



**Testimony
Before the
Committee on Small Business and
Entrepreneurship
U.S. Senate**

**Statement for hearing entitled,
“The Recovery Act for Small Businesses:
What is Working and What Comes Next”**

Statement of

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Good afternoon, Chairwoman Landrieu and members of the Committee. 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 participation of small businesses in the American Recovery and Reinvestment Act (ARRA) at the NIH. As you know, small businesses provide an important source of innovative technological research at NIH primarily through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) program. Among the 11 Federal agencies that participate in the SBIR/STTR program, the NIH is the largest civilian funder of this program, and the largest Federal supporter of biomedical research. First allow me to speak to the NIH SBIR/STTR program.

IGNITING IMAGINATION AND SPURRING DISCOVERY: IMPORTANCE OF SBIR/STTR

Fueling a complex innovation cycle, the NIH SBIR/STTR 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 to benefit public health. The NIH, in accordance with statute, sets aside 2.5 percent of its extramural research and development budget for a SBIR program and 0.3% for STTR. In fiscal year (FY) 2009, the total NIH SBIR/STTR set-aside is about \$672 million. These programs are one means by which the NIH Institutes and Centers (ICs) accomplish their R&D objectives and are ideally suited for creating research opportunities for U.S. small businesses to stimulate technological innovation. A unique feature of the programs is the focus on commercialization of research outcomes. Thus,

the program serves to supplement the robust basic and applied research programs of NIH.

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).

RECOVERY ACT IS HELPING SMALL BUSINESSES SUCCEED

Most recently, the NIH received \$10.4 billion in funds through the American Recovery and Reinvestment Act. The Agency is extraordinarily grateful to the President, Congress, and the American people for the opportunity to participate in the crucial effort to stimulate the economy. Our motto is “Recovery to Discovery.” Thanks to the Recovery Act, NIH can now support even more research to fuel the economy through job retention and creation and push the boundaries of science to accelerate progress in finding new treatments and cures for some of our most devastating diseases. Small businesses are participating fully in the NIH ARRA program, and I am pleased to say that they responded, like the rest of the research community, with unprecedented enthusiasm for the funding opportunities NIH had to offer. NIH developed a multifaceted strategy in implementing the ARRA program and small businesses were participants throughout the range of Recovery Act funding approaches. By including qualified small businesses in almost every ARRA funding opportunity offered by NIH, we were able to assure that small businesses had opportunities where they traditionally may not have

participated in the past. They were able to put forth promising projects and compete with academic applicants. In addition, NIH created and implemented a number of new Recovery Act programs specifically designed for small business. All in all, small businesses have taken full advantage of the opportunities provided by the additional NIH Recovery Act funding.

THE IMPACT OF ARRA

The response from the small business community has been strong and the results impressive. Of the \$8.2 billion received for scientific research activities, an estimated \$7.3 billion is classified as extramural R&D. As of September 30, 2009, NIH has obligated almost \$5 billion for almost 13,000 awards. NIH has expended approximately \$97 million of stimulus dollars to meritorious small business concerns and has already committed about \$50 million in additional stimulus funds for second-year commitments of the FY 2009 awards – that is almost \$150 million of ARRA funds dedicated to small businesses to date. Additional Recovery Act funds will be expended in FY 2010 for new programs that target the U.S. small business community, which I will detail below, and potentially additional supplement and competing revision awards.

Notably, without ARRA funds, a number of SBIR and STTR applications that were previously reviewed and determined to be meritorious would not have otherwise received support. NIH ICs have thus far used approximately \$31 million of ARRA dollars to fund these applications, as well as administrative supplements to previous SBIR/STTR awardees. Supplements are used to accelerate the pace of the science, one of NIH's major goals for the Recovery Act.

One beneficiary of this effort was *Visionquest Biomedical* of Albuquerque, New Mexico, an SBIR Phase II awardee that is developing a low-cost, high-resolution camera that can produce retinal and optic disc images with five times greater resolution than cameras used today. Through ARRA, the National Eye Institute was able to reach beyond its pay line and provide this Administrative Supplement award to enable the company to progress more quickly in commercializing this product.

