of $20, $30 million a year and they qualify. So I think the rule change was based on the fact that, as you said, you wanted greater than 50 percent ownership to be domestic ownership, and I think they use that as a means of saying that 50 percent or 50-plus percent should be owned by individuals; and for this particular application, the individuals or a venture firm was not defined as an individual. And I think that was the basis of the whole change in policy.

Chairman WU. Mr. Ignagni.

Mr. IGNAGNI. I certainly agree that I think the 51 percent ownership issue is really irrelevant from my perspective from what we are trying to do. We have to raise enough money to be able to commit to clinical trials, and to do that we have to find funding from available sources; and if that means going to a venture company

to find that funding, that is what we had to do. And it is—you know, we are not bringing in revenue. We have made $1 million since our inception, so it is not supporting us as a company but it is allowing us to continue in ways—in increased our technology platform in ways that a venture company is not going to support. So we can go after larger markets, but continuing to help people with spinal cord injury, people with ALS, those are orphan markets, those are niche markets, and those aren't things that are going to be supported by the venture community.

So we would have to let go of those if we didn't have this kind of support.

Chairman WU. Mr. Schmidt, your response to——

Mr. SCHMIDT. Yes, thank you.

Chairman WU.—those statements.

Mr. SCHMIDT. I am extremely troubled by Dr. McGarrity's domesticity issue. I'm not quite sure whether he's suggesting the United States taxpayer support incorporations. I am just not—I don't know where that is going. On the size issue, what I am most concerned about is having large company and large VC control over these small companies.

Chairman WU. Would you have an objection—let us say it were a 20-employee biotech but it had 51 percent VC ownership. Would you object under those circumstances?

Mr. SCHMIDT. Well, when you have got Intel forming VCs and all of a sudden they go out and buy, you know, ABC Company with 20 employees, they are not a 20-person employee anymore—20-person company anymore. They are, you know, a billion-dollar corporation. And the Milliken Institute which——

Chairman WU. With all due respect, Mr. Schmidt, when I have spoken with Intel VCs, they have no—they rarely have any interest in a strategic ownership of the underlying entity. It is purely a financial relationship for the most part, trying to grow out the ecosystem where they are going to take down Intel chips that has become a future ecosystem for consuming Intel chips, their core business.

Mr. SCHMIDT. I think it always becomes a strategic interest from a large corporation, but on the fact of the VCs, the Headtron type of VC, you have still got this very large group of investors and we have no—so you understand our position—we have no objection to small VCs owning a majority of the company which happens now and is allowable under the rules. And under Dr. Zerhouni's letter, which Dr. McGarrity was referring to—in fact, later on in the letter Dr. Zerhouni goes on to say the affiliation rules should not be changed.

So in the Milliken Report they go on and say that there are six ways that they suggest which I would like to include in the record that we can fund large drug companies or tiny drug companies to become manufacturers of large drugs, and none of them involve the SBIR Program. And when we have an $800 million to $1.2 billion investment in a drug, that means the entire NIH SBIR budget can't produce one drug.

Chairman WU. My time has expired. We will return to this topic. But let me ask folks' indulgence just for a moment to ask Mr. Held

if this ownership issue is of concern in the DOD SBIR realm as opposed to those programs in other departments.

Mr. HELD. It is not an issue that we looked at in our research, so I really couldn't give you a good answer on that.

Chairman WU. Thank you, Mr. Held. And I would like to recognize Dr. Gingrey for five minutes.

Mr. GINGREY. Mr. Chairman, thank you. This is it seems to me a very crucial question as we develop, go forward with reauthorization and the markup that will be done later on in the year. That is the reason we have these hearings, of course, is to try to improve to go forward with what is good, to eliminate what is bad, and to make changes based on expert testimony. And so that is why it is so important that we are doing this here today.

And it seems that this question, this 51 percent rule provision, is very critical; and I am not sure I completely understand it. I think I understand the basics of it, but I thought maybe Mr. Baron, if I would address my question to you because you have a fairly long history as you explained in your—both your statements and your written bio going back to the time that you were on the Small Business Committee, just give us a glimpse into the legislative history of this, this 51 percent rule—I guess it is—and was it originally to encourage domestic innovation? What was really the reason why the SBA made these new interpretations? Just kind of take us back and walk through the history of it.

Mr. BARON. Okay. I would be happy to. The legislation basically defined small companies as having 500 or fewer employees for the purpose of this program and left it up to the great discretion—or left great discretion to the SBA to apply that and develop regulations and so on and to use its normal rules as to what constitutes a small company with 500 employees, if it is owned by a larger company or affiliated with a larger company.

So basically, the statute itself gives SBA a lot of discretion and for most of the history of the program, SBA allowed in—did not have this ownership, this particular ownership rule. So this was a change in the way that they—SBA interpreted what constitutes a small business. That wasn't based directly in the legislation.

Mr. GINGREY. My understanding is that in 2003 is when they made this most recent interpretation, this change if you will. Were there certain other times in the 25-year history of the program where they made other step-wise changes other than the 500-employee rule?

Mr. BARON. They have made other changes, none I think quite as had as much affect on the program as that one. They do make changes over time in things like how strictly they interpret the size of SBIR awards that an agency can grant, things like that, whether they allow flexibility to go over the $100,000, $750,000 mark, things like that; but they tend to be more modest changes. This was a larger one.

Mr. GINGREY. Well, you haven't quite completely answered my question. What do you in your opinion—are you an attorney?

Mr. BARON. I am.

Mr. GINGREY. Good. Doctors don't hate all attorneys. Explain to us what you think their reasoning was behind this reinterpretation of this change in 2003.

Mr. BARON. I am not intimately familiar with their reasoning, but I think the general idea was that it didn't really qualify as a small business for the purposes of what Congress has intended if it is owned by a venture capital firm if that is the majority entity.

Let me mention one other thing if I could. As I mentioned in my testimony, I think a big challenge in the SBIR Program is focusing SBIR funds on companies that are serious about commercialization, not just doing research but taking that research and converting it into a product. A company that has obtained some venture funding has—I would think is the kind of company that is more likely to be able to convert their research. They are clearly motivated. A venture capital firm would not have contributed money to the company if it hadn't reviewed the business plan and seen that there was a market size. So I think my own feeling about the underlying policy is that it probably inhibits the success of the program in converting research into viable new products.

Mr. GINGREY. Mr. Chairman, I see my time has expired. I hope we will have more time to—in our second round to come back to this and continue to pursue it. It may be that some of the other witnesses want to comment on that as well, and I guess they probably would.

Chairman WU. Dr. Gingrey, I think that you and I will have multiple rounds. Now that I know that you are an attorney, Mr. Baron, is there a statutory basis for the ALJ's Decision about venture capital ownership or is this shall we say a broad interpretation of the SBA's authority?

Mr. BARON. There was not an underlying statutory change that caused the SBA to change its interpretation. This was just a decision that was initiated by the SBA with the idea that they were interpreting what Congress wanted in saying funds under this program should go toward small businesses.

Chairman WU. Mr. Baron and Mr. Schmidt, I think that there was some expressed concern about skewing, whether it is towards size, domesticity, or any other factor. Since this decision was handed down in the relatively recent past, has there been a change in pattern? Was there skewing before that has been addressed by this decision?

Mr. BARON. I am probably not in as good a position to comment on that. The other witnesses I thought were fairly compelling in evidence from NIH that the—it has excluded some companies that otherwise would have participated.

Mr. SCHMIDT. Just as a moment of history, the way I understand this, and we will get you more information and provide that over the next week or so, but it is my understanding that a 1952 statute—so we have had 55 years of legislative history on independently owned and operated—so we go back to Eisenhower, you know, in those years to talk about—actually, this would have been Truman—to be able to say this is what the small business is all about from 1952. And that has not been changed since 1952, this independently owned and operated and 500 employees.

Chairman WU. That is with respect to SBA statutes——

Mr. SCHMIDT. Well, SBA——

Chairman WU.—and not SBIR.

Mr. SCHMIDT. It incorporated in the 1982 statute, and none of that ever changed. The only thing that happened in 2003 was they finally decided to enforce it. So by going back and changing it now, we are overturning the last 55 years of history in this area.

Chairman WU. Well, with the 2003 change——

Mr. SCHMIDT. It wasn't a change, it was an enforcement.

Chairman WU. Well, there was certainly a change in 2003, whether it was a change in interpretation or a change in enforcement, was there a skewing problem that was addressed by that?

Mr. SCHMIDT. I can't answer that question of what this was. What we had was corporations that were violating the rule that finally were enforced against.

Chairman WU. Dr. McGarrity and Mr. Ignagni.

Dr. MCGARRITY. Well, I would say we looked at the interpretation, and we applied like everyone else. So I can't say we were violating the rules. That was what the SBA was enforcing from the beginning. As far as experiences, I will go back to the NIH saying that, one, the number of grant applications of SBIR has gone down, and number two, the quality of SBIR grants has gone down. If you look at the success stories that I said, there are companies like Amgen and Genintech and Genzyme that are wonderful success stories in our industry. They got SBIR grants in the early stages, and one would hate to think what might have happened if that rule were applied to them. In our own particular case, as I said, I think the emphasis has to be on the innovation and what the Congress needs and what the Nation needs as far as R&D. The first application that we made to the NIH, the review committee, 18 to 20 experts in the field said they wanted to double our budget. Now, when was the last time you heard a government agency saying we want to double your budget? The next grant that we put in, a different review committee said this was one of the most innovative, thoughtful, and exciting application they ever read.

So the NIH and my company, Intronn, invested several million dollars that had great promise in cystic fibrosis, and it was just cut short. So I would say, you know, the objective here should be what is best for the Nation's need and the Nation's research. Mr. Schmidt said it takes $800 million. We can't do that from NIH's budget. That is not even relevant to the point. What you need is what you said in the beginning, Chairman. The crying need for biotech companies is in the early stages. If you can get that financed to a point where you are in clinical trials or you have proof of concept, then you can get equity investment and then you can get larger companies partnering in. So we need the help in the early stages of development where conventional financing in this field simply is not available.

Chairman WU. Thank you very much, Dr. McGarrity. And before I turn to Dr. Gingrey, Mr. Ignagni, you were eager to have some input on this particular discussion.

Mr. IGNAGNI. I think Dr. McGarrity did mention what I was going to mention also that according to the NIH's website, there has been a significant reduction in the number of qualified applications in the years since the 2003 rule change. And certainly from my own perspective, I did not—there have been certain times in the development of Synapse that we had to make a decision. Do we

want to go after more grants and try to keep more ownership or do we really want to step foreword and go forward with helping patients and go after an ALS trial, to commit to an ALS trial of the magnitude that we have. We needed significant funds, and those funds aren't available in the grant world for us. So we had to go after VC funding. And so just the nature of the type of company we are running clinical trials, two pivotal studies, we had to go after VC funding; and there are decisions that have to be made at this point, whether or not we go after more VC funding or whether we try to hold back and not help as many patients and grow as fast.

Chairman WU. Thank you. Dr. Gingrey.

Mr. GINGREY. Mr. Ignagni, you mentioned I think in your testimony that you used the term angel investor. I do now know what that is, but it was only recently that I realized what an angel investor was; and you might—maybe nobody in this room or everybody in this room knows exactly what you are talking about, but you might define that for us, and I am curious to know whether angel investors in a small start-up technology type company, biomedical company that both you and Dr. McGarrity are involved in, do those count against you in regard to the percentage rule that the Small Business Administration has handed down back in 2003?

Mr. IGNAGNI. Since the angel investors and angel investors are individuals, friends and family, high net worth individuals in the community, they are individual people identified as such, so that they would not count against that 51 percent rule. Groups like Jump Start, which is an entrepreneurial assistance program in Cleveland but is made up of a large consortium of people, specifically to help companies such as Synapse get off the ground and get started. They would be, you know, in my calculation, my way of interpreting the rule, they are counted against us because they are a consortium of a number of unnamed individuals.

Mr. GINGREY. Well, do you count them—it is not actually—you are not counting individuals, you are counting the percentage of the worth of a company, the equity in the company? So if the company is worth $6 million as an example on the books and then $3,000,001 of that has been sold essentially to a venture capitalist, whether it is one venture capitalist who just has a lot of money, you wouldn't consider that person an angel investor, because they are in the business of lending money. It could be one or it could be a consortium. But the 51 percent or 50 as the Chairman pointed out, 50 percent plus one is based on the total dollar amount, right?

Mr. IGNAGNI. Correct.

Mr. GINGREY. Mr. Chairman, I will yield back at this point, and I look forward to the next round.

Chairman WU. Terrific. Let us return perhaps a little bit later to this issue of size versus capital structure and whether capital structure ought to be used as a proxy for size, domesticity, or anything else.

There was discussion earlier about using the track record of commercialization as a factor in granting future SBIR grants, and Mr. Baron, can you describe for us first of all how you think this would work and secondly, what the impact would be on commercialization

rates. And perhaps Mr. Held, Mr. Schmidt, you would care to comment on that also.

Mr. BARON. Yes, at the Department of Defense, which is the agency I am most familiar with, its SBIR program, one of the things that they do is ask each company in submitting an SBIR application to provide just basic information on previous SBIR awards that were won and commercial sales that resulted from that, either to the government or to the private sector, as well as any additional investment they raised, which are two good proxies for whether the thing actually got commercialized, assuming enough time has passed. And so there is very good information for each applicant which is hard to gain on whether they have actually done anything with the prior SBIR awards. And it shows, you know, in general that there are some companies that are excellent commercializers, including some multiple award winners are excellent commercializers. And then there are some companies like those I have described which have very strong research capabilities, win SBIR awards, but consistently do not convert them into products that succeed in either government or private-sector markets.

So one thing that could be done, that information is not used in a sizeable way in the proposal evaluation process but it could be. In order to focus funds, it would be possible for agencies to revise their proposal evaluation criteria to focus SBIR awards on either companies that are new to the SBIR Program or to companies that have a strong commercialization track record and to focus funds away from companies that have repeatedly won and have not turned the grants into research into viable products. That is one simple way, I think a fairly straightforward way it could be done.

Chairman WU. Would that straightforward method be more applicable to SBIR programs at some agencies rather than others?

Mr. BARON. It is a very good question because at some agencies in different fields, it takes longer to commercialize, like in the biomedical field to go through a commercial trial and all of that, than it would at an agency like the Department of Defense. You might have slightly different rates, time periods you would look at for the commercialization track record. However, if an SBIR project has gone through—they went Phase I, Phase II, and then a couple of years have elapsed and nothing has happened, no additional money, even in the biomedical field, no additional money, no additional investment, no sales, no nothing, you can be pretty well sure—there is good evidence to suggest from the DOD data that that project is never going to be turned into a commercial product. Very unlikely, too.

So I think the time period may differ by agency and by field, but in general that kind of additional money and track record is probably a very good indication of whether the company is a good commercializer.

Chairman WU. Mr. Held, according to your data at DOD, how applicable is this commercialization rate? Are there other proxies that would be applicable to the DOD situation?

Mr. HELD. Yeah, the DOD does have a pretty good metric for looking at commercialization. It is called the Commercialization Achievement Index. The biggest issue with it right now is using

that metric as a criteria when they are judging proposals and making it a more important criteria, particularly for companies that have won multiple SBIR awards. So you might think about making this something that the—as they have won five, ten, or more awards over a certain number of years, the commercialization index becomes more important in terms of how you judge that particular award.

Chairman WU. Thank you. Dr. Gingery.

Mr. GINGREY. Mr. Chairman, that is a great question that you asked, and I want to continue with it because my thinking is that, as Mr. Baron and Mr. Held both have described, it does make sense that you want to, unlike Willy Sutton, you want in this instance not go to where the money is to take it out but you want to go to where the success it to put it in. And I understand that. You want to make a good investment of the taxpayers' dollars and you want to make sure that that metric of commercialization and track record I guess is the way you were putting it, but it would seem to me that that might adversely discriminate against the little start-up.

I will give you an example. I have a—and by the way, to recuse myself, to my knowledge he has not applied for any kind of small business innovative research grant—but spent many years as a stockbroker for one of the large firms and then retired or was retired maybe a little earlier than he wanted to be but got involved with a Russian scientist, and this is sort of getting into the medical field, too. This probably would be—if he were so interested an application through NIH—but what they were trying to do is develop a marker, a blood marker, a blood test to determine who might truly be suffering from a traumatic brain injury who has sustained a bump on the head, or maybe even much worse than that. Or in Iraq, been inside a Humvee when it went over an improvised explosive device but thank God didn't lose a limb or had no visible injury except shock. They also felt that they have the ability to, with a blood test, to determine who is likely—any of us in this room—to have a stroke at some point in the future. And so that is pretty much what they are involved in. Well, he has no track record of innovation or success or commercialization. And I know in fact that—that is when I first understood what an angel investor was. You see, I am a doctor and of course we don't know much about business. We are very poor businessmen and women. But he was telling me about it. I asked, I said, Bob, how have you kept going these three or four years, five years now that you have had no income. You are the president of the company but, you know, how have you sustained yourself and how do you keep it going? He told me about angel investors and of course, at that point I wasn't—I didn't have the privilege of serving with Chairman Wu on this subcommittee and understanding all these programs that were available, otherwise I would have told him about it.

But somebody like that, Mr. Baron, Mr. Held, may be at a little bit of a disadvantage, particularly in maybe one of the agencies or departments that participate in this program. It would be kind of easy to just say, well, let us just make these grants to the ones that have good track records, and we don't have to worry about the due diligence. You know, if somebody is a little bit on the lazy side, it

may be that it would discriminate against folks like this little start-up company that I am talking about back in Atlanta, Georgia. Dr. McGarrity?

Dr. MCGARRITY. Yes, I would just like to extend that thought a little bit, Congressman, because if you look at the rules and the interpretations presently, if you look at angel investors, if I am John Smith and I want to put $100,000 into your friend's company, if I do it as John Smith, it is fine as far as SBIR is concerned. If I put it in as John Smith Trust, that is a separate legal entity; and if I do it as the Smith Family Foundation or Smith and Friends, that is a distinct legal entity, and they are not counted as individuals according to the current guidelines. So even that kind of murkiness exists whether it is an angel investor as an individual or doing it as a trust or a family LLC if you will.

Mr. GINGREY. And I want to—Mr. Schmidt, you can respond to this if you like, and I am sure we will get back to you on the next round, but the idea of maybe having a set-aside for new companies.

Mr. BARON. I think the issue you raise is extremely important. I think it could be actually addressed in a way that would provide more money for new companies in the following way. The proposal evaluation process and criteria could be set up to give priority or advantage to companies that are either new to the SBIR Program, like the situation you just mentioned, or that are strong—have a strong commercialization track record, and focus funds away from the companies that have a weak—that have consistently not commercialized, thereby conceivably, and I think plausibly, increasing the amount of money that would be available for new companies and the good commercializers. I think that would be one way to handle it.

Mr. GINGREY. Mr. Chairman, I see my time is up, but I yield back to you and look forward to you yielding back to me.

Chairman WU. Thank you very much. Several of the witnesses refer to providing for a relatively small percentage, perhaps as small as one percent, administrative fee for the agencies to administer SBIR. What kinds of improvements can we hope to see from SBIR by providing for these administrative costs, and secondly, what kinds of costs would you include in this set-aside for administrative costs, and what kind of costs would you exclude from that?

Mr. BARON. My suggestion on this, having been the program manager for the Department of Defense, I think it is very easy to—there were some things that we did like establishing the commercialization achievement index, tracking commercialization outcomes, etc., that I think were very useful and valuable to the program. There were other things that have been done with administrative—currently with administrative money, like holding conferences and commercialization training and all that. And you know, as the manager of the program, I always wondered, is this just a lot of activity or are we really doing any good here? I think my short answer is it is very easy to spend—everyone is always asking for more administrative money, and it is easy to spend that on things that may not be that valuable. And so I sympathize with a lot of what Mr. Schmidt said about not taking too much off the SBIR Program.

That being said, I would suggest a small—one thing which is desperately I think—desperate is too strong—a critical missing piece needed to improve the SBIR program and more of those breakthroughs is knowledge about different rules like you have been talking about, what sort of selection criteria, what sort of training, how do you set up the program so as to get the right kind of companies in there and produce more of these breakthroughs, these important outcomes. We don't know how to do that. We are talking about all these different rules, a little bit in a vacuum of evidence about which ones will work and which ones don't. I would suggest a small set-aside that is devoted specifically toward trying new approaches, trying new approaches to administering the SBIR program like commercialization track record and evaluation criteria and then evaluating outcomes in a rigorous evaluation.

So I would suggest in the short-term, spending it on different ways of administering the program coupled with a rigorous evaluation, preferably of the type I mentioned before where you might use random assignment to make sure it produces scientifically valid evidence about what works.

Chairman WU. Mr. Ignagni, you were eager to say something.

Mr. IGNAGNI. Yes, I actually want to answer part of Mr. Baron's question as to the value of conferences and the assistance programs that the agencies run. I have written four SBIR grants myself and been fortunate to receive three awards, and I don't think I would have received any of those awards if I had not attended some of those conferences. I mean, Dr. Goodnight who I saw in the back provides valuable, extremely valuable information, to start-up companies and especially the small companies. Your friend that started a company, if he had attended one of these conferences, he could have found out about the aspects of taking knowledge, an idea through the SBIR Program and how to commercialize it. They run seminars on providing that kind of commercialization assistance, how to generate the Phase III, if you will. And those are all things that I think these kinds of—that kind of set-aside should continue to support.

Chairman WU. Thank you, Mr. Ignagni. Mr. Schmidt, you were most concerned about the effect of an administrative set-aside on the availably of SBIR funds to a broad range of small businesses, for this phase of my questions, I will give you the close on what costs should be excluded.

Mr. SCHMIDT. Well, thank you. I am glad Tony acknowledged Dr. Joanne Goodnight. Raise your hand, because she is an extremely capable, valuable person in this program at the NIH and runs the program there. And quite frankly, you know, we are not against administrative costs. The SBTC's position is, don't suck away from the program the little bit that we have now. I testified that it had one-eighth of what it should have, if it was fair. But don't take that to mean we believe that an increase of one percent of the new money going beyond 2007 funding should be allowed for administrative expenses.

