FULL COMMITTEE HEARING ON LEGISLATION TO REAUTHORIZE THE SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

COMMITTEE ON SMALL BUSINESS UNITED STATES HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

MARCH 13, 2008

Serial Number 110-79

Printed for the use of the Committee on Small Business

Available via the World Wide Web: http://www.access.gpo.gov/congress/house

U.S. GOVERNMENT PRINTING OFFICE

40–853 PDF WASHINGTON : 2008

For sale by the Superintendent of Documents, U.S. Government Printing Office
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FULL COMMITTEE HEARING ON LEGISLATION TO REAUTHORIZE THE SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Thursday, March 13, 2008

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

The Committee met, pursuant to call, at 10:00 a.m., in Room 1539 of the Longworth House Office Building, Hon. Nydia Velázquez [chairwoman of the Committee] presiding.

Present: Representatives Velázquez, Cuellar, Chabot, Graves and Buchanan.

OPENING STATEMENT OF CHAIRWOMAN VELÁZQUEZ

Chairwoman VELÁZQUEZ. Good morning. I am kind of disoriented because this is not our Committee room, and I am accustomed to the fact that Mr. Chabot is always on my right. Today he is on my left, and I do not know if there is a subliminal message here.

[Laughter.]

Chairwoman VELÁZQUEZ. I call this hearing to order.

Today we will examine legislation modernizing and extending the Small Business Innovation Research Program. SBIR is one of the government's largest sources of funding for innovation. It awards more than $2 billion in research grants every year, which enables the work of thousands of America's most innovative small firms.

As science and technology evolve, however, so must this initiative. The authors of the program had great foresight. Twenty-five years ago they recognized early stage firms could make important contributions regarding technological development. SBIR made it practical for these small and innovative companies to conduct research on behalf of the federal government.

This has yielded ground breaking advances, including unmanned aviation, needleless insulin patches, and a promising malaria vaccine.

SBIR awards have supported R&D that has strengthened our country's national security and public health infrastructure. In the process, it has helped launch leading technology companies, such as Amgen, Qualcomm, and Symantec, employing thousands of Americans.

From the Committee's perspective, continuing this success is dependent on three primary issues. First, the number of small firms that apply for SBIR awards must increase.

Second, awardees must have access to financing of all types, including venture capital.

Third, the commercialization of SBIR funded research projects must be more of a priority.

The draft legislation we will consider this morning seeks to address each of these elements. In order for more firms to apply for SBIR, it doubles award sizes, providing more capital for important research projects.

It also establishes a 90-day period for a decision on applications. This provision will enable small firms to get more capital more quickly and reduce the time it takes for research to go from the lab to the marketplace.

Emerging economic sectors, including women, veterans, and minorities, are also brought into SBIR. This is achieved through the reauthorization and expansion of the Federal and State Technology Partnership Program. FAST will increase competition for federal research dollars giving the taxpayers a better value.

While SBIR has been a successful program, one of the critiques we have heard is that it is difficult to take the next step. The legislation addresses this by establishing a new Primers Initiative which will provide the technical know-how and a system many small firms need.

The draft bill also assures companies can choose from a wide array of external financing sources, and that the SBA does not make this decision for them.

We have included a provision that is identical to the amendment offered by Ranking Member Chabot on the House floor last fall. This gives certainty that businesses can make their own financing choices. It also frees them from worrying about being second guessed by the government.

SBIR funded research needs must reach the consumer, whether it is the government or the private sector, and this legislation places a greater emphasis on commercialization.

The changes consolidate the existing fragmented effort and expanded government-wide wage benefits of research sectors, including health care, energy, and agriculture. This improvement will entice, enable, and permit more small companies to advance the innovations that have made our economy so diverse and vibrant. It will help insure that SBIR awards remain competitive, fund topnotch research, and produce cutting edge breakthroughs.

As a result, the SBIR program will keep pace with the very innovation that it seeks to promote and will continue to foster next generation technologies and therapies. That also means it will solidify our efforts to increase U.S. competitiveness worldwide.

I look forward to today's hearing, and I want to thank all of the witnesses in advance for their testimony. I now recognize Ranking Member Chabot for his opening statement.

OPENING STATEMENT OF MR. CHABOT

Mr. CHABOT. Thank you.

Good morning, and, Madam Chairwoman, I want to thank you for holding this hearing to review a Committee print of legislation reauthorizing and modernization the Small Business Innovation Research Program.

I would like to extend a special thanks to each of our witnesses who have taken the time to provide the Committee with their testimony, and especially Dr. Charles H. Matthews, who has a Doctor of Philosophy in management from the University of Cincinnati. Dr. Matthews is a professor of entrepreneurship and strategic management at the University of Cincinnati's College of Business, and he is also the founder and Executive Director of the University Center for Entrepreneurship, Education and Research, and the Director of the university's College of Business Small Business Institute.

We want to welcome you this morning, Dr. Matthews, and coincidentally Dr. Matthews and I happened to go to the same grade school, same class, St. Catherine's in Cincinnati, and the same high school, class of 1971. So we have known each other from a long, long time. He is here despite that, not because of that.

And we also want to thank Mr. Preston for being here today. I know he has an extremely busy schedule. So I think it is very commendable that he is with us here today, and we really do appreciate that.

Today's hearing is the third in a series designed to collect information and data to help this Committee draft legislation reauthorizing the SBIR Program. On January 29th, we held a hearing that reviewed how well the SBIR Program is performing.

On February 13th, this Committee's Oversight and Investigation Subcommittee held a hearing to review the SBIR Program's role in the development and commercialization of innovative health care technologies.

At each of these hearings, the Committee received valuable information from academics, small businesses, and trade associations on the performance of the program. Based on this input, the Committee developed draft legislation for the SBIR Program's reauthorization.

We are working toward developing legislation that modernizes and strengthens the SBIR Program. The draft we have before us goes a long way toward achieving these goals. As the National Academies of Sciences noted in its report on the SBIR Program, there are not adequate measures of performance in the SBIR Program.

The draft legislation before us addresses that issue by requiring agencies with an annual SBIR Program at $50 million or more a year to create an SBIR advisory board to review the program quarterly and recommend improvements in that agency's operation of the program. The creation of these advisory boards and the annual report to Congress will allow far greater oversight and better management of the program.

The draft bill also mandates that agencies required to have an SBIR advisory board must complete evaluation of competitive SBIR proposals within specific time frames.

Additionally, the legislation doubles the authorized SBIR Phase 1 and 2 award amount and makes numerous other technical but important positive changes to the program.

That said, I do have some concerns with a few of the provisions in the draft before us. I am certain that the Chairwoman and her staff, as she and her staff have done since the beginning of this

Congress, will work with me and with our staff in a bipartisan manner in an attempt to hammer out any differences that may come up as we continue with this process.

To the Chairwoman's credit, as I have said many times, she has worked very cooperatively with the minority, and we expect nothing less in the future.

Today we have excellent witnesses as I mentioned before here to provide us with discussion and comment on the draft legislation. We want to, again, thank you, Chairwoman, and thank you, Mr. Preston, for being here. We look forward to working with you on the improvement and reauthorization of the SBIR Program.

And I yield back the balance of my time.

Chairwoman VELÁZQUEZ. Thank you, Mr. Chabot.

And now I have the great pleasure of welcoming the Honorable Steven C. Preston, Administrator of the United States Small Business Administration. He has served in this capacity since July of 2006 and has testified several times before this Committee.

Welcome, sir.

STATEMENT OF THE HONORABLE STEVEN C. PRESTON, ADMINISTRATOR, U.S. SMALL BUSINESS ADMINISTRATION

Mr. PRESTON. Thank you very much, Chairwoman Velázquez, Ranking Member Chabot.

SBA is very supportive of the Small Business Innovation Research Program. We look forward to working with the Committee as legislation moves forward to the sunset date on September 30th.

I also appreciate, Madam Chairwoman, the three points that you raised, increasing the number of firms in the program, making sure that these firms have access to financing, and your folks on commercialization. I think those are all very important priorities, and I appreciate your finding that as such.

