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

The SBIR and STTR Programs at the National Institutes of Health – How are the Programs Managed Today?

Statement of

Jo Anne Goodnight

SBIR/STTR Program Coordinator
Office of Extramural Research
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:00 p.m.
Tuesday, June 26, 2007

Good afternoon, Chairman Wu, Ranking Member Gingrey, and members of the Subcommittee. My name is Jo Anne Goodnight. I am the Coordinator for the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs at the National Institutes of Health (NIH), an agency of the Department of Health and Human Services. Among the eleven Federal agencies that participate in the SBIR program, the NIH is one of the largest funders, second only to the Department of Defense, and the single largest supporter of biomedical research.

Thank you for the opportunity to provide this statement on how the SBIR/STTR programs are managed at the NIH and also for the recent opportunity for NIH to submit a statement for the record at the Subcommittee's April 26 hearing on SBIR program effectiveness and efficiency. I welcome this opportunity because the SBIR/STTR programs play an important role in achieving our mission of improving human health, particularly with respect to translating scientific findings and advances into tangible products and services that touch the lives of every individual.

My testimony focuses on the following topics and includes the six specific areas that you requested in your letter of invitation:

- Importance of the NIH SBIR/STTR programs;
- Enhancements to improve program efficiency and effectiveness;
- Gap funding programs;
- Key trends; and
- Outreach efforts to increase participation.

Woven through each of these topics is this overarching theme: program flexibility is key to enable us to achieve our mission of improving health and saving lives.

Overall, the SBIR/STTR program has complemented NIH's mission to advance science while reducing the burden of illness on public health. But the program has not increased participation at the same rate we have seen across the other sectors of the extramural

research community at NIH. While the number of NIH grant applications submitted by those sectors skyrocketed during the doubling of the agency's budget, the numbers of SBIR/STTR applications and firms participating in the program have begun to decline. While the reasons for this trend are not clear, factors that may contribute include firms losing eligibility, going out of business, not applying because of a perceived lack of incentives, or being too new to have fully developed the necessary infrastructure to successfully compete for an award. NIH is committed to maintaining the integrity of SBIR/STTR programs and ensuring that technology developments will be translated and disseminated for the benefit of all Americans.

IMPORTANCE OF THE NIH SBIR/STTR PROGRAMS

The NIH SBIR/STTR programs encompass 23 of NIH's 27 Institutes and Centers (ICs). Each IC has a mandate with well-defined priorities that address science and health from a specific perspective, disease area (e.g., cancer), or area of concern (e.g., aging). The SBIR/STTR programs, like other research and development (R&D) programs, are a means by which the ICs accomplish their R&D objectives. The unique feature of the SBIR/STTR programs is research with the potential to transform discoveries into real-world practice. Thus, they serve to supplement – but not supplant or diminish – the traditional research programs of NIH.

The many scientific advances achieved by NIH-funded researchers investigating the prevention, causes, treatments, and cures for common and rare diseases now allow people to live longer and healthier lives. Today, as the age of our population shifts, so too does the landscape of health problems -- from acute to chronic diseases such as heart attack, obesity and stroke; and healthcare costs are growing at a rapid pace. We are in a race, and we can win, but only through transformative discoveries and their

rapid translation from laboratory to patients. Projects funded through the SBIR/STTR programs focus on just that – the development of products resulting from innovative research.

Following are a few examples of how SBIR/STTR products are touching people's daily lives: vaccines and immunotherapeutics for applications including biodefense and food safety; novel anesthesia delivery devices to relax children during medical procedures; improved monitors to control blood glucose levels; safer methods for laser vision correction; needleless infusion patches to deliver drugs such as insulin; and improved research tools for studying dementia.

As is the routine for all grant applications submitted to the NIH, these successful projects underwent a competitive application, review and award process. A more in-depth description of the review and award process follows.

