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SUBCOMMITTEE ON CONTRACTING AND TECHNOLOGY HEARING ON LEGISLATIVE INITIATIVES TO STRENGTHEN AND MODERNIZE THE SBIR AND STTR PROGRAMS

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BEFORE THE

COMMITTEE ON SMALL BUSINESS
UNITED STATES
HOUSE OF REPRESENTATIVES

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SUBCOMMITTEE ON CONTRACTING AND TECHNOLOGY HEARING ON LEGISLATIVE INITIATIVES TO STRENGTHEN AND MODERNIZE THE SBIR AND STTR PROGRAMS

Thursday, June 4, 2009

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:10 a.m., in Room 2360, Rayburn House Office Building, Hon. Glenn Nye [chairman of the Subcommittee] presiding.

Present: Representatives Nye, Ellsworth, Halvorson, and Schock.

Chairman NYE. Thank you all for being here today. I am going to read an opening statement and then invite our ranking member, Mr. Schock, to give an opening statement and then we will ask for our witnesses, our panelists, to give their statements.

Economist Peter F. Drucker once described innovation as the specific tool of entrepreneurs, and it is exactly that. Small firms produce 13 times more patents than big businesses, sparking breakthroughs in virtually every industry from health care to technology.

To the casual observer, it may look effortless. We have all heard about Mark Zuckerberg running Facebook out of his dorm room, but the truth is developing a new product is no easy lift. Innovation is a risky, resource-intensive process. Without proper funding, even the most brilliant invention may never make it from the drawing board to the marketplace. For entrepreneurs with limited resources, this is a very real danger.

In today's hearing, we are going to examine that challenge and look at legislation to address it. The proposals before us would improve and modernize the Small Business Innovative Research and Small Business Technology Transfer programs. This is key because an investment in innovation is an investment in our economy.

SBIR and STTR are critical resources. Each year, these initiatives help 1,500 companies get off the ground. Those firms have triggered revolutionary achievements in everything from bioengineering to antivirus software. And yet for every groundbreaking new product, countless more don't make it past the laboratory doors.

The proposals we are considering today will address the challenges of commercialization. As of now, the majority of SBIR and

STTR projects, particularly those in the defense industry, never come to fruition.

It is important that the SBIR program develop products that agencies need. We are addressing this issue by requiring communication between SBIR program managers and procurement personal. This ensures that when DOD, for instance, needs a product the SBIR program is focused on meeting that need.

Understanding what makes a product marketable is also important. But unless you have the time and money to create that product, you can only go so far.

By increasing award levels and permitting equity capital, this legislation would give small firms those resources. This is particularly important today. With capital increasingly difficult to come by, it just doesn't make sense to limit options for entrepreneurs.

In the last year, the economic landscape has changed considerably. So has the face of entrepreneurship. While the word innovation often sparks images of Silicon Valley, the truth is that it comes from everywhere. That is why these proposals are so important. They encourage R&D in underserved communities and amongst historically underrepresented populations, including veterans. Because, if nothing else, innovation thrives on diversity of thought.

Despite inherent value, neither SBIR or STTR have been updated in nearly a decade. Today, they are in sore need of modernization. In the last Congress, the House passed a bill to modernize and extend the programs, but the legislation died in the Senate. With these proposals, we can restart that process.

As we work our way out of this recession, innovation will play an integral role. After all, downturns have a catalyzing affect on inventors. Take the recession of the mid-1990s, which ushered in the age of the Internet; or consider the Great Depression, which has been called the most technologically progressive area of the 20th century, bringing us such breakthroughs as synthetic rubber and a little-known fact here, canned beer. Who knew?

Once again, our country is facing historic challenges, but with a fresh investment in homegrown ingenuity we can begin turning things around. These proposals mark a critical first step in making that happen.

Now I would like to thank all of you for being here today; and I would like to yield to our ranking member, Mr. Schock, for any opening comments.

Mr. SCHOCK. Thank you, Mr. Chairman. Good morning.

Thank you, Mr. Chairman, for holding this hearing to review legislative proposals to reauthorize and modernize the Small Business Innovation Research, or SBIR, program.

I would like to extend a special thanks to each of our witnesses who are here today for taking the time to provide this Committee with their testimony.

The SBIR program is one of those government programs that actually works. Specifically, the program encourages and supports risk and entrepreneurship within the small business community. The program is based on the correct theory that responsible government assistance at the right time can be critical in start-up and development stages of a small firm. Not only does it spur growth

in individual companies, the program stresses the importance of expanding and diversifying research opportunities for the pool of companies the Federal Government uses to procure products and services. Thus, the SBIR program encourages both economic growth and innovation.

Created in 1982, the SBIR program offers competition-based awards to stimulate technological innovation among small firms while providing government agencies new, cost-effective technical and scientific solutions to meet their diverse needs. The development of these programs not only are critical to the unique needs of each of the participating Federal agencies but also to our national economy.

Small businesses invigorate the U.S. economy by introducing new products and cheaper ways of doing business, many times with substantial economic benefits. They play a key role in introducing technologies to the market, often responding quickly to new market opportunities. Some of greatest technological innovation come from small business owners experimenting in their workshops and labs, and the SBIR program provides these innovators with an opportunity to grow their ideas into practice, provide jobs, and improve our economy.

The SBIR was last reauthorized in the year 2000; and I am sure, as everyone in this room would admit, undoubtedly a lot can change over that length of time. And to fully capitalize on the benefits of this program, this is a very opportune time to reauthorize and also modernize it.

The proposals we have before us go a long way toward achieving the goals of modernizing the SBIR program with greater efficiency and accountability. For example, the legislation before us raises the award sizes for both Phase I and Phase II grants. This is essential because the award sizes have not been increased since the program's inception.

Additionally, the National Academy of Sciences' report on the SBIR program made note of the difficulty of properly studying and measuring the performance of the program because of inadequate data collection. In response, these bills will improve the way small businesses and sponsoring agencies share information by creating online databases to improve information flow between agencies and the participants.

The proposals before us today will also create an interagency policy among the participating agencies that require reports on specific findings to the relevant congressional Committees. The creation of these Committees and databases will allow for greater oversight and better management of the SBIR program.

However, I along with members of this Committee have some concerns about some of the provisions of the drafts. And while these concerns in no way overshadow my support of the SBIR program and the good-faith effort that is being made here today to improve the program, I remain certain that, as this Committee has done in the past under the leadership of Chairman Nye and Chairwoman Velázquez, together we will work with those members on the Committee to rectify any philosophical difference that may come up as we continue through this process.

I look forward to working with Chairman Nye and all of my colleagues on this Committee as we work on this important legislation. Again, I thank each one of the panelists for being here today. I look forward to your comments.

And I yield back, Mr. Chairman.

Chairman NYE. Thank you, Mr. Schock.

What I would like to now is go ahead and invite our panelists—I will call on you one by one—to make any opening comments you would like to make.

We are going to try to stick to the 5-minute rule. You have a device in front of you with some lights. It will start out green; and when it gets to yellow, it means you have 1 minute left to sort of wrap up your comments; and when it turns red, your 5 minutes are up.

Chairman NYE. I would like to start by recognizing Mr. Leahey, President and CEO of Medical Device Manufacturers Association, for any opening comments you have.

STATEMENT OF MARK B. LEAHEY

Mr. LEAHEY. Thank you, Mr. Chairman.

Chairman Nye, Ranking Member Schock, members of the Subcommittee, on behalf of the hundreds of innovative companies that the Medical Device Manufacturers represent across the country, I would like to thank you for your efforts to strengthen and modernize the SBIR and STTR programs.

MDMA's mission is to ensure that patients have timely access to safe and effective products, most of which are developed by small, innovative medical technology companies. After reviewing the Subcommittee's various legislative proposals, I am confident that, if enacted, these improvements ensure that small, innovative companies have access to necessary resources to develop life-sustaining and enhancing products.

Given the advances in science, increasing regulatory requirements, and access to venture capital that are often needed to develop the technologies, it is critical that changes are made. Furthermore, with today's economic climate, government assistance for small companies has never been more important.

One of the cornerstones of the government investment in small companies has been the SBIR and STTR programs. Resources from these programs, in addition to private investment, have greatly improved the quality of care over the past 20-plus years. However, as you are aware, the Small Business Administration's reinterpretation of the definition of ″individual″ has hindered the landscape of the public private-partnership envisioned by the SBIR program.

Since SBA's reinterpretation of ownership requirements under SBIR, the number of medical technology companies applying for grants has significantly declined. Applications for SBIR grants at the National Institutes of Health, the most prolific granter of SBIR grants to medical technology companies, have dropped nearly 12 percent in 2005, 14-1/2 percent in 2006, and 21 percent in 2007. As a result, many promising technologies from smaller companies did not receive support from SBIR; and patients have suffered as a result.

MDMA strongly believes that the SBIR program should support small companies with promising clinical technologies, regardless of whether venture capitalists have partnered with the company. Fortunately, this Subcommittee is taking the necessary steps to correct the actions of SBA and ensure that the SBIR and STTR programs are restored to their critical roles of providing promising entrepreneurial technology companies with the resources needed to develop the clinical solutions of tomorrow.

I would now like to focus my remarks on a few key elements of the Subcommittee's legislative proposals that are welcome improvements to the current programs.

First, as stated above, the reauthorization should include language to restore the participation of venture-backed companies, especially the redefinition of the ownership requirements for business concerns. This will serve to provide SBIR grants to the most promising technologies, which are likely to provide the greatest public benefit and patient benefit.

Second, MDMA believed that increasing the dollar amount of the Phase I and Phase II grants to $250,000 and $2 million respectively is critical to address increasing developmental concerns. In addition, it will help provide the necessary incentive to encourage more companies to apply for grants. Given that the award levels have not been modified since 1992, this change is long overdue.

Third, MDMA supports allocating additional resources to conduct outreach efforts to increase participation and provide application support and entrepreneurial skills to perspective participants. These initiatives should serve as an important tool for small companies to achieve the ultimate goal of successfully commercializing technologies that will benefit patients and caregivers.

Fourth, MDMA supports efforts to evaluate recipients of multiple Phase I awards but who are unsuccessful in receiving Phase II awards. This is an absolutely critical element to ensure that the program funds are allocated to those with the greatest likelihood of commercialization success.

Finally, it would be beneficial to remove the requirement that a company must have applied for a Phase I grant in order to apply for a Phase II grant. If this rule changed, MDMA believes that small business participation in the SBIR program would increase.

Adopting these challenges outlined above and included in the Subcommittee's legislative proposals are consistent with the SBIR and STTR programs to ensure that the Nation's small, high-tech, innovative businesses are a significant part of the Federal Government's research and development efforts. They are also consistent with the SBA's mission to strengthen the Nation's economy by enabling the establishment and validity of small businesses.

Thank you again for your efforts and leadership to improve and modernize these important programs, and I look forward to answering any questions that you may have. Thank you.

Chairman NYE. Thank you, Mr. Leahey. We appreciate your comments. And I again thank everybody for making the trip in today.

[The statement of Mr. Leahey is included in the appendix.]

Chairman NYE. I would like to introduce our second panelist, Mr. Jack Biddle, who is the founding partner of Novak Biddle Venture

Partners, Bethesda; and he is also speaking on behalf of the National Venture Capital Association.

Mr. Biddle.

STATEMENT OF JACK BIDDLE

Mr. BIDDLE. Thank you, Chairman Nye and Ranking Member Schock and members of the Committee.

I am a founding partner of Novak Biddle Venture Partners. I ask that my written testimony be added to the record.

Chairman NYE. So ordered.

Mr. BIDDLE. I have a few additional comments and would be pleased to take some questions. I hope I get asked questions about four real examples of where we have failed badly.

Because of our proximity to Washington, D.C., and the Federal Government, Novak Biddle is in a position to appreciate the power of collaboration between government and entrepreneurs. As someone who comes from a military family and has volunteered a great deal of time working with our military establishment in the last 5 years, I have donated about a million dollars worth of my time working with the Department of Defense trying to bridge the gap between the entrepreneurial community and the needs of the government. I have seen how the collaboration between many brilliant engineers and scientists has broken down. In my view, this isn't the best outcome for our government's U.S. military or our national security.

In past years, the best and brightest scientists worked in the government; and the most promising innovation emerged from the work done by the Federal Government. In the 1960s, the best and the brightest worked for NASA. The Naval Research Labs won six or eight Nobel prizes. In the 1970s, the best and brightest worked for Bell Labs and IBM making computers for the National Security Agency. Today, there are entrepreneurs all over the country, and they don't go to government conferences, they do not read Broad Area Announcements, they do not interact with the government, and we are missing them.

The SBIR program is much more important than just money. It provides a legal authority for scientists in the commercial world to collaborate with government scientists. That is a big deal. I had to become a dollar a year employee of the government to be able to give the government advice. So that authority is key.

The SBIR allows small business procurement if you are successful. A 14-person company we have financed has no more chance against Lockheed than an unventure-funded 14-person company. So the procurement rules are a critical part of success.

And the SBIR allows current year unallocated money to be used opportunistically. There are 57 programs in the Department of Defense all around $1 million that are designed to go discover technology. If they collaborate and put this money together, it turns into an F-22 in the middle of the night. The SBIR dollars can't be turned into an F-22. They have to go to small businesses.