Since this program has been in place, as you commented, it has helped many firms get access to federal research and development funding. Today it is over $2 billion annually going to these firms to fund research and foster innovation and commercialization of products.

Every federal department with an extramural R&D budget in excess of $100 million participates in SBIR. There are currently 11 federal departments that meet this criterion and participate in the program and we are at the SBA responsible for promulgating regulation and policy directives to govern the program while other federal agencies utilize the program to foster innovation.

The purpose of SBA's regulations is to insure the benefits of SBIR reach small business entrepreneurs and that the R&D advances resulting from SBIR Program benefit our country.

For a business to be eligible for participation in the program, they have to be organized for profit. They have to be at least 51 percent owned and controlled by one or more individuals who are citizens or permanent residents to the United States, or be at least 15 percent owned and controlled by another for profit business which may be a venture capital firm that is at least 51 percent owned and controlled by individuals and have including its affiliates not more than 500 employees.

In 2001 and in 2003, our Office of Hearings and Appeals did confirm the interpretation that an individual is a natural person, not a corporate entity. These decisions constituted neither a new eligibility rule nor a new restriction on the program. However, we do understand that the clarification provides some consternation in the industry.

Concurrent, however, with these rulings, SBA decided to update its regulations to account for some of the more complex investment structures that have emerged in order to facilitate the funding required to launch new technologies. In 2004, SBA issued a rule providing the opportunity for future venture capital involvement under the SBIR program, and under that rule, a venture capital company may invest in 51 percent or more of the small business, and that small business can, in turn, receive SBIR awards provided that the venture capital firm is, in fact, 51 percent owned by individuals and meets the 500 employee small business size standard.

In other words, in these circumstances a venture capital firm can even wholly own an SBIR recipient. The issue is not for us the value of venture capital investing in innovation. Venture capital has been the financial fuel behind many of our most ground breaking advances in technology and health care and defense. As such, venture capital has enabled innovation and growth that has helped our economy keep strong and dynamic.

We all understand the value of venture capital. It has great value to our SBIR firms. Many of them receive it today, and we encourage their getting funding from venture capital sources.

From our perspective with the proposed legislation, the issue is much more limited. Two, point, five percent of extramural research dollars are set aside for a program that focuses on early stage small innovators. Ninety-seven and a half percent, or 82 billion in research dollars, is available for firms that are not considered small.

So the issue is: should firms owned and controlled by large venture capitalists and universities be able to compete for 2.5 percent or should this funding come from the 97 and a half percent? Effectively, where do we draw the line and what should that definition be?

SBA's goal is to insure that the integrity of the program is maintained and that it remains program for small business.

Beyond SBIR, and this is something I think we just need to clarify, we are concerned that changing the affiliation rules with regard to venture capital participation raises some other issues in the other programs, our procurement programs namely. Any changes to SBA's size standards could potentially affect our other programs, and federal programs targeted for small business could be open to a business concern that is controlled by what would be considered a large business.

So we ask the Committee to proceed with caution on those. We just want to make sure that understand what your intention is and make sure that we clarify that.

The administration is concerned with the proposed legislative change to the definition for purposes of venture capital, and while recognizing that a venture capital investment is crucial to small business growth, the administration is nonetheless concerned that the Committee print offers too broad of a definition to the affiliation standards.

And once again, we also are concerned about other conflicts within the legislation.

We are committed to continued improvement, to expanded monitoring of the SBIR Program. We hope to work with the Committee as well as other agencies in the administration to insure that small business is defined in a manner that effectively minimizes ineligibility of actual small businesses, while minimizing inadvertent eligibility of large businesses.

So I appreciate the opportunity to share our views on it, and I look forward to clarifying these views and answering any questions you have.

[The prepared statement of Mr. Preston may be found in the Appendix on page 37.]

Chairwoman VELÁZQUEZ. Thank you very much, Administrator.

I would like to ask you about the draft legislation that we have before us, it includes provisions that reauthorize, modernize, and extend the Federal and State Technology Partnership Program. FAST, of course, is a program to encourage SBIR application from small firms located in areas that are under represented in the SBIR Program.

My question is: will the SBA support reauthorization of FAST?

Mr. PRESTON. We think FAST has a lot of value, and at this point I believe we will, but I am still clarifying that with some of my colleagues.

Chairwoman VELÁZQUEZ. Okay. In your written statement, you outline the legal basis for SBA support of current SBIR eligibility rules. Your statement does not, however, address the fact that leaders in both the public and private sector believe the SBA's eligibility rules are having a negative impact on the overall objectives of the SBIR Program.

Keep in mind that the firms that are rendered ineligible for SBIR because of their ownership structure often have fewer than 25 employees. How would you respond to those, including people from your own administration like the Director of the NIH, argue that the current rules undermine the statutory purposes of the SBIR program?

Mr. PRESTON. Well, I think there are a lot of issues inherent in that question, and the question I have in that is there are a few issues.

First of all, the language as it is drafted right now defines a venture capital firm as being small if it has fewer than 500 employees. I think that will cover virtually every independent venture capital firm in the world. So really, you know, major multimillion dollar venture capital firms who do early stage investing may have 20 or 25 partners. So I think the important thing from my perspective is to understand what truly is a large firm.

Now, I understand the other issue is I think this program focuses on two and a half percent of the dollars, and the question I have is why do we need to open up a program that has two and a half percent of the research dollars to firms that are supported by very large venture capitalists when 97 and a half percent or $82 billion is also available?

I think it is important for us to keep the integrity of the small business nature of this program. Now, let me make one other comment, ma'am. I do believe that there may be a better way to look at size within the venture capital world, and I would love to roll up my sleeves and work with this Committee and with the industry and with other people in the executive branch to figure out if there is a better way, to make sure that good small businesses are not being excluded.

But I do think the language as it is written right now would allow some very large venture capitalists in the program.

Chairwoman VELÁZQUEZ. So, we will work with you on the eligibility rules because what we are discussing here is the SBIR program and the objective of the program.

Mr. PRESTON. The objective of the program as I understand it is to work with small businesses to seed early stage innovation that has a viable commercialization possibility, and so the question is: what is a small business, which I think is what you are asking?

If it is a different question, I apologize if I did not answer it.

Chairwoman VELÁZQUEZ. Under current law, the Department of Defense is permitted to use available SBIR forms for expenses incurred through the administration of commercialization programs. In your written statement, you caution Congress to avoid refocusing the program in a manner that involves direct support for commercialization activities more appropriately performed by the private sector.

Could you elaborate on what that means?

Mr. PRESTON. Well, right now our program provides grants for Stage 1 and Stage 2 research. As a firm moves toward commercialization, they are available for other federal funding, but under the program as it is structured as I understand it, that Stage 1 and Stage 2 funding is SBIR. Once they get to Stage 3, they can seek other federal grant funding. Obviously they can seek venture capital funding.

The other thing is once a firm gets its stage 2 grant, the ownership restrictions effectively recede and they are free to, you know, continue to raise money from wherever.

Chairwoman VELÁZQUEZ. Let me ask you, does the SBA oppose the Department of Defense commercialization pilot program?

Mr. PRESTON. I am not familiar with their program in detail. I would be happy to answer that for the record though.

Chairwoman VELÁZQUEZ. Well, I am asking that question because in the draft bill we extend the commercialization pilot program to all the agencies, and this is important for me to know and for the Committee whether or not you support the Department of Defense's pilot program.

Mr. PRESTON. So you are saying that the two and a half percent specifically in SBIR would now be able to be used for Stage 3. Is that what you are proposing?

Chairwoman VELÁZQUEZ. No.

Mr. PRESTON. Okay.

Chairwoman VELÁZQUEZ. No. Let me go to the next question. The Defense Department's commercialization program allows the agency to use one percent of the SBIR set-aside for payment of administrative costs. This provision has the effect of—

Mr. PRESTON. Oh, I see. Yes, I understand.

Chairwoman VELÁZQUEZ. So if the agency supports the pilot project, that is my question.