Review Process. The NIH employs a rigorous, external peer review process for all grant applications, including SBIR/STTR, as required by statute. Scientific Review Groups (SRG) identify projects with the highest scientific and technical merit based on five review criteria: Significance, Approach, Innovation, Investigators, and Environment. Commercialization potential is important in the review process and is considered under the "Significance" criterion. In addition, applications for SBIR Phase II grants place greater emphasis on commercialization by requiring a succinct Commercialization Plan.

Award Process. ICs consider several factors when making funding decisions: 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).

ENHANCEMENTS TO IMPROVE PROGRAM EFFICIENCY AND EFFECTIVENESS

NIH is continually focused on ways to streamline the application-to-award process and make the process easier and more efficient for small businesses to interact with us. In addition, we have enhanced our efforts to make the program more effective. We are seeing the fruits of some of those efforts in products that our awardees are developing. NIH attributes efficiencies and successes of the SBIR/STTR programs to several factors, the most significant of which is program flexibility. Flexibility is critical at a time when science is changing rapidly, becoming more complex, more interdisciplinary, and ever more expensive (e.g., it takes an average of $1.2 billion and 8-12 years to bring a drug to the market). We have been proactive to accommodate the changing nature of biomedical and behavioral research while aiming to increase the efficiency and effectiveness of the program.

Since the last reauthorization of the SBIR (in 2000) and the STTR (in 2001) programs, there have been numerous changes in our agency to respond to national health challenges. For example, following the tragic events of September 11, 2001, and the spate of anthrax infections, NIH's role in biodefense and public-private research partnerships changed dramatically, and we responded with some new funding opportunities that invited the small business research community to help address some of the challenges. For example, the anthrax attacks that followed the September 11th catastrophes made it very clear that the threat of bioterrorism with pathogens or biological toxins represents a serious danger to our Nation and to the world. Thus,

biodefense became a top national security priority. This emphasis has led the NIH to develop an expanded paradigm with respect to biodefense product development. As the lead Institute for biodefense research at NIH, the National Institute of Allergy and Infectious Diseases (NIAID) issued a special biodefense SBIR/STTR funding opportunity to engage small business partners from the pharmaceutical and biotechnology industries in the early stage development of biodefense products. From 2002 to 2006, the NIAID awarded $170 million to over 200 small businesses to advance the development of vaccines, therapeutics, and diagnostics for biodefense. Tangible examples of research achievements include advancement of the following:

- a promising smallpox therapeutic (ST-246);
- a novel skin patch delivery system for anthrax vaccine; and
- platform technologies that not only rapidly diagnose infections but also distinguish biological threat agents from more common infections with similar symptoms.

Examples such as these are why the NIH SBIR/STTR programs are important to our mission and to the entire innovation process.

Table 1 depicts SBIR/STTR requirements and summarizes the major enhancements made by NIH so that the programs can provide the maximum benefit to our mission.

Table 1: SBIR/STTR Requirements and NIH Enhancements

Considerations	SBIR/STTR Requirements per SBA statute, Program Policy Directives and/or Regulations	Enhancements to NIH SBIR/STTR Programs
Set-aside Amounts	SBIR: 2.5 percent of agency's extramural R&D budget each year through FY 2008. STTR: 0.30 percent of agency's extramural R&D budget each year through FY 2009.	SBIR/STTR budgets are allocated to each of the 23 participating NIH Institutes and Centers (ICs) based on their extramural R&D budget.
FY 2007 NIH Budgets	SBIR: $580.7 million STTR: $69.7 million **Total:** $650.4 million	NIH ICs work together to co-fund the most meritorious applications relevant to the NIH mission.