So if we can set aside some money to manage this program better and they can be more proactive on the discovery side, we can benefit the government and back the most promising companies.

Thank you.

Chairman NYE. Thank you, Mr. Biddle.

[The statement of Mr. Biddle is included in the appendix.]

Chairman NYE. I would like to introduce now Mr. Joe Hernandez, President and CEO of Innovative Biosensors, Incorporated, in Rockville, Maryland, also speaking on behalf of the Biotechnology Industry Organization.

STATEMENT OF JOE HERNANDEZ

Mr. HERNANDEZ. Good morning, Chairman Nye.

I appreciate the opportunity to share a little bit about my story—I am an entrepreneur, so I have to figure this thing out. I appreciate the opportunity to share a little bit about our story and my personal story with relation to early stage companies, especially in the biotech industry.

I currently serve as the President and CEO of a local company by the name of Innovative Biosensors. I will tell you a little bit about the company in a second, but my history, this is really my third involvement in early stage biotech companies.

I was involved early on with a company by the name of AlphaMetrics in the Silicon Valley area. We developed a revolutionary technology to really put a human genome on a computer chip, and that technology has been used to really explore the nuances and the complexity of the human genome. So we really started that company and funded it through some early government funds.

The second company I was involved in was also in Maryland, by the name of Digene, and that company developed the first FDA-approved cervical cancer diagnostics for human papilloma virus, a very important tool in the health care arena and I would argue one of the most important diagnostics in the last 10 years or so.

So this is my third company. This particular company is involved in the area of rapid infectious detection. We are a 4-year-old company. We were originally funded by DARPA, by the Massachusetts Institutes of Technology, published in the Journal of Science. This is a real vetted technology from a technology perspective.

Our technology—we are very proud of the fact that our technology is a truly deployed technology. We are deploying our technology in a very critical infrastructure within the national capital region for bioweapons protection. I can't go into further details on that technology application, obviously, but it is a technology that has its genesis really in the early government programs.

We are 20-person company. We have about raised about $20 million in venture capital in several rounds of financing. And our personal story is that we received the Phase I back in 2005 for the development of a rapid prion test for Mad Cow Disease, if you guys are familiar with that disease. Unfortunately, we could not move to a Phase II program because the venture requirements that currently exist prohibited us from really moving forward in that development; and, unfortunately, we did not move forward on that project.

You know, the SBIR program plays a very important role, as Mr. Biddle alluded to. First of all, it is a validation for private capital. It really removes some of the technical diligence that some of the firms have to do to validate the technology is real. So it does play

that important role. It funds projects that are too risky for private capital; and I think had it not been for the Phase I SBIR we probably would not have done the first project.

So it really allows us to take on the high-risk projects. It really is a great tool for innovation. It allows us to really be able to push the envelope with capital, that I think ultimately, as these technologies move, it benefits society as a whole.

So a couple of recommendations here as we are suffering through what I call the Grand Canyon of Death—the Valley of Death no longer exists. It has gotten bigger. We have a couple of recommendations.

The first thing is that we need to increase the size of these awards. As a company, time is money, and there is a time value of money, so we really need to make sure that these funds are worthwhile in terms of size.

We need to reinstate the eligibility of a majority of VC-backed companies. I think that is really important. We are a capital-intensive business. We depend on friends like Mr. Biddle here to support our endeavors, and we shouldn't be prohibited from really targeting those types of application. I would argue that if you had that aspect reinstated, you would have more competitiveness; and I think you would have better quality SBIR programs by definition.

I think the clarity around affiliation rules is really important. Just because we are invested, we are part of a portfolio of 10 companies does not mean we have relationships with any of those companies. It is truly a unique and different investment.

We need to maintain agent flexibility. These agencies know what they are doing with regards to what is important in their respective fields. So we need to allow them to do that, and then we need to speed the response.

In our business, as I said, time is money. We are capital intensive. We burn lots of money on a monthly basis. And every month that goes by we don't hear from the SBIR grants it costs us a lot of money. So we really want to expedite the process.

So, with that, I thank you for the opportunity. I would be happy to answer any additional questions. Again, thanks for the opportunity.

Chairman NYE. All right, thank you very much, Mr. Hernandez.

[The statement of Mr. Hernandez is included in the appendix.]

Chairman NYE. I would like to now introduce Ms. Marion Blakeley—Blakey, President and CEO of Aerospace Industries Association, for any opening comments.

STATEMENT OF MARION C. BLAKEY

Ms. BLAKEY. Thank you, Chairman Nye, Ranking Member Schock, Congressman Ellsworth. We are delighted to be here and testifying before you.

I do represent the Aerospace Industries Association and our almost 300 member companies. I think in this economy it is important to point out that our industry is responsible for almost 2 million well-paying jobs. We had $95 billion in exports last year and that contributed to a positive foreign trade balance of $57 billion. That is the largest for any manufacturing sector.

Aerospace Industries has a very keen interest in the Small Business Innovative Research and Small Business Technology Transfer programs. In fact, the major part of AIA's membership of 175 small companies make up our Supplier Management Council. Our large members also rely on these companies because they make machine component parts, electronic subsystems, the kind of system software that become integral to the aerospace equipment that the U.S. Government depends on.

And our large companies understand that SBIR is often what gives their smaller partners the ability to be innovative and to bring the best work into the large projects. For example, it was a successful SBIR project, sponsored by NASA, that led to the development of a robotic device that allows an astronaut to position a joystick with a sense of feel that is very real world and actually contributes to the manipulability. This has led to multiple applications beyond the device's original plan, and in fact it is on the International Space Station. But we also find it is operating in satellite docking research and now in military unmanned ground vehicles, just an example.

As you can see, small business is an important part of driving technology innovation for the aerospace industry. So we do have specific recommendations on the program going forward, four of them, in fact.

First, we think it is critical to the integrity of the SBIR program not to be weakened by allowing large companies access to these funds. While modifying the program to allow venture capital participation we think is a sign of the changing times, we believe that the fundamental principle to be preserved here is venture capital firms who don't meet the size standard definition of small business should not be allowed access to SBIR funds.

Our second concern, particularly for small businesses who are working on Defense technology research and development projects, is that there is currently a technology readiness gap. SBIR currently funds the so-called Technology Readiness Level 4. Military contractors generally won't consider a new technology into the acquisition process until you hit Technology Readiness Level 6. This gap is crucial. It stands between pure research and development and the rubber-hits-the-road activity of testing, evaluation, and manufacturing that represents the real maturation of technologies that go from prototypes to actual production.

Closing the gap between TRL-4 and TRL-6 with new funding—and we are thinking in terms of Phase II for technology and manufacturing—is important and would allow the SBIR program to a more effective tool.

Thirdly, I think everyone on the Subcommittee is well aware of the technological advances that program has spurred, but it is only allocated 2.5 percent of the Federal R&D budget. We recommend that figure be increased to 5 percent of the total eligible R&D funds.

In addition, to take into account 15 years of inflation, we recommend that the award levels be increased to $250,000 for Phase I and $2 billion for Phase II awards.

My final recommendation this morning deals with extending the authorization period for the program. We believe the authorization

period should be extended to September, 2022. It seems a long way away, doesn't it? But we do believe that is important. Based on SBIR's history of 7-to-10-year reauthorization, we believe this is a reasonable extension that will allow an opportunity for the changes to be implemented and the effectiveness evaluated.

So, in closing, let me just say small business innovation is a hallmark of this country's leadership and competitiveness and this is a real stimulus program. These programs are often the only game in town for small business when it comes to government funding; and we believe a strong reauthorization bill focused on the current realities will help this program keep pace with economic and technological innovation change and yield untold results.

Thank you very much.

Chairman NYE. Thank you very much.

Can you tell me if I got your name wrong? Is it Blakeley or Blakey?

Ms. BLAKEY. I like very much that you corrected it. It is Blakey, and I think I am the only one in the phone book, but there are a lot of Blakeleys.

Chairman NYE. Blakey, okay. I am trying to be detail oriented here and get those right. Thank you very much.

[The statement of Ms. Blakey is included in the appendix.]

Chairman NYE. Finally, I would like to invite Mr. Loper to make a comment. Mr. Brett Loper, the Senior Executive Vice President and Director of Government Affairs at AdvaMed. So thank you for joining us.

STATEMENT OF BRETT LOPER

Mr. LOPER. Thank you.

Chairman Nye, Ranking Member Schock, and members of the Subcommittee, thank you for holding this hearing today and for continuing your efforts to reauthorize and improve the Small Business Innovation Research grant program. My name is Brett Loper. I am Senior Executive Vice President of Government Affairs at AdvaMed, the Advanced Medical Technology Association.

AdvaMed's recommendations for SBIR reauthorization are straightforward: Eliminate the arbitrary venture capital ownership rule, expand the total pool of funding available for SBIR grants, and increase the capital in individual grant awards.

Rather than repeating my written statement, I would like to illustrate through a few examples what advances in medical technology mean for the public health and how the innovation ecosystem makes them possible.

Advances in medical technology have no less a wow factor than those of the personal computer or the iPod. A generation ago, treating cataracts required patients to undergo invasive surgery and stay in the hospital for up to a week. Today, with better outcomes for vision and fewer complications, patients are treated through minimally invasive surgery that allows them to return home the same day. There are literally thousands of examples of similar advancements, common procedures and complex, from the last 30 years.

Because of the nature of the industry, many of the advances along the way, both incremental and breakthrough, came from

small, pre-revenue, risk-taking entrepreneurs. In fact, 80 percent of medical device and diagnostics companies have fewer than 100 employees.

In the medical technology sector, small business entrepreneurs are the norm; and they are fueled largely by venture capital. Biotech and medical devices were 31 percent of venture investment in 2007, and $3.9 billion of that went to medical devices.

But even with that significant investment there are still what many patient advocacy organizations refer to as the Valley of Death between basic research primarily funded by National Institutes of Health and clinical development and commercialization of new patient treatment.

Consider for a moment chronic pain. Great progress has been made in the past several years with a medical device that focuses on spinal cord stimulation. It works by sending electrical impulses from an implantable device to the spinal cord.

One company, Advanced Neuromodulation Systems, was founded by an electrical engineer who wanted to advance neurostimulation technology in order to help his sister who suffered from Multiple Sclerosis. ANS was eventually acquired by St. Jude Medical, and the technology is treating more than 45,000 people with chronic pain in 35 countries. This technology is now being innovated to help people suffering from depression, Parkinson's disease, chronic migraine, and other neurological disorders. It holds a great deal of promise.

Venture funding alone will not fund the innovations like these that are on the horizon or eliminate the Valley of Death. But expanded SBIR grants can be an important part of addressing the Valley of Death.

The small companies that drive the innovation ecosystem rarely have revenues from existing sales to fund their research, don't benefit from the R&D tax credit, couldn't raise a dime from an IPO, and cannot access bond markets for financing. Many rely on personal savings, loans from friends, borrowing from credit cards, or even the equity in their house. An SBIR grant not only gives them the time and capital resources necessary to reach a tollgate in a product development cycle, it has the added benefit of incentivizing venture investment.

At the same time, venture seed money during the early stages of product development may come in several small pieces and an SBIR grant which augments that can be the difference between success and failure. Arbitrary limits on award grants sizes and limitations on the source of capital financing only pivot advances in technology.

In summary, the unique nature of the medical technology innovation ecosystem necessitates an SBIR program which helps emerging companies to not only get off the ground but also leverage private resources.

AdvaMed looks forward to working with the Committee to achieve reauthorization of this important program. Thank you for the opportunity to testify, and I look forward to any questions you may have.

Chairman NYE. Thank you.

[The statement of Mr. Loper is included in the appendix.]

Chairman NYE. I heard some positive comments about the program, and I am glad to hear them. Clearly, what we are trying to do today is to try to determine how we can strengthen and improve the program and make it work better in practice; and that is what you are all here to help us figure out.

I have a couple of questions. I want to focus first on this Valley of Death—or Mr. Hernandez said the Grand Canyon of Death—issue in terms of the third phase. I want to start with Mr. Loper because you suggested that has been a problem, and then I will ask Mr. Hernandez to answer the same question.

But I would just like to get your thoughts on whether or not our proposed changes in the legislation will be helpful in solving that problem, if we are on the right track, if there is something else we ought to be thinking about.

Mr. LOPER. Certainly I think the draft legislation would make significant improvements in moving to stem that problem.

Chairman NYE. Mr. Hernandez?

Mr. HERNANDEZ. I believe one of the critical things that needs to be looked at is really how one leverages these Federal dollars to bring in the private sector dollars. While the venture community is quiet for the time being, there is still plenty of capital around that will be probably deployed in coming years. So I think using these dollars to leverage the dollars into the system is really the best strategy to provide these sort of public/private interests.

My opinion, the best way to do that is to make those amounts be larger. I think it is really critically important. $100,000, takes a lot of time to put these together. I had the pleasure of being involved in a couple of them, and sometimes you really do not pursue these grants simply because the dollars are not worth it. So increasing it would really, in my opinion, make it a little bit more competitive.

Also, allowing these venture-backed companies to play in proposed higher-risk projects they typically wouldn't do I think is the other way to really stimulate and play an important role in getting this thing moving.

Chairman NYE. Thank you.

I have a question I would like to put to Ms. Blakey. You mentioned that venture capital participation is useful in the program but with appropriate size standard limitations. Can you just elaborate on how you think the best approach is towards the venture capital angle in this program and how it will be determined what the right kind of limitation would be?