But in general, you know, I think they know how to run their program, and I would give that discretion to the individual agencies. The one thing that I would suggest, though, is that anything above that in administrative expense go toward this commercializa-

tion pilot program type of endeavor which is in the Defense Department to be able to make sure technologies get commercialized through DOD, this Section 252 of last year's authorization bill and have something like that for NIH to get us from technology readiness levels four or five which is typically where Phase II lets off to technology readiness level eight which gets you further through the development phase of clinical trials, in the NIH case in flight tests or wind tunnel tests in DOD's case, things along those lines where you do more of the development work that is beyond the scope of a traditional Phase II. It takes about $10 million to develop a little widget in today's market places.

So this $850,000 of the Phase I, Phase II, you know, doesn't get you a tenth of the way there to be able to have a real product.

Chairman WU. Thank you, Mr. Schmidt. And Mr. Gingrey, if I may, I thought that Mr. Held wanted to make a contribution to this particular discussion.

Mr. HELD. I do. I think this is an extremely important issue to discuss. As we looked at how the SBIR Program is managed in the Department of Defense, one thing that is clear is the mismanagement processes is a fairly complex one. It is time consuming, it takes a lot of resources; and what I am talking about are things like contract management, technical oversight. You can start to look at some of the integration issues with larger systems that some of these technologies may be going into. So there is a lot that has to go on in terms of administering and managing the resource that is going on in the SBIR program. And by separating the costs associated with managing the program from the projects themselves, you create disincentives to want to actually manage the projects in the acquisition programs out there. And hence they get pushed out of those and the opportunities to commercialize are decreased as a result of that, at least commercialized in the sense of going into DOD systems. If a set-aside—and I think it is substantially larger than the one percent that has been discussed here—can be put together and attached to the projects and the program itself, you will start to diminish some of those disincentives and actually see an ability to start to commercialize the technologies more.

Chairman WU. Thank you very much, Mr. Held. And now I would like to recognize Dr. Ehlers, the gentleman from Michigan with whom I have had the privilege of working on this subcommittee as his Ranking Member in the last Congress. Dr. Ehlers.

Mr. EHLERS. Thank you, Mr. Chairman. Actually, the last hearing we had on this subject the roles were reversed. I was sitting in the chair, and you were not. I actually thought that was a good arrangement. But if I had to choose someone to take my place, Mr. Wu, it would have been you. And I appreciate your leadership on this.

Let me ask a heretical question and that is, does it make sense for the administration of this still to be centered in the SBA, and I am responding in part to your question, Mr. Held, of management of the program. In the last hearing we had on this, several Members and I came away concerned about whether SBA really has the expertise, research expertise, that is needed for the overall management. Now, I know it is a very complex structure handled by

the different agencies and so forth. But I came away wondering if perhaps an agency such as NIST might be better, simply because NIST already does a lot of this through the MEP program, also through what used to be the ATP program which is being superseded, thanks to this committee. If the Senate agrees, we will replace it with a different program. And again, they have a lot of experience in this area. It may be perfectly well to leave it where it is, but I am just trying to get your opinion. So Mr. Held, you started the thought process in my mind, so you can start first.

Mr. HELD. Well, it is not an area that we look at at all in our research, so I am not sure I am qualified to answer that question very well.

Mr. EHLERS. Thank you. Mr. Baron.

Mr. BARON. Yes, I think it is an interesting question. The program more or less is managed right now. The SBA's role in managing this program is somewhat limited right now. The program is managed more by each of the individual agencies that administer the program. They have control over the budgets and make most of the decisions about program management. So the SBA has—when I was involved directly in the program as the program manager at DOD, SBA played a benign role and a good role in sort of setting out the rules. They had a policy directive that helped guide the program. They did not get involved in the technical decisions. Since then, you know, there has been this venture capital question whether SBA ruling may not have been the best judgment. But I think in general, maybe with that exception, the sort of the current structure of the program with SBA sort of playing this facilitative role has worked reasonably well.

Mr. EHLERS. Thank you. I noticed the staff in the next row visibly whispering and you're handing notes back and forth, but I just like to hear what you think. Mr. Schmidt?

Mr. SCHMIDT. Yes, Dr. Ehlers, thank you very much. Your question is intriguing, but I guess I would have to ask how much interaction and how much knowledge do NIST officials have about small business; and that is one of the keys because they have got to have that understanding of the individual entrepreneur, of what drives them and what is taking this to the next level. The technology aspect from NIST is probably better, but it is this, you know—my house is on the line, and I have got to make this thing work that is even more important at that early stage that we are talking about.

Mr. EHLERS. Okay. Dr. McGarrity.

Dr. MCGARRITY. Well, my previous company had approximately four or five SBIR grants all from the NIH, and I am probably one of the world's biggest fans of the NIH. I think it is a shining star. So I think as far as the interaction, the ability to judge innovative research, I think it is certainly there. So I think there should be flexibility on this, and as far as my company's actions with the SBA I would go with what Mr. Baron said, they are more or less transparent. There were no dealings directly with them. Interacting with the NIH has always been a pleasure, and they are capable and competent. So I feel very, very comfortable about that interaction.

Mr. EHLERS. Yeah, and my question probably is least relevant to NIH grantees because NIST is primarily in the physical sciences.

Dr. MCGARRITY. Yes.

Mr. EHLERS. Mr. Ignagni.

Mr. IGNAGNI. I can echo those comments, because our grants are through the NIH, and it has been transparent to the SBA, but certainly the flexibility that the NIH has experienced has been good. I think the Medical Device Manufacturers Association would like to get back with more information as we evaluate that question.

Mr. EHLERS. Okay. Well, I was just interested in your comments in response to—I don't know whether it was Mr. Baron or Mr. Schmidt. NIST does have the expertise. They are using it with MEP and whatever ATP is going to become and what it was in the past. They worked with small businesses, small and medium-sized was their main aim. And they have good expertise there.

I would not, incidentally, propose that SBA be left completely out of the loop. They have a very important role to play here, too. But I am just looking for some way to get uniformity of treatment towards the applicants from one field to another. And that is where NIST can play a very good role because they do this all the time. But also—well, I will leave that thought on the table for the moment. I don't want to start a whole new field of inquiry, so I will stop at this point. I have probably done enough damage already. I yield back. Thank you.

Chairman WU. Thank you very much. And in fairness to Dr. Gingrey, I am just going to ask one question and then recognize Dr. Gingrey. A couple of you have recommended increasing the set-aside for SBIR, and let us say I think one witness recommended doubling the set-aside to five percent. Mr. Schmidt, would increasing the set-aside at least partially address your concern about where shares of SBIR go to the different kinds of applicants in the SBIR process?

Mr. SCHMIDT. Well, absolutely. You know, administrative costs, certainly if there is more money, the agencies need to get paid like the rest of us. And so that is very important for that issue. On the VC issue, though, this is really more of a political issue. I am very concerned that over time this program could become the billionaire's funding program versus the small business program. I have absolutely no objection to a separate, similar side program where VCs are allowed to be able to participate. But what I am concerned about is that we are going to politically put the entire program at risk over the years by having this with lots of large players and a couple of things I want to——

Chairman WU. Well, let me turn to Mr. Baron and Mr. Held about their views of what an increase in the SBIR percentage would mean in enlarging the program by 100 percent. But Mr. Schmidt, let me just say that when Congress wants to say 500 employees, Congress is perfectly capable of saying 500 employees; and if Congress wants to address form of corporate ownership, then Congress is also perfectly capable of addressing it in those terms. Mr. Baron, Mr. Held?

Mr. HELD. What I would like to see, I think—and again my research is focused on DOD—is more evidence that this is producing technologies that the DOD can use. That is not to say it is doing

bad work now, but that technology transition process hasn't been working as well as it should be. So before the set-aside is increased, I think we need to fix that technology transition process to get this to be a more effective and efficient program for the Department of Defense.

Chairman WU. This might be more appropriate for some agencies than for others——

Mr. HELD. Absolutely. Yes.

Mr. BARON. I would echo that in the sense that I think the greatest gains, for the reasons that I mentioned in my testimony, can be made by improving the incentives in the program to focus in on companies that are more likely to convert research into something that is going to benefit the world, in other words, the Defense Department or the economy. And so that is where I would suggest focusing most effort, and I am not sure that raising the size of the program by that magnitude would necessarily fund more companies that have the right kind of capabilities that you are looking for.

Chairman WU. Thank you, Mr. Baron. Dr. Gingrey.

Mr. GINGREY. Thank you, Mr. Chairman. This question about the transition from Phase II to commercialization is a real good one that Mr. Held and Mr. Baron just spoke of, and as I understand the program, you have got a Phase I, $100,000 grant, you have got a Phase II, $750,000 grant, and you have got a Phase III, nada grant, assuming that at that point that they are over the hump, so to speak. But obviously the percentages of these companies, particularly the start-ups, the ones who don't have a track record—and I agree, Mr. Baron, that we have a situation where you focused on a company with a good track record and you focused on a start-up. You try to avoid those with a bad track record, but is it possible that we need to consider some funding in Phase III? Is that maybe a part of the reason why there are so many that get grants in Phase I or Phase II that never make it to commercialization? They are almost there but they are not quite there? Maybe they need a Phase II–B or C bump, an opportunity to get a little more money to get them where they need to be.

Mr. BARON. I think there is—the incentives in the SBIR Program are, and I think appropriately, for providing the initial money, the Phase I and the Phase II with the idea that in most cases it is going to take much more money to get a product to develop, manufacture, further refine, et cetera, a product toward commercialization. And SBIR has always been focused on the earliest stage.

That being said, I think there are some excellent ideas that have been—pilots that have been tried that are designed to help companies make the transition to additional money. One of them has been piloted by the National Science Foundation, and there is a similar version at the Department of Defense which provides a larger SBIR Phase II award to companies that get a little bit of matching funds, matching cash, from a third party investor. So it is a way for the company essentially to take their SBIR money and leverage it to obtain additional outside money that they will need in Phase III. That is called a Phase II–B. I think it is a very promising experiment. Again, I would suggest I think there is a fairly easy way to test that, whether it actually produces better commer-

cialization outcomes. That gets back to the evaluation idea I had in my testimony.

Mr. GINGREY. Okay. So the answer to my question is that that already exists.

Mr. BARON. That is sort of matching and the incentive for matching funds, yes, it provides additional funds for Phase II—you can even call that a Phase III—coupled with—conditioned on the company raising outside funds to match it.

Mr. GINGREY. Right, but this would be over and above the $750,000—it would be in addition to that?

Mr. BARON. That is the way that it works at the Defense Department. I am not sure about the National Science Foundation, but yes.

Mr. GINGREY. Mr. Chairman, I wanted to ask another question. I see I have a little bit of time left. Mr. Schmidt, in your testimony you mentioned your experience with the program, and it is extensive. And I understand—you and I talked earlier. You have more than one company, in fact. You have been very successful, and I was wondering how many grants your company received, let's say in the year 2006, and, if you know this, which different agencies did you receive the awards from? And I would actually at this time, Mr. Chairman, if Dr. McGarrity and Mr. Ignagni could also respond to that question.

Mr. SCHMIDT. Well, I don't have the exact number but it is about ten to 12. And so obviously this is important to us. One of the ways in which we helped leverage some of that commercialization funding is that we have spun off a couple of new companies as well. And so we were able to raise outside money from those—from outside funds from the spin-off. And that is the way we addressed this, so we have two other companies that are proceeding with the commercialization there.

Dr. MCGARRITY. My present company, VIRxSYS, as far as I know, we have never had an SBIR grant, and the reason for that is—and I am sitting here as a company that is eligible for the program. We have focused all our energy, all our resources on our AIDS treatment. Now, however, we have earlier stage programs coming up, and in all probability, we will apply for an SBIR grant in the summer, the first time. My previous company, Intronn, over a course of six years, we had approximately four, five SBIR grants.

Mr. GINGREY. Mr. Ignagni.

Mr. IGNAGNI. We have—we had one Phase I STTR grant. Unfortunately, the market feasibility at the end of that was such that I didn't feel was sufficient to proceed to a Phase II. The principal investigator did submit for Phase II, but I probably dissuaded him from doing that. We have one Phase I that is actually moving forward into a Phase II later this year, and as a matter of fact, we have done some early testing on a young woman from Michigan yesterday in that Phase I and that worked very well.

Mr. GINGREY. You currently have a Phase I——

Mr. IGNAGNI. We have an award pending for a Phase I right now.

Mr. GINGREY. Mr. Chairman I just wanted to ask Mr. Schmidt, if you don't mind, if you will submit that to us for the record. I know you didn't have the exact numbers and the different agencies,

but if you would submit that for the record I would appreciate it. Thank you.

Chairman WU. Thank you, Dr. Gingrey, and I am just going to ask one question of the entire panel before turning back to Dr. Ehlers. Several of you have addressed the issue of award size. A dollar does not buy the same in 2007 that it did in 1992, and I would like to just go down the row and have you all address the issue of award size and what, from a statutory perspective, if we were not to provide a flexible cap, would provide enough moving room for the next three or four years for a reasonable period of authorization. We will begin with you, Mr. Held.

Mr. HELD. Well, as I stated in my testimony, I think at a minimum we need to account for inflation, and if you want to set a limit that has some flexibility, you would move up from there. SO you know, perhaps $200,000 for a Phase I and $1.5 million for a Phase II, something along those lines.

Mr. BARON. I think it would make sense to adjust with inflation over time but also—and I think the current statute actually does this to allow for a fair amount of flexibility to go over the amount. In the example that I provided, if a company can obtain outside matching funds, some of the agencies do allow you to go over the amount. So I think there is a fair amount of flexibility now, but the base rate might be increased with inflation.

Mr. SCHMIDT. This was an extensive discussion at SBTC and among their members, and we came down in favor of the $150,000 and $1.25 million goals for these—for the Phase I an Phase II. The issue becomes, you know, how much do you go above it? And there was a comment about a $6 million Phase II, and the issue becomes how many new Phase I's do you give up for these very large Phase II's or don't deliver your other items. And so what the SBTC's position was is that there needs to be certain guidelines and caps on that to be able to limit that. I think there has got to be flexibility within the agency that they can do this to fund those particular programs that are most important to them and which seem to them to have the greatest scientific breakthrough, but that is another reason why, to go back and reconvene it again on a Phase II continuation or a Phase II–B or C, they can get another bite at the apple—but they have to show that they chewed the first bite properly.

Dr. MCGARRITY. I would agree with what Mr. Baron said as far as at least accounting for inflation since the last figure was set. And I would also echo his sentiments that, you know, the Congress and the SBA shouldn't micromanage this. I think you should set the guidelines, and they are appropriate; but give the agency the flexibility if they have to and if it is justified to go over the dollar amount for particular awards, if it is justified on either a piece of equipment or a special case or something to have that ability to address the needs of the particular grants and their overall program and mission.

Mr. IGNAGNI. Again, in agreement down the line here. We advocated a $150,000 limit for Phase I. Our guideline for Phase I as well is one-fourth million. And just to note that with NIH grants, there is flexibility. WE have—as long as the budget is justified, well-justified and they have the ability to come back and say no,

we disagree with your justification and you should get X amount of dollars; but ours have been well-justified. We have gotten 30 to 50 percent over the guideline in our two grants.

Chairman WU. Thank you all very much. While I am sympathetic to granting agency flexibility, sometimes—well, it depends on what they do with that flexibility. And you know, Dr. McGarrity, you might be a little bit concerned about the claimed flexibility about capital structure and the interpretation there. Mr. Schmidt, I appreciate your discussion of a higher limit of $6 million; and while I personally think that an adjustment above the inflation rate is warranted because in working with SBIR folks before I came to Congress, that was a tremendous amount of work to do for a modicum of money and that perhaps an above-inflation adjustment rate might be warranted. But we might not be able to hit that $6 million mark. With that, Dr. Gingrey, further questions?

Mr. GINGREY. I would like to go back to Mr. Schmidt in regard to this issue of venture capitalists MAT companies, and I know that you are—in your testimony, I know you have some concerns over that; and you don't think they should be eligible and are therefore in agreement with the ruling of the SBA back in 2003. And I really wonder if your thoughts that nine different agencies that participate with the 2.5 percent set-aside maybe should be increased. And you were talking—used the analogy of the bite of the apple. Let me use one. I am not sure that we are comparing apples to apples in regard to the issue that Mr. Ignagni and Dr. McGarrity raised, because of the type of business that they are involved in. I guess those grants would come through the NIH in the biomedical field, and the necessity of trying to raise some capital just to get off the ground almost forces them to go in that direction unless there are a lot of angel investors around. If I had to look for an angel investor in my family, I would be dead in the water.

And so I just wonder maybe if in your logic on this, if you would not agree that maybe you treat these apples and oranges a little bit differently. In some situations, some agencies that participate in this program, maybe that rule would make sense, but in others specifically, the funding through the NIH wouldn't make sense. Comment on that.

Mr. SCHMIDT. Congressman Gingrey, I just wanted to clarify one thing just to make sure everyone is on the same page. The current rules from '52 before the SBIR program to '82 with the SBIR Program, and the rules have been the rules all the time, do not prohibit VC ownership, small VCs with less than 500 employees combined, from owning a majority of the shares. So they can own 99 percent of the shares under the current rules, as long as their conglomeration is less than 500 employees.

The second thing is that a large VC with more than 500 employees underneath their domain can own 49.99 percent. So the only thing that is prohibited is large VCs having majority ownership. So you know, that is the only thing we are talking about with this.

The second thing to answer your question previously is whether things have gone down since this ruling. The GAO report in 2006 showed the percentage of venture-supported companies at the NIH has increased in the two years following the SBA clarification, and we can make that available. So that is not reduced VC funding at

the NIH at all. So the only thing that they are prohibiting is majority ownership by large VCs.

So I guess I look at this and say, you know, should you make an exception for the NIH? Well, what I would suggest instead is having another similar program. We have STTR, we have SBIR, and I would suggest a growing businesses innovation research or other similar kind of program where this VC rule does not apply, that you can allow those people in that program; and that way we do not mix these individuals and this program because, Representative Gingrey, you asked about your friend, you know, that the one person got it. And I was one of those guys. When I started with the companies, it was me and my wastebasket. And I kept yelling at my wastebasket that it wasn't producing the reports I needed. Of course, you work these 80 to 100 weeks for years on end. I mean you get one, two days off, in a quarter and that's a big deal. So, in going through all of this, the SBIR Program provides for those small companies, and the majority of their companies are under 20 employees. So that's what the SBIR program does. So by including large VCs into this and having majority ownership, you are going to make it that much harder for that individual guy to be able to get up and run. So if you have a parallel program, that is something that, we can live with, there is more money for that. I mean, I spend a lot of time in Cleveland arguing for angel groups, and I am an angel in two different groups. And having more VC money into our area. I mean, I argue all the time for that. It is a big deal. It is important. But to take the SBIR Program and change that purpose, my opinion and the opinion of the SBTC and the NSBA is that that would be a mistake.

Mr. GINGREY. Mr. Chairman, I am going to yield back to you. I think if you want to——

Chairman WU. Mr. Ignagni, I believe you may have wanted to respond to that.

Mr. IGNAGNI. I just have one point that I think is a part of the confusion around this argument. It is the example—and Mr. Schmidt brings up the small VC versus the large VC; and I really don't know what that means. I mean, a small VC company in Palo Alto, California, three large partners, six people, six partners in the firm with several assistants and everything. But they get money from Ford Motor Company's pension fund to invest some small portion, and there are however many people. This is a hypothetical example. But they are affiliates, and it is written as employees over affiliates. I don't know if there is such a thing as a small VC. As soon as they become an institutional investor and get money from, whether it is University Hospitals pension fund or just some other larger company that is investing in them, I think they are considered affiliates; and that would make my life a lot easier if it were just the number of employees at the VC firm.

Dr. MCGARRITY. And just another supplement to that, the wording is that it has to be owned by 51 percent of individuals, and I think a significant change was whether the VCs were listed as individuals as they were in the past or now that they don't count as individuals, you have to have ownership by individual people. Actually, if you go back to the original investment legislation, that legislation actually said that investment firms would be counted as in-

dividuals, and the legislation that introduced the SBIR was actually mute on that point. So I think maybe that is the reason why this has been so vague and open to interpretation through the years.

Chairman WU. Well, as we proceed I think that we will focus a substantial amount of attention on this form of corporate organization and whether it is relevant or not to small business definitions and the SBIR Program.

There has been some discussion—one of the strengths I view of the SBIR program is a relative uniformity of cross-federal agencies in terms of a percentage set aside that it is handled. There has been some discussion today of different percentage set-asides for different agencies and perhaps handling this VC issue differently between different agencies. Mr. Held, Mr. Baron, do you see problems where they're starting to treat different agencies differently under the SBIR program or the STTR program?

Mr. BARON. Yes. I think you want some flexibility but different agencies have different missions, needs, and so forth. But the uniformity as you mentioned in your question, some degree of uniformity has a real purpose. This program is for companies most—is intended for a lot of companies that have never done business with the government before and don't know all about arcane rules of government granting and contracting and all of that. You want the process to be, I would think, as simple and streamlined as possible and to have a set of fairly clear rules across the agencies, similar sizes of awards, proposals limited to 25 pages. It serves a great benefit in allowing—in making the process more merit-oriented and not less oriented on knowing the nuances of how each individual agency's rules operate.

Mr. HELD. Yeah, I think I generally agree with that. There is a lot of advantage in terms of efficiency and in terms of making it easy for small businesses to participate in the program, to have as much uniformity as you can across the government. Having said that, there has to be flexibility in the program to structure each individual agency's program so that it can best meet the goals of that particular agency.

You look, for example, within DOD, there are agencies like the, DARPA, Defense Advance Research Project Agency that does very risky, very far-out kind of research; and then there are the Armed Services which are trying to get things fairly near-term into the hands of soldiers and airmen and sailors and marines and so forth. And the program, because it draws from each of those agencies, has to be able to have the flexibility to manage those different goals.

Chairman WU. Mr. Schmidt.

Mr. SCHMIDT. Mr. Wu, just one example in our little sleep monitoring device, we developed a radio underneath NIH funding. We then took that radio and put it on missiles for the Air Force. We improved the radio and then put it back into this device, and we are now coming up with a fifth generation radio to be able to go back into the military and other places. We are doing brain monitoring from NIH and now applying it for Homeland Security and Department of Defense issues after a chemical warfare attack. The problem is that it is most beneficial for the Nation to be able to

take these technologies and move them across. If you have different rules for different agencies and you say, oh, you have got 51 percent funding from a VC, you are okay over here, but you know, you are going to hit that wall right there when you are trying to take that over to another agency, I think that would be detrimental for overall technology development.

Chairman WU. Mr. Ignagni.

