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

HEARING CHARTER
"Small Business Innovation Research Reauthorization
On the 25th Program Anniversary"
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 cross 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.

[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."

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% 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% of SBIR program awards in FY05 (DoD and HHS/NIH alone, 81%).

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.

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% 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 FY2005, 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 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, 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 underrepresented 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 FY2006 [P.L. 109-163] contains elements to strengthen the SBIR program in DoD, including a stronger

[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

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*. EO 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 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 the administration budgets since FY05 for the SBA Federal and State Technology Partnership (FAST) program and Rural Outreach Program (ROP).

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[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 noneconomic 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 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)

Participation could broadly be increased by raising the set aside above the current 2.5% for SBIR. The initial set aside in 1982 was 1.25% of extramural R&D. That was increased to 1.5% in 1992 and 2.5% in 2000. There have already been significant increases in SBIR funding in the last 8 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 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 approval 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

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

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.