Table 1: SBIR/STTR Requirements and NIH Enhancements		
Considerations	**SBIR/STTR Requirements per SBA statute, Program Policy Directives and/or Regulations**	**Enhancements to NIH SBIR/STTR Programs**
Small Business Eligibility (summary from SBA's regulations, 13 C.F.R. § 121.702)	o independently owned and operated. o U.S.-owned and operated in U.S. o organized for-profit. o At least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, or for SBIR only, it may also be a for-profit business concern that is at least 51% owned and controlled by another for-profit business concern that is at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. o 500 employees, including its affiliates, and meets the other regulatory requirements found in Title 13 CFR Part 121.	None. NIH makes awards to small business concerns based on eligibility rules set by Small Business Administration (SBA).
Solicitations	Must issue a *minimum* of one Solicitation annually to announce research topics.	NIH issues *multiple* solicitations throughout the year for Grants, Contracts, and Cooperative Agreements.
Award Period	SBIR Phase I – *normally,* 6 months STTR Phase I – *normally,* 1 year SBIR/STTR Phase II - *normally*, 2 years	Agency discretion as provided by SBIR/STTR Program Policy Directives to exceed project period guidelines where scientifically appropriate for the project.
Award Amount (Statutory Guidelines)	SBIR/STTR Phase I – *normally,* $100,000 SBIR/STTR Phase II – *normally,* $750,000	Agency discretion as provided by SBIR/STTR Program Policy Directives to exceed budget guidelines where scientifically appropriate for the project.
Subcontracts	SBIR: *normally*, no more than 33% in Phase I and 50% in Phase II. STTR: Small Business Concern (SBC) MUST perform 40% minimum and Research Institution (RI) MUST perform 30% minimum of R&D.	SBIR: Agency discretion as provided by SBIR Program Policy Directive to subcontract more than 33% (Ph I) or 50% (Ph II) where scientifically appropriate for the project (e.g., animal studies or patient studies at a university). STTR: Small Business Act does not permit departure from 40% (SBC) and 30% (RI) minimum.
Principal Investigator	SBIR: Primary employment (>50% time) with company at time of award and during award. STTR: Primary employment with small business not stipulated. (NIH requirement: Must devote minimum of 10% effort to R&D.)	SBIR: Agency discretion as provided by SBIR Program Policy Directive to permit less than 50% employment where scientifically appropriate for the project.

Table 1: SBIR/STTR Requirements and NIH Enhancements		
Considerations	**SBIR/STTR Requirements per SBA statute, Program Policy Directives and/or Regulations**	**Enhancements to NIH SBIR/STTR Programs**
Performance Site	SBIR: R&D must be performed entirely in U.S.; part of research must take place in company-controlled research space. STTR: R&D must be performed entirely in U.S.; part of research must take place in company-controlled research space **and** part in that of partnering U.S. research institution.	Agency discretion as provided by SBIR/STTR Program Policy Directives some work may be performed outside the U.S; in rare circumstances that necessitate the use of foreign site (e.g., need patient populations) because of the study design/testing, investigators must thoroughly justify the use of site(s) in the application.
Program Change Between Phases (e.g., Phase I STTR to Phase II SBIR)	Phase II must follow the same program as Phase I.	None.
Direct Phase II Entry	Must receive Phase I award before obtaining Phase II award.	None.
Gap Funding	Agencies are encouraged to develop gap-funding programs.	**Phase I/Phase II Fast Track:** Simultaneous submission/concurrent review of Phases I and II (but not concurrent award) **Competing Renewal Phase II awards:** Agency discretion for projects that require clinical evaluation, Federal regulatory approval, and/or testing/assessment. Examples: drugs, vaccines, medical devices, imaging protocols, etc. Awards: Up to $1M/year for up to 3 years. **Administrative Supplement Awards** to Phase I/Phase II grants
Administrative Support	SBIR/STTR funds cannot be used for administrative purposes (e.g., salaries, travel, project monitoring, and outreach).	Non-SBIR/STTR program resources used, as available.
Program Evaluation	Under Congressional mandate, the National Research Council (NRC) required to conduct an evaluation of SBIR program. 5 largest agencies to pay for study. 3-year study is currently underway.	Non-SBIR/STTR program resources used for NRC study and the following NIH evaluations: Trans-NIH Evaluation of the SBIR Program: NIH SBIR awardees 1992-2001. Report: http://grants1.nih.gov/grants/funding/sbir_report_2003_07.pdf Regular Updates to document progress.