Mr. IGNAGNI. I think uniformity and DMA thinks that uniformity is good, but unfortunately in the NIH, and the amount that it takes to do a clinical trial, to get a clinical trial started, is very substantial; and to get a device through all of the compliance requirements, all of the certifications that you need to get into human trials, or animal trials for that matter, is expensive.

Chairman WU. Thank you all very much. We have tapped at least most of the horses that we need to tap as we go forward in the legislative process. We are at risk of reflogging some of those horses now, and I want to thank all the witnesses for a very, very productive hearing; and thank you very, very much for being here today. If there is no objection, the record will remain open for additional statements from Members, for questions or answers to the witnesses or from any Committee Members; and without objection, so ordered, and the hearing is now adjourned. Thank you all very, very much.

[Whereupon, at 3:05 p.m., the Subcommittee was adjourned.]

Appendix 1:

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Bruce J. Held, Director of the Force Development and Technology Program, Rand Arroyo Center, The Rand Corporation

Questions submitted by Chairman David Wu

Q1. In your testimony, you comment about DOD's solicitation schedule and recommend more frequent solicitations to provide flexibility to meet DOD technology needs in a timely manner. What do you estimate would be the additional administrative cost of this flexibility? Do you think there is an appropriate legislative solution for this?

A1. Under current procedures, the additional administrative cost could be substantial, though additional study is merited to determine what that cost would be. Current procedures issue a service/agency-wide call for topics. Submitted topics then are modified and approved through various levels of command and management; ultimately the Office of the Director of Defense Research and Engineering provides the final approval. This centralized process is administratively burdensome, so most agencies and services limit their topic proposal and SBIR solicitation exercise to only one or two of the regularly scheduled DOD SBIR solicitations per year in order to improve process efficiency. Increasing solicitation frequency should, therefore, be linked to other SBIR program reforms intended to improve overall flexibility and utilization of research outcomes.

Potential legislative solutions could include providing for final topic approval at a level lower than the DOD level. This would allow the services/agencies to significantly stream-line the topic approval process. Additionally, legislation could mandate an "open" solicitation, at either the service/agency level or at the DOD level, to which SBIR topics could be added at any time. Given the current sophistication of available Internet search and alert tools, an open SBIR solicitation would have the same effect as regularly scheduled solicitations in providing small businesses a simple means for learning about opportunities available in the program.

Q2. What improvements would you recommend in the award application process which would lower application costs for small businesses and reduce the funding gap between Phase I and II awards?

A2. It is not clear that the application process for Phase I awards could be improved significantly to lower application costs without detracting from competition or reducing the amount information required to make informed award decisions and collect information necessary to manage and monitor the SBIR program. Phase II award costs could be reduced in some cases by making Phase II an option on the initial Phase I contract. (The term "option" as used here is different than the Phase I Option program that provides bridge funding when a Phase II award is anticipated.) This would also have the added benefit of reducing the funding gap between Phase I and Phase II. Rather than have the small businesses prepare a second proposal and enter into a second contract, a Phase II option would allow contracting officers to simply exercise the option upon successful completion of Phase I and a decision by the benefited command, program office, laboratory or research center to continue the work.

Since Phase I studies are usually feasibility studies, managing Phase II awards as options on the Phase I contract will require some additional work and innovation in drafting and negotiating the Phase I contract. For example, there would need to be provisions that allow for adjustments in the technical direction of the project and in the anticipated cost of Phase II. Nevertheless, the additional effort could be rewarded by much less effort in making Phase II awards and a much reduced funding gap between research phases.

Q3. You make the case for flexible program administration, including award size. In addition to award size, what other specific areas of program administration would benefit from flexibility? Please describe how flexibility should be implemented? Is there a need for statutory change?

A3. I mentioned above, in answer to Question 1, that solicitations should be more frequent, or there should be some provision for an "open" solicitation to make the initiation of SBIR research more responsive to the needs of the DOD's technology customers. In addition, the actual schedule and pace of the research should be responsive to the requirements of the DOD technology customer and to the progress of the research. For example, in some cases, Phase I might require very little time. By using a Phase II contract option, as I described in Question 2, Phase II could

be started very quickly. Depending on the research, such an approach would have the benefit of moving the technology through research and development much more quickly.

I believe the current SBIR law already allows enough flexibility with regard to project and solicitation schedule flexibility. At issue are established procedures for managing the SBIR program in DOD. These procedures evolved mainly in response to process efficiency requirements. Legislation that requires administrative funding for the SBIR program to be drawn from the SBIR set-aside could change the incentives that make process efficiency in the DOD SBIR program more important than research utilization.

Flexibility concerning the kinds of research and development appropriate to the SBIR program would also be very useful. The word "innovation" does not just mean cutting-edge science and technology. In fact, and as currently recognized in the law, one common interpretation of innovation is the development of existing science and technology for new uses. Some examples of how to be more innovative about "innovation" are illustrative.

a. The SBIR program could be a particularly effective resource for conducting engineering improvement programs for already fielded items of equipment. Program offices managing fielded equipment, particularly when there is no product improvement program approved, usually have very few resources for improving the equipment they manage; for example, developing more robust components to replace ones that wear out quickly. The SBIR program can be this kind of resource, providing development funds that potentially improve equipment performance and save other resources.

b. The SBIR program could be engineered into a resource for the rapid development of technology urgently needed by deployed forces. Though there are other programs and processes to do this, realigning funding can be time consuming. The SBIR program could be an accessible source of innovation funding that doesn't need reprogramming.

c. Provide SBIR awards to take a technology through several steps in development. For example, a Phase I and II award might be used to develop a brass-board prototype of a technology, a second Phase I and II might take the technology from brass-board to operational prototype and a third Phase I and II might provide for full up testing and product refinement. (There are some efforts along these lines now.)

A broad, legislative restatement of what is meant by innovation and how that applies to the SBIR program would help resolve debate about the appropriate use of SBIR resources.

Q4. What specific percentage administrative cost recovery of the SBIR set-aside dollars do you recommend and what types of administrative costs would you include; what would you exclude?

A4. There are a number of research management comparisons that can be used to develop an estimate for a specific percentage administrative cost recovery of the SBIR set-aside dollars. For example, the Navy's SBIR program appears to be more successful in commercializing its research results. That program taxes its RDT&E accounts an additional 6.5 percent of the value of the SBIR set-aside to fund administrative and commercialization costs. Commercial venture capitalists draw an annual management fee that averages about 2.5 percent of funds under management, plus they earn a significant portion (~20 percent) of any return on investment that is earned. In the DOD, the account for RDT&E Management Support averaged nearly eight percent between FY 2000 and FY 2008. Based on these benchmarks, I recommend that the percentage administrative cost recovery of the SBIR set-aside dollars be at least six percent, and perhaps even higher.

Administrative cost recovery funds should be allowed to address most administrative costs associated with managing the SBIR program, including contract management, topic and solicitation writing, proposal evaluation, technical support and oversight, and the programmatics associated with integrating SBIR research with other acquisition and R&D programs.

Whether administrative cost recovery funds should be allowed to fund business development activities for participating DOD SBIR companies is a matter that requires more research and explicit policy decisions concerning these kinds of activities. In fact, current law already allows some SBIR funds to be used for these purposes.

Q5. In your written testimony, you say there are Department of Defense SBIR award winners in what you describe as "research houses" who provide research as a

service but without the ultimate goal to develop a marketable product. Why don't these firms focus on commercialization? How widespread is this practice? What can be done to focus on the commercialization goals of the SBIR program?

A5. The business model of these firms is to provide a service, and that service is research. Firms that focus on research as service do so because selling research services can be a successful business model. Research is also what motivates the people in these firms rather than the other tasks that go into commercialization, such as marketing, sales, product development and manufacture. Research services like this are also important to organizations that require the work but don't have an in-house capability for it and, for any number of reasons, do not want to develop the capability.

In the SBIR program, research houses can be very valuable contributors, provided that their work will ultimately result in a product, process or technology used by the DOD. A mechanism for enforcing this requirement is available in the Commercialization Achievement Index (CAI). Research houses that conduct numerous SBIR projects should be able to achieve reasonable CAIs through licensing fees, follow-on research contracts and other additional investment from companies interested in the technology. Those that do not achieve reasonable CAIs should not continue to receive SBIR awards.

Our research did not examine how widespread this business model is.

Getting more focus on the commercialization goals will require more "mainstreaming" of the DOD SBIR program into the acquisition activities of the DOD. So long as most of the DOD SBIR program is managed from the laboratories and R&D centers, technology transition and commercialization will remain difficult. Management of the program should be more aligned with sources of SBIR funds. Since the DOD's acquisition programs provide most SBIR funds (6.4 and 6.5 dollars represent the largest categories of DOD RDT&E funding) this kind of alignment would give acquisition program managers greater control of SBIR funds and projects. In keeping with my theme above, if acquisition managers are given more control of SBIR projects, they should also be given the resources to adequately manage and integrate the research into their programs.

It should be recognized that in recent years there have been efforts to make the DOD's acquisition community more involved in the SBIR program. With the possible exception of the Navy, these efforts remain inadequate, however, and more needs to be done.

Q6. You recommend increasing the role of the Department of Defense's (DOD) acquisition staff in managing SBIR projects, such as in award topic selection. What are the current best practices in DOD which support integration with DOD's acquisition processes? Is a change in the statute needed?

A6. The Navy currently provides examples of best practices. It does a number of things differently, and these appear to have had an impact on commercialization success.

First, the Navy directly funds SBIR technology transition management. It collects an additional .1625 percent on top of the 2.5 percent of extramural R&D to provide funding for technology transition assistance and management.

Second, the Navy participates in all four DOD SBIR solicitations.

Third, the Navy's philosophy concerning use of SBIR resources seems to be that organizations should benefit from the program more in relation to the contribution they make toward the program.

Fourth, the Navy has personnel at each SYSCOM/PEO funded by and dedicated to managing the SBIR program.

Fifth, the Navy's leadership appears to be pushing management of SBIR projects down through the PEO structure to individual program management offices (PMO). This is currently most evident in NAVSEA and NAVAIR, where topic selection, proposal review, and project oversight are managed by personnel in the PMOs and PEOs, rather than the laboratories and R&D centers. This greatly increases the chances that a particular project will be responsive to the needs of an acquisition activity.

Legislation that could support these kinds of best practices include:

a. Allowing funding of SBIR administration costs from the SBIR "tax" on extra mural R&D.

b. Requiring some percentage of SBIR projects be managed by the acquisition community. The actual percentage should probably be made a function of the SBIR tax the programs in each PEO pay into the SBIR program.

c. Legislatively defining "innovation" and "commercialization" such that pursuit of the SBIR program's innovation and commercialization goals will necessarily require more participation by the acquisition community.

d. Requiring greater application of commercialization achievements as a proposal evaluation criterion.

Q7. You describe the DOD SBIR leadership focus is on statutory compliance rather than research outcome and utilization. Given this assessment, what is your view on doubling the size of the SBIR program? You also suggest the question around increasing small business participation should be on increasing the quality of the participation not the overall number of companies participating. Is this a current problem?

A7. The DOD SBIR program should not be doubled in size until and unless it is demonstrated that the results of the research are being incorporated into DOD equipment, processes, or other DOD R&D activities. This demonstration requires that appropriate and measurable metrics be defined and goals established that benchmark acceptable SBIR research utilization success.

The most consistent complaint we heard from the small business SBIR program participants was that there was no path to take their research forward after the end of each project. Therefore, by "quality of participation," I mean that SBIR research projects should be selected and managed so that they directly support and are integratable into DOD acquisition programs and research initiatives. This kind of participation is much more likely to result in the results of the research being incorporated into DOD equipment or contributing to important research efforts. Too often, SBIR projects today are managed as something outside mainstream efforts and result only in reports that are rarely read after the conclusion of the project. Simply increasing the number of small business participants will not relieve this issue. On the other hand, if SBIR projects are perceived as valuable contributors to acquisition program success or to research that leads to future acquisitions, then demand for SBIR resources will increase, and more small businesses will seek participation in the program.

Q8. What do you see are the most significant data gaps with respect to program evaluation and the most effective ways to address these gaps in the future? Who needs to gather this information, and what are the impediments to compiling this information today?

A8. The DOD SBIR program currently collects sales and additional investment data from companies that previously participated in the federal SBIR program and are making a new SBIR proposal. This data can provide insights into whether SBIR research is being used in the development of military equipment. Additional data that is more specific on actual use could provide greater insight. Such data might include the specific examples of use, time to use and TRL levels. Actual metrics, however, will require additional development to determine what information can be feasibly collected. Whatever metrics are ultimately required, they need to be collected on an on-going basis and would best be collected by SBIR managers assigned to specific PM/PEO offices, laboratories and R&D centers.

The ability to collect adequate data for assessing the DOD SBIR program is currently impeded by two things. First, metrics for assessing SBIR program success are ill-defined and actual reporting requirements are focused on program execution. Second, the resources dedicated to managing the SBIR program are too few to adequately evaluate and oversee the program much beyond the execution metrics that are reported up through the DOD, to the SBA and ultimately to Congress.

Q9. Please recommend how you would structure on-going administrative oversight and evaluation of the DOD SBIR program? Are these recommendations appropriate to other SBIR agencies?

A9. Oversight of the SBIR program needs to be more closely tied to the program's legislative purpose. In order to make this possible, specific criteria and benchmarks that are directly related to the program's legislative purpose must be established, and metrics that can be used to assess how well the SBIR program is addressing the criteria and meeting the benchmarks must be developed, and the data collected. Reporting requirements for the SBIR program also need to be more closely tied to the legislative priorities for the program.

In addition, the structure of SBIR oversight and evaluation responsibilities should more closely align to the legislative priorities. For two of the services and to some extent at the DOD level, much of the oversight and evaluation responsibility is established in Science and Technology organizations, such as the Office of the Director of Defense Research and Engineering (DDRE) and the Director for Research and

Laboratory Management in the Army. These organizations certainly have a stake in the SBIR program and should retain organizational responsibility for oversight and evaluation of SBIR projects that are comparable to research conducted under the DOD's RDT&E research categories 6.1 through 6.3. However, acquisition organizations should have organizational responsibility for oversight and evaluation of SBIR projects that are comparable to research conducted under the DOD's RDT&E 6.4, 6.5 and 6.7 research categories.

The DOD's current SBIR management structure is too lean to provide more than program execution oversight and some level of policy guidance. Adequate oversight of SBIR program utilization is not practicable without sufficient information to inform evaluation and people to actually conduct evaluations. Since the DOD SBIR program consists of two to four thousand on-going projects and many thousands of completed projects, and because these are research projects whose transition into fielded products is a very complex process, evaluating success is necessarily a labor intensive endeavor. That is one reason why I recommend at least six percent of the program funds be set-aside for administrative costs. More personnel are needed at the DOD level, the service/agency level and the major command/PEO level to collect, analyze and report progress in the DOD SBIR program.

Administrative oversight and evaluation of the SBIR program should be structured to the purpose of the parent organization. Since these purposes vary, and our research did not examine other SBIR organizations in detail, I cannot comment on how they should structure their SBIR program oversight and evaluation.

Q10. Looking at Small Business Administration (SBA), how well has SBA done to date in providing management and oversight of the SBIR program? What do you recommend to improve management and oversight?

A10. Our research did not examine SBA practices with regard to the SBIR program, so I cannot comment on Question 10.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Jon Baron, Executive Director, Coalition for Evidence-Based Policy, Council for Excellence in Government

Questions submitted by Chairman David Wu

Q1. How should we address the situation of recipients of multiple SBIR awards who have no record of commercialization? How widespread is this practice, and what has been the impact on the program? How could award criteria be revised and applied by review committees to be sure prior award and commercialization experience is considered by the review panel?

A1. The GAO studies of the SBIR program, and DOD data, show that some SBIR companies—perhaps as many as half of those that have participated long enough to build a track record—consistently are unable to convert their SBIR awards into viable new products sold to commercial or government customers.

To ensure that an SBIR applicant's prior award and commercialization experience is considered by agency review panels, I'd suggest that an applicant's track record in commercializing its prior SBIR awards comprise at least 30 percent of its evaluation score. As noted in my testimony, some agencies such as DOD collect excellent data on companies' commercialization track records, which could readily be used in this process.

This criterion would only apply to applicants that have won a sizable number of prior SBIR awards (e.g., at least three prior phase II awards); thus applicants that are relatively new to the SBIR program would not be affected by this policy. (An agency could even give such new SBIR applicants a competitive priority—e.g., 10 extra points out of 100—if the agency wishes to encourage their participation in the program.)

Q2. You describe firms who are consistently unable to convert their SBIR awards into viable new projects. You provide examples of agency approaches to improve SBIR award company entrepreneurial skills. Would you please identify which approaches you believe are most effective?

A2. I think the most promising approaches are to incentivize firms to (i) hire individuals with the experience and motivation to commercialize, and (ii) give these individuals a key role in running the company. Suggested incentives are discussed in response to the next question. Based on my experience and discussions with companies that have been highly successful in commercialization, I believe that bringing such experienced individuals into the company is likely to be more effective than training or providing other assistance to existing company personnel who have little background in commercialization.

Q3. What types of incentives do you recommend to significantly improve commercialization? Please also describe how these incentives should be administered, considering the different skill sets of award winners.

A3. Revising the SBIR proposal evaluation criteria to give greater weight to an applicant's commercialization track record, as described under question 1, would be a powerful incentive.

Another strong incentive would be to provide a larger phase II award, and/or a competitive priority in the phase II proposal evaluation process, to SBIR companies that obtain at least a partial match of funds (cash, not in-kind) from a third-party investor. The National Science Foundation's "Phase II–B" award, and DOD's "Fast Track" and "Phase II Enhancement" policies are specific versions of this approach. The rationale for this approach is that an investor's hard commitment of matching funds is a strong endorsement of the SBIR company's entrepreneurial capabilities and the market size (commercial or military) for its technology. The National Academy of Sciences' study of DOD's Fast Track provides initial evidence that this approach yields much higher commercialization and research outcomes.

You might consider including both of these incentives in the reauthorization legislation.

Q4. What do you think would be the impact of doubling the size of the SBIR program by increasing the set-aside to five percent, including the impact on the competitiveness of the awards and the potential for commercialization of the projects?

A4. I think it's hard to project the impact of doubling the SBIR set-aside. I think it might be more productive for the reauthorization bill to focus on revising the in-

centives in the existing SBIR program, as discussed above, because there's strong reason to believe that doing so could greatly increase the program's contribution to American technological and economic capabilities.

Q5. You recommend agencies be directed to allocate one percent of SBIR funds to conduct scientifically rigorous evaluations of new approaches to build awardees' entrepreneurial skills? What information is required and is it feasible to collect this information? Who do you recommend conduct these evaluations?

A5. As I discuss in my testimony, scientifically rigorous evaluations of new approaches to administering the SBIR program—such as the incentives I describe above—are often feasible at modest cost and with minimal administrative burden.

For example, an agency could randomly assign half of its SBIR awardees to a "treatment" group that is eligible for a larger phase II award if it obtains matching funds from a third-party investor (as is done under the National Science Foundation's "Phase II–B" process), and its other awardees to a control group that participates in the agency's usual SBIR process, without this Phase II–B. The evaluation would then track commercialization outcomes for the two groups over time, to determine whether the Phase II–B incentive made a difference in such outcomes. At agencies such as DOD that already track commercialization outcome data for most of their SBIR awardees, this rigorous study could be conducted at a low cost by using such data—perhaps $250,000 per year over five years as a rough estimate.

In addition to tracking commercialization outcomes, the evaluation could also survey the agency scientists or engineers who monitored the SBIR projects to assess whether the projects in the treatment group made a greater or smaller contribution to the agency's research goals than the projects in the control group.

To conduct such a study, I would suggest that the agency engage an independent evaluation firm with a demonstrated track record in conducting high-quality evaluations using random assignment.

Q6. Looking at Small Business Administration (SBA), how well has SBA done to date in providing management and oversight of the SBIR and STTR Programs? What do you recommend to improve management and oversight?

A6. SBA has played a very useful role in making sure that the agencies follow the clear, streamlined SBIR procedures set out in the SBA policy directive, and that the program is administered in a fairly consistent way across the agencies. This is an important role, because it ensures that firms which are new to the government granting and procurement process can compete on the basis of merit with firms that have more experience with the government process. Put another way, SBA is an effective counter-weight to the pressures that often exist in the agencies to complicate the SBIR application and review process. I would suggest that the reauthorization legislation and/or report language focus SBIR on this key role and not, as some have suggested, on other aspects of program administration where SBA has less institutional expertise (e.g., collecting commercialization outcome data).

Q7. You have significant experience with the STTR program in addition to SBIR. What separate recommendations would you make for the STTR program to improve program efficiency and effectiveness?

A7. The STTR program serves as an important complement to the SBIR program by harnessing a new and different source of innovative ideas—ideas that originate with a scientist or engineer in a university or federal laboratory. These researchers cannot participate in the SBIR program in a central way—e.g., as principal investigator—as long as they remain primarily employed at their research institution.

Because STTR projects include significant involvement of research institutions—which sometimes don't have a strong interest in technology commercialization—I'd suggest it is particularly important for the program to ensure that the small businesses partnering with the research institutions have strong commercialization capabilities. Thus, incentives such as those I outline under Questions 1 and 3, and in my testimony, may be especially important to include in the statutory authorization of STTR.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Robert N. Schmidt, Founder and President, Cleveland Medical Devices, Inc., and Orbital Research, Inc.

Questions submitted by Chairman David Wu

Q1. You have proposed increasing the set-aside for the SBIR program to five percent over time. The current Administration's American Competitiveness Initiative would double funding in the physical sciences for NSF, DOE and NIST. Similarly, NIH funding doubled between FY99–FY03. What is the basis for your recommendation? How much funding would the SBIR program be if your recommendation is implemented and Congress also funded the President's budget proposals for NSF, DOE, and NIST?

A1. SBTC recommends that the SBIR allocation be gradually increased to five percent for two major reasons. First, there are new needs within the Program. These include the need to increase award sizes, which have not been adjusted in fifteen years, the need to strengthen SBIR Phase III, and the need to provide the participating agencies with additional administrative funds.

Second, we believe that Congress should acknowledge the proven capabilities of the SBIR Program—as well as a growing gap between where American scientists and engineers actually are and where federal R&D dollars are going. For almost ten years, SBIR companies have been obtaining more patents than all U.S. universities combined. Today it's about 30 percent more. Meanwhile, smaller companies are employing an increasing share of the Nation's scientists and engineers. Today, about a third of all U.S. scientists and engineers—and more than half of those in the private sector—work for smaller companies. Yet the percentage of federal R&D dollars awarded to smaller companies, including SBIR companies, is an astonishingly low 4.3 percent. And SBIR is the only Program that Congress has ever devised which actually succeeds in empowering small technology-based companies to obtain federal R&D contracts.