Mr. PRESTON. Yes. We do not have an issue with your taking a portion of the money, and I know you have some funding. We do not have an issue providing funding to help support firms during that transition. I am more concerned with, you know, the essence of the grant program being shifted toward commercialization when we are trying to use it primarily to seed early stage innovation.

Chairwoman VELÁZQUEZ. My question is: do you support the use of money for agencies' expenses or will you oppose it, or it should be solely used for R&D?

Because if we allow the Department of Defense to use money to cover administrative expenses, then we are taking money away from money that is supposed to go to R&D. We are just supporting the agency's bottom line.

So what is your position regarding that issue? Should the money go just for research or should we allow for agencies to use the money to cover operating expenses, and administrative expenses?

Mr. PRESTON. Okay. I am not familiar with the DoD program. I apologize. I would be happy to look into it and give you questions for the record.

I do know you have some provisions in your language to support firms going through that process, and that is what I thought you were getting at, but I would just have to look into that further.

Chairwoman VELÁZQUEZ. Let me ask this last question, and then I will recognize Mr. Chabot.

Congress has received testimony alleging that the SBA is not adequately meeting its responsibility under the current SBIR statute. One example is SBA's inability to collect and distribute meaningful data about the SBIR Program.

Would you provide the SBA's Office of Technology with additional resources so that it can carry out its responsibility?

Mr. PRESTON. Well, I think what I need to do is understand specifically what responsibilities you are talking about in detail, and then assess whether or not they are, in fact, not meeting those. So I would rather not make a—

Chairwoman VELÁZQUEZ. Well, the Office of Technology is charged with the collection of data, and they have not done that, and it went from 13 people, staff, to only four. So, do you think that the fact that they are not fulfilling their responsibility is because of manpower?

I mean, would you assign more resources?

Mr. PRESTON. Ma'am, I am not willing to accept that they are not fulfilling their responsibilities based on your statement. I am willing to work with you to understand what the concerns are and address them in a very hands-on way.

Now, I will also tell you that we do expect to expand the technical system right now to provide much of the data that has been lacking in the program, and I believe that launch is going to be in the next six to eight weeks, but I would be happy to work closely with the Committee to keep you abreast of the advances we are making there and also understand any specific shortfalls so that we can address them.

Chairwoman VELÁZQUEZ. I welcome that.

And I recognize Mr. Chabot.

Mr. CHABOT. Thank you, Madam Chair.

Mr. Preston, you have already touched on this to some degree, but let me ask. What is the impact of the size standards as set forth in the previous legislation?

And if there is a problem, would you be willing to work with the Committee to come up with a reasonable size standard in order to preserve this as a small business program and allow for venture capital investment in small firms?

Mr. PRESTON. Oh, absolutely. And you know, a number of our SBIR recipients already receive venture funding. I think venture funding is an essential part of this program. I think what we are interested in is preserving the small business character of the program, and I fully accept that there may be a more enlightened way to define small business given the complexity of, you know, venture cap. ownership and venture cap. funding.

I think it is a very different animal than a typical procurement program, and we should be looking at it in a way that specifically meets the needs of the program.

Mr. CHABOT. Thank you.

With all of the rule changes that have taken place over the years, would you agree that the eligibility rules for venture capital companies have become too complex?

Mr. PRESTON. I think they are complex, and I think there are ways that, you know, firms can go forward with a significant percentage of venture cap. ownership if they need certain subsidiary structure requirements, and I think it would be helpful for all of us to have a more simplified process in place, more simplified structure in place.

Mr. CHABOT. And where is the administration willing to work with the Committee to permit venture capital investment in small firms?

Mr. PRESTON. Well, as I said before, Mr. Chabot, I think venture capital ownership is really essential to the success of this program. It's essential for these people to be able to commercialize their product. In many cases it's essential for them to be able to continue well before commercialization.

And let me just say, you know, in my career before coming to this role, I have structured joint ventures with venture capitalists. I have been on advisory boards from private equity firms. I have taken biotech companies public. You know, I appreciate the value of venture cap in the world of innovation, and I do not think our country would be where it is today if we did not have that capital fueling innovation.

And I think there is a very important role for venture capital in this program.

Mr. CHABOT. Thank you very much.

Madam Chair, I will yield back the balance of my time.

Chairwoman VELÁZQUEZ. Mr. Graves.

Mr. GRAVES. Thank you, Madam Chair.

My questions have actually been addressed, but I do want to say for the record I want to thank you and Ranking Member Chabot for having this hearing. As you know, this issue is very important to me, and I have worked on it for some time, and I think it is very important to small business. I appreciate what the Committee is doing. I am looking forward to this.

I think that we do need to change the eligibility requirements. Small businesses are the backbone of the economy in this country, and I think this program is just one of them that would go a long way, and I think we do need to fix this.

But thank you both for doing this.

Chairwoman VELÁZQUEZ. Mr. Preston, I have some other questions now. In your testimony you indicate that SBA would like to develop quality metrics that can assist agencies in developing standards to limit the perceived effect of so-called SBIR mills. What is your view of the reporting requirements of the draft bill which require the SBA to report on our deeds that have won more than 15 Phase 1 grants and no Phase 2 grants over a five-year period?

Mr. PRESTON. Well, I think your whole intention of providing greater transparency, greater metrics, greater reporting in the program is great. And I would really look forward to working with you and your staff and the industry to figure out what that should look like and specifically to make sure that that process goes forward effectively.

Chairwoman VELÁZQUEZ. Thank you.

In January, a leading law firm issued an advisory indicating that participation in the SBIR Program creates significant risk for venture backed companies under the False Claims Act. Is the SBA concerned that its confusing affiliation rules are causing all venture backed companies, not just companies that are majority owned by venture firms, to forego participation in the SBIR Program?

Mr. PRESTON. Well, I do not know the text of that advisory, but certainly if firms are going for these funds inappropriately they should be concerned, and I think we all should be concerned if firms are in any aspect of federal contracting not qualified as a small business and they are going for a small business program.

That having been said, I am not familiar with the text of that discussion, and I think our affiliation rules are fairly straightforward. It is 500 employees in the affiliated group and 51 percent ownership by individuals.

I do think that there are other structures that some people can use to avail themselves of the program that begin to get more complex, and that is what I think we should think about simplifying.

But, you know, as I hear your statement, I think any firm that avails themselves inappropriately of a program should be concerned with—

Chairwoman VELÁZQUEZ. Well, I am not talking about firms that are illegally applying like those firms that have gotten contracts with the federal government claiming that they were small firms. I am not talking about that.

I am talking about small firms that consider the affiliation rules so confusing that they are so concerned about getting venture capital money.

Mr. PRESTON. Well, I have not heard that firms that qualify under the affiliation rules are walking away from the program because of confusion. You know, I would assume that that is focusing on firms that do not qualify.

Chairwoman VELÁZQUEZ. Well, that is a matter, I think, of concern, and maybe we should revisit this issue because for those companies that should go, especially those who finish Phase 1 and are willing and able to move to Phase 2, and in order to move to Phase 2 and to get into commercialization, they have to show that they can secure money from the private market, and these confusing rules will inhibit them from doing so.

I hope that you are going to leave your staff here for the second panel, these are issues that we are going to discussed during the second panel.

So it is not enough to say that those who are applying for this type of money are ineligible for SBIR. We are talking about people who are playing by the rules, companies that are playing by the rules.

Mr. PRESTON. Well, I think that advisory you mentioned implies that companies are not playing by the rules, and if the text of that is different and there is any detail in there that would give us a better understanding of how to clarify those rules, we would love to look at that.

Chairwoman VELÁZQUEZ. Well, I guess what the statement implies is that the rules are so confusing that people are, companies are, concerned by the unintended consequences of violating the affiliation rules even when they are playing by the rules.

Section 9 of the Small Business Act specifies that for an SBIR company to be eligible for Phase 2 awards, it should be able to demonstrate that it can secure private funding from non-SBIR sources. The SBA's current view, however, runs counter to this.

How can you reconcile the program's statutory basis with your agency's current stand against venture capital investments?

Mr. PRESTON. We do not have any stance against venture capital investment. Many of these firms get venture capital investment. The only stance we have is majority ownership by large venture capital firms.

