skip navigational links

Assistant Secretary for Legislation (ASL)
DEPARTMENT OF HEALTH & HUMAN SERVICES
Mission | Divisions | Grants | Testimony | Other Links | ASL Home

SEARCH
HHS HOME
CONTACT US

Testimony

This is an archive page. The links are no longer being updated.

STATEMENT OF

JO ANNE GOODNIGHT

SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR)

PROGRAM COORDINATOR

NATIONAL INSTITUTES OF HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

THE SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

SUBMITTED FOR THE RECORD

TO THE

COMMITTEE ON SMALL BUSINESS

United States Senate

JUNE 21, 2001

I am Jo Anne Goodnight, Coordinator of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs at the National Institutes of Health (NIH). Our mission is the conduct of biomedical and behavioral research to improve the health of the nation. On behalf of NIH, I am pleased to have the opportunity to provide written testimony for the record on the Small Business Research and Development Enhancement Act of 1992, which was reauthorized by the Small Business Reauthorization Act of 1997.

This act is the enabling legislation for the STTR Program. The STTR and SBIR Programs are important components of the NIH extramural research portfolio. Within the Department of Health and Human Services (DHHS), the NIH constitutes about 98 percent of the Department's entire SBIR program and 100 percent of the HHS STTR Program. In addition, the NIH budget now constitutes the second largest amount of SBIR and STTR funding available across the Federal government. In FY 2000, the NIH awarded 1629 SBIR awards (including R&D contracts) amounting to $353.4 million and 138 STTR awards amounting to $21.8 million. In FY2001, we expect to award 1,800 SBIR awards and 145 STTR awards for a total of more than $435 million.

Technologies funded through our SBIR and STTR Programs have resulted in significant improvements to the health of the nation's people. The NIH STTR Program serves as an important complement to the SBIR Program by providing an effective mechanism for supporting commercially viable innovations that originate in our nation's research institutions.

The SBIR and STTR Programs share a number of common features. Each is structured as a three-phase process; each focuses on stimulating and fostering scientific and technological innovations; and each provides an effective means for commercializing innovations derived from Federally-sponsored research. The Programs, however, differ in two very important aspects. First, to be eligible for an STTR award, a small business must establish a formal collaborative relationship with a non-profit research institution; under the SBIR program this is not required. Second, under the SBIR Program, the Principal Investigator (PI) must have his/her primary employment with the small business concern; under the STTR Program, there is no such requirement.

My statement will focus on examples of the effectiveness of the NIH STTR Program as well as some of our recent efforts toward enhancing and streamlining the Programs to better serve the needs of the small business community. Because of the similarities between the STTR and SBIR Programs, my comments are not solely limited to the STTR Program.

Effectiveness of the NIH STTR Program

The STTR Program, like the SBIR Program, is well-integrated within the overall scientific programs and goals of the NIH. It has enhanced collaborative efforts between the small business research community and the academic research community. Under the "partnering" concept of the STTR Program, collaborations may be initiated either by researchers at the small business concern ***or*** the research institution. Collaborative opportunities such as these are most likely to result in innovative projects that have the greatest commercial potential and societal benefit.

We are pleased that the results of a recent study (GAO-01-766R) of the STTR Program conducted by the General Accounting Office (GAO) indicate that the partnerships between companies and research

institutions are contributing significantly to R&D and that a large number of companies have already realized sales of a product, process or service. We are also pleased that results of previous studies conducted by the GAO and the Small Business Administration indicate that the NIH SBIR program has one of the highest rates of commercialization of all agency SBIR Programs. Even those projects that have not realized the goal of commercialization have generated information for the equally important purpose of contributing to the knowledge base of science through peer-reviewed publications.

The success of our STTR and SBIR Programs may be attributed to several factors, the most significant of which is flexibility in our administration of the Programs. What have made our Programs so appealing are the opportunities for firms to propose R&D initiatives with truly revolutionary outcomes rather than restrict their ideas to projects that can only be conducted under a prescribed amount of time and money. Our experience is that the conduct of certain types of biomedical and behavioral research, such as nanotechnology, clinically-related studies, vaccine development, and drug discovery, does not routinely lend itself to prescribed maximum time and dollar levels. These are exceptions, but such projects can be important steps in integrally involving small businesses in some of the most exciting, cutting-edge research.