Gradually increasing the SBIR allocation would not only build on the proven success of the SBIR Program. It would also tap into a huge pool of underutilized R&D talent. And it would increase the share of federal R&D dollars awarded to small companies from today's 4.3 percent to perhaps six or 6.3 percent.

As we suggested in our testimony, SBTC favors the Administration's American Competitiveness Initiative. We think it is needed, and we hope Congress approves it.

Having said that, we would note certain limitations to the ACI. The FY 07 appropriations for the agencies covered by ACI was $10.6 billion. The FY 08 request for the same agencies is $11.5 billion, an increase of less than $1 billion (and less than eight percent), if approved by Congress. The FY09 request, whatever it may be, is the last budget that the current Administration will be able to monitor and promote through the Congressional appropriations process. These requests, then, represent only modest increments compared to the "doubling" of the R&D budgets of these agencies by 2016 that the ACI envisions.

Such an outcome is highly speculative at a time of large budget deficits and changing political leadership, but, again, we hope it occurs.

Yet even if the FY08 and presumably higher FY09 requests are approved, the increases that NSF, DOE and NIST would receive will affect only a small fraction of the government-wide SBIR Program.

For FY05, the most recent year for which SBIR data is relatively complete, the agency SBIR budgets were as follows:

- DOD $1.2 billion
- NIH $525 million
- DOE $104 million
- NSF $61 million
- NIST $3.1 million

The DOD SBIR Program accounts for more than half of the government-wide SBIR Program funds. The Administration request for DOD science and technology funds in FY08 is $10.8 billion, down nearly 20 percent from the FY07 appropriation of $13.3 billion, and more than offsetting the request for increased R&D funding for the ACI agencies.

Looking at the broader DOD RTD&DE budget outlays, these are reduced from $75.5 billion in 2007 to $72.9 billion in 2008 in the Administration's budget.

NIH accounts for about another one-third of all SBIR funds, and that funding appears to be flat or increasing more slowly than inflation for the foreseeable future. This year's NIH request, for example, is 1.1 percent below last year's actual.

Such decreases will likely exceed by a wide margin any R&D funding increases in the much smaller NSF, DOE, and NIST R&D budgets, and therefore the SBIR Programs that are based on them.

Comparing the actual number of SBIR awards made in FY05 (the last year for which such data is relatively complete):

- DOD made 3082 awards,
- NIH made 1160,
- DOE made 427,
- NSF made 252 and
- NIST made just 23.

Clearly, with DOD declining and NIH flat, the other three agencies would have to make up an enormous amount of ground to grow the entire SBIR Program.

Will they? Looking beyond the current Administration's FY08 budget submission next January, (and the budget that it submits during its waning hours in January 2009), there is no solid indication of where federal R&D funding is actually headed. A new Administration and a new Congress in January 2009 will certainly have their own set of priorities, not only for R&D in general, but also for the types of R&D to be funded.

SBTC's recommendation for a gradual, phased increase in the proportion of R&D dollars allocated to the SBIR Program is based on three major factors.

- First, award sizes need to be increased to account for inflation and other cost factors since the award sizes were last set in 1992. A permanent inflation-adjustment mechanism needs to be set in place. But doing this will shrink the overall reach of the Program—its numbers of awards, its technologies accessed, and its awardees—unless the Program itself grows.
- Second, agencies need to be incentivized to make SBIR Phase III much more of a reality.
- And third, some new funds need to be allocated to the administrative and management expenses associated with agency participation in the Program.

Along with that is the simple fact that SBIR works. With more of the Nation's science and engineering talent migrating into smaller companies, and with SBIR having a demonstrated record as the only successful method yet devised for providing these smaller companies with access to federal R&D contracts, it is hard to see how the Federal Government can continue meeting its R&D needs at a reasonable cost without a strengthened SBIR program.

Q2. If the set-aside is doubled, will this be at the expense of university research, cutting their research budgets? Please explain.

A2. If overall federal R&D funding increases under the ACI, as anticipated in the above question, then the dollars actually going to universities may well increase, even with a slightly larger SBIR Program allocation.

But the larger point is this: SBTC does not at all view university R&D and SBIR R&D as mutually exclusive. Rather, we see the two as mutually reinforcing. As we noted in our testimony, many, if not most, SBIR companies utilize university expertise. I myself have partnered with 14 universities in my SBIR work.

A recent study by the New England Innovation Alliance (NEIA) examined the university ties of 17 SBIR companies responding to a poll. These companies had a combined total of 175 subcontracts to 101 different universities, for an average of 10.3 subcontracts to universities per company. An average of about six universities were funded by each company.

Thus my companies CleveMed and Orbital Research, which have contracted with 14 universities (or an average of seven per company) fall close to the norm of the NEIA study.

The NEIA study also found that the companies it examined provided a total of $28,124,005 subcontracting dollars to universities. These university subcontracts involved 243 faculty members and grad students.

As my own experience and the data from the study show, the SBIR Program helps universities attract and retain talented science and technology faculty by linking those faculty members to remunerative outside commercial projects. Faculty members contracting individually with the companies in the NEIA study received an additional $3,108,700 directly in funding.

Moreover, within just these 17 SBIR companies that NEIA polled:

- nine firm founders were university faculty members
- 49 firm executives held academic positions
- 45 firm employees or consultants held faculty positions
- 33 firm employees came from science and technology graduate school programs, and
- 25 firm employees were currently adjunct professors at universities

Not only do these SBIR firms offer R&D employment and contracting opportunities to universities and faculty members, they also provide a significant spur for researchers to focus their efforts on innovations that will aid the universities financially and have a positive economic impact on the locality, the region and even the Nation, particularly by creating new jobs, a key goal of the SBIR Program.

In general, SBIR projects can help universities commercialize research by identifying ongoing R&D with potential downstream commercial applications, leading to new revenue streams to the universities through sales and licensing.

For their part, universities are increasingly active in creating spin-off companies, especially in economically distressed areas. For example, in Cleveland, The Cleveland Clinic is looked upon as an engine of economic growth, and the SBIR program is an integral part of the Clinic's strategy. If a slightly larger SBIR Program were to translate into a small incremental decrease of a few percentage points in basic research dollars available to research institutions like The Cleveland Clinic, that decrease could be more than offset by gains to the research institutions from royalties, sponsored research, and capital appreciation from equity they hold in these spin-offs—many of them SBIR Program awardees—not to mention the value to the Nation of the new jobs and products created by these companies. In the long run, such a strategy would help research institutions enhance their own assets and endowments, and become less dependent on the Federal Government for research funding.

And just as SBIR companies depend on the flow of new science and engineering graduates from the universities, so also the universities need to demonstrate the availability of attractive yet realistic job opportunities to appeal to students in the first place. For many prospective science and engineering students, the challenges and the relative freedom, as well as the upside income potential, of working in a leading-edge small company, will be exactly what they are looking for. SBIR companies offer students not only vivid examples of future employment, but practical and near-term internship opportunities to experience first-hand the world of innovative, small company R&D. My own company offers about a dozen college internships a year, for example.

Because SBTC sees this university-small company relationship as so symbiotic, we have asked Congress to phase in a tripling of the STTR Program, which directly links universities and small companies in federally-funded R&D.

Q3. You recommend increasing award size but firmly limit the ability of agencies to exceed SBIR award caps. Would this strict cap have a negative impact on any agencies funding projects which contribute to their overall mission? Please explain your reply and identify what should be the source of funds if review panels determine additional funds are needed to appropriately fund SIBR projects.

A3. With respect to the award size caps, SBTC generally endorses the formula approved by the Senate Small Business and Entrepreneurship Committee last year. That formula would set the caps at $150,000 for Phase I and $1,250,000 for Phase II, and would allow for annual inflation adjustments The Senate bill also would permit agencies to exceed these caps by 50 percent in selected instances. Thus, the initial Phase I "override" would be $225,000; the Phase II, $1,875,000.

Congress does have a "balancing act" to deal with on this issue.

Relatively small caps permit the agencies to explore innovative ideas without creating major economic fallout if the innovations don't pan out.

Then, too, the purpose of the SBIR Program since its inception has been to harvest as much of the small company R&D relevant to the Federal Government's needs as possible. Historically, these companies and their technologies have been largely precluded from the federal R&D contracting process. Keeping the award sizes small helps promote a broad search for promising innovations and promising companies.

These basic thrusts need to be maintained. Agencies do, after all, have other sources of funds to expand the funding for exceptionally meritorious individual projects.

Still, the SBIR Program also needs to be flexible. Perhaps, instead of using the 50 percent override mechanism favored by the Senate bill, Congress could authorize

participating agencies to allocate as much as 10–15 percent of their overall SBIR funds to individual projects that hold unusual promise for helping an agency meet its mission.

But we must be realistic about how much additional technological advance the agencies can achieve by shifting these limited SBIR funds. For example, the entire annual SBIR budget at NIH would not suffice to put a single new drug through human testing. The October 2006 Milken Institute study that we have provided to the Subcommittee, Financial Innovations for Accelerating Medical Solutions, notes the scale of funding needed and suggests a number of (non-SBIR) financing solutions to meet such biomedical needs.

Q4. In your testimony, you support addressing commercialization funding gaps and comment favorably on several agency efforts. Based upon the experience of SBTC member companies, which programs are most promising?

A4. From what SBTC has observed and learned from federal agencies and SBIR companies, the most promising commercialization activities currently underway in the SBIR Program are the "II–B" awards in the Navy submarine program, NSF's "Phase II–B," and NIH's "Phase II continuation" awards. While the details of these programs differ to suit different agency needs, all appear to be working. The Commercialization Pilot Program (CPP), approved by Congress last year, is showing great promise at DOD, but initial results are a year or so away.

The term "commercialization" is a relative one, however. For agencies like DOD, and to a significant extent NASA and DOE, commercialization entails insertion of the technology into larger systems that the agency itself is acquiring. Such agencies need to be incentivized to do exactly this, since they are, in effect, the customers for the technology.

For agencies that expect the private sector to develop and acquire the technology, such as NIH and NSF, commercialization entails incentives to bring partners into the development and marketing phases of the technology. As NSF and NIH have shown, there is more than one way to do this successfully. SBTC believes the SBIR reauthorization should state what Congress expects from the agencies regarding commercialization, but should give them the flexibility to address that goal in their own ways.

It should be noted that when SBIR was created in 1982, Congress foresaw the need to include customer acceptance testing in the SBIR program. Section 9 (e) (4) of the statute defines "research and development" to include "(B) a systematic study directed specifically toward applying new knowledge **to meet a recognized need;** or (C) a systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development and improvement of prototypes and new processes **to meet specific requirements."**

Q5. You recommend Congress provide incentives to agencies to match the success in SBIR Phase I and II in SBIR Phase III. What incentives specifically do you recommend? What should be included in the expenditures you recommend for testing and evaluation? How should this be funded?

A5. To advance Phase III of the SBIR Program, SBTC recommends that Congress devote about one-third of the phased increase in SBIR (that we have requested) to Phase III incentives. These incentives should include funds for testing and evaluation, as well as the movement of SBIR technologies into the acquisition processes of agencies like DOD, NASA and DOE, (as discussed above in answer 4).

In the case of DOD, most Phase II SBIR technologies exit the SBIR Program at "Technology Readiness Level 4" (TRL 4). This technology will need to be advanced to about Technology Readiness Level 8 (TRL 8) in order to be inserted into mainstream DOD acquisition programs.

Agencies like DOD—that have an unfortunate history of paying large contractors to reinvent SBIR technologies—should be incentivized to purchase the original SBIR technologies instead.

As an example, one approach at DOD might be to offer an award fee to prime contractors on programs over $100,000,000 that insert the SBIR technology into major systems or that provide subcontracts to SBIR companies equal to or greater than a set percentage of the prime contract. For NASA, DOE and DOT, a similar award fee could be provided for prime contractors on programs over $10,000,000 if they meet similar conditions.

Agencies that don't purchase technologies, or that don't purchase many technologies, should be incentivized to identify successful commercialization paths and strengthen them. But to reiterate the earlier point, SBTC urges Congress to set the goals in this area while leaving it up to the agencies to invent the best approaches to meeting the goals.

Q6. You recommend re-allocating one percent of SBIR total dollars to new agency administrative costs? What administrative costs should be included? What do you estimate to be the cost for each of these activities?

A6. SBTC recommends that Congress allot one percent of total new SBIR dollars to new administrative costs. We believe the agencies should have some flexibility in allocating these funds. Salaries and expenses of new personnel devoted exclusively to the SBIR Program will absorb some of the dollars; new conferences and manuals might absorb others. COTR's could be given funding for site visits and coordination. The agencies should be required to report to Congress regularly on how they are using the new dollars. For its part, Congress should monitor these reports carefully, to be sure that the new funds are not being used to displace existing SBIR administrative and management funds, and are not being diluted by allocations to personnel and programs that have other tasks besides SBIR.

To the largest extent practical, training and mentoring funds should be made available directly to the SBIR companies. Within certain guidelines, these companies should decide on their own best use of the funds. The same is true of the content of the training. Agencies cannot always know what a company's competencies and needs are. Companies should be able to choose training options.

Q7. You noted in your testimony the importance of effective management and oversight of SBIR/STTR programs. How well has SBA done to date in providing management and oversight? What needs to be done to strengthen the SBA Office of Technology?

A7. With respect to SBA, SBTC would note that while the SBIR Program has quadrupled over the past twenty years, SBA's staffing resources for administering it have declined by 50 percent. This has led to problems like slower turnaround times on agency waiver decisions, slower posting of SBIR award information and statistics on the SBA website, and less oversight and coordination with the agencies. With more personnel, SBA's Office of Technology could provide more timely and helpful guidance for participating agencies in the SBIR Program, as well as more targeted oversight data for Congress. It will also allow the SBA to coordinate "best practices" sharing and training among the agencies. Congress also should consider elevating the Office of Technology within SBA to signal the importance of its mission.

Q8. In your written testimony, you identify an issue with intellectual property rights of SBIR companies. Would you please explain the issue and the remedy you recommend?

A8. The intellectual property rights case that SBTC referenced in its testimony is Night Vision v. U.S., relating to the use of an SBIR company's proprietary technology by the Air Force. The plaintiffs allege that the Air Force "reverse engineered" their technology and then gave the resulting intellectual property to another contractor to further advance the technology. Whatever the merits of the allegation, it would appear that the Court misinterpreted Congressional intent with respect to IP rights in the SBIR Program (and predecessor legislation like the Bayh-Dole Act), thereby setting an unfortunate precedent. For a strong SBIR program and a strong American technology-based economy, it is imperative that the IP rights of SBIR technology remain with the small business, and not be usurped by the government. This will allow the SBIR companies to grow the technologies that they created. SBTC intends to work with Congress to clarify these points for the courts going forward.

Q9. You state in your written testimony that 250 SBTC firms have won SBIR awards. Which agencies are the primary sources of award funds to SBTC firms? What percentage received awards from DOD and NIH? What percentage of the 250 SBTC companies has commercialized products?

A9. SBTC's members who have obtained SBIR contract awards are distributed across federal agency SBIR Programs in roughly the same proportions as the relative sizes of Programs. For example, DOD, which accounts for a bit over half of the SBIR Program dollars, also accounts for about half of SBTC's SBIR awardee members. NIH, which represents about a third of the SBIR Program, also represents about a third of SBTC's SBIR members. And so on. As to commercialization, the last time we sampled SBTC members on this question, the results were distributed in a "bell shaped curve," with most SBIR awardees having commercialization scores of around 50 percent.

Questions submitted by Representative Judy Biggert

Q1. Your written testimony states that, "Thanks to their deep-pocket backing, the companies that the VCs fund will be able to submit multiple proposals per solicitation." Given your concern about the number of proposals submitted and potentially the number of SBIR awards granted to a particular company, do you think it would be reasonable to limit the number of grants any one company can receive in a year or over 10 years across all agencies?

A1. The question as formulated equates two very different issues. The first issue is how Congress should respond to the prospect of large companies devising strategies to siphon off funds that are legally restricted to small business. The second issue is what steps, if any, Congress or an agency might take to limit the number of SBIR contracts awarded to individual small companies.

The essence of the first issue is preventing potentially illegal activity and upholding the integrity of a program that Congress and the American people expect to be dedicated to small business.

The essence of the second issue is selecting the most effective policies within a small business program.

As far as having large companies illegally undermine this or any other small business program, SBTC is opposed to it. As far as the policy choice of whether to limit the number of SBIR contract awards that an individual company may obtain, SBTC understands both sides of the issue, but believes, on balance, this would not be desirable—just as it would not be desirable to limit the number of R&D awards to major universities or large businesses.

SBIR is a highly competitive program. Usually, there are between four and thirty proposals for every award. The proportion of applicant companies obtaining contract awards varies between agencies, from about one in five applicants to about one in 12.

By contrast, this intensity of competition is hardly ever seen in larger federal contracts. Except in rare circumstances, neither the agencies nor Congress question the awarding of multiple, *non-competitive* R&D contracts to large companies and major universities.

Thus, SBIR companies must struggle much harder *against competitors* to prove the value of an innovation than do most of their larger counterparts, such as major "defense contractors" (whose very name suggests their focus on repetitive DOD contracts) or major universities seeking large research grants from NIH.

SBTC supports the overall SBIR goal of securing the widest possible array of needed R&D from small business. But we also believe that it makes little sense for federal agencies to bypass the *best* technologies to emerge from these crucibles of SBIR competition—and select the *second or third best* solutions to the government's needs—simply to prevent a small business from obtaining one too many SBIR contracts.

Given the SBIR Program's increasing emphasis on commercialization, SBIR awardees also represent a significant public benefit. This benefit takes on added importance in an environment of global competitive challenges, many of them technological, faced by the United States. It would be most unfortunate to undermine these benefits of the SBIR Program.

It is the companies who have won a number of SBIR contracts—most of whom have relatively high commercialization scores—that are more likely to be commercializing the technology—domestically and globally.

Two examples from my companies: Cleveland Medical Devices is beginning to penetrate Asian markets. We are now receiving orders from Malaysia, Singapore, India, and the Philippines for our sleep apnea diagnostic devices.

Orbital Research is developing a third generation of flight control, which we call Aerionics. We recently received third party confirmation of interest from South Korea, where the technology would be used on a missile defense system. The South Koreans say that they believe Orbital Research is the "leading company in the world" in this new technology.

Why would we cut off promising research like this to hold small companies to a set number of awards? We don't do that with defense contractors or leading universities. Why would we declare the most promising new companies as *personas non-grata,* just when they are starting to deliver on the whole long-term promise of the SBIR Program? That would surely tempt some such companies—that U.S. taxpayers have invested in—to relocate in countries like Singapore that invest much more heavily in new technology than the U.S. does, on a *per capita* basis.

Q2. Your companies have successfully participated in the SBIR program. Prior to 2003, did you encounter problems participating in the SBIR program? What is

the number of SBIR awards that companies that you lead received prior to 2003 and have received since 2003?

A2. As my companies became more technologically mature and more acquainted with the SBIR Program, their performance improved. This has nothing to do with date of 2003 or any other particular year. It has everything to do with the companies' internal trajectories of technological and business development. But to answer the question, prior to the date of 2003, Cleveland Medical Devices won 36 Phase I and 21 Phase II awards, an average of about five per year. Orbital Research won 31 Phase I and 14 Phase II awards, also an average of about five per year. From 2003 to the present, CleveMed won 22 Phase I awards and 17 Phase II awards, an average of about eight a year, and Orbital won 23 Phase I awards and 10 Phase II awards, an average of about six per year. There has never been a "spike" in the number of our awards. They increased incrementally. So, too, did the college interns that we trained, the work with our university partners, (now numbering 14), as well as the jobs and inward investment that we provided in inner city Cleveland—together with the awards that the companies won from Harvard University, *Inc* magazine, and others for these accomplishments.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Gerard J. McGarrity, Executive Vice President of Scientific and Clinical Affairs, VIRxSYS Corporation

Questions submitted by Chairman David Wu

Q1. What changes to the SBIR program do you recommend to increase the number of small businesses applying for awards in the life sciences? In your response, please estimate the typical dollar cost to a firm to prepare an application in Phase I and Phase II, and the size of Phase I and Phase II awards that would attract more SBIR applicants in the life sciences. What types of flexibility in the application process are important to applicants?

A1. The primary reason small biotechnology companies are not taking advantage of the SBIR program is that many of the companies are ineligible for the program based upon their capital structure. As a result of a 2003 Administrative Law Judge (ALJ) ruling companies with majority-venture capital backing are ineligible to compete for SBIR grants. Small biotechnology companies do not have product revenue, so companies have to raise funds through venture capital in exchange for equity in the company. As a result of these capital needs, a significant portion of biotechnology companies are ineligible to compete under the 2003 ALJ ruling, and subsequent change in SBA policy. Biotechnology companies will apply for these grants if Congress clarifies that those domestic companies with fewer than 500 employees can compete for these grants. A recent survey of 144 small emerging biotechnology companies' CEOs and CFOs found that 84 percent of companies would apply for an SBIR grant if they were eligible despite their capital structure.[1]

While the cost of the application will likely vary depending on the companies experience with writing grant applications, in my experience with the SBIR program it takes approximately two months of staff time for two senior staff to apply for a Phase I SBIR grant, costing in the range of $20,000–$30,000. To apply for a Phase II SBIR grant usually requires 3–4 staff and four months time, costing approximately $80,000-100,000. These estimates are based on experience with one company.

The broad scope of the SBIR program requires that maximum flexibility is maintained so that grants can serve a variety of agency missions. Likewise, differences in product development timelines require agency flexibility so that SBIR grants are meaningful across industries. For example, in the biotechnology industry it takes eight to 10 years or more to bring a product to market.[2] Such flexibility should include award size and the ability to directly obtain a Phase II grant where the science merits such flexibility.

Q2. Please explain your views on how the NIH peer review groups accesses whether a project is adequately funded.

A2. The peer review process is the only appropriate mechanism for making factual funding determinations. While it is not a perfect system, and in some circumstances errors may occur, it is a system in which a group of scientific experts evaluate the appropriateness of the budget. When I was in academia, I served on an NIH Study Section for several years. I have also been a grant reviewer for the NIH since I have been in industry. I have always been impressed with the enthusiasm and the competence of the reviewers.