Ms. BLAKEY. Well, I think we see that venture capital certainly has an appropriate role to play, and flexibility to do that makes sense. But we think the size limitation of 500 employees for organizations that the venture capital is controlling is an appropriate size limit.

When you get to very large venture capital organizations, the dynamics begin to change and there is a question as to whether or not these funds are critical when you are talking about what essentially a larger business is. The larger venture capital and the experience we have, at least in our domain area, is often involved with a real press for profitability and shorter term turnaround than is

sometime possible and appropriate in the kind of R&D that we do. So those are considerations there.

I think I would put one final question before you, and that is one also should take a look at the source of funding. When you are dealing with the aerospace and military arena, foreign capital is something you have to look at as an area where you may need additional safeguards.

Chairman NYE. A question for Mr. Leahey. I just want to make sure I understand the value in allowing companies to apply for Phase II without being involved in the Phase I. Can you give us your thoughts on where the benefit is there?

Mr. LEAHEY. Certainly. I think, actually, the draft legislation—we are not suggesting that without the proper data and meeting the requirements of Phase II that without the underlying feasibility studies done that they should be permitted to jump in.

I think what we are seeing right now is, particularly in this economic environment, you may have a situation where a company through family, friends was able to raise some initial funding and conduct feasibility studies on their own and perhaps never envisioning to go to the SBIR route. But now with alternative revenue streams or investment streams drying up, I think if companies have those feasibility studies and that would satisfy kind of the Phase I requirements of SBIR, to have them actually repeat that process and duplicate it in Phase I before they can get to Phase II, I don't think is a useful source of the resources.

So, again, I think the legislation here and allowing that to happen as long as the company has a feasibility study is certainly a welcome improvement.

Chairman NYE. I have one more question, and then I will yield to Mr. Schock.

But, Mr. Biddle, you suggested that there had been some areas where there have been some failures evident and were hoping you would get asked about that, so I am going to ask would you mind commenting on where you think things have not gone well just so we have the lessons that we can apply?

Mr. BIDDLE. Yeah, let me describe what a venture capital business is. We are a 14-person small business in Bethesda, and we live to discover and fund small start-up companies. And we have been successful. We have created over 10,000 jobs in the Washington area in the last 10 years. For our last fund, we were offered $2 billion. We took $200 million so we could continue to do small investments.

I have got a company in Washington, two 24-year-old kids we backed in 1997. They have a thousand employees today. Does that mean my 4-person startup—and I do not control that company, but under the SBA rules I do. We are affiliated? My partner is lead director. So my entire portfolio can't work with the government. And these are some of the smartest people on the planet, and they can't work with the government. It makes no sense.

So I will tell you some real-world stories.

A meeting yesterday. There is a company that we have, an ex-government scientist we backed about 3 years ago. There are two investors. We own 52 percent of this company between us. We put in $11 million. He has a breakthrough in the national security area

that is incredible. There is a multi-agency task force who wants to procure millions of dollars of this stuff. This is a 14-person company who can't make payroll in 30 days, by the way. We will have to put in more money. And the small business procurement rules are what allow a 14-person company to be able to work with the government, whether he is venture backed or not.

We got a call yesterday from a procurement officer at the Special Operations Command. They say they are a large business. They are ineligible. They have to do large business procurement. This is critical technology.

Another one which we didn't get to finance, a Taiwanese immigrant, naturalized U.S. Citizen, bootstrapped a company. His expertise was in wireless security, and the Department of Defense wanted us to use more commercial technology, but it is not secure enough. He had bootstrapped his business with friends and family, Taiwanese friends and family, and they owned about 20 percent of the company. Through multiple phases, he won a Phase III $100 million award from the U.S. Navy. He then needed to raise capital.

We put together a term sheet. I brought together a syndicate of Intel who would take this technology commercial once we proved it in the military and Carlyle and ourselves. We each would have owned I think 13 percent of the company. When you added it all up, it would be 52 percent.

The attorneys we hired to look at this said, ″this is gray; you could be ineligible. If you represent you are a small business, you could be charged with a crime.″ And Intel and Carlyle said, ″we can't do stuff that is gray.″ They withdrew their term sheet, and he couldn't raise the money to meet the contract, and he sold out to a big contractor.

So there are other stories like that, and we are really doing ourselves a disservice.

I think the misunderstanding here is talent is a pyramid. And we don't get them all, but the venture capital industry gets about half of the companies that become great companies with a tiny percentage of the capital. The guys at the top of the pyramid are not there because they are venture backed. They are venture backed because they are at the top of the pyramid. So we are the best in the world at going under every rock in this country and finding talent and getting money behind them and helping them built big enterprises. That is what we are after. We start with these small companies.

Thanks.

Chairman NYE. Thank you. I appreciate your frank comments.

Again, I want to thank all the panelists for giving us the real-world perspective to help shape the program going forward. Noting there are some other members here, I would like to go ahead and yield to Mr. Schock for as much time as he would like to consume.

Mr. SCHOCK. Thank you, Mr. Chairman.

Thank you to the panelists here today for your very insightful comments and perspectives.

I had questions about the venture capital portion, but you have, Mr. Biddle, done a very good job of explaining the rule that organizations like yourself play in not only the grant participants in the SBIR program but in the entrepreneurial community in our coun-

try; and I would say that that is an important role, given all of the talk around this campus about stimulating the economy.

Since 60 percent of the American citizens get their paycheck from a small business, it seems this Committee and our work and the folks we look out for are important always but especially now as we try and stimulate the economy. So I think programs like SBIR are always justified, but I think especially so. That is why I want to make sure that the reauthorization, the language in here is exactly what needs to happen.

There was some discussion about needing to increase the grants. I believe in that. It is a portion of the language that I brought forward, and in the draft form that we have now the Phase I grants would include an increase from $100,000 to a quarter million and then the Phase II grants would go up to $2 million.

I just want to give each one of you the opportunity that wish to comment on that and whether or not you think those are sufficient levels or you think another figure or a different level—obviously, the sky is the limit, but, realistically, what do you think are appropriate amounts? Given there has been quite a lapse in updating these figures since 2000, obviously, the time value of money has some effect on what $100,000 will get you in terms of research and development.

Mr. Biddle.

Mr. BIDDLE. I don't think the size of the program needs to be increased. I think the program can be made more effective. I think that increasing the grant size is important to make the grants worth the effort. Because what you are trying to do here is discover things, but you are also trying to co-opt people to think about government applications, things that could be useful.

I think the most important change besides the grant size is taking a percentage of this money to manage the programs within the Department. You won't want to hear this, but in a lot of agencies this is viewed as a congressional tax. They pay the tax and go back to work. So a lot of this money is not well spent, and it is not managed by the real customers.

The gold standard in the military is the submarine program. The Program Executive, the guy who builds submarines, owns the SBIR program; and he uses it as a discovery tool and a tool to go find talent to solve his problems. But most of the government has it down in a basement. They publish Broad Area Announcements to the usual suspects, and it doesn't get acted on. So I think that taking 2 or 3 percent to put talent around this money and bring it closer to the internal customers is as important as increasing the fund size.

Mr. SCHOCK. Very good.

Mr. Hernandez.

Mr. HERNANDEZ. To comment on the size, my father used to have this old saying that too much money makes people lazy. So I am not an advocate for too much money in these programs.

That being said, we are a very capital-intensive industry; at least the biotechnology industry is. We don't believe the $100,000 is the right size. Again, it takes so much time to write these things; and I would rather have my scientists focus on other things besides a

$100,000 effort. So I think the 250 feels right. The 2 million on Phase II is definitely I think the right number.

I would argue that there are other mechanisms that allow one to, for example, fast track these programs to really combine them so that there is no gap in funding between Phase I and Phase II. I think that would be an important element to look at.

Again, you have to remember these grants, these fundings can be used to leverage additional capital, additional private capital. So it really allows us to be able to do that by validating the technology and approach in some regard. So the number sounds right. I would ask for more, but, again, think I think we want to make sure we manage it and get the private sector involved as well.

Mr. SCHOCK. Okay.

Ms. BLAKEY. We like the size that you all have designated. Two hundred and fifty and two million seems appropriate for us.

We do believe, though, that the overall monies aggregated here should be larger. As I said, I suggested 5 percent of R&D. We think it is appropriate for these smaller companies. We like that 90-day turnaround, also. I agree with you. And I think we want to see better data collection as the program goes forward so we are all clear about the steps toward utilization in State commercialization, and some of that undoubtedly would mean better administration of the agencies programs.

Mr. LOPER. I think the burden of the application and time it takes to secure the grant award, which often entails hiring an outside advisor or consultant to assist with the application, diminishes the value of the grant; and I think that in part has led to the drop of the applications, particularly in the medical technology industry that Mr. Leahey referred to.

Mr. LEAHEY. If I could follow up on two comments. I think 2 to 3 percent set aside again to help with the administration and really implementation, I think that would help achieve the objective of commercialization.

And then also addressing this issue of timing, we actually had our annual meeting here in D.C. Over the past few days. About 150 CEOs of small medical device companies came in. I chatted with one of them, and they talked about the Valley of Death even within the SBIR program because of the gaps between Phase I and Phase II. And although there are goals out there which they are supposed to achieve, to respond in time, sometime there is a significant lag.

So I think some of the time lines in the bill are certainly helpful, but if there is any additional oversight mechanisms that are in place to help ensure that companies aren't sitting on the sidelines waiting for Phase II grants, it certainly would be a welcomed improvement.

Mr. SCHOCK. I agree.

The bill that we are putting forward or the language that we are submitting actually allows for fast-track authority within each of the agencies that would basically allow simultaneously for them to issue a Phase I and a Phase II grant to the same company or to the same venture. So I would encourage you to take a look at it and get back to me or the Committee if you think there needs to be further improvements, but I think it speaks to all the concerns that you have raised.

Follow-up on that, I am curious with the venture capital funds, Mr. Hernandez, when your company or similar entrepreneurs are awarded an SBIR grant, to what degree does that help you raise the eyebrow and get the attention of a potential VC fund, or does it not?

Mr. HERNANDEZ. Well, there are a couple of things that I would argue in my experience in raising venture capital. I raised venture money from five major investment houses, so I have kind of figured out the business a little bit.

One of the risks that is assessed beyond the most critical one, which is the management risk, is the technical risk. Oftentimes, these venture capitalists are quite savvy and hire the right people to give them perspectives on the validity of that technology or that company. But I would argue that when you have a panel of highly sophisticated scientists that have no dog in the fight, if you would, to vet or give a perspective on a technology of an SBIR funding mechanism, I think that adds immense credibility to the effort. The danger is to ensure that the programs that are pursued are ones that are high risk but still have a market opportunity, and I think that that has been another challenge that needs to be looked at.

So I would argue that the technical validation is probably the most important role that these funds play in addition to the plain offering of capital to get the company and the venture going.

Mr. SCHOCK. Very good.

Mr. Biddle, do you want to comment on that? Do folks who come forward with an idea and they do or don't have—I mean, do you often refer folks, to say, hey, you have a great idea. There is this government program out there that might be able—I mean, obviously, 250 grand I am sure does not compare to the type of investment your organization typically funds, but to what degree does this program interface with what you do?

Mr. BIDDLE. Well, it does more than the money. As I said before, you can sole-source procure from a Phase III winner, and that is a big deal. I will not back a company that thinks it can compete against Lockheed, period, for a government-type business, because they can't. So the ability to sole-source procure a Phase III winner is a big deal. And then the ability to collaborate with the scientists, with the legal authority to collaborate—otherwise, you can't talk to each other—is a big deal.

My fund is different because the world-class science that is in Washington tends to be science that comes out of the intelligence community and DARPA and the DOD. So half my companies are government Ph.D.s who are building commercial companies and the government doesn't want these guys to go completely native. They know how the system works so they will participate in SBIR.

But my brethren in Boston and Chicago and Silicon Valley, they just don't deal with government anymore. So our government scientists don't see them, and they don't see the gaps. So it is broken on the information technology side.

The vetting is important. Being close to a customer is important. The way that gap is bridged is with a customer. And the government—some of the SBIR money belongs to customers like the PEO of the submarine program. Some of it belongs to academics. There is no customer there. They are not working with a program of

record. That is where the real money is that can build big companies are programs of record.

So the SBIR money needs to be closer to the customer; and it needs to have dedicated management focused on discovery, not just publishing broad area announcements.

The SBIR program should be more similar to what I do. I don't have on my Web site, ″are you a battery company? Check box. Submit plan.″ I go out. I go to universities. I go to conferences. I will be at the Navy's SBIR program on Monday. I am looking for stuff. I scour the country looking for stuff that solves problems that I am aware of, whether they are government or commercial. And that is what this program should be doing. Then you have the highest value.

So you don't want to just fund companies for the sake of funding companies. You want to create wealth and create value. You want to create big companies. And they come from small companies. They are the most innovative. And that is where a disproportionate share of our talent works today. The culture has changed. Working for small companies is now cooler than working for NASA. We should exploit that.

Mr. SCHOCK. Great. Well, in the interest of time and the other members who are here who wish to ask questions, I appreciate all of you for being here and the work that you do and Mr. Chairman for hosting this Committee.

I yield back.

Chairman NYE. Thank you.

I would like to recognize Mr. Ellsworth for any questions.