Table 1: SBIR/STTR Requirements and NIH Enhancements		
Considerations	**SBIR/STTR Requirements per SBA statute, Program Policy Directives and/or Regulations**	**Enhancements to NIH SBIR/STTR Programs**
		PODS - Performance Outcomes Database System: Dynamic monitoring system to track SBIR project outcomes.

As shown in the summary table above, NIH has utilized the discretion provided under the policy directives to achieve programmatic successes. For example, NIH exceeds judiciously the current $100,000/$750,000 Phase I/Phase II award guidelines when the science warrants a deviation to produce successful outcomes. 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. From FY 2000 through FY 2006, the size of our Phase I and Phase II awards has been increasing. The SBIR median award size in FY 2006 was $137,000 for Phase I and $833,000 per year for Phase II projects. For STTR, the median award size was $149,000 for Phase I and $816,000 for Phase II.

As another example of flexibility, there is no topic number on the NIH's grant application form. Therefore, applicants may propose investigator-initiated research for any project that fits the NIH mission.

GAP FUNDING PROGRAMS

In addition to providing flexibility to award levels, we offer several gap funding programs -- some for Phase I and some for Phase II awardees -- to enhance the current phased award structure to encourage private equity participation, provide commercialization

assistance, facilitate partnering opportunities, and ultimately to help small businesses cross the proverbial commercialization “valley of death” in moving their products into the marketplace. These programs are necessary since the funding needs of biomedical and behavioral research does not neatly fit into the linear process set out in the three phases of the SBIR/STTR program structure.

Phase I/Phase II Gap Funding. In an effort to narrow the funding gap between Phase I and Phase II, NIH established a Phase I/Phase II Fast-Track review option where applicants submit both the Phase I and Phase II application for concurrent review. We realize that the Fast-Track option is not appropriate for all types of research; therefore, NIH offers additional ways to bridge the funding gap. These include extensions in time without funds, extensions in time with funds, and permitting applicants to submit their Phase II applications on any of our three annual receipt dates, at any time after Phase I is awarded. In addition, we encourage small businesses to seek potential State matching resources.

Phase II/Phase III Gap Funding. Gap funding between Phase I and II is important to continuing the research momentum; however, gap funding between Phases II and III is important to facilitating the transition of R&D into tangible products. Therefore, NIH recently began offering an opportunity to eligible Phase II awardees to seek a competing renewal Phase II award. This funding opportunity is intended for projects (e.g., development of drugs, medical devices, or biologics) in which clinical investigations must be conducted and Federal regulatory approvals obtained, or for projects in which testing and evaluation (e.g., computerized patient assessment tools) are required to realize the potential of the product. The standard Phase I and Phase II

award amounts often represent only a small fraction of the funds and time necessary to complete the studies required for approval and licensing by the Food and Drug Administration (FDA) and/or other Federal agencies. These products have the potential to contribute significantly to the health of the Nation. The intent of the SBIR/STTR Phase II competing renewal grants is to support such long lead-time and high-cost R&D projects. We recognize the need to track the awardees under this new opportunity to ascertain if the Phase II Competing Renewal award is associated closely with higher levels of commercialization.

In addition to gap funding programs, and as provided for in the SBIR Program Policy Directive, the NIH has developed a menu of technical assistance programs that are targeted to companies' individual needs. A description of the current programs that we offer is provided below.

Niche Assessment Program: Often, scientists do not have the entrepreneurial skills to assess whether there are other applications or niches for their SBIR-developed technology, so they typically under estimate its true market value. The Niche Assessment Program is for Phase I awardees to help them assess the market opportunities and needs and concerns of the end-users and help to discover new markets for possible entry.