It is reasonable to allow or even encourage agencies to establish suggested guidelines for determining the budget for an award, but ultimately strict rules and limitations are arbitrary and will minimize the ability to get the most of the SBIR awards. This may be an appropriate area for the agency or department in question to determine how often budgets are accepted as submitted and how often they are adjusted upwards or downwards. Typically, the budget is adjusted downward, because the reviewers do not see the justification for certain requested items. On the other hand, the first SBIR grant that my former company Intronn received, the reviewers actually increased the requested budget because they were impressed with the potential of the technology.

Q3. You have described the importance of venture capital in meeting the capital needs of biotechnology companies because of the high cost and length of product

[1] Survey of 144 BIO emerging member companies CEOs and CFOs. Conducted by third-party during March, 2006.

[2] Tufts Center for the Study of Drug Development. *http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69*

development. If a venture capital firm has already invested in an SBIR award recipient, how could the SBIR program be structured to encourage the venture capital company to provide additional investment and commercialization assistance for the SBIR project beyond that offered by the SBIR award itself?

A3. Typically, biotechnology companies will receive venture capital financing for a lead product and would like to obtain SBIR funding for early stage products that may be viewed as too high risk for venture capital investment. SBIR grants provide an opportunity for companies to start or restart research on a product that may be sitting on the shelf due to lack of funding. SBIR funds will therefore provide an opportunity to further along development of this project, through proof of concept and feasibility. This furtherance of development alone makes the research more attractive to venture capitalists. Additionally, there is strong evidence that the SBIR program creates a "halo effect" that attracts private investment because the research has received a certification of sorts from the granting agency.[3] While venture capital investment in biotechnology companies remains strong, the majority of the investment occurs in later stage companies or projects, especially those that are in Phase II clinical trials. It is much harder to attract investments in pre-clinical projects.

In addition to the inherent benefits of the SBIR program with regard to attracting additional investment, Congress should provide additional flexibility to agencies to implement demonstration projects in Phase III. For example, an agency could provide matching funds, up to specified dollar amount, in Phase III to companies that receive private sector investment for the SBIR project within a specified amount of time upon completing Phase II grants. Any such demonstration projects could be shared with all the agencies and departments participating in the SBIR program, so best practices can be identified. However, given the breadth of agencies, departments, and participating industries demonstration may not be appropriate for all facets of the SBIR program.

Finally, given that the SBIR program rightly invests in high-risk research, it is appropriate that some of the funded research will not produce the intended outcomes and attract private sector investment. This is similar to the research funding that the NIH provides to the academic community. It is important to also be mindful that the focus on commercialization should not drive the granting agencies and departments to award grants to projects that are "safe." Doing so would undermine one of the unique contributions that the SBIR program makes to greater knowledge and the economy.

Q4. SBIR awards are granted in support of agency missions—in the case of NIH, to make medical discoveries that improve health and save lives. If the market opportunity for an SBIR project is small, what would encourage venture capital company financial support and commercialization assistance for the SBIR project over time?

A4. There are a variety of factors that venture capitalists consider when determining whether or not to invest in research, including, but not limited to, the quality of the science, stage of development, intellectual property protections, market size, existence of similar or competing products, quality of management team, quality of scientific expertise, and possible insurance coverage and reimbursement policy. Likewise, a company with a platform technology will conduct a similar assessment in determining which therapeutic areas to focus development of a product. Not all these factors are given equal weight, and strength in one particular area may overcome weaknesses in another area. Venture capital companies review the opportunity in its totality. Additionally, venture capital companies' estimation of opportunity of particular research will not be unanimous.

It is the case that many biotechnology products in development are for non-traditional markets, such as for orphan diseases or for diseases predominately found in the third world. The barriers to bringing orphan drugs to market have been well recognized by Congress and are the basis for the Orphan Drug Act of 1983. This law aims to provide incentives through market exclusivity and tax credits for private sector investment in orphan products. In 2001, the Department of Health and Human Services Office of Inspector General studied the impact of the Orphan Drug Act and found that it was particularly successful in attracting venture capital financing for orphan products being developed by biotechnology companies.[4] A BIO

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[3] Charles W. Wessner, National Research Council, "SBIR Program Diversity and Assessment Challenges, Report of a Symposium," pg. 27.

[4] Department of Health and Human Services, Office of Inspector General, "The Orphan Drug Act, Implementation and Impact" May, 2001, pg. 8, *http://oig.hhs.gov/oei/reports/oei-09-00-00380.pdf*

survey found that 80 percent of private biotechnology companies pursuing an orphan product have also received venture capital.[5]

Despite the fact that orphan products often successfully attract venture capital financing, it continues to be an area with additional challenges. This is also true for biotechnology products being developed to treat illness predominately affecting the third world. Foundations have been particularly effective in supplementing funding for orphan products and third world diseases. For example, the Cystic Fibrosis Foundation has invested or committed $290 million to early stage development work since 1998.[6] Similarly, the Bill & Melinda Gates Foundation is supporting research and development in the private sector for therapies and vaccines for Malaria, Tuberculosis, and diarrhea, amongst other diseases.[7] These foundations can help fill gaps that exist in traditional venture capital financing.

As a part of Phase III SBIR commercialization, the NIH could facilitate connecting companies that are pursuing research in orphan diseases or diseases impacting the third world with the appropriate foundations that are making venture capital investments in these areas.

Q5. What criteria do venture capital companies use when making a decision to invest in a company and a specific project? If a company has venture capital funding and a company project receives an SBIR award, but the project does not meet venture capital criteria for investment upon completion of Phase II, how will that project be managed? For such an SBIR project, what are the possible options and issues in spinning out that project to another company?

A5. As previously stated, there a variety of factors that venture capitalists consider when determining whether or not to invest in research, including, but not limited to, the quality of the science, stage of development, intellectual property protections, market size, existence of similar or competing products, quality of management team, quality of scientific expertise, and possible insurance coverage and reimbursement policy. Not all these factors are given equal weight, and strength in one particular area may overcome weaknesses in another area. Venture capital companies review the opportunity in its totality. Additionally, venture capital companies' estimation of opportunity of particular research will not be unanimous.

For example, the May 22, 2006 Bioentrepreneur article, *Trendspotting: Betting strong but playing safe,* found "Venture capital investors also appear to be investing more effort in ensuring that the clinical development program described in a potential portfolio company's business plan makes sense and is realistic. Because setting the wrong goals in the program or getting the timing wrong by just a little bit can have disastrous consequences in subsequent fund-raisings, VCs are engaging medical consultants as clinical advisory panels to validate and modify the programs as a prelude to making their investments. The panels are asked to determine, among other things, whether the investors are funding to the appropriate endpoints based on the correct assumptions."

A biotechnology company's subsequent management of a project that has not been successful in attracting venture capital will likely depend on the reason for its failure to attract investment. If the project is failing to get additional financing because research into the proposed biologic mechanism failed to produce expected results, then the project may no longer be pursued or require a reworking and return to proof of concept stage. Alternatively, if the lack of investment is being driven by concerns about the company's management or research team, then a company has the opportunity to bring in additional personnel resources, consultants, or enter into a joint venture to address the concern.

Alternatively, if the reason that venture capital firms are not interested in a project is due to the small market size, SBIR grants can serve as a critical resource in driving the project forward. As described above, SBIR awards can be combined with Foundations and private philanthropy to bring a therapeutic solution to a commercially unattractive disease.

It is in a biotechnology company's interest to pursue as many potential therapies as is possible because it diversifies the risk in a scientific area with a high failure rate. As such, a biotechnology company is likely try to address the concerns being raised by venture capital companies if it is possible and reasonable to do so. Outside of these efforts, other options that exist include the before-described opportunities

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[5] Survey of 144 BIO emerging member companies CEOs and CFOs. Conducted by third-party during March, 2006.

[6] *San Francisco Business Times,* "Foundations move in where VCs fear to tread," December 8, 2006, Sara Duxbury (article attached).

[7] *http://www.gatesfoundation.org/GlobalHealth/Pri_Diseases/*

with foundations and possibly licensing the technology to a company that has complementary technology or expertise in this area in order to further the research.

Q6. What definition do you recommend for an eligible venture capital company when determining eligibility of an SBIR applicant? What would this definition include what would it exclude?

A6. Allowing small (fewer than 500 employees) domestic companies the opportunity to compete for SBIR grants is important to the SBIR program and the industries or companies that are currently excluded based upon their capital structure. Small domestic companies with private investment from eligible venture capital companies, foundations, and trusts should be eligible to apply for SBIR grants. Currently, a company with any of above mix of investment that exceeds 51 percent ownership is precluded.

As it relates to determining an eligible venture capital company, there are existing references in current law, listed below, that should encompass US venture capital companies. Additionally, BIO supports *excluding* venture capital companies established by large corporations from the definition of an eligible venture capital company for the purposes of SBIR.

(1) Venture Capitol Operating Companies

These are VCs defined in a Labor Dept. regulation, 29 CFR 2510.3–101(d), whose managers have some "management rights" with respect to the portfolio companies in which they invest, and exercise such rights in at least one such portfolio company. Such management rights are not inconsistent with minority VCOC ownership positions. For example, having a single Board seat constitutes a "management right," even though it affords no VC control over management and operations of the small business.

(2) VC firms registered under the 1940 Investment Company Act

Most VCs with greater than 100 employees are required to register with Securities and Exchange Commission (SEC) under the 1940 *Investment Company Act.*

(3) VC firms not required to register with SEC, because they fall within a 1940 Act exception for firms with <100 investors

This covers most smaller VCs—including most VCs that invest in small, emerging companies—who tend to have fewer than 100 employees.

Q7. In your written testimony you cite 252 FDA approved biologics developed by BIO companies, and 32 percent of the companies and affiliates received an SBIR/STTR award. What percentage of the companies and affiliates that received SBIR/STTR awards also received venture capital backing?

A7. 162 companies were involved in the development of the 252 FDA approved biologics. Of those, 52 were past SBIR or STTR award recipients. Of those 52 companies 39 or 75 percent definitively received venture capture capital financing prior to becoming a public company. For the other 13 companies BIO was unable to determine if they received venture capital financing, either because the company has merged or changed ownership a number of times, or because existing databases on private companies were not in existence prior to the company going public. However, it would be unusual that a biotechnology company would secure sufficient investment from individuals alone prior to becoming public.

Questions submitted by Representative Judy Biggert

Q1. Can you illustrate for me why a health sciences company with venture capital financing, even significant financing, would desire to participate in the SBIR program, where the award sizes are significantly smaller than a round of venture financing?

A1. A biotechnology company is a collection of research projects. A recent BIO survey found that on average an emerging biotechnology company has five products in development. The typical biotechnology company's lead product will be in Phase II clinical trials, with one product in Phase I clinical trials, and three products in preclinical development. A biotechnology company will most likely be able to raise venture capital for their lead product and maybe the product in Phase I clinical trials as well.

These venture capital funds are generally not interchangeable; but instead funds are tied to specific development milestones for a specific product. Most often companies are unable to use venture capital funds for a lead product to conduct pre-clin-

ical research and development. However, SBIR grants provide an ideal opportunity to further very-early stage development without diluting a company's equity. Through Phase I and Phase II awards the research project can be furthered to the point where it is considered attractive to venture capital investment.

Q2. What role have SBIR grants historically played in your industry?

A2. For the first twenty years of the SBIR program biotechnology companies were able to compete for SBIR grants. In biotechnology, the SBIR program has played a role in advancing the science and research of companies that have ultimately brought a product to market. For example, there are 163 companies and affiliates involved in the development of the 252 FDA approved biologics, 32 percent of those companies and affiliates have received at least one SBIR/STTR award. Additionally, the Small Business Technology Council's written testimony before the Subcommittee highlighted 13 outstanding SBIR graduates of which were four biotechnology companies (Amgen, Biogen, Genzyme, and Chiron).

This record clearly shows that the original SBIR system was working. Biotechnology companies with highly innovative technologies and program were able to compete for limited funds and bring many of these breakthrough products to successful treatments of patients who had no alternatives.

San Francisco Business Times - December 11, 2006
http://sanfrancisco.bizjournals.com/sanfrancisco/stories/2006/12/11/focus2.html

SAN FRANCISCO Business Times

BUSINESS PULSE SURVEY: Gas prices outta whack

Foundations move in where VCs fear to tread

Cutting-edge research gets some help

San Francisco Business Times - December 8, 2006 by Sarah Duxbury

Nonprofits are taking the role of venture capitalists in funding early stage biomedical research.

Spencer Brown
David Brown, head of drug discovery at OneWorld Health.
View Larger

Pursuing their social missions to find cures, foundations that support disease research -- particularly of rare, so-called orphan diseases that afflict fewer than 200,000 Americans -- are increasingly funding translational medicine, bringing science from the ivory tower to patients.

Venture capital firms once did this work, identifying promising therapies and building relationships to speed them to market in search of profits. As VCs have grown chary of big risks, nonprofits have taken the venture role upon themselves, recasting their work as biomedical venture philanthropy.

Using a venture model to fund a nonprofit mission is a popular trend more readily identified with the social services sector. What is new with biomedical venture philanthropy is that nonprofits are funding industry and drug discovery, carving a niche for foundations in the biomedical field. Local giants like Genentech and Gilead expect to benefit.

Foundations drive

"You almost have to be at Phase II clinical trials before venture capital is willing to come in on some of these drug developments," said Robert Beall, president of the Cystic Fibrosis Foundation in Bethesda, Md., which has invested or committed $290 million to early stage development work since 1998.

That is even more true for orphan diseases like cystic fibrosis and multiple myeloma, whose small patient populations mean it doesn't make good business sense for big pharma to invest heavily in finding a cure. That prompted foundations to assume the early risk to get pre-clinical trials done.

Beall said his foundation will take promising early stage discovery technology and fund biotech companies to test a therapy, even if there's no hard science yet linking it to cystic fibrosis.

For example, one company had a product that worked for dry eye, a symptom associated with cystic fibrosis. The foundation gave $2 million to test the drug on cystic fibrosis patients, and it is now in Phase III clinical trials. Over 30 cystic fibrosis treatments are in a pipeline that was once empty; almost all bear the Cystic Fibrosis Foundation's financial imprint on some stage of their development, Beall said.

Showing the way

Such successes can attract industry money and attention, once a nonprofit has funded a treatment's proof of concept.

That's what happened with Accelerate Brain Cancer Cure, or ABC2, which was founded by brothers Dan and Steve Case, and last year moved from Burlingame to Washington, D.C. When San Francisco business leader Dan Case was diagnosed with brain cancer in 2001 (he died in 2002), there were 10 to 15 clinical trials of treatments for Glioblastoma multiforme, or GBM, a particularly virulent brain cancer, each year. Last year, there were 80 new trials, thanks in part to ABC2.

At its start, ABC2 selected 100 therapies it thought would be most promising when applied to GBM and tested them at Duke University. Over one-third of those therapies extended lives of afflicted animals. ABC2 took those results, which it underwrote, to biotech companies and helped them identify a group for clinical trials.

In addition to being committed to finding a cure, nonprofits know the players, both researchers and patients, in a disease field better than the business folk. VCs recognize the value of working with such nonprofits, allowing them to assume much of the early risk.

"It makes sense from a venture capitalist perspective, because it's non-dilutive financing," said Andy Schwab, a partner at Menlo Park's 5AM Ventures, which invests in early stage biotech companies. "Also, these philanthropic organizations have a lot of pull, a lot of resources, and if they put their momentum behind a product they think is interesting in their communities, it's a positive."

That suits the nonprofits, too, since their mission is to further the research. To date, few if any have taken an equity stake in companies they've funded or taken a place on a company's board of directors. They are not in it for the money, but they are happy to sweeten the market for those who are, provided it serves their missions.

"We recognized that if we could help the biotech industry know what our top targets were in

myeloma and our best guess to identify those top targets, we could seek out their support or their interest," said Kathy Giusti, founder of the Connecticut-based Multiple Myeloma Research Foundation.

Venture capitalists are looking for just that kind of quantitative and qualitative support.

"They're blessing your product, opening their network up to you and funding it," Schwab said. "What they're trying to get out of it is funding medicines for disease, so they're absolutely hitting their goals."

Multiple Myeloma Research Foundation has set aside $6 million that it will directly invest in biotechs whose early stage work looks useful to finding a cure for multiple myeloma, and who can't find funding from traditional sources. The foundation has just made its first two lead grants to a company in Indiana and one in Israel, each for $1 million, provided the companies meet specific milestones.

Since it was founded in 1998, the foundation has raised almost $70 million and is funding 30 compounds at the pre-clinical stage. Its first clinical trial was with Chiron for a kinase inhibitor. Velcade, another drug it helped fund, is now available for patients.

The foundation also established a consortium in 2004 of the top 11 academic centers focusing on myeloma to get them working in concert to speed up clinical trials, much as a VC firm might. That consortium now does tissue banking, Phase I and Phase II trials and is working on mapping the multiple myeloma genome.

Turning heads

Venture capital has begun to follow what these foundations are doing, but that wasn't always the case the case. Beall said in 1996, the Cystic Fibrosis Foundation had success with an antibiotic it helped develop. Few companies were interested in it. Finally, it was sold to PathoGenesis, a biotech that Chiron purchased, which branded it Tobi. Today it is being used by 16,000 patients.

The foundation also gave $1.6 million to Corus Pharma, a Seattle biotech, to seed development of an antibiotic that can be used to treat cystic fibrosis.

"That gave it our Good Housekeeping seal of approval. It has subsequently raised nearly $100 million from venture capital," Beall said. Gilead bought Corus Pharma for $365 million in August. The proposed drug is in Phase III trials and could come to market in 2008.

Though the Cystic Fibrosis Foundation is larger than many, it has set a compelling example that numerous other foundations are emulating.

"What's excited us is we're starting to see other diseases starting to develop this model and become very focused on the issue of pipeline," Beall said.

Recognizing a greater need to get early stage funding to companies developing new drugs, ABC2 spawned the Brain Trust Accelerator Fund. It is still raising its first round of funding, but when it starts investing next year, it will take a true venture role in funding early stage treatments for brain diseases, including brain cancer, said John Reher, its executive director.

Not tied to profit

Across the board, nonprofits are catalysts in drug development. "Philanthropy is playing an interesting role in drug development," said James Hickman, vice president for communications at the Institute for OneWorld Health. Because nonprofits' primary focus is social -- finding a cure for disease -- they are paradoxically free to use their funds to take risks and try existing therapies in new ways or underwrite early stage trials of promising compounds that scare venture capital firms.

But for some diseases, the translational medical work they do does not always turn into big business opportunities for biotechs and VCs.

Whereas medical foundations that serve orphan diseases are trying to make a compelling business case to attract for-profit investment in finding a cure, OneWorld Health knows that some diseases that affect millions will never receive the same sort of investment as a promising cystic fibrosis treatment.

Take, for example, diarrhea. An estimated 6 million children in the developing world die annually from diarrhea or related causes, but they couldn't pay for a treatment if one existed. OneWorld Health, a nonprofit biotech company in San Francisco, therefore raises money from other philanthropies -- think Gates Foundation -- and uses it to bring together partners to produce the medicines it intends to bring to the developing world.

It, too, acts in a way like a venture capitalist, but this time because the afflicted are too poor, despite their vast numbers, to tempt the business community.

OneWorld Health scored its first major victory earlier this year when it received approval from the Indian government for the use of Paromomycin, a drug to treat visceral leishmaniasis, the second most deadly parasitic disease in the world.

"Big pharma and large biotechs don't work in these areas -- even diarrhea none of the big companies is working on," said David Brown, head of drug discovery at OneWorld Health. But now that OneWorld Health has done the leg work on Paromomycin, big pharma is bidding on the opportunity to manufacture it, since even they are interested in the social return on being good corporate citizens.

"The philanthropic dollars from Gates and other foundations fund that part of the process that the

big pharmaceutical companies don't want to fund, essentially R&D," Brown said. "They're quite happy to help us downstream with manufacturing and even distribution" if OneWorld Health's research investment pays off.

In that sense, OneWorld Health is no different from the other nonprofits seeking a cure, and planning to engage big business downstream, when it is ready to wade into a given disease.

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ANSWERS TO POST-HEARING QUESTIONS

Responses by Anthony R. Ignagni, President and CEO, Synapse Biomedical, Inc.

Questions submitted by Chairman David Wu

Q1. What changes to the SBIR program do you recommend to increase the number of small businesses applying for awards in the life sciences? In your response, please estimate the typical dollar cost to a firm to prepare an application in Phase I and Phase II, and the size of Phase I and Phase II awards that would attract more SBIR applicants in the life sciences. What types of flexibility in the application process are important to applicants?

A1. One of the key elements in applying for awards in the SBIR program is the timing from initiation of a proposal to award then the timing from completion of the Phase I to Phase II. Upon recognition of a grant opportunity for a Phase I SBIR, the time required to formulate the hypothesis and consider alternatives, perform background and literature searches, develop the project plan, determine the budget, and develop an initial commercialization strategy takes (as suggested by NIH) at least three months to prepare properly. The effort during this time varies but can easily exceed a cumulative 80 man-hours of preparation, writing, and internal review prior to submission of the grant. If an academic or clinical institution is involved, then there are also significant contractual issues to be addressed up front that can add time and legal expense. Further, if regulatory submissions (either animal or human) are needed, then there is significant effort in obtaining the appropriate approvals prior to submission. When using an external agency to assist in compiling the grant, the preparation time is not significantly reduced as there is much interaction in translating the requirements, tasks and reviewing the output. Between the internal staff time and consultants (for grant writing, regulatory submissions, and legal contracts) the estimated costs for a Phase I grant surely can exceed $15,000. In a Phase I grant this is money that has a low percentage yield and is only potentially realized in 6–9 months after the grant is submitted. Alternative approaches may be to have an initial (faster) Phase I review that could provide feedback on the acceptability of the proposal prior to committing to regulatory and contractual arrangements. Another approach may be to combine Phase I & II approvals, such that when Phase I milestones are reached the grant continuation to Phase II is automatic. This would avoid funding gaps between grant phases and mean that the initial capital risk of developing the proposal has a larger payoff.

Q2. Please explain your views on how the NIH peer review groups assess whether a project is adequately funded?

A2. The only feedback we have on our prepared grant budgets to date has been "seems appropriate." As we have been working with the NIH on our budgets we have been encouraged, during early discussions, to budget what is appropriate with justification for the amount. This has allowed us to fund the scope of work adequately.