Mr. ELLSWORTH. Thank you, Mr. Chairman and Mr. Schock, for holding this meeting.

I was notified—did they call votes or just notify us about votes.

Chairman NYE. I think we have until about 11:15 or so for votes.

Mr. ELLSWORTH. Mine won't take that long. Thank you both and thank you all for this very informative meeting.

The benefit of going third—or the detriment—is that most of the questions you are interested in asking get asked before you get down here, so it has been very informative.

I guess one of the things I would talk about when we talk about increasing this was one of the things I wanted to ask was if it was enough money. And in a time when—a couple weeks ago, we had tea parties and everyone is talking about less government spending, us included, that we hope your organization, when you are putting out the newsletters and the e-mails, that you will back up that we know that we are going to invest in these programs that are going to solve problems and fix people, that you will be our cheerleaders, not just us going back to the town halls but you will go out to your organizations and your members and tell the same thing: We are investing in good products and good organizations.

One of you—and I cannot remember which one—was talking about the technology readiness gap. I don't know if that was Mr. Loper or Ms. Blakey?

Ms. BLAKEY. Yes.

Mr. ELLSWORTH. Would you elaborate on that point, please, and clear that up for me, if you can, and how you might suggest that

we close that gap between 4 and 6? Help me understand, if you don't mind.

Ms. BLAKEY. I think it really does come down to the fact that at that point you are looking at the stages where you have gone from the concepts, you have done a certain amount of the work, but getting through from a prototype to the point that you really have manufactureability and you are at that low-rate production level, that is very critical. And the military is very exacting about that, and there are very specific requirements, as there are for NASA, et cetera. So that area right there is where you often find that things bog down, and at that point you may find that the program simply stops. This is where we would like very much to see Phase II have a component, if you will, that looks at that very specifically and looks to solve the gap problem.

Mr. ELLSWORTH. Thank you very much.

One of the things I always like to do is give somebody a chance to dispute something they heard from the other panelists. Not that I want to cause a fight, but if anyone heard something from another panelist—Mr. Biddle, I know you raised your eyebrows a couple of times with some of the other ideas. If anybody would like to dispute something they heard from somebody else, I would love to give you that opportunity.

Mr. BIDDLE. I love these press releases that talk about these billionaires who own these small companies who are trying to hide behind the SBIR program. My venture fund is owned by the Virginia's Police Pension, the Teachers Pension Plan, the University of Virginia's Endowment, Howard Hughes Medical Institute, Episcopal ministers. I mean, it is American money. It belongs to American individuals. The success here pays for scholarships at Georgetown, Carnegie Mellon, and Notre Dame. So there are no billionaires with these companies.

And the fact that we have done a good job and I have created 10,000 jobs shouldn't mean that my four guys in a garage can't collaborate with the government on a piece of science that could make a big difference.

So the aggregation is just silly. I mean, the last thing I want to do is run a company. I am on 10 boards. I can't run these companies. What I tell my entrepreneurs is, ″is this ownership thing is a myth. If I own 5 percent of your company and you can't make payroll, it is my company. If I own 60 percent of your company and you are doing great, it is your company.″ So we provide coaching and finance, but each company is separate. Each of our funds is a limited purpose entity. It lasts for 10 years, and it goes away. Our limited partners give us cash. They expect to get cash back. And that there is collaboration or collusion between these companies is just ridiculous.

So, typically, most great companies take capital because the entrepreneur wants capital because he wants 10 percent of a billion instead of 100 percent of a million. So each of us will typically own 10, 15, 20 percent of a company. But it is so easy to get to 51 percent. These are consenting adult transactions. These guys want our money, and they want to exchange stock for the potential to be the next Google or Cisco.

So being venture backed is a badge of honor. It shouldn't disqualify you from being able to work on national security issues.

So I am here for the NVCA, but I am really here for the Department of Defense. The military needs to engage our inventors. If I was designing a program from scratch to allow that to happen, I would want current year unallocated spending authority. I would want small business procurement rules. I would want a legal authority for my scientists to collaborate with government scientists.

I go on the road. The Navy did this with me and eight other VCs, got us clearances, told what the problems were, asked us to keep our eyes open and look for people who have stuff that, with a twist or a little money, could solve big problems. That is what we should be doing.

Mr. HERNANDEZ. If I could just echo that sentiment as it relates to affiliation rules. While we are backed by five major investors, venture capitalists, the reality is they are small players in the company with regards to the equity that they individually have. These funds are pretty large funds. They invest in numerous companies. Each fund has typically an average of 10 to 15, probably 20 investments, in some cases. So they manage or invest in a large number of companies. They do not run my company. I run my company, and the buck stops with me.

That being said, they play an important and integral role in our ability to commercialize these technologies. Without the capital, we couldn't do it.

I think it is ridiculous that the affiliation notion exists. Half the time I don't even know the investments these other funds make, nor do we have affiliations with them. So I think we need to make sure that there are clarification rules around that.

We are a unique entity. Yes, we are backed by five different funds that have probably an aggregate of over 100 investments. We don't interact with those companies. So I think we need to really make sure we pay attention to that.

So getting rid of the eligibility of VC-backed companies, I think we really, really have to do that. That is prohibiting competition within these programs. And I would argue devaluing these dollars that get deployed, and this is the criticism that you often get with government dollars being poorly deployed, and I think we need to add more competition to the system.

Mr. ELLSWORTH. Mr. Chairman, I know my time has expired. If I could close by saying I think we definitely need to spell out the difference in what you are saying between—with all the reputation and things going on the last 5 months on Wall Street and the separation between venture capitalists and the companies on Wall Street, the bailouts, I think it is a very important point to bring up and that people understand the venture capitalists aren't part of these closures.

Thank you. I yield back.

Chairman NYE. I want to again thank all the panelists. We expect to be called for votes here relatively shortly, but I do want to offer an opportunity if anybody feels like there is a thought that came up during the testimony and they want to add it at the end here and didn't feel that they had a chance to say it. If anyone has any final comment, I want to offer that chance.

Mr. LOPER. I don't want to jump on the bandwagon here, but—

Chairman NYE. Please do.

Mr. LOPER. I think what we are talking about, boiling it down to a more simple discussion, I guess, the forms of financing here that we are discussing, venture versus other, there are different industries, and there are different business models, but I think it is important to consider if you have a choice between going to get a loan from a commercial bank that has tens of thousands of employees and tens of thousands potentially of shareholders, someone ultimately owns that financing. There is a difference certainly between that mechanism of financing, one, because it is harder to get in the case of a company that owns very little and the venture. It is a risk equation.

The commercial bank in our setting is not going to offer financing to a start-up company like the ones we are discussing. They have nothing essentially to repossess except ideas. So the venture funding is critical to the medical technology industry in order to get that product from idea to bedside. It is a question of risk. And the venture firms exist on the financing spectrum for a reason, because they are willing to take certain risks that others are not. I think that, in short, is the critical issue for us as the program is reauthorized.

Ms. BLAKEY. Well, one thing I would say, and I think there is a commonality up here. But in all the talk about venture capital, I don't want us to lose sight of the fact that one of the critical things here is a longer reauthorization period, so you have program stability. You can build awareness. You can build competition. And then adding into that the larger award amounts as well as a larger pool of money, again, will bring the best and the brightest and will make it a much stronger program.

So those three elements, please don't lose sight of how critical they are in this. Thank you.

Mr. BIDDLE. I don't think the size of the program needs to be increased. I think it just needs to be better managed. I have also heard discussions about quotas and stuff for venture capital. I think a legitimate venture fund is easy to define: multiple limited partners, domestic money, no more than X companies in the portfolio, limited life. We should be defined as persons for ownership purposes for all of the small business programs, if they are in fact small businesses. It is the management piece here that I think you can get much more bang than increasing the program size and throwing the venture community a bone. You know, report it, collect it.

The venture-backed companies are 20 percent of the GDP, 10 percent of the employment. Pound for pound, these are the most promising companies in the country. And we don't get them all; we get about half of them. About half of them are venture-backed. And to exclude those from solving critical national problems is just foolish.

Chairman NYE. All right.

Well, again, let me thank you all for being here. And I want to thank you for not only sharing your experience with us today, but also for everything that you all do to drive the economy forward. I see it as our role here in Congress to work together to try to

maintain an enabling environment for you and your members to do what you do to create the innovations, to come up with new technologies, to create the new jobs, and to really drive our economy forward. So we appreciate all of what you are doing every day to make that work.

In conclusion, I would like to ask unanimous consent that members have 5 days to submit statements and supporting materials for the record.

Without objection, so ordered.

And in bringing this hearing to a close, the hearing is now adjourned. Thank you again.

[Whereupon, at 11:15 a.m., the subcommittee was adjourned.]

GLENN NYE, VIRGINIA
CHAIRMAN

AARON SCHOCK, ILLINOIS
RANKING MINORITY MEMBER

Congress of the United States
U.S. House of Representatives
Committee on Small Business
Subcommittee on Contracting and Technology
2361 Rayburn House Office Building
Washington, DC 20515-6315

STATEMENT
Of the Honorable Glenn Nye, Chairman
House Committee on Small Business, Subcommittee on Contracting and Technology
"Legislative Initiatives to Strengthen and Modernize the SBIR and STTR Programs"
Thursday, June 4, 2009

Economist Peter F. Drucker once described innovation as "the specific tool of entrepreneurs." And it is exactly that. Small firms produce 13 times more patents than big businesses, sparking breakthroughs in virtually every industry, from healthcare to technology. To the casual observer, it may look effortless--we've all heard about Mark Zuckerberg running Facebook out of his dorm room. But the truth is that developing a new product is no easy lift.

Innovation is a risky, resource-intensive process. Without proper funding, even the most brilliant invention may never make it from the drawing board to the marketplace. For entrepreneurs with limited resources, this is a very real danger. In today's hearing, we're going to examine that challenge, and look at legislation to address it.

The proposals before us would improve and modernize the Small Business Innovation Research and Small Business Technology Transfer programs. This is key, because an investment in innovation is an investment in our economy.

SBIR and STTR are critical resources. Each year, these initiatives help 1,500 companies get off the ground. Those firms have triggered revolutionary advancements in everything from bioengineering to antivirus software. And yet for every ground-breaking new product, countless more don't make it past the laboratory doors.

The proposals we are considering today will address the challenges of commercialization. As of now, the majority of SBIR and STTR projects--particularly those in the defense industry--never come to fruition. It's important that the SBIR program develop products that agencies need. We are addressing this issue by requiring communication between SBIR program managers and procurement personnel. This will ensure that, when DoD needs a product, the SBIR program is focused on meeting that need.

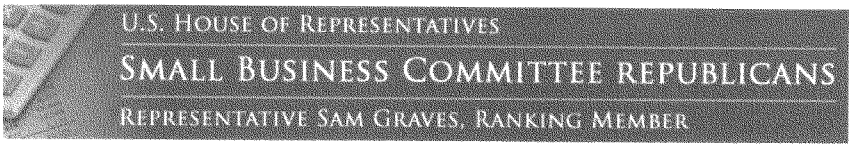
Understanding what makes a product marketable is important. But unless you have the time and money to create that product, you can only go so far. By increasing award levels and permitting equity capital, this legislation would give small firms those resources. This is particularly important today. With capital increasingly difficult to come by, it just doesn't make sense to limit options for entrepreneurs.

In the last year, the economic landscape has changed considerably. So has the face of entrepreneurship. While the word "innovation" often sparks images of Silicon Valley, the truth is that it comes from everywhere. That's why these proposals are so important. They encourage R&D in underserved communities, and amongst historically underrepresented populations, including veterans. Because if nothing else, innovation thrives on diversity of thought.

Despite their inherent value, neither SBIR nor STTR have been updated in nearly a decade. Today, they are in sore need of modernization. Last Congress, the House passed a bill to modernize and extend the programs. But the legislation died in the Senate. With these proposals, we can restart the process.

As we work our way out of the recession, innovation will play an integral role. After all, downturns have a catalyzing effect on inventors. Take the recession of the mid-90's, which ushered in the Age of the Internet. Or consider the Great Depression, which has been called "the most technologically progressive" era of the 20th century, and brought us such breakthroughs as synthetic rubber and--little known fact here--*canned beer*. Who knew?

Once again, our county is facing historic challenges. But with a fresh investment in homegrown ingenuity, we can begin turning things around. These proposals mark a critical first step in making that happen.



Opening Statement of Ranking Member Aaron Schock
Hearing: "Legislative Initiatives to Strengthen and Modernize the SBIR and STTR Programs"
Committee on Small Business
United States House of Representatives
Washington, DC
June 4, 2009

Good morning. Thank you, Mr. Chairman, for holding this hearing to review legislative proposals to reauthorize and modernize the Small Business Innovation Research (or SBIR) program. I'd like to extend a special thanks to each of our witnesses who have taken the time to provide this committee with their testimony.

The SBIR program is one of those government programs that actually works. Specifically, the program encourages and supports risk and entrepreneurship within the small business community. The program is based on the correct theory that responsible government assistance at the right time can be critical in the startup and development stages of a small firm. Not only does it spur growth in individual companies, the program stresses the importance of expanding and diversifying research opportunities for the pool of companies the federal government uses to procure products and services. Thus, the SBIR program encourages both economic growth and innovation.