So I think it is important that we draw the line appropriately here. These firm get venture cap. They should get venture cap., and they are going to need it to grow.

The other thing I would tell you is today in the program only ten to 12 percent of these firms have any venture cap. funding. So when you look at that ten to 12 percent and then we are talking about going to majority venture cap. funding before they even get these grants, I think we are talking about a relatively small subset of the firms.

And then when you take it further to say we think they should be able to be majority owned by large venture cap. firms, I think you are getting into an even smaller subset.

Chairwoman VELÁZQUEZ. I believe that the way you structure the affiliation rules, you limit venture capital participation, and I guess that if you listen to the testimony and the discussion that we are going to have in the second panel, this is a real concern that cripples the ability of companies to move from Phase 1, Phase 2 to commercialization, and I guess that we have work to do on this issue.

It is an issue. It is a problem, and it is just not enough to say that small firms that play by the rules can apply for grant money and there will be no unintended consequences.

The draft bill grants federal agencies the express authority to increase the size of the SBIR awards they issue. It also includes provisions clarifying that agencies have the authority to issue more than one Phase 2 award for promising projects.

What are the SBA's views on these provisions?

Mr. PRESTON. We agree that it is time for the size of the grants to increase, and in fact, we have been working in house on a rule to address that. So I think, yes, it is time, and so we are supportive of an increase.

Chairwoman VELÁZQUEZ. Very good. Well, any other questions, Mr. Chabot.

Mr. CHABOT. Thank you. Just one final question, Madam Chair.

In regard to the affiliation rules, would it make sense or more sense to apply an asset limit on venture capital participation as opposed to an employee numbers limit?

Mr. PRESTON. You know, I think that is a possibility, sir. I would really on this size issue much prefer spending time with my colleagues at other agencies and people in the industry to come up with, you know, what we think is a fair standard.

And so I don't know that I feel comfortable saying that an asset size or an equity under management or some other standard is going to be the right thing. It is possible, and we have batted around some of those concepts with other people. But at this point I am not ready to come out on one side or another on that issue.

Mr. CHABOT. All right. Thank you.

I yield back the balance of my time, Madam Chair.

Chairwoman VELÁZQUEZ. Thank you, Administrator.

Mr. PRESTON. Thank you.

Chairwoman VELÁZQUEZ. Thank you.

Mr. Preston, if I may, who from the staff will be staying here?

Mr. PRESTON. We have got two gentlemen from our SBIR Program, Edsel Brown and Ron Cooper, and are you staying as well? And one person from—

Chairwoman VELÁZQUEZ. Will you please identify yourselves for the record? Your names?

Mr. COOPER. Ron Cooper.

Mr. PRESTON. Ron Cooper and Edsel Brown.

Chairwoman VELÁZQUEZ. Thank you.

I would ask the witnesses from the second panel to please take your seats.

Sorry for the inconvenience of the room.

Good morning, gentlemen, and it is always a pleasure to have the opportunity to welcome our former colleague, the Honorable James C. Greenwood, to our Committee. He is the President and CEO of the Biotechnology Industry Organization in Washington, D.C.

Prior to his appointment as President of BIO in January 2005, he represented Pennsylvania's Eighth District in the U.S. House of Representatives. BIO represents more than 1,150 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations.

Welcome, and each witness will have five minutes.

STATEMENT OF THE HONORABLE JAMES C. GREENWOOD, PRESIDENT AND CEO, BIOTECHNOLOGY INDUSTRY ORGANIZATION

Mr. GREENWOOD. Well, good morning, Chairwoman Velázquez, Ranking Member Chabot, members of the Committee, ladies and gentlemen. As the Chairwoman said, I am Jim Greenwood, President and CEO of the Biotechnology Industry Organization, otherwise known as BIO.

I am privileged to be here this morning on behalf of BIO's more than 1,000 member companies, academic institutions, state biotechnology centers, and related organizations in all 50 states.

The role the SBIR Program has had in bringing breakthrough therapies to the American people is a matter of public record. There are 252 FDA approved biologics that have been developed by 163 companies, and 32 percent of those companies have received at least one SBIR/STTR award.

Despite its noble past, however, 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.

Congress created the SBIR Program in the early 1980s in order to utilize the capabilities of small, innovative, domestic companies to fulfill federal research and development needs. Congress recognized that some promising scientific research failed to be funded by private sector capital because it was viewed as too high risk. For 20 years the program worked well for U.S. life science companies engaged in high risk, cutting edge, medical research.

However, in 2003, the Small Business Administration's Officer of Hearings and Appeals ruled that a biotechnology firm, Cognetix, did not meet the SBIR size standard because multiple venture capital investors in the aggregate owned more than 50 percent of the company's stock.

The ruling, which is not based on statute nor based, in my opinion, on congressional intent at all ignores the realities of the marketplace where small biotechnology firms must raise tens of millions of dollars to conduct incredibly capital intensive research. The implementation of the SBA's decision has caused many small American companies that had participated in the program for 20 years and who were a fundamental part of the program's success to be suddenly deemed ineligible.

Additionally, applications for the SBIR Program at NIH have decreased dramatically, and the number of new businesses applying is at the lowest level it has been in a decade.

I commend Chairwoman Velázquez, Ranking Member Chabot, and the members of the Committee for their insight in including a remedy to the eligibility issues affecting many small life sciences companies in the reauthorization legislation soon to be introduced. It is the right thing to do, and this is the right time to do it.

On behalf of America's biotechnology companies, I look forward to working closely with you to see this much needed change enacted into law this year.

BIO also supports provisions in the bill that will allow agencies to maintain flexibility. Each agency should be able to administer SBIR grants based on scientific merit and each agency's unique needs.

The provisions in the reauthorization providing agencies with the flexibility and authority to determine the amount and number of awards the project can receive will help accelerate the development of those projects with the most promising potential to improve human health.

I would also like to commend the Committee for drafting legislation that reaffirms and fosters the original goals of the SBIR program, namely, the commercialization of new technologies by small, innovative, American companies. Specifically, BIO supports the modernization and reauthorization of the Federal and State Technology, or FAST, Program and the authorization of funds for agencies to develop and expand their commercialization programs.

Finally, I would like to discuss the provisions in the bill aimed at addressing the concern that some companies are receiving multiple awards without progress towards commercialization. These provisions would require the SBA to release the names of firms that have received multiple Phase 1 grants and zero Phase 2 grants and promulgate rules for the agency to address these awardees.

We fully support this effort and would encourage the Committee to be even more vigilant in assuring that companies are not gaming the system.

We look forward to working with the Committee to ensure the intent of these provisions is fully realized.

Again, I thank you for the opportunity to testify today. I would be happy to answer any questions members of the Committee might have.

[The prepared statement of Mr. Greenwood may be found in the Appendix on page 41.]

Chairwoman VELÁZQUEZ. Thank you, Jim.

Our next witness is Mr. Mark G. Heesen. Mr. Heesen is President of the National Venture Capital Association. Before joining the National Venture Capital Association, Mark was an aide to a former governor of Pennsylvania and was the Deputy Director for Federal Funds reporting to the Texas legislature.

NVCA's mission is to foster greater understanding of the importance of venture capital to the U.S. economy and support entrepreneurial activity and innovation.

Welcome.

STATEMENT OF MARK G. HEESEN, PRESIDENT, NATIONAL VENTURE CAPITAL ASSOCIATION

Mr. HEESEN. Thank you.

Venture capitalists invest in small, high risk, emerging growth companies in areas such as life sciences and information technology, homeland security, and clean technology. Our goal is simple: to bring the best and most innovative new products and services to market in the most efficient manner.

I must note NVCA's utmost frustration with SBA's campaign to exclude our industry from the SBIR Program. Doing so is a disservice to our country and denies government access to cutting edge technologies. We urge Congress to reauthorize the program with provisions that ensure venture backed companies have a fair chance to thrive alongside their non-venture backed counterparts.