Commercialization Assistance Program (CAP): CAP provides entrepreneurial training assistance and one-on-one business counseling to Phase II awardees in order to develop and implement an appropriate business strategy that will help commercialize the products that have resulted from their SBIR research projects. CAP culminates with an investment event at which the participants present their business opportunities to a

targeted group of potential investors and/or strategic partners. A recent enhancement to the CAP makes available publicly the abstracts and company presentations upon completion of the CAP in an effort to facilitate the identification of commercialization partners after the opportunity forum. As part of CAP, NIH is tracking each participating company's commercialization progress for 18 months following completion of the program. Although investments and deals take time to mature, we believe the CAP is having positive impacts on SBIR companies seeking investments and partnerships. For example, one company is developing a technology to create a living blood vessel. This exciting medical advancement holds promise for coronary bypass candidates, lower limb amputation candidates, and hemodialysis patients. As a CAP participant, the company 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 in conjunction with the National Institute of Standards and Technology Manufacturing Extension Partnership (MEP) program to help companies make 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).

All of these enhancements are focused toward helping companies succeed through the SBIR/STTR phases. Equally important is the need to track outcomes for the investments we are making, as commercialization is a major goal of the SBIR/STTR programs. However, for NIH awardees, there is often a lengthy time of 8-12 years before Phase III commercialization is realized, a period that routinely extends well

beyond NIH support. Thus, although commercialization may be one metric for judging program success, NIH also considers other metrics, such as published papers, patents, FDA testing/approvals of drugs and devices, Initial Public Offerings, and the use of the technology in other research projects.

SBIR Program Databases. Based on these metrics, the NIH conducted a comprehensive evaluation of its SBIR Phase II awardees that received funding between FYs 1992-2001. The results and findings of the survey formed a baseline for a dynamic monitoring system, called Performance Outcomes and Data System (PODS), to evaluate the performance of the SBIR program that includes measuring the success of award recipients in commercializing products or services resulting from their research. Unlike static annual reports, PODS is an efficient dynamic monitoring system that enables NIH administrators to determine better the outputs and outcomes from SBIR projects. Regular updates since 2002, the most current being March 2007, enable the NIH to document the continued achievements of those SBIR awardees over time. For instance, since the 2002 survey, some key data are: the number of awardees receiving additional non-SBIR funding or capital increased 33%; the number of awardees with FDA-approved projects increased 51%; and the estimated cumulative sales of those awardees increased over 200%.

Most recently, we established an *NIH Pipeline to Partnerships*, a virtual space for our awardees to showcase their technologies and product development to potential strategic partners, investors, and licensees. This exciting opportunity for SBIR/STTR awardees is expected to be launched formally in July 2007.

KEY TRENDS

This year marks some major milestones in the history of the SBIR/STTR programs. First, we celebrate the 25th anniversary of the SBIR and the 15th anniversary of the STTR program. Since the inception of these programs, the NIH has invested more than $5 billion in more than 19,000 projects to over 5,000 small businesses. In spite of our commitment to small businesses and our proactive enhancements to the NIH SBIR/STTR programs, small business participation in these programs has been decreasing since FY 2004, at a time when non-SBIR applications have increased significantly (see chart below).

NIH SBIR Program Percentage Change in Applications from Prior Fiscal Year.