Created in 1982, the SBIR program offers competition-based awards to stimulate technological innovation among small firms while providing government agencies new, cost-effective, technical and scientific solutions to meet their diverse needs. The development of this program is not only critical to the unique needs of each of the participating federal agencies, but also to our national economy.

Small businesses invigorate the U.S. economy by introducing new products and cheaper ways of doing business, many times with substantial economic benefits. They play a key role in introducing

technologies to the market, often responding quickly to new market opportunities. Some of the greatest technological innovations come from small business owners experimenting in their workshops and labs. The SBIR program provides these innovators with an opportunity to grow their ideas into practice, provide jobs, and improve our economy.

The SBIR was last reauthorized in the year 2000. As everyone has undoubtedly noted, a lot can change over that length of time. To fully capitalize on the benefits this program can bring, this is a very opportune time to reauthorize and modernize it. The proposals we have before us go a long way toward achieving the goals of modernizing the SBIR program with greater efficiency and accountability. For example, the legislation before us raises the award sizes for Phase I and Phase II grants. This is essential because the award sizes have not been increased since the program's inception.

Additionally, the National Academies of Science report on the SBIR Program made note of the difficulty of properly studying and measuring the performance of the program because of inadequate data collection. In response, these bills will improve the way small businesses and sponsoring agencies share information by creating online databases to improve information flow between agencies and participants. The proposals before us today will also create an interagency policy committee among the participating agencies to report specific findings to the relevant Congressional committees. The creation of these committees and databases will allow for greater oversight and better management of the SBIR program.

However, I, along with other Members of the Committee may have concerns about some of the provisions in the drafts. While these concerns in no way overshadow my support of the SBIR program and the good faith effort that is being made here today to improve the program, I remain certain that, as this Committee has done in the past, Chairman Nye and Chairwoman Velazquez will work with those Members on the Committee to rectify any philosophical differences that may come up as we continue with this process. I am looking forward to working with Chairman Nye, and all of my colleagues on the committee on this important legislation.

Again, I would like to thank everyone for being here today. I yield back.

Testimony of:

Mark B. Leahey, Esq.
President and Chief Executive Officer
Medical Device Manufacturers Association

Before the U.S House of Representatives Committee on Small Business

"Legislation to Reauthorize the Small Business Innovation Research (SBIR) Program"

June 4, 2009

Introduction

Chairwoman Velázquez, Ranking Member Graves, and Members of the Committee, thank you for inviting me to testify today regarding reauthorization of the Small Business Innovation Research (SBIR) program.

My name is Mark Leahey and I am the President and Chief Executive Officer of the Medical Device Manufacturers Association (MDMA). MDMA is a national trade association representing innovative, entrepreneurial medical technology companies across the country. Our mission is to ensure that patients have timely access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies. With advancements in science, increasing regulatory requirements and market access challenges, significant investments from the government and venture capital are often needed to develop these life enhancing and life sustaining technologies. In return, Americans are living longer, healthier and more productive lives.

One of the cornerstones of government investments in small medical technology companies has been the SBIR program. Resources from the program, in addition to private investment, have greatly contributed to the growth of the medical device industry over the past twenty years. However, as you are aware, the Small Business Administration (SBA) implemented a change that significantly worsened the landscape of the public-private partnership envisioned by the SBIR program. As a result, many promising technologies from smaller companies did not receive SBIR support and patients suffered as a result. Fortunately, this Committee is taking the necessary steps to correct the actions of the SBA and ensure that the SBIR program is restored to its critical role of providing promising, entrepreneurial medical technology companies with the resources needed to develop the clinical solutions of tomorrow. To this end, MDMA supports the efforts to strengthen the SBIR program that focus on the successful commercialization of new medical technologies.

Background

The SBIR program was established in 1982 to offer competition-based awards to small private-sector businesses to stimulate technological innovation with the intention that the small business would take the product through to commercialization, all the while helping to stimulate U.S. economic growth and international competitiveness. The SBIR program is structured into three phases:

- Phase I is the feasibility study in which award winners undertake a limited amount of research aimed at establishing an idea's scientific and commercial promise. Phase I awards are generally $100,000 for six months.
- Phase II funds are used to finance more extensive research and development and the grant awards are usually around $750,000 for two years.
- Phase III is the commercialization stage and companies must use non-SBIR funds to get their product into the marketplace.

The SBA establishes the eligibility criteria for participation in the SBIR program. As such, only United States small business concerns (SBCs) are eligible for an SBIR award. The SBC must be organized as a for-profit with its place of business in the United States. It must also be independently owned and operated, and it must meet one of two ownership criteria: it must be at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, or, it must be a for-profit business concern that is at least 51 percent owned and controlled by another (one) for-profit business concern that is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. Finally, the SBC must be small in that it must have no more than 500 employees including affiliates.

Public and Private Investment in Medical Technology

The majority of the most innovative advances in medical technology over the past twenty years have been developed by small, entrepreneurial medical technology companies. These technologies are continually advancing and improving the health care for many Americans everyday. At the same time, these innovative products are reducing long-term health care costs by improving outcomes, reducing hospitalization time and increasing productivity.

The SBIR program was instrumental in the development of many of these medical technologies. However, SBA's interpretation of the term, "individual" has created a barrier for smaller companies to receive SBIR assistance. The development of a medical device often involves the collaboration of public and private investments, including resources financed by various venture capital investors. Since the SBA's reinterpretation of ownership requirements under SBIR, the number of medical technology companies applying for grants has significantly declined. As evidence of the impact of the new rules on medical device and biotech companies, applications for SBIR grants at the National Institutes of Health, the most prolific grantor of SBIR grants to medical technology companies declined by 11.9 percent in 2005, 14.6 percent in 2006, and 21 percent in 2007. In addition to reducing the number of companies receiving grants, one may also conclude that the new interpretation prevented SBIR from supporting those projects that showed the greatest promise for clinical benefit simply because of its ownership structure. The SBIR program should support small companies with promising clinical technologies, regardless of whether venture capitalists have invested a certain amount.

Medical device companies typically raise multiple rounds of venture capital funding to finance the years of pre-clinical research and development needed to advance a new therapy into clinical trials and, ultimately, gain approval by the Food and Drug Administration for sale to the public. Additional trials may be required to satisfy private and public payers as well. Without the assistance from the private and public sector, the vast majority of medical device companies would not be able to finance the many millions of dollars worth of cutting-edge R&D needed to develop a new medical device.

Legislative Proposals

Based on our initial review of the legislative proposals developed by the Committee, we are pleased to see that steps are being taken to reverse the 2003 Small Business Administration's modification for program participation. The draft proposals address several of the concerns regarding the venture capital ownership restrictions, which dramatically affected program participation by many innovative medical technology companies. Specifically, the proposal defines a business as "independently owned and operated" if it is owned in majority by natural persons or venture capital operating companies meeting specified requirements, including that there is no single venture capital operating company. This is absolutely critical to the further advancement of medical innovation.

Further, the draft legislation also provides a critical increase in resources for Phase I and Phase II awards. Specifically, Phase I awards will increase from $100,000 to $250,000 and Phase II awards will increase from $750,000 to $2 million. These awards are necessary to provide resources to companies with innovative medical products, especially during a challenging economic climate.

Recommendations

As the Committee moves forward with reauthorization of the SBIR program, the Medical Device Manufacturers Association would like to reiterate our support for the SBIR program and offer the following recommendations that will help reestablish the program's success.

First, the reauthorization should include language to restore the participation of venture backed companies, especially the redefinition of the ownership requirements for business concerns. It is critical that this language be included so that small, venture-backed medical technology companies are not excluded from the program. This will serve to provide SBIR grants to the most promising technologies which are likely to provide more patients with access to life-saving medical devices.

Second, MDMA believe that increasing the dollar amount of the Phase I and Phase II awards is warranted given the increasing development costs and will provide a greater incentive for companies to participate in the program. These award levels have not changed since 1992. Therefore, Congress should move forward with increasing these awards as proposed under the reauthorization. Providing $250,000 and $2 million for Phase I and Phase II awards, respectively, will help provide the necessary incentive to encourage more companies to apply for the grants. If the awards are too low some companies may determine they are not worth the time and effort required to submit a successful SBIR application.

Third, MDMA supports providing agencies with more flexibility in administering the SBIR program. Specifically, MDMA believes it would be helpful to agencies if a small

percentage of the SBIR set-aside could be used for administering aspects of the program. MDMA agrees that it would be appropriate to allow two to four percent of the SBIR funds to pay for activities such as conferences aimed at helping small businesses to compete successfully, commercialization assistance programs to help companies transition to the marketplace, and improved systems for assessing program effectiveness. These resources will help to administer the SBIR program and assist agencies in making improvements to the program without diverting funds from other funding resources. To this end, we support the proposals expand the SBA's outreach to increase small business participation in the program.

Finally, it would be beneficial to remove the requirement that a company must have applied for a Phase I grant in order to apply for a Phase II grant. Under the current rules, only companies that have applied for and received a Phase I SBIR grant are eligible to apply for a Phase II grant. If this rule were changed, MDMA believes that small business participation in the SBIR program would increase. This change would also be aligned with the mission of the SBA to strengthen the Nation's economy by enabling the establishment and validity of small businesses. Contrary to what some may argue, MDMA does not believe that the program would shift funding to only later stage companies, but agencies should be encouraged to keep the balance of the innovation lifecycle in "check."

Thank you again for your efforts to improve and reauthorize this important program. MDMA appreciates the Committee's efforts and supports the reauthorization of the SBIR program incorporating the important changes outlines above.

Testimony of:
Jack Biddle, Founding Partner
Novak Biddle Venture Partners

Hearing on
"Legislative Initiatives to Strengthen and Modernize the SBIR and STTR Programs"
June 4, 2009

Subcommittee on Contracting and Technology
US House of Representatives

Introduction

Chairman Nye, Ranking Member Schock, and members of the Committee, my name is Jack Biddle and I am a founding partner at Novak Biddle Venture Partners (NBVP), a venture capital firm in Bethesda, Maryland. I am also a member of the National Venture Capital Association based in Arlington, Virginia. My views today represent 460 member firms which currently comprise approximately 90 percent of all the venture capital under management in the United States.

Novak Biddle Venture Partners was established in 1997 to provide equity financing and assistance to the management of young, information technology companies. NBVP is backed by a number of the country's most prestigious limited partners, and has over $580 million under management. The vast majority of our venture capital dollars comes from University endowments and US pension plans and the "owners" of our portfolio companies are in fact University students on scholarship, cops, teachers, and ministers. We have taken a hands-on approach to architect and help build dozens of start-up companies from the ground up. I personally invest in the early stage technology and fast growth opportunities and am focused on opportunities related to national defense that offer promise to produce the best military capabilities for our country, fight the war on terrorism, and protect our national security.

I would like to thank the Committee for the opportunity to share with you today the challenges that our small, venture-backed businesses have faced under past restrictions related to Small Business Innovative Research (SBIR) grants and why these grants are critical to the ongoing vitality of innovation, job creation, and national defense in the United States.

As an industry, we strongly support the four current draft legislative proposals that will reauthorize the SBIR program, especially the Investing in Tomorrow's Technology Act, which will restore the ability of venture-backed companies to participate in the SBIR program, so that all of the most innovative small businesses can compete for these critical funding grants. At a time when our country needs to build new businesses, the venture capital industry is committed to working with the government to bring a steady stream of innovation and economic value to market.

SBIR and VC Have Worked Well Together

NVCA and its members are encouraged by the May 22, 2009 National Academies of Sciences report on Venture Funding and the NIH SBIR Program which concluded that:

- there is no indication that "venture-controlled" firms crowded out non-venture-controlled firms;
- the recent exclusion of "venture-controlled" firms seems to disproportionately affect precisely those firms which have demonstrated the greatest potential for significant commercialization;
- restricting access to SBIR funding for companies that benefit from venture capital investments would disproportionately risk affecting some of the smallest innovative businesses and;
- The current exclusion has the potential to diminish the positive impact of the nation's investment in research and development.

The NAS recommends that consideration should be given to either restoring the de facto status by allowing "venture-controlled firms" to participate in the SBIR program or to making some other adjustment that will permit the limited number of majority-venture-funded firms with significant commercial potential to compete for SBIR funding.

Congress relies on the National Academies to provide objective, unbiased analysis. Indeed, past NAS reports are why Congress has so vigorously supported the SBIR program. Congress needs to reauthorize the program based on the recommendations of this recent NAS report. I encourage you to review this report.

Venture Capital Investment Overview

I would like to briefly explain how the venture capital industry creates and grows small businesses. Typically a venture capital firm is a small business itself, often with fewer than 25 employees. NBVP, for example has just 14 employees and 7 investing professionals. We raise our funds of money by contributing our own capital while also seeking resources from institutional investors such as University endowments, foundations, and pension funds with the charter to invest those funds in promising young start-up businesses.

Once a fund is raised, my partners and I look for the best and brightest entrepreneurs in which to invest, usually within a specific industry sector in which we have an expertise. Venture capitalists most often look for companies that are developing disruptive innovations and have the potential to grow from small businesses into large enterprises. For this reason, we are often investing in high technology areas such as early stage IT and defense technologies. Over 40% of our entrepreneurs are scientists or engineers to whom we reach out at university and government defense labs, to whom we are introduced through others who are already in our network, or with whom we have worked in the past on building successful businesses.