Doing so will only strengthen the future success of the program and correct a significant injustice that has gone on for far too long. NVCA strongly supports the draft Committee print which includes a provision allowing for venture backed firms to again participate in the SBIR Program. If the provisions which guarantee a level playing field for venture backed companies are removed or compromised in any way, NVCA will not support reauthorization of this program.

For years SBA's policies regarding SBIR eligibility have been inconsistent, discriminatory, and based on serious misconceptions which they appear to have absolutely no interest in reexamining. I would like to debunk a number of myths employed by the SBA.

First, venture backed companies do not need SBIR Program money because they are strong, fully funded entities. Make no mistake: these companies are small, fragile businesses, typically employing less than 25 people. The only distinction for a venture backed company is that it has demonstrated enough promise to attract an investor whose business it is to find and fund opportunities ready for commercialization.

Second, venture backed companies have access to a bottomless pit of funds. In fact, financial controls at a venture backed company are likely to be much more stringent than their non-venture backed counterparts. Venture backed companies must focus on exclusive projects with narrow trajectories while consistently meeting or beating agreed upon milestones to continue to receive funding.

Third, venture firms have unlimited cash. That, too, is a fallacy. Venture firms raise money in a closed end process. They have a contractually finite pool of resources that must stretch across multiple companies for many years.

Fourth, venture backed companies are able to compete and win broader government R&D dollars. In reality venture backed companies turn to the SBIR Program for funding critical, early stage projects. If there were other avenues to obtain, these much needed funds after all these years of being discriminated against by the SBA, we would have found it by now.

Fifth, the SBA assumes that venture capital firms are the equivalent to large corporations, and therefore, the companies they fund should be excluded from SBIR grants. We agree large corporate owned businesses should not be allowed to participate in the small business program, but venture firms are not large corporations. They're partnerships with typically less than a dozen professionals.

SBA knows this, which is why they have gone to great lengths to manipulate the system and concoct a nonsensical formula to justify their position. Last September we testified before you regarding a portfolio company that was denied a small business waiver from SBA for a $900,000 FDA application fee. While the company employed seven people, the SBA affiliated every employee not only from the venture capital firm (which only had ten people), but also every company in that venture capital firm's portfolio to exceed the 500 people employee threshold.

Aside from this maneuver being absolutely irrational and unjustified, SBA hurt a very small business and delayed a very promising drug discovery.

Sixth, the SBA also wrongly assumes that venture backed companies are controlled by venture capitalists. While venture capitalists do participate on the board, they do not exert day-to-day control of a company. Venture capitalists divide their time among all investment of a venture capital fund. It's impossible and impractical to spend that limited time on the day-to-day business decisions of one particular portfolio company.

If control is equated to 51 percent ownership interest, SBA logic falls again. The 51 percent or more ownership of a company is typically met only when several venture capital firms have invested in the company. Ironically, SBA's policies particularly hurt the very regions that SBA programs are designed to support, like middle America. The scarce venture capital dollars in this region cause venture firms to join together to form a promising start-up. As each firm takes an equity stake in the company, the total venture ownership percentage can quickly rise to 51 percent.

Venture backed businesses have been fighting this battle for far too long. If Congress intends the SBIR Program to generate significant commercial impact, it makes no sense to exclude the companies that empirically are among the most likely to have significant commercial success from the program.

Current SBA practices impede the ability of agencies like DoD, NIH, and the Energy Department to solve serious issues in the homeland security, energy dependence, and quality health care areas.

In closing, the venture capital industry is known for its patience when it comes to our investing, but our patience with SBA's campaign to penalize venture capital companies because of their success is at an end.

We support this bill and reauthorization wholeheartedly, but only if we have an opportunity to contribute to its success.

Thank you very much.

[The prepared statement of Mr. Heesen may be found in the Appendix on page 46.]

Chairwoman VELÁZQUEZ. Thank you, Mr. Heesen.

Our next witness, Mr. Mark Leahey. He is the Executive Director for the Medical Device Manufacturers Association. MDMA is a national trade association that represents independent manufacturers of medical devices, diagnostic products, and health care information systems.

MDMA was created in 1992, and their mission is to promote public health and improved patient care through the advocacy of innovative research driven medical device technology.

Welcome, sir.

STATEMENT OF MARK LEAHEY, ESQ., EXECUTIVE DIRECTOR, MEDICAL DEVICE MANUFACTURERS ASSOCIATION

Mr. LEAHEY. Thank you, Chairwoman Velázquez and members of the Committee.

On behalf of the more than 160 medical technology companies that MDMA represents across the country, I would like to thank you for your efforts to improve and reauthorize the SBIR Program. The Committee's draft legislation will help insure that small, innovative companies have access to the necessary resources to develop life sustaining and life enhancing products of tomorrow.

Given the advancements in science, increasing regulatory requirements and market access challenges, significant investments from the government and the private sector are often needed to develop these technologies. In return, Americans live longer, healthier, and more productive lives.

One of the cornerstones of the government investment in small medical technology companies has been the SBIR Program. Resources from the program, in addition to private investment, have greatly improved the quality of life for more than 20 years.

However, as you are aware, the Small Business Administration's reinterpretation of the definition of "individual" significantly worsened the landscape for the private-public partnership envisioned by the SBIR Program.

As a result, many promising technologies from smaller companies have not received SBIR support and patients are suffering as a result. Fortunately, this Committee has taken the necessary steps to correct the actions of the SBA and insure 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.

With small companies responsible for the majority of medical technology advancements over the past 20 years, the SBIR Program has played an important role in assisting some companies. Unfortunately, since the SBA's reinterpretation, a barrier has been created for many small companies to receive SBIR assistance.

The development of a medical device often involves collaboration of public and private investments, including resources financed by various venture capital investors. Since SBA's reinterpretation of ownership requirements under the SBIR, the number of medical technology companies applying for grants has significantly declined.

For example, applications for SBIR grants at the National Institutes of Health, the most prolific grant of SBIR grants for medical technology companies, has declined by nearly 12 percent in 2005 and by nearly 15 percent in 2006.

In addition to reducing the number of companies receiving grants, one may conclude that the new interpretation has prevented SBIR from supporting those very projects that have the greatest potential for clinical benefit.

The SBIR Program should support small companies with promising clinical technologies regardless of whether venture capitalists have partnered with the company. As the committee moves forward with the reauthorization of the SBIR Program, MDMA would like to reiterate our support for the SBIR Program and the support of the following improvements that will help reestablish the program's success.

First, the reauthorization should include language to restore the participation of venture backed companies, especially redefining the ownership requirements for more business concerns. It is critical that this language be included so that small venture backed, medical technology companies are not excluded from this program.

This will serve to provide SBIR grants to the most promising technologies which are likely to provide the greatest public and patient benefit.

Second, MDMA believes that increasing the dollar amount of the Phase 1 and Phase 2 grants to 200,000 and 1.5 million, respectively, is critical to address the increasing developmental costs. In addition, it will help provide the necessary incentive to encourage more companies to apply for the grants.

Given that the award levels have not been modified since 1992, change is long overdue.

Third, MDMA supports providing agencies with more flexibility to administer the SBIR Program. Specifically MDMA supports allocating a small percentage of the SBIR set-aside to be used for administering the program. These SBIR funds could be used to pay for activities including conferences that would assist small businesses in commercializing and competing in the marketplace.

The funds could also be used to improve systems for assessing the program's effectiveness. These resources would help to administer the SBIR Program and assist agencies in making improvements without diverting funds from other programs or priorities.

Finally, it would be beneficial to remove the requirement that a company must have applied for a Phase 1 grant in order to apply for a Phase 2 grant. If this rule would change, MDMA believes that small business participation in the SBIR Program would increase.

Adopting the changes outlined above is consistent with the mission of the SBIR Program to insure 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 y our effort 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 outlined above and included in the Committee's draft legislation.

Thank you very much.

[The prepared statement of Mr. Leahey may be found in the Appendix on page 54.]

Chairwoman VELÁZQUEZ. Thank you.

And now I welcome Mr. Mark Skinner. He is the Vice President of the State Science and Technology Institute. Since 1996, SSTI has assisted states and community as they build tech based economies and encourage cooperation among and between state and federal programs.