Q3. You have described the importance of venture capital in meeting the capital needs of biotechnology companies because of the high cost and length of product development. If a venture capital firm has already invested in an SBIR award recipient, how could the SBIR program be structured to encourage the venture capital company to provide additional investment and commercialization assistance for the SBIR project beyond that offered by the SBIR award itself?

A3. Additional award levels for matching venture funding toward commercialization of a grant project may attract additional investment. Thus an SBIR award to complete the technical/clinical aspects of the proposal could be made once a venture capital firm invests in the commercialization strategy. This would help mitigate the risk to the VC firm of technical risk and let their investment focus on the market and sustainability risk. Similar to having a academic/clinical collaborator sign on to assist in demonstration of certain technical or clinical aspects of the SBIR, the venture firm could be signed on to assist in funding the commercialization aspects of the SBIR.

Q4. SBIR awards are granted in support of agency missions—in the case of NIH, to make medical discoveries that improve health and save lives. If the market opportunity for an SBIR project is small, what would encourage venture capital company financial support and commercialization assistance for the SBIR project over time?

A4. I'm not sure that SBIR funding would necessarily help attract venture capital to a specific small market opportunity. If the Principal Investigator has a demonstrated track record of being able to attract SBIR support to multiple projects, has good peer review feedback (that may be separate from grant review), and can assemble the funded SBIR projects into a cohesive commercialization plan, there may be an opportunity of attracting venture financing. One key to this is developing relationships with the funding agency that can speak to the venture investor community to establish the worth of the discoveries and potential for commercialization.

Q5. What criteria do venture capital companies use when making a decision to invest in a company and a specific project? If a company has venture capital funding and a company project receives an SBIR award, but the project does not meet venture capital criteria for investment upon completion of Phase II, how will that project be managed? For such an SBIR project, what are the possible options and issues in spinning out that project to another company?

A5. Certainly the venture community is in the business of risking capital for a return to its investors. Given that the VC is investing in the performance of the company, its primary criteria is based on management's competency in adding value to the product portfolio to allow a return on money invested. If a project has a manageable technical risk, there is compelling clinical need, management has capabilities to achieve significant relevant milestones, and there is a clearly articulated strategy to achieve a return on investment for the VC, then there should be a clear decision to invest. If the SBIR program can provide quantification of technical risks, clinical need and demonstration of managements ability to achieve milestones, then it should positively influence investment decisions.

If a completed Phase II SBIR does not fit within the companies strategic vision or opportunity assessment, it should be determined if it is a marketable asset through licensing or outright sale. Certainly intellectual property rights and confidentiality may be at issue if a project is spun-out to another company. Of course this is a risk that has to be weighed against the potential gains from marketing the asset.

Q6. What definition do you recommend for an eligible venture capital company when determining eligibility of an SBIR applicant? What would this definition include; what would it exclude?

A6. As a small business program, I believe that the criteria should be employee size (as it is now) and the revenue/net profit size to qualify as a small business entity. The current small business definition based on size of 500 employees seems quite large. I would base the employee count strictly on full time equivalents (FTE's) on payroll. Further, once a company has reached a critical mass of revenue and bottomline net profit, it should be able to self-fund its research. It seems that once a reasonable amount of revenue is available to fund research, it should be used to do so. A benchmark of revenue generating public companies could be used perhaps to set this bar. Thus a company with revenues of $20–$50 million and 5–7 percent available for research investment could be considered as too mature for the SBIR program.

Beyond the size constraint, I would also include the ability of the company to demonstrate results of impact of past funded projects (that have been funded through Phase II) to have a revenue impact. Without this type of feedback into the system, it could be just funding good grant writers without achieving the desired results of making "medical discoveries that improve health and save lives."

Finally, I would redefine the term "individuals" to allow venture capital backed companies to participate in the program and redefine the affiliation rules for portfolio companies.

From my understanding, sound venture capital firms seek out the best technologies and management teams, which may be the same teams securing SBIR grants. The SBIR grant program is one of the key elements in creating a new company, especially in the life sciences sector. SBIR grants, coupled with venture capital, provide the critical working capital used by scientists and companies in the discovery of new technologies and new therapeutics. For the past 20 years, the dual financing sources of the SBIR program and the venture capital community have allowed many promising companies to conduct groundbreaking scientific research while simultaneously building viable businesses that bring innovative products to the marketplace.

Appendix 2:

Additional Material for the Record

STATEMENT OF MS. LINDA OLIVER
ACTING DIRECTOR
OFFICE OF SMALL BUSINESS PROGRAMS
OFFICE OF THE UNDER SECRETARY OF DEFENSE
(ACQUISITION, TECHNOLOGY & LOGISTICS)

Review of the Department of Defense (DOD) Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

Chairman Wu, Congressman Gingrey and Members of the Subcommittee on Technology and Innovation, House Committee on Science and Technology:

Thank you for the opportunity to submit a written statement about the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs as you consider reauthorization of the SBIR program in the year of its 25th anniversary. I welcome this opportunity because these programs have become important tools for the Department of Defense (DOD) to seed innovation in our industrial base, and, in so doing, develop firms to supply leading-edge technologies to meet warfighter needs today and in the future.

It is the fundamental mission of the Department of Defense to fight and win our nation's wars. In a time of war, the challenges are myriad, as we must sustain critical operations around the world while also preparing for the future—being ready to face the threats of tomorrow. Tasks of particular importance are the supply of materiel to the warfighter to defeat identified threats, and the exploration and development of technologies to enable new or lower cost capabilities. To these ends, the Department has established key goals to ensure we are investing in the right technologies, and cultivating an industrial base capable of meeting our strategic needs. The SBIR and STTR programs play roles in achieving both of these goals. Specifically, consistent with statute, this means to seed technologies through small firms which may eventually provide a materiel solution to our nation's warfighting soldiers, sailors, marines and airmen, either directly as a product or service, or as part of a larger weapon or support system.

It is our obligation as public officials to ensure that we are using taxpayer dollars as productively and efficiently as possible for their intended purpose. In that vein, today I will address the questions presented to me in your invitation and will also highlight actions the Department has undertaken to improve our Program. We at the Department are always ready to work with the Congressional oversight committees, other participating federal agencies and the Small Business Administration (SBA) to ensure that the SBIR and STTR programs are as effective as they can possibly be.

Program Overview

The DOD SBIR Program encompasses twelve constituent Military Department and Defense Agency programs. The participating elements of DOD, hereafter in this testimony referred to as "Components," include, in order of largest to smallest budget in fiscal year (FY) 2007 the: Air Force, Navy, Army, Missile Defense Agency (MDA), Defense Advanced Research Projects Agency (DARPA), Office of the Secretary of Defense[1] (OSD), Joint Office of Chemical and Biological Defense (CBD), U.S. Special Operations Command (SOCOM), Defense Threat Reduction Agency (DTRA), Defense Microelectronics Activity[2] (DMEA), Defense Logistics Agency (DLA) and National Geospatial-Intelligence Agency[3] (NGA). The Department's SBIR budget is determined by a statutory 2.5 percent assessment of its extramural[4] research, development, test and evaluation (RDT&E) budget. Each Component's portion of the overall program is managed to be responsive to its specific mission and

[1] The OSD Program includes funds drawn from the Defense Health Program (DHP) and is managed by the Office of the Deputy Under Secretary of Defense (Science & Technology) within the Office of the Director, Defense Research & Engineering.
[2] DMEA and DLA are new SBIR participants in FY07.
[3] NGA is a voluntary participant in SBIR.
[4] Extramural is defined as the sum of the total RDT&E obligations minus amounts obligated for such activities by employees of the participating agency in or through government-owned, government-operated facilities.

corresponding technology development needs while also being consistent with overarching Department science and technology guidance.

In terms of budget, the Department's Program represents over 50 percent of the total federal SBIR budget, which exceeds two billion dollars. The DOD SBIR Program has experienced substantial growth in recent years, more than doubling in size from FY 1999 to FY 2005 to over one billion dollars, and it continued to grow through FY 2007 to over $1.13 billion. This expansion is driven directly by growth in underlying RDT&E budget, as the set-aside percentage has remained constant over this period of time. In FY06, 883 topics attracted 13,253 Phase I proposals, a rate of 15 proposals per topic—about the average of the prior four years. The Department awarded 1,862 Phase I contracts and 1,172 Phase II contracts.

Which firms received these contract awards? The recipients are all types of technology-focused firms from across the country. To a great extent, these are very small firms. In FY 2006, 68 percent of Phase I contracts were awarded to firms with fewer than 25 employees, while over 42 percent were awarded to firms with fewer than 10 employees. This shows that, to a great extent, the Department taps entrepreneurial firms. Entrepreneurial firms tend to offer the most ground-breaking, potentially disruptive innovation—the type that fundamentally changes how a capability is provided. Also importantly, the DOD SBIR Program is an entry point for firms new to the defense business—those seeking to develop a military customer base. In FY 2006, 21 percent of SBIR Phase I award winners were first-time SBIR award recipients. And among the rest of the firms receiving Phase I awards in FY 2006, 44 percent had previously been awarded four or fewer Phase II contracts. Based again on FY 2006 data, 22 percent of Phase I award winners were minority- or women-owned firms, or from Historically Underutilized Business (HUB) Zones, indicating that a significant portion of resources is utilizing this segment of the business base, consistent with one of the primary goals of the SBIR program. Since the inception of the SBIR program in 1983, the Department has awarded nearly $11 billion to qualifying small firms through over 44,500 contracts.

Examining these statistics, it is clear that the DOD SBIR Program is a very large, resource intensive enterprise. The central challenge is to make the best possible small business technology investments for our warfighters with the resources the Congress provides us. That concludes a brief overview, focusing on the DOD SBIR Program. Let me now move on to address the specific questions posed in the invitation letter with these overview remarks serving as background for the discussion.

Program Efficiency and Effectiveness

The SBIR and STTR programs, due to the sheer volume of topics, proposals, and awards demand efficiency in execution. In the time since the SBIR program was last authorized in 2000, the Department has provided over $5 billion in extramural research and development funding to qualifying small businesses through over 17,000 Phase I and Phase II contracts. On average, the Department has consistently met the goals of awarding phase I contracts within four months of solicitation closing, and awarding phase II contracts within six months of the conclusion of the corresponding phase I contracts.

For administrative efficiency and to make it easier for small businesses to interact with the Department, all approved topics from participating components are packaged into one solicitation and pre-released to the public for a four-week period. During this period, interested firms may seek additional technical information from the technical points of contact, as necessary, to clarify the topics. The solicitation then opens for a four-week period during which proposals are received. Throughout the pre-release and solicitation periods, interested firms may ask questions about the topics of interest via the online SBIR/STTR Interactive Topic Information System (SITIS). After the solicitation closes, all proposals are reviewed by government scientific and technical personnel.

This process occurs three times per year for SBIR and once for the STTR program. SBIR Phase II proposals are submitted to the Department to meet deadlines established by participating DOD components. Topic generation and review, as well as solicitation pre-release, release and proposal submission are entirely electronic, conducted through the DOD SBIR Worldwide Web site (*www.dodsbir.net*). These electronic systems have helped enable the DOD SBIR and STTR programs to accommodate an increase in the number of solicitations conducted and proposals received while meeting time-to-award goals.

The high watermark for SBIR/STTR's effect success or effectiveness in the Department is bringing leading-edge technology solutions to the warfighter by leveraging the unique, entrepreneurial power of small businesses. Of course, the dictionary definition of efficiency is the ratio of the useful output (effect) of a program to the total input. We've discussed the inputs, or costs, elsewhere in this statement. Let's spend

a few moments on the outputs. Accurately quantifying the full impact of technology innovation is a challenge. We measure program output in the form of both documented success stories and commercialization data, using follow-on sales and investment as a proxy for value creation.

The Department collects commercialization data from firms on all Phase II contracts and asks firms to keep this data current. Updates are requested annually and when firms submit proposals. Both the strength and weakness of this data set is that it is self-reported by firms. The Department is thus reliant upon them to report accurate and timely figures. A drawback to this reporting process is that we do not capture commercialization accruing to firms that have "graduated" from the program, growing to be ineligible for future awards either through organic expansion or via acquisition.

Commercialization may be quite substantial, perhaps rendering our data a conservative estimate of program impact. Despite this limitation, Phase II investments of $6.7 billion in fiscal years 1984–2004 have generated total reported commercialization of nearly $13 billion in sales, additional R&D, and capital investment. Allowing three to four years after the completion of Phase II for commercialization to develop, about 65 percent of SBIR topics—statements of technology need—generate some recorded commercialization,[5] while nearly 30 percent of topics generate commercialization in excess typical investment levels.[6] Considering these aggregate program output measures, the SBIR and STTR programs are stimulating the development and sales of innovation within the Department and the broader economy.

In addition to measuring financial outcomes, we track program success stories, which demonstrate in a more concrete way the value the SBIR and STTR programs bring to specific customers. Perhaps the most vivid example of such a success story is Small Arms Protective Inserts (SAPI) and Enhance Small Arms Protective Inserts (E–SAPI) plates, which protect warfighters in theaters of operation from assault rifle and other small arms fire. Based on work done under FY 2000 and FY 2003 Navy SBIR contracts for vehicle armor, and a significant amount of follow-on research and development, ArmorWorks, Inc. of Tempe, Arizona developed high technology body armor plates for the Interceptor Body Armor System using advanced ceramic materials. To date, the firm has supplied hundreds of thousands of ceramic armor plates for use in personal (SAPI and E–SAPI), vehicular and aircraft applications, saving lives of U.S. warfighters every day.

A second excellent example of a success story is the Army SBIR-originated Cockpit Air Bag System, designed and manufactured by Simula, Inc of Phoenix, Arizona. Composed of air bags, gas generators, and a unique three-axis crash sensor, the system is designed to protect helicopter aircrew from potentially fatal impacts in the event of a crash. The Army, Navy, Air Force, and Federal Aviation Administration all participated in the joint development of this system, leveraging prior SBIR-funded work and leading to a 2001 production contract. Simula, Inc. has already fielded the system on hundreds of DOD aircraft.

A third example of a success story is the Phraselator, a hand-held speech translation device developed by Marine Acoustics, Inc. (MAI), a veteran-owned small business based in Middletown, Rhode Island, through an FY 2001 DARPA SBIR effort.[7] Following the terrorist attack in September of 2001, just seven months into their Phase II contract, DARPA requested that MAI accelerate development of a prototype Phraselator. MAI proved quite capable, delivering 200 units in a matter of weeks to U.S. military forces for use in Afghanistan during Operation Enduring Freedom. Over 5,000 Phraselators are now in use in Afghanistan, Iraq, and around the world, and they were used extensively in tsunami relief efforts. There is potentially a large commercial market for the devices, which are particularly helpful in law enforcement and medical applications where situational urgency may not allow time for an interpreter to arrive on the scene.

A final example highlights the ability of SBIR-funded technologies to save the Department money by providing capabilities at a lower cost. It also highlights how two military departments can work together to develop mutually beneficial technologies and then employ the technology rapidly to meet an emerging warfighter need. JENTEK Sensors, Inc of Waltham, Massachusetts developed a thin, conformable

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[5] Again defined as sales, further R&D or further investment.

[6] Commercialization figures are drawn from the firm-reported DOD SBIR Commercialization Database and encompass phase I awards made 1990–2003. Topic commercialization rates are calculated as the mean of yearly averages over this period of time. Considering only DOD-derived sales or investment (via prime or subcontract), 42 percent of topics generated some commercialization while 13 percent generated commercialization in excess of the typical investment amount. Typical investment is set at $850,000, the combined value of Phase I and Phase II contracts based on statutory guidelines.

[7] The Phraselator is now owned and marketed by Voxtec, Inc.

sensor system to perform inspections on difficult-to-access locations of military systems. Using the same Phase III contract, Navy Depots were purchasing the sensors to inspect P–3 propeller blades while the Air Force was adding additional funding to miniaturize the sensors for use in difficult-to-access areas. A serious problem emerged with weld joints on some compressor blades threatening planes to be grounded. The technology available at the time was to disassemble and X-ray each blade at a cost of $200,000 and considerable down time. In response to a Wednesday phone call, Jentek quickly found a solution employing the Air Force modifications under development. On the following Monday, depot technicians were able to complete a plane inspection in an hour using the "meandering, wandering magnetometer" technology at a cost of less than $20,000.

Contract Award Guidelines: Flexibility Is Key

In FY 2006, the average DOD Phase I award was $89,300 and the average Phase II was $720,800. Approximately 30 percent of these awards were modified due to participation in the Fast Track and Phase II Enhancement programs or to address technical or mission needs. Among this set of awards, the average contract award was about $135,000 for Phase I and $1.1M for Phase II.

Current contract award guidelines are $100,000 for Phase I and $750,000 for Phase II. These have been in place since 1992 for the SBIR program and have not been increased to reflect inflation's impact on the price of research and development. The Department would support any SBA effort to increase these statutory and regulatory guidelines.

The cost of technology development and prototyping is part dependent on the type of technology being developed—some technologies are more expensive than others. For example, manufacturing-related initiatives can run into the millions of dollars to effectively prototype and demonstrate. Additionally, test, evaluation and validation can be quite expensive for technologies destined for military use. Thus, regardless of the level of the award guidelines, technology cost variability and the often high cost of bringing technologies to a transition-ready maturity level militate for flexibility in program execution.[8] Thus, the Department appreciates the flexibility to judiciously go beyond the proscribed guidelines when necessary to be responsive to technology transition opportunities and produce successful outcomes.

Small Business Participation: Competition Provides Program Vitality

By almost any measure, the interest and participation in the SBIR and STTR programs has been strong. Small business participation in the DOD SBIR & STTR programs has been very strong. In fiscal years 2003–2006, the Department received an average of about 15 proposals per SBIR topic and 11 proposals per STTR topic. Prior to that, between fiscal years 1998 and 2001, the average was under 11 proposals per SBIR topic and nine proposals per STTR topic. The programs fund only the best proposals in Phase I and only the "best-of-the-best" go on to Phase II. Historical Phase I funding rates are 14 percent for SBIR and 20 percent for STTR, with Phase II conversion rates of just below 50 percent for both programs.[9]

Outreach activities are important to ensure that small businesses have the opportunity to learn about the programs. Outreach is primarily conducted through attending conferences planned for this purpose, and through making information available to the public, primarily via the Internet. The Department and its components support as many conferences as time and resources allow. Strong support of two national conferences and several regional and state events is the norm. Additionally, information contained on the DOD and on DOD component web pages is quite significant, permitting interested firms to learn virtually anything they might want to know about the programs. To supplement, the Department staffs a toll-free help-desk to answer questions firms have about the programs.

As discussed earlier, the SBIR and STTR programs are often gateways to the defense market space for firms, a way for firms to test the market and be tested as a potential new supplier. In fiscal year 2006, around 20 percent of Phase I awardees were first time award recipients while 29 percent of phase II award recipients never received a phase II award before. These are important benchmarks. To maintain a vital, innovative supplier base, particularly for new technologies, it is imperative that the Department encourage new and non-traditional firms to get involved.

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[8] As a general rule, a Technology Readiness Level (TRL) of at least six (meaning a prototype has been demonstrated on a relevant environment) is required for system development to begin.

[9] Looking at Phase I awards and associated Phase II follow-on awards from solicitations in fiscal years 1994–2003.

Financing and Commercialization

The Department employs several mechanisms to address the funding gaps in the phased award structure, increase private equity participation, provide commercialization assistance, and ultimately help increase small businesses' share of federal procurement and non-SBIR/STTR R&D. First, commercialization potential plays a central role in proposals and source selection. Two of three criteria address this issue:

- qualifications of the firm and team to perform the research and development and commercialize the results, and;
- the commercialization[10] potential of the proposed solution.

Further, firms with four or more prior SBIR Phase II contracts are assigned a Commercialization Achievement Index (CAI) score, which is a measure of how well the firm has commercialized prior SBIR technology relative to peers with the same number of Phase II awards. Firms with a CAI in the lowest fifteen percentile—those with the worst record of commercialization—receive fewer points in source selection.

To address the funding gap between Phase I and Phase II, many DOD components employ a Phase I contract option to fund research and development while the Phase II proposal is evaluated for funding. When this approach is taken, it virtually always takes the Phase I award amount above the statutory and regulatory guideline, triggering a reporting requirement. The Fast Track program also offers gap funding to qualified proposals while also attracting external matching funds.

The Phase II Enhancement program (also known as Phase II Plus) offers program funding to match qualifying external funding, sometimes (but not always) from a non-SBIR/STTR DOD source such as a laboratory or system program office, to further develop, demonstrate, test, and validate the technology. The Department's analysis shows that both the Fast Track and Phase II Enhancement programs are associated with systematically higher levels of commercialization.

As with the Phase I contact option, Phase II Enhancements virtually always increase the Phase II award level beyond the statutory and regulatory guidelines, triggering a reporting requirement. Preliminary analysis shows there is more interest among the components in performing Phase II Enhancements than in Fast Track. This is probably because the matching funds are brought to bear later in the research and development cycle when technology transition issues are more likely to be defined, and the potential of the technology is better understood.

Technical assistance programs offer federal agencies the opportunity to provide targeted aid to SBIR and STTR award recipients to increase their chances of success. Section 9(q) of the Small Business Act currently permits $4,000 per Phase I award and $4,000 per year per Phase II award to be used to provide such assistance. However, to make the authority more useful and effective, the Department recommends a couple of changes:

- increase to $5,000 per Phase I award to reflect the economic impact of inflation; and,
- increase Phase II assistance to up to $8,000 per year, and permit federal agencies to provide the assistance directly or through the Phase II contract.

The suggested increase in the level of assistance for Phase II reflects a more realistic cost of providing meaningful assistance to firms that need to cultivate markets for their innovations while simultaneously developing their technologies and capacity to produce them.

Within the DOD program, few components currently provide direct commercialization assistance. The adjustments suggested above and in the section 824 of the Administration's proposed *National Defense Authorization Act for Fiscal Year 2008* forwarded to the Congress on February 6, 2007 (NDAA for FY08), will make the technical assistance more attractive and probably increase the likelihood that DOD components and other federal agencies will use the authority.

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[10] Commercialization refers to the process of developing marketable products or services and producing and delivering products or services for sale (whether by the originating party or by others), to government and/or non-government markets. Funds data reported as commercialization includes the receipt of money for the performance of follow-on R&D (as government-supplied Phase III funds or other sources) and the collection of funds from investors. A related term is SBIR Phase III, which refers specifically to work that derives from, extends, or logically concludes effort(s) performed under prior SBIR funding agreements, but is funded by sources other than the SBIR program. Phase III work is thus typically oriented toward commercializing SBIR research or technology. The terms are often used synonymously and interchangeably when describing outcomes beyond SBIR Phase II.