Venture capitalists are focused on commercializing applied research. In order to be considered for venture capital investment, the entrepreneur typically has a product or service that has gone through the discovery process and is ready to be tested and commercialized. If we believe the product has commercial promise, we will make an initial investment and look for the company to achieve certain milestones before we offer follow-on funding. We stay invested in these companies —both financially and through the sweat equity we offer —for anywhere from 7 -10 years, often longer and rarely less. The ultimate goal is to build the business until it can go public or become acquired, generating a return for all employee shareholders and investors. In 2008, the venture capital industry invested more than $28 billion into over 3800 start-up companies in the United States. Even so, few of these companies ever really make it. Venture-backed companies like those not venture-backed, lurch from crisis to crisis, with failure always looming close.

Venture-backed Companies Drive US Economic Growth and Innovation

Despite the recession, the venture capital industry is open for business. We have money to invest in innovative promising businesses. We recognize that our industry is one of the only asset classes able to create new jobs at this challenging economic time. According to an IRS Global Insight Study soon to be released, in 2008 originally venture-backed companies provided 12.05 million jobs and $2.9 trillion in US revenues, corresponding to 10.5% percent of US private sector employment and 20.5% percent of US GDP. From 2006 - 2008 venture-backed companies grew jobs at three times the rate of the private sector overall. Companies that were once small venture-backed businesses include: Google, Genentech, Intel, Cisco, Starbucks, Microsoft and FedEx.

Venture-backed Small Businesses

These venture-backed companies are quintessential small businesses. Many are pre-revenue and most have fewer than 10 employees. They operate on very tight budgets and must meet designated milestones if they are to receive additional funds. They remain extremely fragile as they face a challenging road fraught with obstacles including regulatory approvals, beta tests, larger competitors, human capital needs, ongoing financing, and ultimately customer acceptance.

It is critical to understand that venture capitalists do not fund basic research projects at our portfolio companies nor as general rule are they interested in government-specific products. The venture capital funds our companies receive are specifically directed to building a business around a discovery that has made it through the basic research process and is ready to be commercialized. Yet, these companies may have other early innovations in the pipeline worth pursuing or applications of technology that could be of high value to the government, but are not large enough to justify the use of company research funds at the expense of purely commercial work. It is for these new projects that these businesses would apply for an SBIR grant, as we venture capitalists can not and will not fund early stage research.

Unfortunately today, these companies are forced to make a choice between pursuing SBIR funding for the new project or continuing to access venture capital to bring existing projects to market since the Small Business Administration's (SBA) current interpretation will not allow many venture-backed small businesses to apply for SBIR grants. This scenario has resulted in small businesses at best delaying important discovery projects and at worst, abandoning this important work altogether.

Public/Private Partnerships

In past eras (e.g., the space race or the early days of DARPA), the best and brightest scientists worked in the government and the most exciting innovations emerged from work done by the Federal government. I strongly believe we live in a world where America's best and brightest no longer grow up wanting to work for NASA, or build computers at IBM for the NSA who was once the big customer. Over time, many of these innovators moved to the private sector and worked for large corporations such as Bell Labs or IBM. Today, some of the best and brightest minds, developing the truly disruptive innovations, are found at small start-up companies. Large corporations simply do not have the internal resources to fund the necessary R&D needed to keep ahead of the innovation curve.

At a time when the national debt is high, government resources are stretched thin, and our need for advancements in defense technology and national security are great, it seems prudent that government agencies would seize the opportunity to work collaboratively with venture capitalists. DoD is loosing the leading edge in defense technology, and the Department needs to engage the VC community because this is where the best scientists and ideas are today.

The DoD and the venture capital community are natural partners. SBIR is a vehicle to allow our government to use the program OFFENSIVELY to go and get our best scientists and engineers re-engaged and thinking about how they could make us more secure with a twist or a spin to a technological innovation they wouldn't otherwise do. DoD knows they need current year loosely allocated money to try and get this world back on their team. That kind of funding cannot politically exist today. With SBIR, it already exists, with the necessary collaboration and procurement authorities. SBIR could give DoD a tool to get these their entrepreneurs thinking

about building ships in a week, in addition to what they are doing anyway – trying to tap billion dollar consumer markets with technology that is years ahead of what DoD currently has.

DoD needs to engage and co-opt our elite innovators to at least think in passing about military applications for their commercial innovation. Our firm is a bit different because we are in Washington, we have high security clearances in DoD, and we do back duel use technologies. SBIR can be a mechanism to get our peers in venture capital beyond Washington engaged, and to at least give passing thought to the military and intelligence applications of their commercial innovations.

Our track record is clear. In the same way that venture capital helped bring about the high tech revolution and quite literally created the biotech industry, venture-backed entrepreneurs and investors stand ready to meet the challenges that have thus far stymied advancements in defense and national security technologies.

VCs are continually seeking out the next generation of technology, but the current SBA eligibility rules throw costly, time-consuming, and unnecessary hurdles in the path of government agencies seeking to collaborate with venture capital-backed companies. We believe this is a huge loss for our country. As a consequence, a large swath of the venture capital community has turned their back on government, to the detriment of our national security. SBIR provides the funds to engage this community, the legal authority for public/private collaboration, and procurement vehicles usable by small business. The venture industry is poised to meet the challenges relating to better protecting our country, and the policies enacted by this Congress and this Administration will either help, or hinder that effort.

Common Misconceptions

With the reauthorization of the SBIR program, Congress has the opportunity to correct a significant injustice that has gone on too long. It has been eight years since an administrative law judge redefined an "individual investor" to mean a "natural person," thereby opening the door to exclude from the SBIR program small businesses that have received venture capital funding. While there has never been an actual change in law or regulation, the SBA used this interpretation in recent years to deny grants to many of our country's most worthy small businesses. Under the past Administration, the SBA's policies regarding SBIR eligibility and how they determined if an entity qualifies as a small business were inconsistent, and based on serious misconceptions which I would like to address.

One of the largest misconceptions is that venture capital firms are equivalent to large corporations, and therefore the companies that they fund should be excluded from consideration from SBIR grants. We agree that large corporate owned businesses should not be allowed to participate in small business programs and have supported past provisions to ensure that this misdirection of small business dollars does not take place. But venture capital firms (and their portfolio companies) are not large corporations with deep pockets and ulterior motives. They are almost entirely private partnerships that are typically comprised of less than two dozen professionals whose sole business is to invest in small emerging growth companies. Venture capital firms focus on the growth of the small business, not to further the agenda of any large corporation. Most often, these small businesses are competing with large enterprises.

Another common mistake is to assume that venture-backed companies are controlled by venture capitalists. While venture capitalists as investors typically take a Board seat, we do not exert day-to-day control of a company for several reasons. We simply do not back people who cannot run their own business. We have neither the time, nor the skills. The partners at

venture firms work with a number of portfolio companies at once. Our time is divided between all investments of the venture fund and it would be impossible and impractical to spend that limited time on the hundreds of nitty-gritty, day-today decisions that the internal management team must make instead of helping the management team make the strategic level decisions necessary to grow. Unlike corporations, venture capital funds are usually limited life entities that make their return on investment only when the portfolio company is sold or makes a public offering of its securities. And lastly, no particular venture capital firm typically has a controlling interest. The 51 percent or more ownership of a company is often achieved because there are several venture firms invested, giving each a smaller, more diluted share in the company. The governance of these companies is most often the result of consensus-building, and the most important voice in the room is that of management, not the investors.

The current policy particularly hurts the regions of our country that the SBIR program was designed to support. The scarce venture capital dollars available in mid-America for instance must cover a greater geographic footprint than in the concentrated areas such as Boston or the San Francisco Bay Area. For this reason, venture funds generally join together to fund a promising start-up, as a single firm indigenous to the region will not have the capital to fund a company fully. As each firm takes an equity stake in the company, the total venture ownership percentage can quickly rise above the 51 percent threshold, thereby making the mid-America start-up company ineligible to apply for an SBIR grant.

Conclusion

NVCA supports the four new draft SBIR reauthorization proposals and believes that Congress should adopt the National Academy of Sciences' recommendation to restore the eligibility requirements for majority venture-backed companies.

The SBIR program provides the authority to allow the DoD to use government grants offensively, and allows the government to work with the best scientists and companies to back leading edge technology. The program also allows the most gifted scientists to become funded —they are funded because they are the absolute best of the best —exactly the ones DoD needs thinking about new applications. The government needs to pursue THEM, and SBIR is an ideal mechanism to do that. This program can become truly interesting for DoD if the SBIR program can be reformed to allow ALL US owned small businesses to be engaged. Then DoD can use it OFFENSIVELY as a vehicle to engage our most clever people.

The SBA's past policies have seriously negated the positive impact of venture-backed small businesses on innovation. Both venture dollars and SBIR dollars play complementary roles in financing innovation. One is rarely, if ever, a substitute for the other. Venture-backed companies seek SBIR dollars because they are needed to help finance research targeted at innovations that are too early in their development for the venture capitalists to cover. SBA has cut off the innovation pipeline so that many of the most promising projects never see the light of day. It is time for a positive change.

No other asset class supports the premise more that small businesses are the life blood of the US economy than venture capital. As investors in these important entities, we are advocates for their viability and growth. We believe that the best use of government dollars is to leverage public/private partnerships in which we all have a role in bringing innovation out of the garages, labs and tiny businesses into the marketplace, the healthcare system, our military, and renewable energy enterprises. The venture capital community is committed to contributing significantly to this endeavor. We have consistently over the years asked Congress and the

Administration to join us. We hope that this year Congress will reauthorize the program with provisions that ensure venture-backed companies have a fair chance to thrive under the SBIR program alongside their non-venture-backed counterparts. Doing so will strengthen the future success of the program, our economy, and our nation.

Thank you.

HEARING TESTIMONY

JOE HERNANDEZ
PRESIDENT AND CHIEF EXECUTIVE OFFICER
INNOVATIVE BIOSENSORS, INC. (IBI)

ON BEHALF OF THE

BIOTECHNOLOGY INDUSTRY ORGANIZATION

BEFORE THE HOUSE OF REPRESENTATIVES COMMITTEE ON SMALL BUSINESS

"LEGISLATIVE INITIATIVES TO STRENGTHEN AND MODERNIZE THE SBIR AND STTR PROGRAMS"

June 4th, 2009

Good morning Chairman Nye, Ranking Member Schock, Members of the Committee, ladies and gentleman. I am Joe Hernandez, President and Chief Executive Officer of Innovative Biosensors, Inc also known as IBI. I am appearing before this Committee on behalf of the Biotechnology Industry Organization (BIO). BIO represents more than 1,200 companies, academic institutions, state biotechnology centers and related organizations in all 50 states.

I am the founder of IBI, a venture backed company developing and commercializing a rapid pathogen detection technology originally developed with DARPA funding at the Massachusetts Institute of Technology. The CANARY technology, as we call it, was born out of a need to develop more sensitive and rapid detection systems for the identification of biological weapons. The technology is revolutionary because it leverages the machinery in nature to give us an ultra rapid, ultra sensitive detection technology. We use the best biosensors available, which happen to be cells of the immune system and then genetically manipulate them into a jelly fish gene that makes the cells glow in the presence of a particular and predefined pathogen. This allows for ultra sensitive tests in a matter of seconds. It's akin to a Canary in the mine. This technology was published in the preeminent scientific journal, *Science*.

We have deployed to technology in building protection and today we are proud of the fact that our technology protects important buildings essential to the operation of our government. This is a big achievement for a company of 20 employees and it is primarily a byproduct of the hard working patriotic employees we have working for us.

We are also developing the technology to be used in the rapid detection of hospital acquired infections such as MRSA and Staph which has important clinical applications.

We have been successful in raising close to $20M in several rounds of sophisticated venture capital and are currently backed by five major investors who have believed in our dreams and have faith in our ability to execute. These investors are funding our lead product, a test for the superbug MRSA, a hospital acquired infection.

The company was successful in raising early SBIR funds that helped us validate the technology. Additionally, this funding served to anchor further investments and provided a means of technical diligence. We received a Phase I award that allowed us to develop a test for prions, the causative agent of mad cow disease. Unfortunately, we were unable to apply for Phase II funding due to the venture capital restriction that currently excludes majority venture-backed small businesses, like ours, from the SBIR program.

As developers of next-generation technology, our business is a risky one. That being said, we continue to push the envelope of science and continue to deliver on the promise of a better quality of life.

We need help in getting these novel technologies of the ground. Our skilled labor and the future laborers of this country require that of us.

The SBIR program is an important piece in the generation of new biotechnology-based companies and we ask that this funding vehicle remains in place after we raise venture capital so that we can continue to develop these life-changing products. This policy is supported by the 2009 National Research Council's 2009 report "Venture Funding and the NIH SBIR Program." This study found that "Restricting access to SBIR funding for firms that benefit from venture investments would thus appear to disproportionately affect some of the most commercially promising small innovative firms" and that the current SBA eligibility rules have "the potential to diminish the positive impact of the nation's investments in research and development in the biomedical area."The report recommends that the SBA ruling be repealed or

modified so that majority-venture funded companies with significant commercial potential can compete for SBIR funding.

The role of the SBIR program in bringing breakthrough therapies to the American people is a matter of record. There are 252 FDA approved biologics that have been developed by 163 companies. Thirty-two percent of those companies have received at least one SBIR/STTR award. Despite its noble past, the ability of the SBIR program to provide critical funding for medical research projects will remain hampered unless SBIR reauthorization updates the program to address the current realities facing small, innovative American companies.