Welcome.

STATEMENT OF MARK SKINNER, VICE PRESIDENT, STATE SCIENCE & TECHNOLOGY INSTITUTE

Mr. SKINNER. Thank you very much for the opportunity.

It seems much of my original testimony needs to be summarized only briefly because it appears that it is in much of the draft legislation, and we appreciate that.

We also appreciate the support for FAST that has been shown by some of the other panelists.

The Committee recognizes, it appears, the role and value that states and local governments play in outreach and assistance for SBIR firms. In fact, since the mid-'80s, the states have viewed SBIR as a tremendous opportunity for economic development through the growth of their high tech firms, and I can attest to that from my own personal experience.

My first real job was to look at how SBIR was affecting the small businesses in Ohio through the Ohio Department of Development, and that was only in the first year of SBIR making awards back in 1983-84.

An appendix to my testimony illustrates nearly every state has already established at least one program dedicated to supporting SBIR proposal development awareness and in many cases direct matching funds for SBIR awards. And additionally, there are probably 1,100 to 1,200 programs at the state and local level that are supporting technology growth through either university commercialization, Phase 3 Angel funds. I believe Mr. Matthews in his testimony, that I saw briefly, may provide a good example of some of the excellent work being done in the Cincinnati area.

While the agency's perspective is that SBIR results need to be commercialized, most states recognize it needs to be commercialized within their boundaries, and many of the concerns that states brought to SSTI's attention regarding FAST, the original introduction of FAST, have also been addressed in the draft.

So I'll direct the rest of my time on comments and initial reactions to the draft legislation which I saw this morning.

This seems to be an awful lot of work for only a two-year authorization. Eight years was definitely too long, given the changes that have occurred in many industries in how R&D is conducted and how innovation occurs, but I believe two years will not give you enough time to identify that the changes you are making having the desired or potentially deleterious effects.

So possibly something along the lines of five years in between would be useful. It also gets you off of the election cycle.

As the National Academy of Sciences mentioned, state assistance, even the small FAST grants, seems to make a difference, and it does. The carrot that the federal government can provide helps direct limited resources toward particular audiences that may not get the attention otherwise based on the limited resources that states already have that they are investing in tech-based economic development.

There are elements of the bill, however, that could be tweaked that would make FAST authorization much more meaningful for the small businesses that you are hoping to help.

I noticed that the award size is set at $250,000. You do recognize the need for multi-year awards of three years or more to provide continuation or continuity in the programs and staffing level and staffing commitments.

However, the authorization program is only for two years. So you're setting some programs up for failure or potential problems or challenges by making three-year awards for a two-year program. So something that we can work out, I believe.

Also, if the Committee means $250,000 for the full three years, then you're inadvertently crippling the programs. So I recommend that I think you mean $250,000 per year for the three years, which would be matched dollar for dollar by the state and local governments, and I think that is a much more meaningful value.

As a result of that though, I recommend that you increase the authorization level to $20 million rather than the $10 million so that you have enough money available to make more awards in more states, spreading the geographic reach of the program.

I noticed the exclusion of commercialization activities from the list of potential uses of FAST funds, and I believe that is a mistake primarily because, based on the awards and the way the SBIR Program is set up, most companies will not win SBIR awards that receive assistance. So if we can provide a structure to help those communities or those companies get into the infrastructure that already exists through venture capital, Angel capital, then it is a much more meaningful program.

And I have run out of time, but my other point is just that FAST did not work well under SBA in its first go-round. The states have recommended that it be moved to or transferred to NSF, which provides an environment that is much more conducive to the flexibility needed. NSF has the understanding already in place of supporting innovation companies.

Thank you.

[The prepared statement of Mr. Skinner may be found in the Appendix on page 59.]

Chairwoman VELÁZQUEZ. Thank you, Mr. Skinner.

And now I recognize Mr. Chabot for the purpose of introducing our next witness.

Mr. CHABOT. Thank you, Madam Chair.

And I am very pleased to introduce our next witness, and I already did that to some degree in my opening statement. I should probably mention that Dr. Matthews and I have literally known each other since the fourth grade. So it has been a long time, and he has been very successful obviously.

Dr. Charles Matthews is a professor and Executive Director at the University of Cincinnati Center for Entrepreneurship, Education and Research. An award winning teacher, Dr. Matthews has taught over 5,000 students ranging from freshmen to doctoral students to executives, from individual instruction to classes of up to 540 students.

He has facilitated over 500 faculty guided, student based field case studies, and has served as a consultant to numerous organizations, including many family businesses.

In addition to his consulting practice, Dr. Matthews has entrepreneurial and family business experience in the automotive, photographic, and real estate industries.

And we welcome you here, Charlie.

STATEMENT OR DR. CHARLES MATTHEWS, Ph.D., PROFESSOR AND EXECUTIVE DIRECTOR, CENTER FOR ENTREPRENEURSHIP, EDUCATION AND RESEARCH COLLEGE OF BUSINESS, UNIVERSITY OF CINCINNATI

Mr. MATTHEWS. Thank you very much, Congressman.

It is a pleasure to be here, and I appreciate the comments. Our history does go way back to the fourth grade, but I must for the record say that your football career was much more distinguished than my football career.

[Laughter.]

Mr. MATTHEWS. And you taught me well to avoid the hits.

Madam Chairwoman, Congressman Chabot, members of the Committee, distinguished guests, it is with great enthusiasm that I present this testimony in regard to the reauthorization of the Small Business Innovation Research Grant Program. It is not often one has the opportunity to speak about a government program that meets and in many cases exceeds its expectations, but in this case I believe the SBIR Program does do that.

The SBIR Program creates a climate for scientific and commercial innovation. It leverages existing resources in the community, and consistently provides critical support that is often unavailable in the private sector. In short, it works.

Quite simply, in order to create the future and to reach the many and considerable goals of enhancing and improving commerce, science and society, we must take the first steps of that journey today. It is not enough to say that we want a better and brighter future, a more robust economy, a cure for cancer, or an improved quality of life for future generations. We must take positive and proactive steps to reach those goals. We must continue to create an environment that supports the pursuit of not only the foundational science needed, but the translation and application of that science to productive uses in business and society.

The Small Business Innovation Research Program was conceived for just such a purpose. It creates and supports an environment that encourages scientific and commercial pursuits that are needed and necessary to advance the applied technologies fundamental to the attainment of goals that benefit the United States and, indeed, the world. It creates an environment that supports and encourages innovation.

Based on data from both the private and public sectors and research education, I can testify first hand to the strong, positive impact that the SBIR Program has had in southwestern Ohio. In the four-county Region V area of Ohio, Butler, Clermont, Hamilton and Warren Counties, in 2004 and 2005 there were a total of 105 Phase 1 and 2 SBIR grants for 92 different ventures totaling nearly $27 million. These SBIR grants cut across a broad range of scientific and commercial applications, including, but not limited to, biology, chemistry, engineering, health care, nanotechnology, and physics, to name but a few.

The Hamilton County Business Center is an integral part of the Hamilton County Development Center, and is one of the most successful public incubators in the U.S. Over a dozen current and graduate HCBC companies have been able to advance both scientific and commercial goals, as well as grow their business with an assist from funding connections and processes associated with the SBIR Program.

A brief sample of these ventures include the Maverick Corporation, which provides cutting edge materials, technologies, setting industry standards for service, and developing advanced materials and technologies of the chemical, industrial, missile, and space industries, the Modal Shop providing structural vibration and acoustic sensing systems to engineers worldwide, Sheet Dynamics whose expertise lies in the field of mechatronics, which is the synergistic combination of mechanical and electrical engineering, and the Advance Biological Technologies, which is developing a proprietary advanced technology process in diabetes analysis.

The Hamilton County Business Center not only sees the SBIR Program as a strong component of the overall capital strategy for the early stage research companies, but also recognizes the value to the stability and vitality of many early stage small business ventures. The competitive processes of the SBIR Program provide companies with a difficult to secure but increasingly needed funding to enhance the innovation and commercialization processes of these early stage ventures.