A second example of administrative flexibility is that while we issue grant solicitations for projects on specific topics, we also encourage investigator-initiated, mission-related and commercially-viable research projects by small businesses. In addition, because of the similarities between the two grant solicitations, both in research topics and in application instructions, NIH now issues a single solicitation for SBIR and STTR applications for multiple receipt dates throughout the fiscal year. The advantages of multiple receipt dates are numerous. If an applicant misses a deadline, the researcher need wait only four months, not a year, for the next submission date of a Phase I (feasibility study) or Phase II (full R&D) application. Applicants may also submit up to two revised applications on any of the receipt dates. Also, a small business with multiple core technologies can use the multiple receipt dates to stagger submissions of applications rather than dedicating all of its resources to just a single project.

A third example of administrative flexibility relates to the formal collaborative activities that must be conducted under the STTR Program. These collaborations may be initiated either by researchers at the small business concern or the research institution thereby creating a fertile ground for scientists and engineers to capitalize on the innovations and intellectual talents of their organizations. Collaborative opportunities such as these are most likely to result in innovative projects that have the greatest commercial potential and societal benefit.

NIH STTR Success Stories

Though STTR is a much younger program than the SBIR Program, a

number of NIH STTR projects have resulted in significant improvements to our nation's health and in increased productivity of other researchers. I would like to describe five successes in particular that exemplify the kind of STTR research NIH supports.

Transonic Systems, Inc.

Transonic Systems, Inc. of Ithaca, New York has used NIH STTR funding to develop tools and techniques to measure flow and pressure in mice. These measurements will help researchers to learn more about diseases, such as hypertension. Transonic Systems saw a need in the research community to have such flow measurement devices for studies in mice. As transgenic mice have become a prime model for physiology studies, researchers needed smaller measurement devices for flow and pressure to conduct acute studies and chronic studies of conscious animals. Transonic Systems developed these devices with great success. The company was able to develop and validate a cardiac output flow for acute and chronic studies. Transonic also developed (at the Cornell nanofabrication facility) revolutionary new manufacturing methods to make even smaller probes that researchers need for hypertension studies.

The *c*ompany president states, "This project would have been impossible without funding from NIH. NIH funding allows us to develop new technologies and make them available to the scientific industry at very modest prices." He also adds, "This project would have been impossible without our eminent researchers at Wake Forest University and Cornell University under SBIR funding, and a host of other researchers in the U.S.A. without NIH funding."

Attached are a few pictures of the new miniaturized probes developed under NIH funding.

Pictures of the new miniaturized probes developed under NIH funding (These images no longer function.)

The development of the miniaturized flow probe marks the first time that anyone has ever been able to chronically measure kidney blood flow in a conscious, exercising mouse. Since the kidneys control blood pressure in both humans and mice, these blood flow measurements will help researchers understand how diet and experimental drugs can alter kidney blood flow and hence kidney function, leading to improved medicines for Americans suffering from high blood pressure/hypertension.

Transonic Systems, Inc., now with more than 100 employees, manufactures and sells its ultrasound transit-time flowmeters, hemodialysis monitors and laser Doppler perfusion monitors to surgeons, nephrologists, researchers and equipment manufacturers around the world.

Vaxin, Incorporated

Through STTR support, **Vaxin, Incorporated** (formerly Vaxin

Pharmaceuticals, Incorporated) of Birmingham, Alabama developed a needle-less vaccine technology. Vaxin researchers discovered that certain recombinant viral vectors could be applied to the surface of the skin, resulting in an immune response to the genetic insert. Funding provided by an STTR Phase I grant funding resulted in the development of a novel tetanus vaccine. NIH has awarded a Phase II STTR grant to complete the pre-clinical development of a vaccine patch and begin the testing of the vaccine in people. Vaxin is currently developing similar vaccines against a wide variety of infections or cancers, all targeted toward painless, needle-less administration using a patch that can be simply placed on the skin.