As you know, Congress created the SBIR program in the early 1980's because it recognized that promising, early stage scientific research all too often failed to be funded through the markets because it was viewed as too high risk. This failure of the markets is often referred to as the "valley of death." The importance of advancing science through the valley of death has never been more important than it is right now as numerous small biotechnology companies are being forced to shelve promising therapies as result of the current economic crisis. In fact in just the last five months, at least 25 U.S. public biotech companies have either placed drug development programs on hold or cut programs all together. These programs include therapies for HIV, cervical cancer, Multiple Sclerosis, and diabetes.

For twenty years small, domestic biotechnology companies competed for SBIR grants. In addition to providing funding, these grants were a powerful signal to the private sector that a company's research was compelling and possessed scientific and technical merit. However, in 2003 the Small Business Administration's Office of Hearings and Appeals (OHA) ruled that a biotechnology company, Cognetix, did not meet the SBIR size standard because multiple venture capital investors, in the aggregate, owned more than 50% of the company's stock. The ruling, which is not based on the SBIR statutory language, ignores the realities of the marketplace where small biotechnology firms must raise tens of millions of dollars to conduct incredibly capital-intensive research. It is estimated that it takes between 8 and 12 years to bring a biotechnology therapy to market and costs between $800 million and $1.2 billion. These small biotech firms typically have less than 50 employees, no product on the market and must raise considerable funds through a combination of angel investors and venture capital firms in order to make a therapeutic commercially available to patients.

The impact of the current economic crises on small biotechnology companies has been and continues to be severe. According to the latest available data, 30 percent of small, publicly-traded biotechnology companies are now operating with less than 6 months of cash on hand, a 90 percent increase relative to

2007. Forty-five percent of these companies have less than 1 year of cash remaining. The total capital raised by the industry in 2008 has seen a steep decline (down 55% compared to 2007).

The SBIR program has always been critical to helping innovative biologic therapeutic development programs traverse the valley of death and move towards a publicly available product. A role that has never been more critical than it is today. A recent joint study by BIO and Thompson Reuters found that the current economic crisis has forced over 80 percent of biotech investors to change their investment approaches. They can no longer afford the high risk that is characteristic of investment in biotech. The decline of the biotech industry jeopardizes not only America's patient population, but also America's competitive edge in the 21st century global economy. The importance of restoring eligibility to small biotechnology companies has never been clearer.

SBA has stated that the ownership rule is meant to be a proxy for determining that a company is domestic. However, the use of capital structure as a proxy for determining domesticity and the subsequent OHA ruling has had the unintended consequence of excluding a sizeable portion of U.S. biotechnology companies that would otherwise be eligible to participate in the program. Even more alarming is the fact that NIH SBIR applications have decreased 40 percent since 2004, about the time that SBIR-participating agencies implemented the new SBA restriction on majority VC-financed companies.

Small biotechnology companies are generally a collection of research projects with one lead product and an average of 5 other therapies or candidates in early stage/pre-clinical research. Typically, a biotechnology company will begin fundraising for its lead product in development. Companies generally raise between $5 million and $15 million in their first round of venture financing, an amount that often results in multiple venture capital companies collectively owning more than 50% of the company. This is especially the case with very young companies whose valuation may reflect their high-risk, early stage nature. However, it is typically the case that no single venture capital company will own more than 15 to 25 percent of the company's equity.

Despite the extensive fundraising a biotechnology company undertakes for their lead product, these funds are not interchangeable, as they are tied to very specific milestones to support the lead product's development. As such, in order to develop secondary or tertiary candidates/therapies a company has to find secondary sources of fundraising capital. At the very earliest stages of development other sources of financing, such as SBIR grants, have been instrumental in advancing research and development in biotechnology. This phenomenon is excellently described in the 2009 NAS study which explains that biologic drug development is not a linear process and has to be examined not just as SBIR funds for

firms, but SBIR funds for projects. The NAS data illustrates how SBIR funds are complimentary to venture capital funds and may be used to develop early-stage research projects distinct from a company's lead research project.

Opportunity to Strengthen/Restore SBIR Program

I appreciate the opportunity to discuss much-needed changes to the current SBIR program. I believe these changes would strengthen the program and ensure that it is funding the best small biotechnology businesses who are working on innovative programs that have the most potential to benefit the public. My recommendations can be grouped under three general goals. First, increase competition for SBIR grants and, as such, foster innovation and commercialization by small companies with the most promise. Second, clarify SBIR eligibility rules to make them easier to understand and increase transparency regarding the program's operation. Third, maintain agency flexibility to make certain the SBIR program continues to serve the needs of individual agencies.

I will briefly discuss each of these important goals.

Increase Competition and Foster Innovation and Commercialization by the Best Small Companies

SBA's 2003 ruling that excludes majority venture-backed companies inhibits the SBIR program from receiving the most competitive pool of applicants possible and stifles the ability of SBIR to carry out its mission to fund projects that will improve public health and have the most commercial potential.

The current SBA interpretation would deem eligible a public company with 499 employees and significant – perhaps hundreds of millions – of dollars in revenue. . However, a private company with 20 employees, no annual revenue and $8 million in venture capital by multiple venture capital funds equaling 56% of the company's equity – even though no one venture capital firm has more than 30% of total equity – is ineligible. Among BIO emerging companies, a significant amount are ineligible, the majority of which would apply to SBIR if able. These companies are working on breakthroughs for the treatment of diseases such as cancer, Alzheimer's, lupus, and leukemia.

The National Institutes of Health (NIH) have documented disturbing trends since the 2003 ruling. Applications for SBIR grants at NIH have declined by 11.9 percent in 2005, 14.6 percent in 2006, and 21 percent in 2007. Additionally, the number of new small businesses participating in the program has decreased to the lowest proportion in a decade.

Small biotechnology companies have high and intense capital needs (over $1 billion) and an unusually long development time of 5-12 years. The vast majority of biotechnology companies raise between $5 million and $15 million in their first round of venture financing for their lead product(s), an amount that usually results in the venture capital firms collectively owning more than 50% of the company. However, the investment group usually consists of several firms, none of which owns more than 15-25% of the company.

SBIR plays a critical role in aiding small biotechnology companies in their early stage research to navigate through the "valley of death" where the concept is too high-risk for private market support. This has never been more important as the "valley of death" is only getting wider in these difficult economic times.

BIO respectfully asks the Committee to reinstate the eligibility of small, VC-backed biotechnology firms to compete for SBIR awards. This will ensure the most competitive pool of applicants and that grants awarded will be based on projects that show the most promise in bringing breakthrough therapies to the public.

BIO supports the provisions being considered for inclusion in the SBIR reauthorization legislation that would reinstate eligibility for small biotechnology companies that are majority-venture backed. These provisions include reasonable limitations on the role of corporate venture capital investors and majority ownership by a single venture capital company.

Clarify SBIR eligibility rules to make the application process more straightforward and user-friendly

It is equally important the reauthorization clarify SBA affiliation regulations. Under current SBA regulations, when determining the size of a business, the SBA considers the number of direct employees at the business as well as affiliated businesses' employees. Businesses are affiliates of each other if the SBA determines that another business has either affirmative or negative control. Current regulations state that a venture capital company that holds a minority share in another business can be considered an affiliate of that business. If the SBA determines a venture capital company is affiliated with the business, not only are the employees of the venture capital company included in the size determination but so are the employees of other businesses in which the venture capital firm is invested.

As a result of these affiliation rules, a small company with 50 employees could be deemed to be affiliated with hundreds of other employees of companies with which the small company has no relationship whatsoever, simply because the companies share a common investor. It is important to note that this can be the case where the VC investor owns a minority stake in the small business applying for SBIR.

Not only are these affiliation rules nonsensical, the manner in which they are applied is often a mystery to the small business applying for the SBIR grant. As a result, a small company may certify in good faith that it is eligible for an SBIR grant, only to later find out that the SBA has affiliated it with a large number of employees at other unrelated companies, thus making the small business ineligible.

BIO supports the provisions being considered for inclusion in the SBIR reauthorization legislation that would create a more rational and effective affiliation process regarding determinations about an SBIR applicant's investor's portfolio companies. Specifically, BIO supports language to clarify that minority investment by a venture capital operating company does not make that company an affiliate of another company for the purposes of determining size. This common-sense provision will provide clarity and peace of mind for small business entrepreneurs looking to participate in the SBIR program.

Maintain Agency Flexibility

BIO also supports maintaining agency flexibility in the SBIR program. One of the great strengths of the SBIR program is that Congress provided the affected departments and agencies with flexibility in establishing the program. Maintaining flexibility in the program is also supported by a National Research Council 2007 report which states, "...flexibility is a positive attribute in that it permits each agency to adapt its SBIR program to the agency's particular mission, scale and working culture."

The reality is that various government agencies may structure their SBIR program in different ways to meet differing agency needs. This is a good thing, so long as the original goals of the SBIR program are preserved. Certain agencies, for example, may need the flexibility to award larger grants, if the project they are funding is in an area where research is typically more expensive. This is sometimes the case for biotechnology companies researching therapies that are especially novel or cutting-edge. For this reason, BIO does not believe that a hard cap should be applied to the SBIR grant amounts.

Additionally, any caps on SBIR grants, if imposed, should apply to particular SBIR phases and should not apply to the entire amount that the agency spends on a particular project. The NIH, for example, has chosen to implement a commercialization assistance program for those companies who may need extra

funding before they can attract private dollars. A hard dollar cap in the SBIR program could threaten such a program and this would be, in BIO's opinion, very unfortunate.

BIO supports provisions being considered for inclusion in the SBIR reauthorization bill that would protect an agency's ability to fund commercialization programs and determine when it is appropriate to exceed award amounts. As the NAS 2009 report made clear, SBA should continue to rely on agency managers' judgment, experience, and understanding of mission needs to effectively administer the SBIR program.

CLOSING REMARKS

Congress can continue to support the United States biotechnology community by allowing the government to partner with small biotechnology companies that have promising science but need additional resources at key stages of development not readily available in the private capital markets. SBIR should be an aggressively competitive program that fulfills federal research and development goals of bringing breakthrough public health discoveries to the public. BIO believes that the modernizations to the SBIR program being considered by the committee will help to accomplish this important objective.

House Small Business Committee
Contracting and Technology Subcommittee
June 4, 2009

Written testimony by Marion C. Blakey, President and CEO
Aerospace Industries Association

Introduction

Good morning Chairman Nye, Ranking Member Schock, and members of the Subcommittee. Thank you for the opportunity to testify before you today on such an important topic as the Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Programs. As the president and chief executive officer of the Aerospace Industries Association (AIA), I represent nearly 300 aerospace manufacturing companies. Our industry is responsible for more than 2 million well-paying jobs and $95 billion in exports last year leading to a positive trade balance of $57 billion – the largest of any U.S. manufacturing sector. While AIA might be better known for our larger aerospace and defense companies, such as Lockheed Martin, General Dynamics, Northrop Grumman, Boeing or Raytheon, our Supplier Management Council is made up of many small businesses such as Morris Machine Company, Inc. in Indianapolis, Indiana; HAAS TCM/Avchem and Southco in West Chester, Pennsylvania; and, Sanmina-SCI Corporation in Huntsville, Alabama.

These companies are the suppliers our major corporations rely on for machined component parts, fabricated subassemblies, electronic subsystems, system software and many other items integral to operation of our aerospace equipment across civil aviation, national security and space. In fact, it is typical that 70 percent of the parts for a weapon system are supplied from outside sources to the prime contractor.

Just as the AIA serves to bring together our industry's prime contractors with suppliers, the SBIR program brings together the nation's small, high-tech, innovative businesses as a significant part of the federal government's research and development efforts. AIA member companies understand the important role that the SBIR program fills. Their managers work with suppliers to identify or develop SBIR projects for those technologies that are not currently being funded, but are necessary to achieve technology objectives resident in areas of critical interest to government agencies.

Companies large and small recognize the important role SBIR has in developing the next-generation of innovations. Therefore, I welcome the opportunity to be here today to discuss AIA's recommendations related to maintaining the integrity of the SBIR as a small business program. These include bridging the gap between high-risk, early-stage innovation and commercialization, updating allocation and award amounts to reflect today's economics and instituting a longer extension of the program reauthorization period.

Maintaining Integrity of the SBIR Program through limited VC participation rules

The SBIR draws on more than six million scientists and engineers that are now employed by small firms or self-employed, representing 38 percent of all the scientists and engineers in America, spawning an average of seven patents a day (67,000 patents since program inception). Yet, small businesses receive just 4.3 percent of the total federal R&D funding – SBIR and STTR accounts for almost two thirds of that 4.3 percent. For most small companies, SBIR remains the only game in town – just as it was when it was instituted in 1983. Reauthorizing the program should ensure that only companies that qualify as a small business be allowed to be the primary participants of the SBIR program to ensure that the nimble ingenuity of the entrepreneurs leading these businesses is not pushed aside.

