Statement of Jon Baron

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Chairman Wu, Ranking Member Gingrey, and Members of Science and Technology Subcommittee on Technology and Innovation:

I appreciate the opportunity to testify on the reauthorization of the SBIR program. My testimony draws on my involvement in the SBIR program since 1990 in several different capacities –

- First, as Counsel to the House Small Business Committee, where I was the lead staffer for the 1992 reauthorization of SBIR and establishment of the STTR program;
- Second, as the Program Manager for the Defense Department's SBIR and STTR programs from 1995-2000, where I introduced and led program reforms that were found highly effective in an independent evaluation by the National Academy of Sciences, and received the Vice President's Hammer Award for reinventing government; and
- Third, as a member of the Steering Committee for the National Academy of Sciences'study the SBIR program since 2003.

However, the views expressed here are my own.

My testimony will briefly address the contribution of the SBIR program to the American economy, and then suggest ways in which the program might be strengthened, so as to increase that contribution.

In several instances, the SBIR program has spawned breakthrough technologies that have transformed their field and made a major contribution to the American economy.

Here are two illustrative examples. Under the Department of Defense and Department of Energy SBIR programs, Science Research Laboratory of Somerville, Massachusetts developed a set of technologies that greatly improved the performance and reliability of "excimer lasers" – improvements which, for the first time, made these lasers a commercially-viable tool for writing circuits onto computer chips. The lasers increased, by about one-third, the number of circuits one can fit onto a chip, rapidly became the state-of-the-art technology in chip production worldwide, and have thereby increased the computing power of virtually every commercial and military system developed since the late 1990s. Sales of excimer lasers now exceed $250 million annually.

As a second example, under the NIH SBIR program, Martek Biosciences Corporation of Columbia, Maryland developed new technologies for producing omega-3 fatty acids called DHA and ARA, which have been approved by the Food and Drug Administration for use in infant formula, so that it more closely resembles breast milk. Martek's DHA and RHA are now added to nearly 90 percent of infant formula used in the United States, and are also sold overseas in more than 65 countries. They have been consumed by over 24 million babies worldwide. Importantly, these fatty acids have been shown in randomized clinical trials to increase the

height, weight, cognitive development, and motor development of pre-term infants by age 2. Martek's SBIR-developed technology has thereby contributed, in a fundamental way, not only to the American economy, but also to the life and health of millions of children worldwide.

There is reason to believe that a few modifications to the SBIR program could substantially increase its success in producing such breakthrough technologies.

Since the SBIR program was launched in 1983, it has spawned perhaps 10-20 "breakthrough" technologies like those I just summarized – that is, technologies which transformed their field and became major commercial successes. In addition to these, the program has produced a number of smaller but still important technological and commercial successes. And then, in a third category, some SBIR projects have not produced significant technology commercialization in either commercial or government markets. GAO studies of the program, as well as the results of DoD's own studies, suggest that over half of SBIR phase II projects fall into this category of no significant commercialization.

In part, that is the nature of high-risk R&D – one can expect that only a fraction of projects will succeed, and fewer still will be breakthrough successes. However, there is evidence to suggest that the program could achieve substantially higher success in producing such breakthroughs. Specifically, the GAO studies and DoD data show that some SBIR companies – perhaps as many as half of those that have participated long enough to build a track record – *consistently* are unable to convert their SBIR awards into viable new products sold to commercial or government customers. These are companies which usually have strong research capabilities – which is why they win SBIR awards – but lack the *entrepreneurial* capabilities, and in some cases the motivation, to convert their research into successful new products. Many of these companies find the commercialization process to be unfamiliar, outside their skill set, and daunting.

Thus, modifications to the SBIR program that provide strong incentives and/or assistance to SBIR awardees to strengthen their entrepreneurial capabilities could potentially correct this source of systematic under-performance, and greatly increase the program's success in spawning commercially-successful technologies that make a major contribution to U.S. economic capabilities.

Many of the federal agencies recognize this problem – that SBIR companies often lack key entrepreneurial capabilities -- and have tried innovative approaches to address it.

Illustrative examples of approaches that agencies have tried include:

- Giving a competitive priority, and/or additional funding, to SBIR applicants or awardees that obtain matching funds from a third-party commercial investor;
- Using a company's track record in commercializing its prior SBIR awards as a key criterion for evaluating its current SBIR proposals.
- Providing training to SBIR awardees in commercializing their SBIR technologies;
- Requiring SBIR applicants to include a streamlined business plan in their proposal;
- Including individuals with business experience on the SBIR proposal review panels; and

- Increasing the involvement of potential customers for SBIR products – such as DoD acquisition program offices -- in the development of SBIR solicitation topics.

However, none of these innovations in program management has ever been evaluated in a study rigorous enough to provide *strong* evidence of its effect on key SBIR outcomes -- outcomes such as commercialization and contribution to scientific understanding.

And so, even though the SBIR program has been around for nearly a quarter-century, we have many good hypotheses but no scientifically-valid evidence about "what works" in improving program performance. That is the central idea I wish to convey in my testimony. The ideas for SBIR program improvement that we're discussing in the current reauthorization process are similar to the ones that were discussed in the 2000 reauthorization, and in the 1992 reauthorization before that. At the agency level, pilots and demonstrations come and go, but without rigorous evaluation, little has been learned about what worked.[1]

Thus, I'd recommend that Congress direct the agencies to allocate 1% of their SBIR funds to conduct scientifically-rigorous evaluations of new approaches to building awardees' entrepreneurial abilities.