Idaho Technology

A fourth example of a successful technology developed through NIH STTR funding is the development of a thermal cycler machine, called the LightCycler (shown below), which was developed by **Idaho Technology (IT.)**

Image of the LightCycler (This image no longer functions.)

In 1995, IT was a six-person niche player in the biotech business. Today IT employs 65 scientists and engineers and sells a growing range of instruments and reagents. IT company president states, "The STTR program gets much of the credit for this growth. Without the initial Phase I grant, we would not have developed the product that has brought us commercial success. The STTR program benefited us primarily by providing the following: (1) Seed capital to prove principal on a high-risk project; (2) A structure for collaboration with the University of Utah; and (3) A requirement for formal project planning and a division of labor between IT and the University."

Tranzyme, Incorporated

Another NIH STTR success story is the development of unique molecular approaches using cell- based assays (TransAssay$^{TM)}$ and gene transfer vectors (TranzVector ^{TM}), by **Tranzyme, Incorporated**, also of Birmingham, Alabama. These platform technologies are being applied to a diverse array of commercial applications, including cell-based assays for drug discovery and target screening, tools for functional genomics, and in vivo gene therapy for the treatment of cancer, ocular diseases, blood-related diseases, and Central Nervous System disorders.

Nanoptics, Inc.

Nanoptics, Inc., of Gainesville, Florida has received several STTR and SBIR and Phase I and Phase II awards from NIH over the last eight years. The awards have been in the following areas:

1. Plastic Optical Fiber

As a result of a Phase I and II SBIR, Nanoptics developed the

technology of making a 1 to 3mm diameter bundle of plastic optical fibers (up to 50,000). The bundle can transmit an image effectively similar to glass fiber bundles. These bundles can be used for endoscopes for minimal invasive medical procedures. The advantage of the plastic bundles is that they are flexible and much lower cost than glass. The first commercialized product is the NANOSCOPETM used in the procedure called intubation.

As stated by the company president, "The key point in the plastic optical fiber bundle development work is that a number of SBIR/STTR grants (totaling about $5M) were required to fully develop this platform technology. Nanoptics is now the world leader and has a number of patents in this area."

There are applications in (a) Low-cost endoscopy; (b) Low-cost biosensors; (c) Heads-up displays; (d) Industrial boroscopes; and (e) Local area network communications using the plastic optical fiber. Nanoptics has recently signed a joint venture agreement with a billion dollar Asian company to construct a manufacturing facility in Gainesville for this type of fiber for use in local area networks.

2. Mammography

Nanoptics has received about $2M in SBIR/STTR funding to improve early cancer detection. This work has been done in collaboration with Eastman Kodak. Two clinical trials are underway using the new approach. Nanoptics is currently having discussions with strategic partners and venture capitalists to commercialize their mammography technology.

Importance of the STTR and SBIR Programs Given Their Similarities

Although the Programs share some common threads, NIH believes that the STTR serves a very important function and one different than the SBIR Program. While SBIR is a vehicle for harnessing innovative ideas in the private sector, STTR taps a pool of technological innovations in our nations' research institutions. STTR stimulates technology transfer by providing an effective mechanism for academicians to partner with a small company to pursue a commercially-promising idea that would otherwise languish on the shelf. Regular research grants typically fund basic research. While academic researchers may play a consultant or collaborative role in an SBIR project, these entrepreneurial scientists/engineers cannot participate in the SBIR program in a significant way as long as their primary employment is with the research institution. Therefore, STTR makes a significant difference to a university professor who desires to be an entrepreneur but cannot leave the research institution to start a small business.

Recently, we have noted that the dynamics of the STTR and SBIR Programs are changing. Research institutions are working toward establishing an entrepreneurial environment to allow academicians to

pursue commercial applications of their innovative technologies. Such efforts to blend two distinct cultures have resulted in the development of mutually beneficial and synergistic relationships whereby the research institution retains the intellectual talent and the researcher is permitted to pursue and capitalize on their entrepreneurial activities. A few examples of research institutions that have successfully created an entrepreneurial environment include Purdue University, the University of Wisconsin at Madison, the Ohio State University, and the University of Alabama at Birmingham.