Fiscal Year	Ph I and Ph II Application Base	Other Research Applications (non-SBIR/STTR)
2000	11.0%	5.3%
2001	-13.0%	21.%
2002	12.8%	6.0%
2003	25.4%	15.4%
2004	19.0%	17.7%
2005	-11.9%	5.4%
2006	-14.9%	6.1%

These decreases are in contrast to the overall increases in the number of other NIH research grant applications (non-SBIR/STTR) since the end of the NIH budget doubling in FY 2003. Even now, these other grant applications have experienced an annual increase, albeit smaller, in submissions. The NIH SBIR program funding level nearly doubled also during that period (FYs 1998-2003), from $264.7 million to $525.1 million, or 98.4 percent. Since FY 2003, there have been modest increases in the NIH SBIR funding level, amounting to $55.6 million, or an increase of 10.6%, with the SBIR set-aside amount for FY 2007 estimated at $580.7 million. In addition, the number of new small business concerns participating in the NIH SBIR program has been decreasing

since 2003, with only about one-fourth of the awardees being new to the program in FY 2006 -- the lowest proportion within the last decade. Also, at a time when the percentage of new SBIR recipients (i.e., organizations with no previous NIH SBIR support) is diminishing and the total number of applications has also been decreasing, the percentage of applications from, and awards to, the top 100 SBIR award recipients has grown significantly since FY 2000. The table below summarizes the landscape.

NIH SBIR Program Landscape (FY2003 - FY2006)					
	Percent Change From Prior Fiscal Year				FY2006 Actual
	2003	2004	2005	2006	
Competing Research Project Grants (non-SBIR)	15%	18%	5%	6%	9,128
Total SBIR Funding Levels	11.5%	7%	1%	0%	$580.7 Million
Total SBIR Applications	25.4%	19%	**-12%**	**-15%**	4,580
Applications from Top 100 SBIR Recipients	9.5%	28%	0%	5%	574
Competing SBIR Awards	8.3%	**-3%**	**-16%**	**-3%**	1,080
Competing Awards to Top 100 SBIR Recipients	0.5%	13%	**-10%**	22%	236
Competing Awards to New Firms	10%	1%	**-27%**	**-15%**	234
Total Firms Participating (Funded Applicants)	8%	**-3%**	**-16%**	**-3%**	765
New Firms Participating (Funded Applicants)	11%	**-4%**	**-26%**	**-14%**	202

Mr. Chairman, you asked what factors may be contributing to the changes in our applicant pool. There are several possibilities. 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 and the number of grants awarded is not a sufficient opportunity incentive.

Just as the biomedical research and disease landscape has been changing, the NIH SBIR/STTR landscape has been changing as well. NIH would like to increase small businesses participation in the SBIR and STTR programs and to use the programs as

one, but not the only, resource for funding innovative, commercially viable ideas. In an effort to increase participation, NIH plans to give funding preference to new firms (i.e., organizations with no previous NIH SBIR/STTR support) and/or to firms that respond to agency-specific priorities.

OUTREACH EFFORTS TO INCREASE PARTICIPATION

Outreach is also key to increasing participation, especially for new companies and those who may find the process confusing or daunting. Attendees learn not only about the programs, but also get an opportunity to meet one-on-one with NIH staff to discuss the "fit" of their technology within our agency. As time and resources permit, we hold an annual NIH SBIR/STTR conference, which typically draws 600-800 attendees, and we participate in national, regional and state conferences throughout the year and around the country, especially those focused on increasing the participation of small firms owned by women or socially and disadvantaged individuals. Our participation in the *Small Business Veterans Conference* (Las Vegas, NV) and the *Alabama A&M University 2007 SBIR/STTR Small Business Conference* (Huntsville, AL) are just two examples of recent efforts to improve the application and award proportion of these groups. My personal key message at each of these events is: "Yes, I'm from the Government, and I really am here to help you… therefore, do not leave with any question unanswered." In addition to these outreach efforts, NIH offers administrative supplements to NIH SBIR/STTR awardees to improve the diversity of the research workforce by supporting and recruiting students, postdoctorates, and eligible investigators from groups that have been shown to be underrepresented.

CONCLUSION

In conclusion, I want to reemphasize the NIH commitment to help improve the health and extend the lives of all people. We are looking to small businesses, primarily through the SBIR/STTR programs, to 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/STTR programs is essential to achieving greater successes in these programs. This concludes my statement, Mister Chairman. I will be pleased to answer any questions you may have.