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**Testimony  
Before the  
Subcommittee on Technology and Innovation  
Committee on Science and Technology  
U.S. House of Representatives**

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**Statement for Hearing entitled,  
“The Role of the SBIR and STTR Programs  
in Stimulating Innovation at Small High-  
Tech Businesses”**

*Statement of*

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Good afternoon, Chairman Wu and members of the Subcommittee. My name is Dr. Sally Rockey. I am the Acting Deputy Director for Extramural Research at the National Institutes of Health (NIH), an agency of the Department of Health and Human Services. Thank you for the opportunity to discuss the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs and the role they play in stimulating innovation. Among the 11 Federal agencies that participate in the SBIR program, the NIH is one of the largest funders of this program, and the largest Federal supporter of biomedical research.

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

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

#### **TYPES OF RESEARCH NIH SUPPORTS UNDER SBIR**

Examples of the types of research that NIH supports through the SBIR program include, but are not limited to, drug discovery, medical devices, biosensors, nanotechnologies, proteomics, imaging, bioengineering, behavioral research, and technologies that reduce

health disparities. Investigator-initiated ideas are the cornerstone of the NIH research portfolio, including projects supported by the SBIR program. Thus, while we solicit projects on specific topics, we also encourage small businesses to propose their own innovative research ideas that are relevant to our mission.

### **NIH SBIR PROGRAM OVERVIEW**

The NIH, in accordance with statute, must set aside 2.5 percent of its extramural research and development budget for a SBIR program. In fiscal year (FY) 2008, the NIH SBIR set-aside was about \$580 million. NIH awarded 806 new Phase I and 288 new Phase II SBIR projects to small businesses working in many different technology areas across the country. Funding decisions are based on several factors: 1) ratings from the scientific and technical evaluation process; 2) areas of high program relevance; 3) program balance among areas of research; 4) available funds; and 5) the commercialization status, when a small business concern has received more than 15 Phase II awards in the prior five fiscal years (FYs).

### **EMPLOYMENT EFFECTS ON NIH SBIR AWARDEES**

Since the program's inception in 1982, the NIH has invested more than \$5 billion in more than 19,000 projects to over 5,000 small businesses. Past studies of the SBIR program conducted by the NIH<sup>1</sup> and the National Research Council (NRC)<sup>2</sup> have shown that small businesses are seen as sources of economic vitality and are especially important as a source of new employment. In looking at job growth of SBIR awardee firms since the receipt of their award, the NRC found the mean employment gain was

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<sup>1</sup> National Institutes of Health, National Survey to Evaluate the NIH SBIR Program: Final Report, July 2003

<sup>2</sup> National Research Council Phase II Survey, An Assessment of the SBIR Program At the National Institutes of Health, 2009

29.9 FTEs. In addition, respondents estimated as a result of their SBIR projects their companies were, on average, able to hire 2.7 full time employees (FTEs), and to retain 2.2 FTEs that might not otherwise have been retained. Although the employee size limit for firms receiving an SBIR award is 500, the median size of companies receiving NIH SBIR awards is actually relatively small: 10 employees. Sixty percent were found to have 15 or fewer employees at the time of the NRC survey. These data suggest that the SBIR program has positive employment effects on small business job creation and growth.

### **PROGRAM EFFECTIVENESS: BRINGING IDEAS TO LIFE**

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

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

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

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

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

#### **PROGRAM FLEXIBILITY IS KEY: ONE SIZE DOES NOT FIT ALL**

NIH is continually focused on ways to address the needs of a diverse business community, multiple industries, different technology sectors, and diverse product outcomes. NIH attributes the success and effectiveness of its program to several factors, the most significant of which is flexibility in our proactive administration of the program to accommodate the changing nature of biomedical and behavioral research while increasing the efficiency and effectiveness of the program.

Examples of program flexibility include the ability to propose research projects in fields that have the most biological potential; the ability for an applicant to resubmit an unfunded application; and the ability to exceed the Phase I and Phase II award guidelines when the science proposed warrants such a deviation to produce successful outcomes. The SBIR median award size in FY 2008 was \$151,440 for Phase I and \$841,381 for Phase II projects. For STTR, the median award size was \$149,711 for Phase I and \$907,970 for Phase II.

In addition, we have developed programs to help companies address funding gaps between Phase I and Phase II and programs to help them negotiate the agonizing period between discovery and commercialization. For example, the Phase I/Phase II Fast-Track award and Phase II Competing Renewal award are aimed at accelerating research projects that have great potential to produce products; and, our commercialization assistance programs are targeted to the specific needs of small businesses funded by NIH.

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

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

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

Simply stated, one size does not fit all.

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

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

## **KEY TRENDS**

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

## **CONCLUSION**

In conclusion, I want to reemphasize the NIH commitment to supporting small businesses, maintaining the integrity of SBIR program, and ensuring that technology developments will help improve the health and extend the lives of all people. We are looking to small businesses, primarily through the SBIR program, to stimulate technological innovation, help us face new challenges and to produce not only new knowledge but also tangible benefits that touch the lives of every individual. We are hopeful that our continuing outreach efforts and actions to modernize the SBIR program will be helpful in that regard. Finally, we continue to believe strongly that flexibility within the SBIR program is essential to achieving greater successes in these programs. This concludes my statement. I will be pleased to answer any questions you may have.