Administrative Costs

SBIR/STTR program administration is quite resource intensive. This is in large part due to the phased program structure and contract award guidelines, which result in thousands of individual contracts. Each contract requires associated Departmental overhead for topic development and review, pre-release and solicitation interaction with industry, technical evaluation and source selection, contracting, and technical oversight and coordination, among other activities. Preliminary estimates by the RAND Corporation put this overhead at or above five percent of program budget, varying by component.[11]

The SBIR and STTR set-aside budgets are drawn from previously programmed, budgeted and appropriated funds for other programs, which when budgeted contained resources for administration of these funds. Thus, the SBIR and STTR budgets contain funds that were identified to support administrative activities. However, the set-aside budgets for SBIR or STTR may not be used to support program administration. Support funding thus must be drawn from other sources.

A legislative change proposed by section 823 of the NDAA for FY 2008 would allow up to three percent of the SBIR and STTR set-aside budgets to be used to fund administrative expenses. The most important activities requiring these resources are contracting, technical oversight, and program coordination with systems developers and end-users. Benefits derived from this change will ultimately manifest themselves in overall program performance, such as through the aggregate rate and magnitude of commercialization achieved. Modification of the current discretionary technical assistance authority (15 U.S.C. 638(q)), as suggested above, would provide ample resources for this task, particularly when combined with resources made available through the Commercialization Pilot Program (CPP) authority (15 U.S.C. 638(y)). Lastly, I would caution against raising the program set-aside from the current 2.5 percent absent analytically solid determination that such a change would produce value in excess of the additional direct and opportunity costs it would impose.

Conclusion

To conclude, I would like to recognize the efforts of our DOD SBIR program managers and the civilian and uniformed technical representatives and contracting officers, as well as contractors that support them. These dedicated, professional individuals work hard, day in and day out, to ensure that our SBIR dollars are spent on the most promising and relevant technologies. They don't always see immediate results from their labors—that is the nature of early-stage research and development (R&D). However, when projects develop into useful military products, the fruits of their labor can be seen saving lives and contributing to a wide variety of missions in Iraq, Afghanistan, and elsewhere around the world. We need not look further than these places to see that the program can make a positive impact, and that is due directly to their efforts.

In summary, again I thank you, Chairman Wu, for the opportunity to testify on the SBIR and STTR programs. I hope my testimony has provided you with an understanding of how we run the program at the Department and will assist in you and your colleagues as you consider program reauthorization. I would be happy to answer any questions you and the Members of the Subcommittee may have.

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[11] Drawn from "Evaluation and Recommendations for Improvement of the Department of Defense Small Business Innovation Research (SBIR) Program." The study efforts are funded by the Office of Small Business Programs, Office of the Under Secretary of Defense (Acquisition, Technology & Logistics).

STATEMENT OF DR. NORKA RUIZ BRAVO
DEPUTY DIRECTOR FOR EXTRAMURAL RESEARCH
OFFICE OF EXTRAMURAL RESEARCH
NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chairman Wu, Ranking Member Gingrey, and Members of the Subcommittee: I am Dr. Norka Ruiz Bravo, Deputy Director for Extramural Research at the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). The NIH is the primary federal agency for conducting and supporting biomedical research.

I appreciate the opportunity to provide for the record testimony about the Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer Program (STTR) and ways to strengthen the participation of small businesses in the NIH SBIR/STTR programs.

IMPORTANCE OF SBIR/STTR PROGRAMS AT NIH

The NIH mission is to uncover new knowledge that will lead to better health for everyone. Helping to lead the way toward important medical discoveries, NIH-supported scientists investigate ways to prevent disease as well as investigate the causes, treatments, and cures for diseases and disabilities. The key to achieving our mission is that the rapid and fundamental advances in biomedical and behavioral sciences will be translated into prevention strategies and clinical treatments for rare and common diseases and then further applied to real-world practice. With new scientific discoveries comes the opportunity for small businesses to translate research results into the commercial marketplace.

The SBIR/STTR programs provide qualified small business concerns with opportunities to propose innovative ideas and to explore their technological potential. Projects funded through the NIH SBIR/STTR programs focus on commercialization of the outcomes of research. The SBIR/STTR programs are fully integrated into the NIH research agenda, particularly with respect to promoting innovative, cutting-edge research ideas, as well as translating scientific findings and advances into tangible benefits for the American people. Thus, they serve to supplement—but not supplant or diminish—the traditional research programs of NIH.

The NIH SBIR program and STTR program represent about 98 percent and 100 percent, respectively, of HHS' programs in these areas. The NIH contributes the second largest amount of SBIR/STTR funding across the Federal Government. In fiscal year (FY) 2006, the NIH SBIR program provided over $580 million to fund 1,275 new Phase I (feasibility testing) and Phase II (product research and development) SBIR projects. We provided more than $70 million to fund nearly 200 new Phase I and Phase II STTR projects. Since the programs' inception, the NIH has invested more than $5 billion in more than 19,000 projects to over 5,000 small businesses.

PROGRAM EFFECTIVENESS: BRINGING IDEAS TO LIFE

The NIH SBIR/STTR programs are focused on creating research opportunities for U.S. small businesses to stimulate technological innovation and to translate discoveries into products/services that will improve human health. The programs seek 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 but uncertain verification or feasibility.

- GlycoFi Inc. (NH), a biotherapeutics company, used the NIH SBIR program to explore the feasibility of making injectable proteins—so called "biotech drugs"—using a glycoengineered yeast strain. GlycoFi's work is an example of exciting translational research where they use an innovative approach called *GlycoDesign*™ to control a protein's glycans (sugars) in order to optimize a therapeutic protein. GlycoFi demonstrated successfully the technical feasibility to develop a yeast system for producing therapeutic drugs in large scale. In May 2006, this six-year-old company was acquired by Merck & Co. for about $400 million in cash, the largest such deal ever reported for a private biotechnology company.
- IntraLase Corporation (CA) used SBIR funding to develop a safer and more precise way to create the corneal flap in LASIK surgery. Today, using a bladeless technology to generate light pulses as short as one-quadrillionth of a second, IntraLase's femtosecond laser technology is improving the safety and efficacy of laser vision correction.

- Electrical Geodesics Inc. (OR) has used the SBIR program to develop important research tools. It has developed a new generation of high-resolution electroencephalogram (EEG) measurement and analysis systems for use in medicine, psychology, and neuroscience research. Based on a patented Geodesic Sensor Net technology, EGI's systems are now in use in research laboratories in the U.S., Europe, and Asia, in projects ranging from infant language comprehension to EEG pathology in dementia.
- Altea Therapeutics (GA) has used NIH SBIR funding to develop the PassPort™ System, which enables fast, controlled delivery of drugs (e.g., insulin) and vaccines painlessly through the skin using a needleless infusion patch.

These examples demonstrate why the SBIR/STTR programs are important to the innovation process. Marking the 25th year of the existence of the SBIR program, the time is ripe to reflect on how the programs have evolved and matured over time and to consider ways to develop program operations to improve program efficiency and effectiveness.

PROGRAM FLEXIBILITY IS KEY: ONE SIZE DOES NOT FIT ALL

The SBIR program now includes 11 participating agencies, each with very diverse missions. 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. These changes were focused on addressing the needs of a diverse business community, including multiple industries, different technology sectors, and diverse product outcomes.

Examples of program flexibility include the ability to provide funding levels that in some instances exceed the norm established in Small Business Administration (SBA) guidelines; the ability to propose research projects in the fields that have the most biological potential; the use of less rigid receipt dates; the permissibility of application resubmissions and gap funding options, including a Phase I/Phase II Fast-Track option to accelerate projects that have great potential for commercialization; and the opportunity to compete for Phase II Competing Renewal awards for projects that must address FDA regulatory requirements (e.g., clinical evaluation).

Simply stated, one size does not fit all. Flexibility is key, particularly in addressing the current challenges noted below.

PHASE I/PHASE II AWARD LEVELS

The median award size in FY 2006 was $143,725 for Phase I and $415,952 per year for Phase II projects. Our experience is that the conduct of certain types of biomedical research, such as nanotechnology, clinically-related studies, vaccine development, and drug discovery, do not routinely lend themselves to prescribed maximum time and dollar levels. NIH appreciates the flexibility that the SBA has provided to exceed their guidelines, where appropriate, for particular projects, rather than to restrict ideas to projects that can only be conducted under a prescribed amount of time and money. Accordingly, we encourage small business concerns to propose realistic budgets and project periods appropriate for the successful completion of an SBIR project.

SMALL BUSINESS PARTICIPATION

Outreach is an important link to the participation of small businesses in the SBIR/STTR programs. We are continually enhancing our outreach efforts at conferences and forums aimed at increasing participation of all small businesses, and particularly socially and economically-disadvantaged and women-owned small businesses; the *Small Business Veterans Conference* and the *Alabama A&M University 2007 SBIR/STTR Small Business Conference* are just two examples. In addition to outreach, NIH provides administrative supplements to NIH SBIR/STTR awardees to improve the diversity of the research workforce by supporting and recruiting students, post-doctorates, and eligible investigators from groups that have been shown to be under-represented.

SUSTAINING THE INTEGRITY OF THE SBIR PROGRAM

Small businesses are increasingly recognized as important contributors and partners to technological innovation. Yet small business participation in the NIH SBIR/STTR programs is experiencing another trend of decreases. SBIR/STTR has been decreasing since FY 2004, as it did in FY 2001, at a time when non-SBIR applications have increased significantly. In FY 2006, NIH saw a nearly 15 percent decrease from the number of SBIR applications submitted in FY 2005 (see chart below). This

reoccurrence of decreases is of serious concern to NIH, and we understand that several other agencies are also experiencing a decrease in submissions.

Percentage Change in Applications from Prior Fiscal Year:

Fiscal Year	Ph I and Ph II Application Base
2000	11.0%
2001	-13.0%
2002	12.8%
2003	25.4%
2004	19.0%
2005	-11.9%
2006	-14.9%

The downward trend may be the result of several factors. Some firms are no longer eligible. Some have gone out of business. Some firms are new start-ups that have not yet fully developed the necessary infrastructure to successfully compete for an award. Some believe the time and cost for applying relative to the award levels is not a sufficient opportunity incentive. (Only about one-third of our SBIR and STTR awardees are new to the program each year.) NIH encourages small businesses to participate in the SBIR/STTR programs and to use the programs as one, but not the only, resource for funding innovative, commercially viable ideas. In considering ways to increase the participation of innovative small businesses in the SBIR/STTR programs, NIH plans to give preference to new firms that have never received NIH SBIR/STTR awards and/or to firms that respond to agency-specific priorities, given a firm's level of expertise and evidence of likely ability to produce innovative products.

FINANCING AND COMMERCIALIZATION ASSISTANCE PROGRAMS

SBIR/STTR program reauthorizations have consistently emphasized the goal of addressing financing gaps toward product commercialization by requiring agencies to include as a review criterion the commercial potential of proposed projects. To help NIH SBIR awardees navigate this proverbial "valley of death" and move their products into the marketplace, NIH has developed a menu of technical assistance programs that provide technical and/or commercialization assistance specific to the companies' individual needs. These programs are:

Technology Niche Assessment (TNA™) Program: The TNA™ program assesses the market opportunities and needs and concerns of the end-users and helps to discover new markets for possible entry.

CAP: CAP provides Phase II awardees with assistance in developing and implementing an appropriate business strategy that will help commercialize the products that have resulted from their SBIR research projects. CAP is having positive impacts on some SBIR companies seeking investments and partnerships. For example, Cytograft Tissue Engineering (CTE) received SBIR funding that enabled the company to explore the potential of an innovative technology to create a living blood vessel called Lifeline™. This exciting medical advancement has potential for coronary bypass candidates, lower limb amputation candidates, and hemodialysis patients. As a CAP participant, CTE has raised $17 million in private equity financing to fund some of their clinical studies.

Pilot Manufacturing Assistance Program: In FY 2007, NIH initiated a pilot assistance program together with the National Institute of Standards and Technology Manufacturing Extension Partnership (MEP) program to help companies with making manufacturing decisions when developing their operational transition strategies (e.g., method of scale-up, quality control, prototyping, facility design, vendor identification and selection, plant layout).

NIH believes the technical assistance to SBIR awardees is very important in helping companies transition to the marketplace.

PARTNERS: GOVERNMENT AND SMALL BUSINESS

The overarching intent of the SBIR program was stated best by President Reagan in signing the initial legislation: "We in government must work in partnership with small businesses to ensure that technologies and processes are readily transferred to commercial applications." As researchers tackle ever more complex biomedical challenges and the rising cost of scientific research, strategic partnerships between NIH and private industry are becoming more important for advancing science and communicating results of medical advances to improve the quality of life for all people.

NIH is committed to increasing the participation of small businesses in the SBIR/STTR programs, ensuring that only *small* business concerns receive SBIR/STTR awards, and encouraging the participation of new start-up SBIR/STTR firms by giving them preference in award selection, much like new investigators are often given preference in traditional research grant programs (see *http://grants.nih.gov/grants/new_investigators/institute_center_practices.htm*). We need to find ways to innovate and collaborate, and promote scientific advances, and take advantage of every opportunity to improve public health.

CONCLUSION

In conclusion, it is our intention and hope that SBIR/STTR programs will continue to maintain their integrity and ensure that technology developments will be translated and disseminated for the benefit of all Americans.

Thank you for the opportunity to share with you my thoughts regarding the SBIR/STTR programs.

STATEMENT OF LARRY JAMES
SBIR/STTR PROGRAM MANAGER
U.S. DEPARTMENT OF ENERGY

Mr. Chairman and Members of the Committee: thank you for giving the Department of Energy (DOE) the opportunity to provide this Statement for the Record about the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs at the Department.

The DOE Office of Science (SC) manages the SBIR and STTR programs for the Department and has done so since the SBIR program was formed in 1982 and the STTR program in 1992. In addition to SC, six other DOE programs participate in the SBIR and STTR programs: the Offices of Fossil Energy, Energy Efficiency and Renewable Energy, Nuclear Energy, Environmental Management, Defense Nuclear Nonproliferation, and Electricity Delivery and Energy Reliability. The Department's naval reactors and weapons activities programs are exempt by law and do not contribute to SBIR and STTR programs.

The SBIR/STTR programs are viewed within the Department like any other research and development (R&D) program, namely, as a vehicle by which the Department accomplishes its R&D objectives. The Department has benefited from small business participation through the research and resultant new knowledge and technologies developed by small businesses that have supported various Department R&D activities over the years. Examples of commercialization successes from the programs include development of new photovoltaic systems for utility scale solar energy production, shock-resistant and temperature-tolerant ceramics for more energy efficient engines, and fast-growing hybrid poplar trees as a sustainable and economical biomass energy source. Successful collaborations between small businesses and the DOE laboratory complex have also led to new insights and innovative technologies that enable advancement of the Department's program missions; for example, technologies that will significantly improve the performance of current and future DOE scientific user facilities.

Program Effectiveness

The statutory SBIR and STTR programs have several purposes: (a) to stimulate technological innovation; (b) to use small businesses to meet federal R&D needs; (c) to foster and encourage participation by socially and economically disadvantaged small businesses; and (d) to increase private sector commercialization of innovations derived from federal R&D.

In accordance with the U.S. Small Business Administration's (SBA) SBIR Policy Directive, the SBIR program is administered in three phases. Phase I is to evaluate the scientific or technical merit and feasibility of ideas that appear to have commercial potential or meet the internal needs of the Department. Phase II builds on Phase I work and comprises the core research and development effort. Phase III refers to work that derives from, extends, or logically concludes efforts performed under SBIR funding agreements, but is not itself funded by the SBIR program. Phase III work is typically oriented towards private sector commercialization or direct transition of the SBIR research or technology into the Department's research complex. That is, the SBIR funding pays for research or R&D meeting DOE objectives (Phases I and II); non-SBIR capital provides follow-on developmental funding to meet commercial or program specific objectives (Phase III).

The SBIR and STTR programs both involve a two-phased research approach. The major difference between the SBIR and the STTR programs is that STTR grants must involve substantial cooperative research collaboration between the small business and a research institution. At least 40 percent of the research or analytical effort must be allocated to the small business, and at least 30 percent of the effort must be allocated to a single research institution. The percent set-aside for the STTR is small, 0.3 percent, relative to the SBIR set-aside at 2.5 percent of federal agency extramural R&D budgets.

The Department's SBIR and STTR programs' goals include: 1) funding high quality projects with relevance to the Department's mission needs; 2) increasing private-sector commercialization and Departmental transition of technology developed through DOE SBIR-supported R&D; 3) stimulating technological innovation in the private sector; and 4) improving the return on investment from federally-funded research for economic and social benefits to the Nation.

The Department believes its SBIR and STTR programs are meeting these objectives. SBIR and STTR program performance compares favorably with that of other DOE research programs. The DOE SBIR and STTR programs have and continue to

support high-quality, competitive R&D, which results in spin-off companies, new technologies, and knowledge which all contribute to advancing DOE missions.

DOE's SBIR program is also a model for the provision of commercialization assistance. According to the Small Business Administration (SBA), DOE was the first agency to offer commercialization assistance to awardees, beginning in 1990. Awards from the SBIR program help small businesses attract outside investment by affirming that the companies have excellent technical capability, thus reducing some of the uncertainty involved in early-stage investment. Several comprehensive reviews of the federal SBIR and STTR programs by the Government Accountability Office (GAO) have found it to be successful in enhancing the role of small businesses in federal R&D across the participating agencies, stimulating commercialization of research results, and supporting the participation of small businesses (Testimony Before the Subcommittee on Environment, Technology, and Standards, Committee on Science, House of Representatives, *Federal Research: Observations on the Small Business Innovation Research Program,* June, 28 2005, GAO–05–861T, and references therein).

The efficiency and effectiveness of the DOE SBIR and STTR programs could potentially be improved with two changes in the allocation of set-aside funds:

(1) Increase the provisions for discretionary technical assistance within the existing set-aside allowed by law under SBIR. SBA-directed funding limits in Phase I and Phase II are not adequate to support a strong technical assistance program, including commercialization assistance. Currently up to $4,000 in Phase I (above the awarded amount) can be used per award for commercialization assistance activities and up to $4,000 per year per award in Phase II (included as part of the awarded amount) can be used towards these activities. SBIR Phase II recipients have indicated in qualitative surveys that the commercialization assistance programs and services offered by DOE's SBIR program are valuable to their product development and commercialization efforts. Also, quantitative data from DOE's SBIR Commercialization Opportunity Forum Program, a program that helps companies develop a business plan and interact with potential strategic allies and investors, indicate that more than 50 percent of the graduates from the program received follow-on investment within 18 months.

(2) Make a small fraction of the existing set-aside available for agency administrative purposes. Appropriate operating resources are important to maintain and continue to improve the SBIR and STTR programs. The use of a small percentage of the SBIR and STTR programs' funds for administrative purposes could improve their effectiveness by providing the resources for better evaluation of the successes of participating small businesses and their impacts on DOE mission goals. For example, such resources would allow program staff to improve Phase III follow-up, track commercialization and non-commercialization successes, and provide more outreach to increase small business participation. More comprehensive, long-term data collection would allow better assessment of the results of the programs and enable the programs to adjust management practices as appropriate.

A key element in the success of the SBIR and STTR programs is the flexibility of the SBA Policy Directive which lays out the basic rules by which each agency manages its mission specific programs. Each of the federal agencies which participate in the SBIR/STTR program manages its program through processes that work best for that agency. Efforts to restrict this framework, which has evolved over the 24-year history of the SBIR Program, would be a step backward and would limit the agencies' ability to meet the goals of the program.

Award Levels

The SBA is currently considering new award level upper limits for the SBIR program to account for inflation. In general, higher award level limits will give agencies added flexibility in managing their programs and enable support of a broader range of innovative technology proposals.

Small Business Participation

Over the 24 years of its existence, the DOE SBIR Program has matured and evolved significantly. We have issued 25 Phase I solicitations, reviewed approximately 31,797 proposals, and selected for funding 4,413 Phase I projects and 1,816 Phase II projects. The SBIR budget for Fiscal Year 2006 was $114 million. The Department received 1,309 Phase I grant applications from 809 companies, of which 1,021 were sent out for external peer review. We selected 260 applications for Phase I awards resulting in grants to 173 small businesses in 33 states. Sixty-seven of the 290 grantees were first time winners with DOE. Thirty-four of the 67 were first time applicants to DOE. Thirty-one applicants selected for funding were from so-

cially and economically disadvantaged small businesses and thirteen were from small businesses located in a HUBZone (historically underutilized business zone). In FY 2006, the Department received 226 Phase II proposals and funded 123 awards to 96 small businesses. Approximately 95 percent of Phase I awardees submit Phase II proposals.

Below are additional statistics from prior years:

Phase I SBIR

Year	Number of Application Submissions	External Peer Reviewed	Number of Awards	Number of Individual Companies that Submitted	Number of Companies with Funded Projects	First-time Awardees	Small & Economically Disadvantaged Small Business Awardees	HUBZone Awardees
2006	1309	1021	260	809	173	67	31	13
2005	1490	1037	259	823	179	85	26	7
2004	1312	857	247	736	187	83	31	14

Phase II SBIR

Year	Number of Application Submissions	External Peer Reviewed	Number of Awards	Number of Individual Companies that Submitted	Number of Companies with Funded Projects	First-time Awardees	Small & Economically Disadvantaged Small Business Awardees	HUBZone Awardees
2006	226	226	123	158	96	39	16	7
2005	227	227	107	175	93	39	11	4
2004	198	198	117	150	93	36	11	9

DOE actively participates in national, regional, and state sponsored outreach activities, as do other federal agencies, to engage small businesses and provide information and resources to better position them to participate in the SBIR and STTR programs. These outreach activities generally consist of two- to three-day conferences featuring presentations and panel discussions involving agency program managers and experts in the areas of proposal preparation and budget formulation. One-on-one meetings with prospective small businesses are also provided to allow attendees to discuss their technology concepts and how they might address agency needs. Agency participation in these outreach activities is often limited, however, by an agency's limited administrative resources.