In addition to the expanded support of already reviewed applications, NIH utilized ARRA funds to expand scientific research with new programs:

- The Challenge Grant program focuses on specific knowledge gaps, new technologies, data generation or research methods in 15 broad scientific areas. As of September 28, 2009, NIH received over 20,000 applications to this program, and has obligated almost \$400 million in Challenge Grant funds to over 750 projects. About \$7 million of these funds went to small businesses, with an additional \$6 million already committed for FY10.
 - For example, *Hepregen, Inc.* of Winchester, Massachusetts, received a Challenge Grant award to address a broad need in the area of regenerative medicine, specifically aimed at developing miniaturized living human tissue microarrays for evaluating drug disposition and drug-induced liver injury, a serious challenge for patients, regulatory agencies, and pharmaceutical/ biotechnology industries.

- Another program supported by ARRA funds to which small businesses have applied is the Research and Research Infrastructure “Grand Opportunities,” or “GO” grants, which are aimed at applicants proposing to develop and implement critical research innovations to advance the research enterprise, stimulate future growth and investments, and advance public health and health care delivery. As of September 28, 2009, NIH received over 2000 applications and has obligated almost \$450 million to over 250 projects. NIH has to date provided over \$30 million of these funds to small businesses and has already committed an additional \$24 million.
 - One recipient of a GO grant is *Titan Pharmaceuticals, Inc.*, of San Francisco, California, which received funds to evaluate an innovative Probuphine treatment of opioid addiction through a subcutaneous implant formulation to address important health issues of compliance with treatment. Over 1.6 million people in the U.S. and 15 million people globally (0.2% of the global population) are abusing or dependent on opioids.
- The Summer Research Experience for Students and Science Educators program provides supplementary awards throughout the two-year ARRA period to encourage students to pursue research careers and provides summer internships at NIH-funded laboratories for science teachers. Under this program, NIH will provide a total of \$45 million in FY 2009 and FY 2010 to over 1,000 awards in virtually every State. These funds support almost 5,000 placements over the two summers. Small businesses received 42 such awards for a total of

\$1 million to create opportunities for over 100 students and science teachers to participate in ongoing research studies, join research teams, and gain first-hand insights by learning state-of-the-art techniques in modern biomedical sciences. This is a unique opportunity for students to experience how science is done at small businesses, exposing them to an often overlooked venue for careers in biomedical research.

- For example, *Techshot, Inc.* of Greenville, Indiana, a recipient of a SBIR Phase II award, received funds under the Summer Research Experience program to support undergraduate students to participate in a project leading to magnetic separation technology that provides an improvement in potency and yield of pancreatic islets for transplantation, which showed reversal in insulin dependence in Type 1 diabetics in clinical trials.

NIH has also launched two new programs specifically targeted at the U.S. small business community:

- The Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) pilot program, is intended to address the funding gap and provide a critical bridge across the so-called “Valley of Death” between discovery and commercialization for U.S. commercial enterprises. We received 742 applications for this program and anticipate completing the review process and making funding decisions in early FY 2010. NIH has designated at least \$30 million for this program.

- The Small Business Catalyst Awards for Accelerating Innovative Research (Catalyst) program aims to encourage high-risk, high-reward ideas with high commercial potential to lead to products that will improve public health and generate significant value and economic stimulus. Applications from small business concerns and entrepreneurs of exceptional creativity without a history of prior NIH funding are especially encouraged for the Catalyst program. The Catalyst program utilizes the SBIR Phase I funding mechanism. This program received 689 applications, and funding decisions are expected in early FY 2010. NIH has designated at least \$5 million for this program.

Therefore, we expect that in the course of the fiscal years allotted for expending ARRA funds (FYs 2009 and 2010), more NIH funds will be directed to small businesses than in prior years as our Institutes and Centers continue to commit new dollars. We are very pleased to be able to enable many small businesses maintain their momentum on important health projects and help kick start even more new cutting-edge ideas.

CONCLUSION

In conclusion, I want to recognize the efforts of the small business community in responding to the opportunities provided by Recovery Act and reemphasize the NIH commitment to supporting small businesses through ARRA, maintaining the integrity of SBIR/STTR program, and ensuring that technology developments will help improve the health and extend the lives of all people. We are looking to small businesses, to help us face new challenges and to produce not only new knowledge but also tangible benefits that touch the lives of every individual. Finally, we continue to believe strongly that

flexibility in proactive program administration is essential to achieving greater successes and effectiveness of NIH programs for small businesses.

This concludes my statement. I will be pleased to answer any questions you may have.