To quote Mr. Pat Longo, Director of the HCBC, without SBIR dollars, the number of HCBC best success stories would not have made it to being successful product driven, market focused companies they are today.

In addition to the Hamilton County Business Center, Southwest Ohio is fortunate to have a state of the art life science incubator located on the University of Cincinnati campus, BIOSTART. Under the leadership and direction of BIOSTART President, Carol Frankenstein, the past ten years bear witness to the leveraged success of the creation of an that fosters creativity and innovation at the nexus of science and commerce.

The SBIR Program enables these life science companies to conduct initial proof of concept and preclinical and clinical field studies to move their products to market. To quote Ms. Frankenstein, ″This is a niche that even early stage funds are reluctant to fill because of the high risk and long time to market.″

Clearly, the SBIR Program is making a strong and sustained difference in advancing these scientific and commercial opportunities.

Finally, I would like to comment on a program which I had a hand in helping to start, Cincinnati Creates Companies. Together with the University of Cincinnati, the College of Business, Engineering and Medicine, and the UC Center for Entrepreneurship, Children's Hospital Medical Center, BIOSTART, CincyTech USA, and the Hamilton County Business Center, put together a hands-on, outcome oriented program that supports innovation through the development of people, tools, and the infrastructure needed to connect new scientific discoveries to practical and commercial applications.

Overall, the program has worked with over 150 applicants, accepting 47 nascent technology ventures into the program involving 100 participants. I would like to comment that the process here has resulted in a number of companies that have received SBIR funding, and that four of the companies are now at BIOSTART. I will not go into the details on those companies, but those four companies have done quite well.

It takes a dedicated effort to create and sustain an environment that encourages and facilitates the ideation, conceptualization, formulation, and implementation of technology ventures. The mission mantra for the Center for Entrepreneurship is quite simply to remove barriers and create gateways for the next generation of entrepreneurs.

I encourage you to fully consider the vital role that the SBIR Program plays in removing barriers and creating gateways for future entrepreneurial activity. The SBIR Program encourages today's entrepreneurs to aim high and dare to create a vibrant future built on foundations of science and commerce.

Thank you for the opportunity to provide these comments.

[The prepared statement of Dr. Matthews may be found in the Appendix on page 73.]

Chairwoman VELÁZQUEZ. Thank you, Dr. Matthews.

I would like for any of the witnesses to comment on my first question. Mr. Preston made the point that small companies that are majority owned by venture capital firms can apply for 97.5 percent of all federal government's R&D dollars. For this reason, according to Mr. Preston, these small companies should be barred from SBIR participation.

How would you respond to Mr. Preston's comment? Mr. Greenwood?

Mr. GREENWOOD. I would respond that while that statement may be technically accurate, the fact of the matter is that, yes, 97.5 percent of the NIH's budget, and I will speak specifically of the NIH, is available to universities and businesses, exactly .4 percent of that goes to businesses.

So the Administrator said 97.5 percent is available; 97.1 percent continues to go to the universities, and only .4 percent to businesses. So our companies do not have success. The universities are well entrenched, and of course, as we know in the case of the NIH, even though we doubled the budget, it has been flat since then, and so universities are scrambling to try to maintain their existing R&D programs.

So I do not see, even if Congress continues to increase slightly the budget, I do not see a lot, if any, being left for small businesses.

Chairwoman VELÁZQUEZ. ?Thank you.

Mr. HEESEN. I totally agree with Mr. Greenwood, but I will take it from the other side, let's say, the DoD or the Department of Energy perspective. You know, if we have a venture backed company, once again, it may be 15 employees. Realistically, are they able to go up against Lockheed? Are they able to go up against Exxon?

It is totally impractical. These are 15 people companies, you know, in the wind, in the solar area. They are not going to be able to compete. First of all, they do not have resources to even start that process, and then are they really going to have a realistic ability to go up against these multinational corporations? It is unrealistic.

Mr. LEAHEY. In addition to the two previous comments, I can only speak to practically what our member companies are saying to us, and time and time again, they are coming back and saying, "Do you know what? Because of this new interpretation we do not have access to these funds."

And I think it is also important, with all due respect to Mr. Heesen and his members and some of which are members of ours, venture capitalists are looking for, you know, an ROI, and there may be certain applications of a technology that may not be as profitable, but may serve the greater public good, and these are the ones simply because of this investment mechanism that will be left on the shelf, and really that is the great tragedy here.

Chairwoman VELÁZQUEZ. Any other member want to?

Thank you.

We should recess now. We have two votes. We will go to vote and right after we will come back. So the Committee stands in recess.

[Recess.]

Chairwoman VELÁZQUEZ. The Committee is called back to order.

Mr. Skinner, one of the objectives of the SBIR Program is to foster and encourage participation by minorities and women in the SBIR Program. Despite this fact, a National Academies of Science report recently concluded that agencies do not have a uniformly positive record funding research by women and minority owned firms.

How will the Federal and State Technology Partnership Program, as it is reauthorized in the draft bill, help federal agencies address this concern?

Mr. SKINNER. I believe it is very smart of the Committee to include in the legislation a requirement that the FAST awards specifically address how they are going to identify two particular groups: those geographic areas that are not served well, and populations that do not win awards. It is going to require the state programs and the local programs involved to demonstrate what they are already doing in those target audiences, but increase or set aside additional funding to address particular ways to reach women scientists and engineers that they may not be doing currently.

But I think that is one of the advantages of FAST, is it takes advantage of the 1,100 to 1,200 organizations already in existence around the country to help the agencies reach into places that they cannot reach from their installations or their centers.

Chairwoman VELÁZQUEZ. Thanks.

Dr. Matthews, the guidance for Phase 1 and Phase 2 grant sizes has not increased since 1992. The Committee print doubles the grant size guidelines to $200,000 for Phase 1 and $1.5 million for Phase 2. Given what you do with small, innovative companies, how do you expect larger average awards will impact increases in the commerce solicitation rates of SBIR funded research?

Mr. MATTHEWS. That is an excellent question because obviously things have changed over a period of time, and costs have gone up across a number of sectors and in a variety of areas.

Specifically with regard to the amount of money that is needed especially in early, early stages, which is, I think, one of the hallmarks of the strengths of SBIR, has escalated over time. Especially a lot of them have long lead times. There is a need for more capital expenditure at the front end of that period. So I would support those increases.

Again, I think this is a leverage program. I do not think it ever can stand all by itself. It has to be used in combination with other sources of capital, and the source of capital is a broad continuum from friends, families, and founders all the way up to venture capital, and SBIR falls within that continuum. So I would definitely support that increase.

Chairwoman VELÁZQUEZ. Thank you.

Mr. Heesen, an important component of small firms' efforts to commercialize the research can be the receipt of an investment from firms such as those that you represent. Why do initiatives that help small firms develop the research to a greater degree of commercial readiness before they graduate from SBIR encourage more VC firms to invest in SBIR graduates?

Mr. HEESEN. As Mr. Leahey said, we are not in this totally for altruistic purposes. We are in this to make money at the end of the day, and so the more certain you are of a company's trajectory, the more likely you are to invest in it.

And so if you see the commercial viability of an entity being much greater because you have basically grown that company to the point where it is just better to see what the future is, you are going to be more apt to invest in that company, just as you will be more apt to know if it has good patent protection, if it has a good management team, if it has an ability to grow a business long term because it understands global competition.

All of these things are part and parcel of growing a company. So if you are able to make these companies more professional, frankly, and more apt to understand the nuances of working in a fast changing environment, we are more likely to invest at the end of the day.

Chairwoman VELÁZQUEZ. Thank you.

Mr. Greenwood, my understanding is that venture capital investments are often tied to the development of companies' lead therapies or technologies. In your industry, this means that companies cannot use the investment to fund research and development of secondary applications of the lead therapy.

If the SBIR eligibility provisions included in this bill became law, how would small firms with venture capital backing be better able to explore secondary applications of their firm's lead research?

Mr. GREENWOOD. Thank you.

