



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

**Statement for Hearing entitled
“The Role of Small Business in Innovation
and Job Creation: The SBIR and STTR
Programs”**

Statement of

Sally Rockey, Ph.D.

NIH Deputy Director for Extramural Research

National Institutes of Health

U.S. Department of Health and Human Services



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Good afternoon, Chairman Quayle and members of the Subcommittee. My name is Dr. Sally Rockey. I am the 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 and our economy. 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. The SBIR/STTR program is a critical component that feeds the innovation pipeline resulting in today's medical advances.

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

The NIH SBIR/STTR programs are ideally suited for creating research opportunities for U.S. small businesses to stimulate technological innovation. Part of a complex innovation system, these programs provide dedicated funding for U.S. small businesses to conduct early-stage research and development (R&D) 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/STTR programs are one means by which NIH Institutes and Centers (ICs) accomplish their R&D objectives. A key feature that sets SBIR/STTR apart from other NIH programs is a focus on commercialization of the results of research. Thus, the programs serve to supplement the more basic and applied research programs of NIH.

TYPES OF RESEARCH NIH SUPPORTS UNDER SBIR/STTR

Examples of the types of research that NIH supports through the SBIR/STTR programs include, but are not limited to: drug discovery, medical devices, biosensors, nanotechnologies, proteomics, imaging, bioengineering, behavioral research, health services, and other 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 primarily encourage small businesses to propose their own innovative research ideas that are relevant to our mission as a way to have those closest to the technology highway drive innovation.

NIH SBIR/STTR PROGRAM OVERVIEW

The NIH, in accordance with statute, must set aside 2.5 percent of its extramural research and development budget for SBIR program and 0.3 percent for the STTR program. The overall set-aside for NIH SBIR and STTR activities in FY 2010 was \$690 million, including \$616 million for SBIR and \$74 million for STTR that supported 681 new Phase I and 246 new Phase II SBIR projects to small businesses working in many different technology areas across the country. Once all applications go through a rigorous and competitive two-tiered peer review process, 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 commercial potential.

The number of SBIR applications and new firms participating in the program was on a downward trend between fiscal years 2004 through 2009. However, the number of

applications increased in FY 2010, as did applications for most NIH grants, likely due to the resubmission of applications that were submitted for the American Recovery and Reinvestment Act funds but not initially funded. As a result, the award success rate in FY 2010 for SBIR programs was lower than for the NIH research line for the first time in five years. The FY 2010 combined success rate—the percentage of reviewed grant applications that receive funding—for the SBIR and STTR programs was at 17 percent, which was below the success rate of 20.6 percent overall for NIH Research Project Grants (RPGs).

Overall, the SBIR/STTR programs have complemented NIH's mission to advance science while reducing the burden of illness on public health.

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 NIH¹ and the National Research Council (NRC)² have shown that small businesses are seen as sources of economic vitality and are especially important as a source of new employment. In looking at job growth of SBIR awardee firms since the receipt of their award, the NRC found the mean employment gain was 29.9 full time employees (FTEs) from before obtaining the SBIR grant. In addition, respondents estimated as a result of their SBIR projects their companies were, on average, able to hire 2.7 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

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

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

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. This data suggest that the SBIR program is associated with positive employment effects on small business job creation and growth.

PROGRAM FLEXIBILITY IS KEY: ONE SIZE DOES NOT FIT ALL

NIH is continually focused on ways to address the needs of a diverse small business community, different industry sectors, and diverse product outcomes. NIH attributes the success and effectiveness of its program to several factors, the most significant of which is a flexible and proactive approach that adapts to the changing nature of biomedical and behavioral research while maintaining a highly competitive and effective 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 fund Phase I and Phase II awards at budgets that may exceed the established guidelines when the science proposed warrants such a deviation to produce successful outcomes. The SBIR median award size in FY 2010 was \$199,000 for Phase I and \$1,120,000 for Phase II projects. For STTR, the median award size was \$178,000 for Phase I and \$1,112,000 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 period between discovery and commercialization. For example, the Phase I/Phase II Fast-Track and Phase II B Competing Renewal award programs are aimed at accelerating research

projects with great potential to produce products and launching them forward into the next R&D stage of development. In particular, the Phase II B competing renewal allows existing SBIR phase II awardees to receive additional funds to continue the project while navigating the regulatory process which often can be a complex and time-consuming process. Additionally, we manage a suite of technical assistance programs, namely the Niche Assessment Program and the Commercialization Assistance Program (CAP), that provide a market opportunity analysis and tailored business mentoring to address very specific needs of selected SBIR companies. Thus we help companies grow into sustainable businesses. Additionally, we have developed a Performance Outcomes Data and Systems (PODS) tool for internal use by NIH program staff, which integrates all data about SBIR and STTR awards, success stories, and tracking data of companies that graduated from our CAP program all into one searchable platform.

For many biomedical technology companies, the SBIR program is an important source of seed funding for unproven, early-stage ideas that dilutes the risk other investors are not initially willing to bet on. However, a venture capital, angel investor, foundation, or other financing strategy is ultimately the only way that innovative products will enter the marketplace. Research and development in public health and biotechnology is characterized by high and intense capital needs to turn an idea into a product (e.g., it takes an average of \$1.2 billion to bring a drug to the market). This usually requires long development times (i.e., 5-12 years), compliance with strict regulations, exceptionally high “burn rates” of capital, and a real need for investment by venture capital companies, some of which are or are not majority-owned by individuals. Often, the necessity for multiple rounds of venture financing to fund the extensive and essential

clinical research is the only plausible way to commercialize a product. Individual firms or the SBIR program, alone, are not available to provide the average \$8 million per deal currently characterizing venture funding agreements as found by the NRC study of 2009 that evaluated the NIH SBIR program. It is important to keep in mind that while venture capital sources are extremely scarce following the recession, it is nevertheless an option a company should be able to pursue as it fits their business strategy without the fear of being excluded from our programs.

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

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 NRC's study found no evidence that participation of companies with multiple venture capital 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 venture capital companies.

PROGRAM ACCOMPLISHMENTS: BRINGING IDEAS TO LIFE

The SBIR program seeks to support the most scientifically promising projects for which private funds are not traditionally available.

The examples noted below demonstrate that tangible scientific benefits can result from a small investment in early-stage ideas with viable, commercial potential.

- Martek Global Services, a Maryland company that studied the effects of DHA, an omega-3 fatty acid important for healthy eye, brain, and heart development, grew into a global leader by developing [Life'sDHA™](#), a supplement contained in infant formulas, products for pregnant and nursing women, and food and beverage products sold worldwide. The company was recently acquired for \$1.1 billion by a Dutch company and this year was inducted into the Small Business Administration's SBIR Hall of Fame.
- The [Sonicare Power Toothbrush](#) is a widely used and dentist recommended consumer home care oral hygiene device effective in reversing gingivitis that has to date grossed over \$1.5 billion in sales. NIH funding allowed the company to create a \$300 million business and over 500 new jobs.

Examples such as these demonstrate the value of investing in early-stage ideas and underscores why the NIH SBIR/STTR programs are important to our mission and to the entire innovation process.

CONCLUSION

In conclusion, I want to reemphasize the NIH's commitment to supporting small businesses, maintaining the integrity of SBIR/STTR programs, and ensuring that technology development will help improve the health and extend the lives of all people. We are looking to small businesses, primarily through these programs, 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/STTR programs 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. We look forward to the reauthorization of this critical program. This concludes my statement. I will be pleased to answer any questions you may have.