NIH Efforts to Enhance and Streamline SBIR/STTR Programs

STTR is a promising program, and NIH supports its continuation. While NIH has been pleased with the success of both the STTR and SBIR Programs, we are taking steps to enhance and streamline the programs, particularly with regard to Phase I/Phase II gap funding, program data collection, and outreach.

In an effort to narrow the funding gap that typically occurs between Phase I and Phase II, NIH established a Phase I/Phase II Fast-Track option designed to expedite the decision and award of Phase II funding. Applicants who satisfy certain criteria that enhance the probability of the project's commercial success may submit Phase I and Phase II applications for concurrent review. Small business concerns are encouraged to obtain commitments of funds and or resources from third party investors for commercialization of the product, process or service resulting from the STTR/SBIR grant. To date (since FY 1997) the NIH has issued 120 Fast-Track awards totaling $15.2 million. We realize that the Fast-Track option is not appropriate for all types of research. NIH informs "non-Fast-Track awardees" of other ways to bridge the funding gap. These include extension in time without funds, extension in time with funds, and allowing Phase II applicants to submit on any of our three annual receipt dates. In addition, we encourage awardees to seek potential State matching resources.

A second area NIH is focusing on to improve the STTR and SBIR Programs is through the establishment of a project monitoring system to collect and maintain information about our awardees. Such a data tracking system will enable NIH administrators to better determine the outputs and outcomes from projects supported through the SBIR and STTR mechanisms. Clearly, commercialization is a major goal of the STTR and SBIR Programs. However, for NIH awardees, there is often a lengthy time of seven to ten or even 12 years before Phase III commercialization is realized, a period that routinely extends well beyond NIH support. Thus, commercialization may be one metric for judging program success, but other measures will be considered as indicators of success, such as published papers, patents, FDA testing/approvals of drugs and devices, and the use of the technology in other research projects.

A third area in which NIH has focused to enhance the STTR and SBIR programs is through our outreach efforts. Each year, NIH participates in

three National SBIR/STTR Conferences, at least one of which is held in a rural state or a state that has not received a large share of SBIR/STTR funding. On July 2 and 3, NIH will host its 3rd Annual SBIR/STTR Conference at which over 900 attendees are expected. In addition, NIH staff routinely participate in regional conferences to provide information about the NIH application, review and award processes and potential funding opportunities. Due to the heightened interest of research institutions to learn more about the STTR and SBIR Programs, we have incorporated sessions focused on STTR and SBIR funding opportunities. We will continue our efforts to raise awareness in States and research institutions within them to disseminate information related to the STTR and SBIR Programs. Broad dissemination of information about the SBIR and STTR Programs is also being accomplished through an NIH ListServe message system, encompassing over 8000 subscribers from the small business community, academia, State entities, and others. NIH established a separate ListServe of STTR and SBIR awardees to inform them of important grant-related policies and procedures.

In recent years, several agencies participated in a SWIFT (SBIR -- Where Innovation Focuses Technology) Outreach Tour in which the Federal Program managers traveled by bus moving to a new State each day to inform small businesses and research institutions of STTR and SBIR funding opportunities. Last year, the SWIFT I "Field of Dreams" tour focused on the Midwest states. We visited Minnesota, Wisconsin, Iowa, Nebraska, South Dakota, and North Dakota. More recently, in May 2001, the SWIFT II "Patriot" Tour focused on northeast states, including Massachusetts, New Hampshire, New York, Connecticut, Vermont, and Maine. SWIFT III, targeted for May 2002, is expected to cover a number of states in the southern part of our country.

Conclusion

In conclusion, NIH is very pleased with its involvement in the STTR Program. Thank you for the opportunity to describe how NIH has utilized the STTR Program and benefited from it.

Last revised: September 24, 2001