Specifically, changes have been proposed related to the participation eligibility of venture capital firms. Modifying the SBIR program to allow for venture capital participation in firms seeking SBIR funds is a legitimate recognition of the changing business environment. However, changes must be made only after carefully considering which venture capital firms are allowed to participate. The integrity of SBIR as a small business program must not be threatened by weakening the safeguards and allowing large businesses access to SBIR funds. This includes venture capital firms who don't meet the size standard definition that states, "A small business concern for purposes of award of any funding agreement under the SBIR program is one which, including its affiliates, has a number of employees not exceeding 500."

Allowances should be made, however, if the venture capital firm qualifies as a small business itself or if the venture capital firm does not own 50% or more of the business concern and employees of the venture capital operating company do not constitute a majority of the board of directors of the business concern seeking SBIR funds.

Another issue relates to venture capital firms whose funding profiles include sovereign nation funds. The question as to what country may have controlling interest in these firms should be of special concern from a national security perspective and safeguards should be built in.

Venture capital, just as large business interests, can play a critical role in the technology commercialization phase of the process once the SBIR concept and potential benefits have been proven during the initial SBIR phases. But without open and competitive early R&D efforts, spread as widely as possible among traditional small businesses, innovations will never reach the level of maturity that can draw in venture capital or other follow-on funding.

Bridging gap between high-risk early-stage innovation and commercialization

The most significant impediment to producing products or having SBIR technology fielded is that Phase II SBIR usually does not get beyond Technology Readiness Level 4 (TRL-4). Military prime contractors require a TRL of a least 6 and the Federal Drug Administration (FDA) requires TRL-7 for clinical trials. Private capital during early-stage technology development is typically non-existent. At the idea stage, and even the development stage, the

risks are too great for all but a few investors, and therefore many innovations can't get beyond those stages without funding. This leaves a significant funding gap for SBIR firms.

AIA recommends developing a new follow-on award to Phase II that focuses on testing and manufacturing, to provide the opportunity for technologies to successfully mature between the current TRL-4 limit towards the TRL-6 needed for defense contracts, for example. Effectively transitioning technology from the working prototype stage to production and utilization by the agencies or the private sector is critical to ensure a maximum return on investment from the SBIR program into true commercial markets.

Developing and funding a new follow-on Phase IItm (for technology and manufacturing) would allow companies to conduct more testing and make initial production runs to test their devices for the intended use with production grade equipment. Implementing this new phase should allow for FDA testing, testing by prospective customers, and initial field tests by the military and other similar operational tests. It should also allow agency certification (FAA, FDA, etc,) approvals to be included as a direct cost. These Phase IItm programs should be competitively bid and selected from the best Phase II contracts/grants based on agency need and projected return on investment. They should be limited in number, and should generally be in the $1 to $5 million range.

Furthermore, effectively transitioning technology from the working prototype stage to Low Rate Initial Production (LRIP) and utilization by the agencies or the private sector needs to be addressed. Agency efforts like the National Institutes of Health's (NIH) Phase IIB and the Department of Defense's (DOD) Commercialization Pilot Program are pointing the way. Successes like those experienced by the Navy show that such transitioning can be accomplished in ways that benefit the government and the taxpayers. AIA urges Congress to incentivize agencies to match the successes of SBIR Phases I and II (and the proposed Phase IItm) in SBIR Phase III by providing funded programs which integrate with early phase SBIR technology. One key to this will be the expenditure of additional dollars on testing, evaluation and manufacturing.

Updating award size and allocation amounts to reflect current economic conditions

Major economic breakthroughs all along have been made by small company innovations, and SBIR accelerates technological innovation and helps attract private sector investment to the most promising innovations. Yet even with the SBIR and STTR programs, small businesses receive just 4.3 percent of total federal research & development funding.

Despite the tremendous advancements made by small business innovations, contract award sizes have not been adjusted since 1992. The real dollar award size of these contracts has effectively diminished and should be increased to compensate for 15 years of inflation. AIA recommends that award levels be increased to at least $250,000 for Phase I awards and to $2 million for Phase II awards.

However, merely increasing award sizes to account for inflation would effectively decrease the total amount of awards given unless the allocation percentage is also increased. The current set-aside of 2.5 percent of all federal extramural research and development funds

was set in 1998. Given the valuable research that has come out of our small businesses through the SBIR program, this set-aside allocation for SBIR should be incrementally increased to 5 percent and 0.9 percent for STTR of the total eligible R&D funds.

Longer extension of reauthorization period

Finally, legislative precedent and tradition often mean that U.S. government programs are authorized for one or two-year periods. However, the unique nature of the SBIR program warrants consideration of a much longer authorization period.

This committee has discussed authorizing the SBIR program through September 30, 2011. However, a two-year authorization does not provide sufficient time to implement and then assess results of any changes made. Historically, it takes at least a year for the agencies to implement the changes, at least another year to award and conduct a Phase I, about a year (6-18 months) to award a Phase II, two years to complete the Phase II and one to two years to study the effects. Thus, six or seven years is the minimum time needed to evaluate any legislative changes.

If additional Phase II continuations, Commercialization Pilot Programs, or other longer term changes are suggested, another two or three years would be required. Thus, 8-10 years would be needed for a complete evaluation by the Government Accounting Office, the National Academies or other organizations. Finally, a two-year legislative cycle would allow political discourse on the proper actions and legislative debate. This takes us to at least 10-12 years to adequately allow time for other exigencies. AIA recommends an authorization period of 14 years or reauthorizing the program through September 30, 2022.

Conclusion

The SBIR program was created to address critical U.S. government needs and to serve as an incubator for future technological development, providing funding for some of the best early-stage innovation ideas that are still too risky for private investors. And no innovation stimulus program in our nation's history has received higher marks across the board.

Keeping the SBIR program at pace with today's economic and technological environment means updating the program as soon as possible, which will yield untold results. In order to ensure this program remains at the forefront of technology and a key driver for our innovative small businesses, AIA recommends the following be implemented as this program is reauthorized:

- Allowing limited venture capital participation so long as necessary safeguards are included to ensure the integrity of the SBIR as a small business program.

- Developing a Phase IItm follow-on program to provide a bridge between promising technological development and potential commercialization and utilization in the defense acquisition process.

- Increasing both the contract award sizes in both Phases I and II and the overall funding allocation percentage given to the SBIR program.

- Reauthorizing the program through September 30, 2022, to evaluate results and provide program continuity.

Thank you again for the opportunity to testify before this Committee. I look forward to any questions you may have.

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HOUSE SMALL BUSINESS COMMITTEE
SUBCOMMITTEE ON CONTRACTING AND TECHNOLOGY

"Legislative Initiatives to Strengthen and Modernize the SBIR and STTR Programs"

June 4, 2009

STATEMENT BY

Brett Loper
Senior Executive Vice President, Government Affairs, AdvaMed (The Advanced Medical Technology Association)

Chairman Nye, Ranking Member Schock and members of the Subcommittee, thank you for holding this hearing today and for continuing your efforts to reauthorize and improve the Small Business Innovation Research grant program. My name is Brett Loper, and I am Senior Executive Vice President of Government Affairs at AdvaMed.

AdvaMed, the Advanced Medical Technology Association, represents over 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of AdvaMed member companies are relatively small companies with sales of less than $30 million per year. Our members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, AdvaMed members manufacture nearly 90 percent of the $86 billion in life-enhancing health care technology products purchased annually in the United States, and nearly 50 percent of the $220 billion in medical technology products purchased globally.

The medical technology industry is a critical component of the U.S. health sector. In addition to the profound contributions of medical technology to the health and well-being of the public, in 2006 the industry employed 357,700 workers; paid $21.5 billion in salaries; and shipped $123 billion worth of products. Taking into account the national multiplier impacts, the industry created (direct plus indirect plus stimulated impacts): 1.96 million jobs; payrolls that totaled $93 billion; and $355 billion in shipments/sales. However, we are not just a major contributor to the U.S. economy based on revenues and jobs. The devices we make also help patients stay healthier longer as well as recover more quickly after treatment, thus allowing patients to participate more fully at work and in the community.

The medical technology industry is fueled by intense competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

Importance of the SBIR Program to Emerging Growth Medical Device Companies

The SBIR program is critical for many emerging growth medical device companies, and I'm proud to say that many of our member companies have thrived after receiving SBIR funds.

When innovators and entrepreneurs first seek to raise private money to bring their innovations into the medical field, they often encounter difficulties, especially if their innovation is so new that it represents a very high risk/high reward proposition. In these cases, venture funding is difficult to obtain. However, the SBIR program was specifically designed to fund research on promising high risk projects. This type of risk is what leads to paradigm shifting discoveries. The SBIR grants serve a number of important roles in getting high risk/high reward companies

off the ground. First they enable the companies to inexpensively test the feasibility of their technology and obtain additional funding if the technology does prove to be feasible. Second, when a company is able to show feasibility and garner additional SBIR funds, this provides an independent scientific validation of the company's approach and opens the door for venture capital and other private fundraising, which allows a company to obtain proof of principle laboratory data and to finalize a prototype device. Finally, a company can prepare to enter clinical trails or do other testing necessary for FDA approval. This progress often cannot happen without SBIR funding. Put simply, without the SBIR program, many high risk/high reward technologies would not be developed and the public would have fewer new treatments for serious illnesses.

The Need for Alternative Funding Mechanisms Beyond SBIR/STTRs

There are a tremendous number of costs associated with any start-up company and SBIR funding only covers a small part of those costs. The program is limited in the funds that it can provide and is very strict as to how that money can be spent. For example, those monies cannot support market research or the bulk of lawyer fees for intellectual property protection.

In addition, there is a long runway for obtaining funds. It can take one to two years to obtain funding. Even for a perfect proposal with clear scientific merit, there is a nine month time window between submission and receipt of funds. Those funds are very limited and we support the Committee's efforts to increase the amounts of funding for both Phase I and Phase II grants. Such an increase would help alleviate some of the burdens on small business. However, it is important that other sources of funds be available as well, since costs of device development continue to accelerate due to elevated FDA standards and higher healthcare industry costs.

There are three main sources for the large amount of capital that is needed to bring a new medical product to market. One is company revenues, another is VC funding, and a final one is to license the technology to or partner with an already established company.

A start-up company with no revenue other than SBIR grants and a small seed amount of investment is in a different situation for getting their product to market. They will need considerable non-SBIR funds. These funds can come from VCs or a partner. Partnering is usually a preferred method of getting one's product to market because the start-up company does not have to develop the expertise needed in this area. However, not all products and not all companies are right for partnering. Many products may help patient populations that are very small and thus not as commercially attractive to a potential partner. In addition, and perhaps more importantly, in order to partner a technology, it is necessary to develop the technology to a later stage than SBIR funding alone can take it. This is where VC funding is needed.

The Impact of SBIR Eligibility Rules on VC Funding

A series of rulings from 2001 – 2003 by the Small Business Administration's Office of Hearings and Appeals resulted in the determination that small businesses that were majority-backed by venture capital investors were no longer eligible for SBIR grants. This regulation prevents many small medical technology companies from participating in the SBIR program – including many that have received SBIR grants in the past and are emblematic of the success of the program – even though these small businesses still have a tremendous need for assistance. This does not seem to be within the spirit of the original intent of the SBIR program, which is to help small businesses develop promising, early stage technologies.

It is far more attractive for a venture group to invest in risky technology if there is a track record of SBIR successes. This greatly reduces the risk of investment, however as the rules are today, many companies would have to give up their SBIR funding in order to obtain venture funding.

This is a catch-22 situation. In order to attract VC funding, a company must obtain SBIR funding first. However, they will lose that funding if the VC invests too heavily. This greatly reduces the amount of VC funds that can be raised, which reduces the probability of success and in the end reduces VC investments.

This regulation also creates a perverse incentive against VC investment. Start-up companies that have scientists from academia with solid track records of grant funding lose an important leverage tool for bringing in VC monies, and potentially at the most critical point in the product development life cycle when new capital is in greatest demand. This reduces overall investment and increases the chance that important technologies will not be developed.

Finally, the NIH is certainly interested in funding the very best ideas available. By removing many small companies from the pool of possible ideas, the current regulations remove some of the best ideas from consideration by the SBIR program.

Legislation to Restore SBIR Eligibility for Small Businesses

Addressing the VC funding issue is a top concern to AdvaMed's small companies that rely on SBIR funding to develop new medical technologies for patients. By limiting the VC funding mechanism from emerging growth device companies, it decreases their chances of success. VC funding is simply the lifeblood for these companies. Commercial financing and public market derived equity are simply not options for medtech entrepreneurs. Companies may or may not eventually require VC funding on the order of 50% ownership, however that arbitrary limit diminishes their overall probability of success.

Additionally, AdvaMed supports increasing the award levels for the SBIR program and supports increasing the SBIR set-aside.

Conclusion

The United States spends a tremendous amount of money on basic research. We lead the world in research funding, in new discoveries, in scientific publications. Our research commitment is important and should be continued. But in order for this research to have a role in the economic recovery, and advances in healthcare delivery, it must be translated into applications. Only when new technology reaches the application stage does it begin generating jobs and improving people's lives.

Chairman Nye and Ranking Member Schock, we thank you for your leadership in the reauthorization of the SBIR program and this opportunity to comment on your legislative process. We look forward to working with the Committee as legislation for SBIR reauthorization moves forward, and we support the proposals contained in the draft legislation. We want ensure that small businesses will continue to drive medical innovation and develop promising new technologies for patients, especially as our nation seeks economic recovery. I'll be happy to answer any questions you may have.

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