The DOE SBIR and STTR programs facilitate and participate in presentations and panel discussions at the Department's annual Small Business Conference. These conferences typically draw between 400–600 participants each year and have been successful in attracting a significant number of small and economically disadvantaged businesses that are strongly encouraged to consider SBIR and STTR program opportunities. Continued outreach efforts by the federal agencies' programs are important. Likewise, efforts by State Economic Development Agencies have shown significant success in helping their small business communities pursue federal SBIR and STTR funding opportunities.

Financing and Commercialization

Because the Department has flexibility to provide partial funding as soon as Phase II awardees are selected, we are able to minimize any gaps in financing under the SBIR and STTR phased award structure. Phase II awardees are typically selected within a reasonable period following their completion of the Phase I grant. The current SBIR Policy Directive encourages each agency to develop a program that reduces the time between issuance of SBIR Phase I and Phase II awards and provides the agency flexibility for optimal implementation.

As stated earlier, increasing the amount of the existing set-aside allowed for technical assistance, including commercialization assistance activities, could potentially improve the commercialization success of SBIR R&D supported by the federal agen-

cies. The Commercialization Opportunity Forum Program in which DOE SBIR grantees are invited to participate brings small businesses with promising technologies face-to-face with potential investors. This program, conducted by a private organization competitively selected and under contract with DOE, provides small businesses the opportunity to work with professionals first to develop and refine a business plan and business plan presentation. Then small businesses are brought together with decision-makers from appropriate partnering and funding sources in a two-day forum that includes both formal presentations and informal networking opportunities. While every small business supported by the DOE SBIR program theoretically has access to commercialization assistance services, in fact, because of resource limitations, not every small business is able to participate in the Opportunity Forum, which involves direct contact with private equity firms. Additional resources for commercialization assistance through programs like the Opportunity Forum could help more participating small businesses develop business plans for their technologies and access the private equity and investment markets essential to successful commercialization.

Multiple Venture Capital Majority Ownership

The Department recognizes the positive impact that opening up competition to multiple venture capital (VC) majority-owned small businesses may have on stimulating technology development, increasing private sector commercialization from federal R&D, and meeting agency mission needs. DOE has concerns, however, with respect to how opening up the competition to multiple VC majority-owned small businesses may impact the participation of small businesses which lack the financial resources of multiple VC majority-owned companies. Because DOE provides financial assistance in the form of Phase I and Phase II research grants to the successful applicant, there is no financial risk to the company if the research and development of a proposed technology does not result in a commercial product in the near-term. The financial risk to these companies comes in Phase III, once the SBIR and STTR programs' funding is no longer provided and small businesses must pursue outside financial resources for further development and commercialization.

Opening up competition to multiple VC-majority owned companies may have the effect of squeezing out new technology start-up businesses that have been the success stories of the SBIR and STTR programs and may limit the ability of the federal program to increase the participation of small businesses in federal R&D, particularly participation by socially and economically disadvantaged small businesses. Interested venture capital companies have sufficient opportunity to provide financial support to the small businesses directly through equity ownership once the technology has proven itself in Phase II. SBA is currently addressing this issue through its public rule-making process. SBA has issued an Advance Notice of Public Rule Making and is reviewing the pros and cons of a possible change in eligibility requirements.

Raising the Set-Aside Percentage

Since its inception, the Department has invested almost $1.5 billion in SBIR/STTR Phase I and Phase II grants. In return, approximately 60 percent of Phase II-supported companies have earned a total of more than $1.6 billion in sales and $1.3 billion in additional Phase III development funding—67 percent of which came from non-federal sources—helping the Nation capitalize on its substantial R&D investment.

As the Committee considers SBIR Reauthorization, the issue of raising the set-aside percentage is likely to be a subject of debate. The Department of Energy works hard to maintain a strong and appropriately balanced core research program through R&D supported at universities, the DOE national laboratories, and U.S. small businesses. The Department believes the current set-aside is adequate. At a time when budgets are particularly constrained, we do not advocate increasing the set-aside for the SBIR and STTR programs. We are most concerned that such an increase would negatively impact other areas of the Department's research portfolio, including maintaining core research funding at universities. The Department recommends that, before any increase in the set-aside percentage is considered, improvements in program efficiency and effectiveness be explored—for example, through change to the allocation of existing set-aside resources to allow additional support for technical assistance and commercialization assistance, as well as for agency administrative expenses. Such changes may better position small businesses to develop and commercialize their technologies and maximize their contribution to agency mission needs without compromising agencies' broader mission commitments.

Conclusion

Again, Mr. Chairman and Members of the Committee, I want to thank you for the opportunity to provide this statement from the Department of Energy. We are committed to the SBIR and STTR programs which have proved their value over many years, and we look forward to working with this committee and others on re-authorization to continue and further improve their efficacy for the agencies which support them and the businesses which emerge and grow from them.

STATEMENT OF DOUGLAS A. COMSTOCK
DIRECTOR, INNOVATIVE PARTNERSHIPS PROGRAM OFFICE
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to submit a statement for the record to discuss NASA's Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program. The SBIR/STTR programs are managed by the Innovation Partnerships Program Office (IPPO) whose primary mission is to provide leveraged technology and capabilities to NASA programs and projects through partnerships with industry, academia, government agencies, and national laboratories.

The SBIR/STTR programs provide an opportunity for small, high technology companies and research institutions to participate in government sponsored research and development efforts on key technology needs. Below, I have addressed the six issues posed by this Subcommittee: program effectiveness, award level, small business participation, financing and commercialization, administrative cost and venture capital.

Program Effectiveness

Many technologies funded by SBIR/STTR have made important contributions to NASA programs and projects, and many have also been commercial successes that are bringing important benefits to society. The agency is actively working to increase the number of NASA-funded SBIR/STTR technologies with applicability and adequate maturity for use in NASA's missions and projects.

Some examples of SBIR/STTR technologies that are making important contributions to some of NASA's programs and projects are provided below:

- NASA's Mars Exploration Rovers are using SBIR technologies including lithium ion batteries from Yardney Technical Products of Pawtucket, Connecticut, heat switches from Starsys Research of Boulder, Colorado, and ASCII chips from Maxwell Technologies of San Diego, California.
- Space Shuttle return-to-flight after the *Columbia* accident used SBIR-developed wireless sensors from Invocon of Cunroe, Texas, for the impact detection system in the wing leading edge of the Shuttle. These wireless sensors are also used for vehicle health monitoring and microgravity instrumentation on the International Space Station.
- The Cassini-Huygens Mission now at Saturn used several SBIR technologies including a helium magnetometer from Polatomic of Richardson, Texas, a coilable boom to deploy the magnetometer from AEC–Able of Goleta, California, and filters for several instruments on the spacecraft from Barr Associates of Westford, Massachusetts.
- The Hubble Space Telescope is using a miniature, high speed, vibration free turbo-alternator from Creare of Hanover, New Hampshire.
- The heat shield on the return capsule for the Stardust mission—first ever sample return from a comet, and fastest ever Earth entry at 12.9 Km/sec—was enabled by an SBIR with Fiber Materials Incorporated (FMI) of Biddleford, Maine. FMI scaled up the heat shield fabrication technology for Phenolic Impregnated Carbon Ablator (PICA) from ~0.1m maximum size at the time, to the ~1.0m size needed for Stardust.

A few examples of successful commercialization of SBIR/STTR technologies are provided below, and from the breadth of examples it is evident that SBIR/STTR program technologies have potential application in every key industrial sector:

- An STTR contract from NASA's Langley Research Center led to application of ultra-precise GPS for tractor-steering systems. Developed by Novariant Corporation of Menlo Park, California, these systems are in use around the world increasing crop yields, reducing chemical use and conserving irrigation water.
- Weston Solutions of West Chester, Pennsylvania, is using a technology developed through NASA STTR funding to clean up high concentrations of harmful chlorinated solvents from dye and paint manufacturers, dry cleaners, chemical manufacturers, metal cleaning and degreasing facilities, pharmaceutical and aerosol manufacturers, and other industries.
- Quantum Devices of Barneveld, Wisconsin, has commercialized light-emitting diode (LED) chips funded through SBIR at NASA's Marshall Space Flight Center. Initially used to grow plants on the Space Shuttle and International

Space Station, these lights are now used for healing wounds and providing temporary relief from chronic pain due to arthritis, stiffness, and muscle spasms.

- Triangle Research and Development Corporation of Research Triangle Park, North Carolina, has used a robotic vision system and SBIR funding from NASA's Goddard Space Flight Center to develop sophisticated crash test dummies and models being used by automobile and component manufacturers in vehicle testing worldwide.
- Mineral identification technologies for Mars rovers, developed with SBIR funding from NASA's Jet Propulsion Laboratory, has been commercialized by InPhotonics of Norwood, Massachusetts for use by U.S. law enforcement agencies and military personnel to identify suspicious liquid and solid substances through glass and plastic packaging materials.
- Ballistic Recovery Systems of St. Paul, Minnesota, has commercialized a lightweight parachute developed with SBIR funding from NASA's Langley Research Center, for emergency use by small airplanes, saving many lives.
- Alcon Laboratories of Fort Worth, Texas has used laser tracking technology for spacecraft rendezvous and docking, developed with SBIR funds from NASA's Johnson Space Center, to commercialize an eye-tracking device for LASIK surgery that tracks eye movements at four times the established safety margin.

Both the SBIR and STTR programs have evolved and matured over time and NASA continues to pursue ways to improve program efficiency and effectiveness. NASA is seeking to improve the effectiveness of the program through achieving increased infusion into programs and projects. By increasing the degree of integration of SBIR/STTR investments into the overall technology development portfolio of NASA's four Mission Directorates (Science, Aeronautics, Space Operations, and Exploration Systems), SBIR/STTR investments will address specific technology gaps, be complementary to other investments, and achieve greater infusion.

Each of the 11 agencies participating in the SBIR program implements the program a little differently, based on their mission objectives. Flexibility in the administration of the program—not using a "one size fits all" approach—has been critical to its success. The ability for each agency to adjust funding levels, define areas of research or subtopics of priority, pursue opportunities for cost sharing, have all greatly enhanced the ability to accelerate projects that have potential for infusion into agency Mission programs and/or commercialization. Flexibility does contribute to program effectiveness by allowing agencies to tailor to their specific needs.

Appropriate Program Award Levels

Adjusting the maximum award levels for phase 1 and 2 to account for inflation would be desirable, if agencies retained the flexibility to adjust awards as appropriate within those bounds. While higher awards would result in fewer awards, the advances achieved by those awardees would be greater given the increased level of funding. A key obstacle for achieving infusion or commercialization success is developing technologies of sufficient maturity or "technology readiness level" in NASA jargon. Higher award levels would help increase the maturity of technologies resulting from the SBIR/STTR investments, thus reducing the risk of incorporating those technologies into missions and increasing the likelihood of infusion.

Small Business Participation

Participation in NASA's SBIR/STTR programs has continued to be more than satisfactory. NASA continues to host a population on average of proposal submits that range between 1,700 and 2,200 proposals annually. NASA's outreach efforts at conferences and workshops continue to focus on increasing participation by the small business community. NASA continues to see a flow of firms new to the NASA SBIR program each year and NASA's SBIR program is working closely with NASA's Office of Small Business Programs (OSBP) to more effectively reach socially and economically-disadvantaged and women-owned small businesses. Achieving higher infusion into programs and projects, a key objective of NASA's SBIR/STTR program, will result in increased Phase III funding for small businesses.

Financing and Commercialization

NASA is pursuing several program improvements targeted at enhancing technology infusion into NASA programs, as well as commercialization assistance specific to the companies' individual needs. NASA has recently consolidated its SBIR/STTR program structure to reduce administrative overhead and to focus more clearly on the infusion of SBIR/STTR technologies into the agency mission programs.

Providing commercialization assistance as an integral part of SBIR/STTR awards could be beneficial, particularly if the award levels were increased, as business acumen is not always present in technological innovators. Existing Phase III SBIR/STTR authorities allow access to SBIR/STTR firms for continued technology development work with non-SBIR program funding on a sole-source basis, without the need for a 'justification for other than full and open competition' or JOFOC. This authority has been beneficial and NASA is seeking to make fuller use of this authority. It provides incentives for NASA's development programs and their prime contractors to continue funding SBIR technologies, and has great potential to increase the infusion of SBIR/STTR technologies into NASA programs and projects, and to increase the amount of federal procurement funding going to SBIR/STTR firms.

Administrative Costs

Administrative cost continues to be a challenge in the SBIR/STTR programs. In October 2006, NASA initiated a new consolidated structure for the NASA's SBIR/STTR programs. The new program structure seeks to reduce program administrative cost, increase operational efficiency, and supports an additional set of objectives focused on technology infusion of SBIR/STTR developed results into Mission Directorate programs, while leveraging more of their resources for administrative support in the program. Allowing agencies to use a portion of SBIR/STTR program funds to support administrative costs would give agencies more flexibility.

Venture Capital Majority Ownership

The objective of SBIR/STTR is to support small businesses that are contributing to agency missions and the Nation's economy. The willingness of venture capital firms to invest in a small business is a positive indicator that people who are putting their money at risk believe in the success of a company. Thus, some venture capital participation might be a good indicator of the likelihood of a small business's future success. Venture capital companies, and other commercial partners, are encouraged to invest in SBIR awardees and may own up to 49 percent of an awardee firm's equity, so long as they do not have the power to control the firm.

However, because a lack of access to capital is one of the defining characteristics of small business, a majority ownership by venture capital organizations may indicate that business is no longer appropriately labeled small and its participation in the SBIR/STTR program needs to be reviewed by the Small Business Administration (SBA) to ensure that its participation continues to meet the intent of the SBIR/STTR legislation. In addition, we have to ask whether funds provided by venture capital firms might merely be a substitute for set-aside SBIR funds that might be more productively used for projects with no venture capital participation. SBA has issued an Advance Notice of Proposed Rule-making (ANPRM) and is addressing this issue through its public rule-making process.

In closing, NASA supports the SBIR/STTR programs. Technological innovation is vital to the performance of NASA's Mission and the Nation's prosperity and security.

NATIONAL SCIENCE FOUNDATION
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ARLINGTON, VIRGINIA 22230

April 27, 2007

OFFICE OF THE
DIRECTOR

The Honorable David Wu
Chairman
Subcommittee on Technology and Innovation
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Thank you very much for the opportunity to provide a statement for the record on your hearing on the "Small Business Innovation Research Reauthorization on the 25th Program Anniversary".

Let me begin by noting that the Small Business Innovation Research (SBIR) program was invented at the National Science Foundation (NSF). As early as 1976, Roland Tibbetts of NSF initiated a new program for the support of the small business community with early-stage financial support for high-risk technologies with commercial promise. In 1982, based in large part on the success of our program, Congress expanded the SBIR program to other agencies by passing the Small Business Innovation Research Development Act.

With this history, it is indeed fitting that the NSF should provide a statement for the record, and the following comments are directly related to the questions that you posed to me in your letter of April 12.

1. Program Effectiveness: The NSF finds the SBIR and STTR programs to meet the objectives to stimulate and commercialize innovation consistent with the NSF strategic plan FY 2006 – 2011 by supporting the NSF vision "Advancing discovery, innovation and education beyond the frontiers of current knowledge, and empowering future generations in science and engineering".

2. Award Levels: The NSF recommends allowing STTR Phase I awards to go up to $150,000 to encourage partnerships and Phase II awards to $1,000,000.

3. Small Business Participation: The NSF supports state outreach efforts to attract small businesses to participate in the SBIR and STTR programs. The SBIR/STTR and EPSCoR programs within NSF collaborate to increase geographic distribution of small business awardees. The NSF uses various supplements to encourage

broadening participation of students and teachers from the underrepresented community into the small business environment.

4. Financing and Commercialization: The NSF offers Phase IB and Phase IIB supplement programs to bridge the innovation gap. The NSF recommends increased flexibility to use a portion of the SBIR/STTR set aside funds to provide commercialization assistance.

5. Administrative Costs: The NSF provides full administrative support to the SBIR/STTR programs. The community will benefit from additional flexibility if program funds can be used to provide on-site monitoring and mentorship to awardees.

6. Venture Capital Majority Ownership: The NSF recognizes that the private sector funds are essential for commercialization of the NSF supported emerging technologies. The NSF supports the definition of a small business as 500 or fewer employees regardless of predominant ownership by individuals or institutions.

Thank you for the opportunity to present our recommendations.

Sincerely,

Arden L. Bement, Jr.
Director

STATEMENT OF THE
COOPERATIVE STATE RESEARCH EDUCATION
AND EXTENSION SERVICE
UNITED STATES DEPARTMENT OF AGRICULTURE

We appreciate this opportunity to submit this statement to the Committee regarding the Small Business Innovation Research Program administered by CSREES on behalf of all USDA agencies. The mission of the Cooperative State Research, Education and Extension Service (CSREES) at the United States Department of Agriculture (USDA) is to advance knowledge for agriculture, the environment, human health and well-being, and communities through national program leadership and federal assistance. In this statement we will provide an overview of the USDA–SBIR program and attempt to answer the specific questions posed by the Committee.

Within USDA, the staff functions necessary to administer the SBIR program have been centralized in CSREES in order to provide the SBIR community effective, efficient and consistent service. These staff functions include solicitation, review and evaluation of proposals, award administration and post-award management. CSREES has well refined systems and procedures for administering grant programs due to a long history of managing extramural research grants. USDA and CSREES are very proud of this program that has supported over 1,600 research and development projects since its inception in 1982, allowing hundreds of small businesses to pursue innovative ideas and explore their technological potential.

Overall there are eight USDA agencies with research and development budgets that set aside 2.5 percent of their extramural research and development awards for the SBIR program. These agencies are Agricultural Research Service (ARS), Animal and Plant Health Inspection Service (APHIS), Cooperative State Research, Education and Extension Service (CSREES), Economic Research Service (ERS), Forest Service (FS), National Agricultural Statistics Service (NASS), Rural Development (RD), and Foreign Agricultural Service (FAS). In fiscal year 2006 these agencies contributed over $19.5 million to SBIR. Of the total USDA funding, approximately 82 percent is contributed by CSREES, about 12 percent is contributed by ARS and approximately three percent is contributed by the Forest Service.

The USDA–SBIR program administered by CSREES has two types of awards. The first is for Phase I feasibility studies that can be up to $80,000 for eight months and the second is for Phase II research and development grants that can be up to $350,000 for 24 months. Approximately 90 Phase I feasibility grants and 35–40 Phase II research and development grants are awarded annually. Successful completion of a Phase I study is prerequisite to receipt of a Phase II grant. Of the applications received, 15 to 17 percent of the Phase I and 50 to 60 percent of the Phase II proposals have been funded each year.

An important aspect of the SBIR program is post-award management. Most of the effort is directed toward Phase II projects that have demonstrated technical feasibility in Phase I and are continuing their research and development. A commercialization assistance program is offered to new Phase II winners so that grantees can work with a contractor who helps identify potential commercialization partners, markets or new business opportunities. In addition, the USDA's SBIR National Program Leaders conduct occasional site visits and work closely with all of the Phase II projects to provide advice and guidance. Since successful commercialization often takes several years, the USDA SBIR program maintains contact with past Phase II winners for many years in an effort to document those projects which achieve commercial success.

Program Effectiveness

The Committee has asked whether the SBIR program is meeting its objectives to stimulate and commercialize innovation in support of agency missions through expanded small business participation in extramural federal R&D and how program efficiency and effectiveness could be improved.

The USDA–SBIR program has effectively supported innovative R&D projects that have led to commercialization of important new technologies that have benefited many aspects of American agriculture and rural development. However, SBIR program managers believe they could encourage more participation by small business firms by increasing awareness of the SBIR opportunities through attendance at State and regional meetings. Program managers also believe site visits would allow them to work with current grantees and help them more rapidly achieve commercial success. Therefore we recommend allowing a small percentage of SBIR program funds be made available for these activities.

Award Levels

The Committee has asked what the appropriate award levels are in light of typical project costs to support agency missions, the trends in seed and early stage financing and the fact that there has not been an inflationary adjustment in award levels since 1992.

Given the size of the USDA–SBIR budget, current award levels are sufficient to meet our needs. USDA would have no objection if the maximum award levels were increased beyond the current $100,000 for Phase I and $700,000 for Phase II awards. However, any such increase would not directly affect our program because we are currently limiting grant levels to $80,000 for Phase I and $350,000 for Phase II.

Small Business Participation

The Committee has asked how the programs can increase the participation of innovative small business in federal R&D including the total number of small businesses, their geographic distribution, and participation of minority and disadvantaged firms.

As noted above, one way to increase small business participation in the SBIR program is through more effective outreach efforts.

Financing and Commercialization

The Committee has asked what common program elements are needed across all agencies to address financing gaps in the Phased award structure to provide commercialization assistance.

Different SBIR programs use different approaches to deal with the funding gap between Phase I and Phase II projects. USDA allows companies to eliminate this funding gap through a combination of a no-cost extension of the Phase I project together with pre-award authorization on the Phase II award. Other Departments allow companies to submit Phase I and Phase II proposals simultaneously. In reality, however, very few companies choose to take advantage of either of these options.

Regarding commercialization assistance, many SBIR programs offer commercialization assistance in Phase I and/or Phase II. The dollar limit on this assistance has been set at $4,000 for over 10 years.

Administrative Costs

The Committee has asked how program administration costs should be addressed in reauthorization in light of the fact that program costs are currently paid out of non-SBIR funds.

SBIR programs are not currently allowed to use any program funds for administrative purposes. This has become a serious problem for the USDA–SBIR program. The administrative costs for the SBIR program have to come from the limited general administrative funds within CSREES. We recommend allowing a small percentage of the SBIR program funds to be used for administrative purposes to improve overall program effectiveness. These purposes should include travel support for outreach efforts, support for commercialization assistance and support for the proposal review process.

As one example, the USDA SBIR program would like to be able to offer Phase II grant awardees a very successful private sector commercialization assistance program that costs $12,000 per company. Unfortunately, the lack of adequate administrative support funds coupled with the commercialization assistance limits precludes the use of this valuable assistance. Funds to support this program could be available if administrative costs were allowed.

Conclusion

In closing the SBIR program has been effective and has encouraged business initiative and innovation in the agricultural sector of our economy. Since its inception, over 1,600 innovators and entrepreneurs have received the resources they needed to examine the commercial feasibility of their ideas and many of these have gone on to achieve some measure of commercial success. With several relatively simple modifications we can improve on this successful track record and help even more small businesses, which in turn will help expand job opportunities in rural America and keep America's agriculture strong.

Thank you for the opportunity to provide these comments.