Wherever possible, these experiments should randomly assign SBIR program applicants, awardees, and/or research topics to the new approach or to a control group that participates in the agency's usual SBIR process. Such randomized experiments are recognized as the gold standard for evaluating the effectiveness of a strategy or approach across many diverse fields because, uniquely, they enable one to determine to a high degree of confidence whether the new approach itself, as opposed to other factors, causes the observed outcomes.[2]

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[1] The one partial exception is the National Academy of Sciences' 1999 study of the DoD "Fast Track," which is the most rigorous and impartial evaluation to date of a new approach to implementing the SBIR program. That study compared research and commercialization outcomes for DoD Fast Track SBIR projects to outcomes for a statistically-matched comparison group of non-Fast Track projects. The study found that the Fast Track projects achieved much higher levels of commercialization and made a larger contribution to the agency's research program than projects in the comparison group. These results, although highly valuable, should nevertheless be interpreted with caution because SBIR companies *self-selected* themselves into the Fast Track versus the comparison group, raising the possibility that any difference in outcomes between the two groups is due to inherent differences in their motivation or capabilities, rather than the Fast Track approach itself. There is consistent evidence from many different policy areas that such comparison-group studies, although extremely useful in generating good hypotheses about what works, may sometimes produce erroneous conclusions about an approach's effectiveness (for a summary of this evidence, see Office of Management and Budget, *What Constitutes Strong Evidence of Program Effectiveness*, http://www.whitehouse.gov/omb/part/2004_program_eval.pdf, 2004, pp. 4-8).

[2] See, for example, U.S. Department of Education, "Scientifically-Based Evaluation Methods: Notice of Final Priority," *Federal Register*, vol. 70, no. 15, January 25, 2005, pp. 3586-3589; the Food and Drug Administration's standard for assessing the effectiveness of pharmaceutical drugs and medical devices, at 21 C.F.R. §314.12; "The Urgent Need to Improve Health Care Quality," Consensus statement of the Institute of Medicine National Roundtable on Health Care Quality, *Journal of the American Medical Association*, vol. 280, no. 11, September 16, 1998, p. 1003; "Criteria for Evaluating Treatment Guidelines," American Psychological Association, *American Psychologist*, vol. 57, no. 12, December 2002, pp. 1052-1059; *Standards of Evidence: Criteria for Efficacy, Effectiveness and Dissemination*, Society for Prevention Research, April 12, 2004, at http://www.preventionresearch.org/sofetext.php; Office of Management and Budget, *What Constitutes Strong Evidence of Program Effectiveness*, op. cit., no. 1.

Some SBIR approaches would readily lend themselves to such a randomized evaluation, at modest cost and administrative burden. For example, an agency could randomly assign half of its SBIR awardees to a "treatment" group that is eligible for a larger phase II award if it obtains matching funds from a commercial investor (as is done under the National Science Foundation's "Phase II-B" process), and its other awardees to a control group that participates in the agency's usual SBIR process, without this Phase II-B. The evaluation would then track commercialization outcomes for the two groups over time, to determine whether the Phase II-B incentive made a difference in such outcomes. At agencies such as DoD that already track commercialization outcome data for most of their SBIR awardees, this rigorous study could be conducted at a low cost by using such data – perhaps $250,000 per year over five years as a rough estimate.

Based on existing evidence, I'd suggest two approaches to improving the SBIR program that may merit particular consideration for these rigorous evaluations.

The first of these is the approach of providing a larger phase II award, and/or a competitive priority in the phase II proposal evaluation process, to SBIR companies that obtain at least a partial match of funds from a third-party investor. The National Science Foundation's "Phase II-B" award, and DoD's "Fast Track" and "Phase II Enhancement" policies, are specific versions of this approach. The rationale for this approach is that an investor's hard commitment of matching funds is a strong endorsement of the SBIR company's entrepreneurial capabilities and the market size (commercial or military) for its technology. The National Academy of Sciences' study of DoD's Fast Track provides initial evidence that this approach yields much higher commercialization and research outcomes – evidence which, I'd suggest, merits confirmation in a randomized evaluation.

The second approach I'd recommend testing in a rigorous evaluation is that of using a company's track record in commercializing its prior SBIR awards as a key criterion for evaluating its current SBIR proposals. As noted earlier, some agencies such as DoD collect excellent data on companies' commercialization track records. These agencies could readily use this data in their proposal evaluation process to focus funds on companies that either have a strong SBIR commercialization track record or are new to the SBIR program, and away from companies that have repeatedly won SBIR awards but not commercialized. A rigorous evaluation could determine whether this promising idea does in fact improve the SBIR program's overall research and commercialization outcomes.

<u>Conclusion</u>: Over time, these rigorous studies could produce scientifically-valid, actionable evidence about "what works" to increase SBIR's success in spawning breakthrough technologies – evidence which, I'd suggest, is the critical missing piece that the agencies and Congress need to turn SBIR into a more powerful engine for American innovation and economic growth.