That is an important question. What frequently will happen is if you can imagine a small company that might have spun out of the university from NIH granted research and develop a molecule that it thinks is a very good candidate to, let's say, cure prostate cancer, and they make enough progress with the help of, among other things, SBIR grants, and then the venture capital companies see them and say, "This company really shows some progress with this molecule. Let's invest in it."

And so they invest, and they invest in that particular molecule to cure that particular kind of cancer. Meanwhile, back in the laboratory, there may be a scientist who says, "Do you know, I think from my research that same molecule might be able to cure brain cancer?" or, "we have another molecule or another protein here that we think can do something else."

The venture capitalist may say, "That is very nice, but that is not why we invested. We watched the progress on that first compound or molecule, and we want you to keep our money there."

Under the current system, since the Administrative Law Judge ruling, that company cannot go back to the SBIR and say, "How about you fund this new idea?" Under your proposed draft they will be able to, and that is critical because having that opportunity to then get some data with that new molecule, to get some advancement in their research. Then they can achieve the kind of milestone or proof of concept that then will attract the venture capitalists or other venture capitalists to come and say, "Okay. Now, that one is worth investing in as well."

And at the end of the day, this is about whether we do or do not cure brain cancer, and that is why in my view the bottom line of this entire program is we put all of that money in the NIH because we want to cure disease, and we ought to construct a system for small businesses, whether they are backed by venture capital or not backed by venture capital, that gets us to the goal: cure disease. We need to keep our eye on that ball.

Chairwoman VELÁZQUEZ. Thank you.

Mr. GREENWOOD. Thank you.

Chairwoman VELÁZQUEZ. I now recognize Mr. Chabot.

Mr. CHABOT. Thank you, Madam Chair.

Mr. Greenwood, I will begin with you if I can, and as the chair mentioned before, we want to welcome you back here.

Mr. GREENWOOD. It is a pleasure.

Mr. CHABOT. You have testified before, and in your years here as a member of Congress, you were one of the more respected members on both sides of aisle because of your integrity and working across party lines.

Mr. GREENWOOD. That is very kind to have you say that.

Mr. CHABOT. So it is good to have you here. It is very true.

Mr. GREENWOOD. Thank you.

Mr. CHABOT. Now I will ask you the tough questions.

[Laughter.]

Mr. CHABOT. No.

Mr. GREENWOOD. And I will try to make a good answer.

Mr. CHABOT. Although it does come up in several other industries, the venture capital issue seems to come up and I think it is most prevalent in the biomedical field, and could you explain why that is the case?

Mr. GREENWOOD. Yes. This is a highly, highly risky business. I was at Amgen's facility. Amgen is one of the biggest, if not the biggest, biotech companies in the world. I was at their facility in Boulder, Colorado last week, and they went through a presentation. They will take 150 different compounds or molecules and begin to try to bring each and every one of them to a place where it can cure a disease. The attrition of the process of success and failure is such that one of those 150 ultimately makes it to the FDA.

This is hard science, and it is risky science. And what happens is, typically as I said, an academician will develop something. They spin off a little company, and they find themselves squarely in the valley of death because they know they have a good idea. The brilliant scientists really believe in this product, this compound, this molecule, but Mr. Heesen's people are going to be skeptical. They have lots of opportunities, and they are risk takers, but they are not extraordinarily foolish risk takers.

So the public-private partnerships, be it SBIR grants, be it state programs that nurture these little companies, are all there for the purpose of helping these entrepreneurial scientists get through the valley of death, prove or not prove that they have something here, and then that is the point that the venture capitalists will come in.

And I can tell you and Mr. Heesen can tell you when you talk to investors today, they are not rushing into the biotech space. They know all kinds of policies that the state and federal governments can adopt. They can contribute to our success or failure.

We cannot do this without the venture capital contributions, and as I have said before, you know, it is clear from the congressional record that congress said years ago when a company attracts venture capital, it is a very good sign that some very smart and skeptical people think they are onto something, and we want to reward companies that can achieve that level of credibility, not punish them.

Mr. CHABOT. Thank you very much.

Mr. Heesen, I will go to you next if I can. Would you expound upon why you consider the SBA, or Small Business Administration's position on independent ownership and control unacceptable as it applies to venture capital firms?

Mr. HEESEN. Sure. As stated in my testimony, when you look at a venture capital firm, it is normally about a dozen individuals that are employed by that firm, sometimes literally only two or three. You know, you look at the ones in your hometown. Blue Chip is the largest, and if they have ten people I would be surprised, and yet they have a major impact on the Cincinnati economy.

So these are very small entities. Now, over the process of having a fund, they may invest in 20 companies. That is high. Maybe 15 companies. Now, when you invest in those companies early on, they may have five, six, ten employees. What you want to do as you are investing in these companies is to grow those companies, of course.

So hopefully you will have companies at the end that have several hundred employees because you have grown those small companies just like you want to. So if you start to aggregate a venture capital firm and all of the other venture capital firms that you are going to co-invest with because you do not invest in a biotechnology company on your own; you do not have that much money, particularly in the Midwest. You are going to get four or five venture capital firms who are going to put their resource together and invest in that biotechnology company.

So you have four or five who have ten employees. So that is 50, but then they all have different portfolio companies out there. I might have 15. Another person might have ten. Another firm might have eight, and they all have, you know, seven to ten employees, but you also have some of those growing companies.

It is very easy to get to that 500 person, and of course, that is what you want. You want to be growing these companies. So the idea that you are aggregating all of these companies and they could be biotechnology companies; they could be clean tech companies; they can be IT companies because a venture capitalist invests in lots of different areas. They might have absolutely no correlation, but under what the SBA is doing is literally aggregating all of those employees and saying, "You now are a large entity and, therefore, that one particular company that is in the portfolio cannot get an SBIR grant."

It just does not make sense at the end of the day.

Mr. CHABOT. Okay. Thank you very much.

Mr. Leahey, I hope I am pronouncing that correctly.

Mr. LEAHEY. Yes, you are.

Mr. CHABOT. Okay. Could you explain further why you believe it is important that the award amounts be increased?

Mr. LEAHEY. Certainly. Well, I think as Dr. Matthews had stated as well, you know, since 1992 obviously the landscape has changed significantly, and although the SBIR funding is not the only source of funding, obviously, it is part of that public-private relationship. I do not think you will find anyone who will argue about the increasing regulatory requirements that are needed at the FDA as it relates to user fees, things of that nature.

The clinical data that is required to satisfy the payer community, both the private insurers and the CMS; so throughout the research and development and life cycle of an early stage company, before they get to commercialization, they are looking ahead and saying, "Okay. I have got to meet all of these endpoints here to satisfy the FDA, to satisfy CMS or the private payers, to satisfy the markets," and not having that move at all since 1992, I do not think sensitizes or appreciate the changing landscape.

That being said, there is a lot of promise ahead, but I do not think anyone can argue that some of the hurdles have been increased. And so increasing that threshold, I think, coupled with increasing or allowing small companies regardless of their venture capital investment structure to have access to these funds, I think, will really, as Mr. Heesen said, achieve the objective insuring that the government and the private sector work together to develop the best technologies to really deliver the care that is needed in the future.

So I commend the committee for the draft for increasing those limits.

Mr. CHABOT. Thank you.

Mr. Skinner, would you comment on the geographic disparity of awardees and why in your opinion some areas of the country are getting more SBIR grants than some others?

Mr. SKINNER. Yes, thank you.

Some of it is inherent to the population centers. More demographically large states are going to receive more awards than some of the other states. There is also, at least in my experience, as one moves away from Washington and certain research centers around the country, one does not think of the federal government as a source of funding for this type of work, or they do not think of it as a friend actually for the most part.

And this is particularly the case and is reported to me by folks in New Mexico, even though they have the large federal labs. They will say companies just do not even think of applying for it.

In the other situations there is not the infrastructure necessarily there to support an environment that encourages entrepreneurship, and that is why states are making an investment to try to encourage that kind of thinking, that kind of risk taking, and that is where SBIR and outreach and assistance efforts can be helpful.

Mr. CHABOT. Thank you very much.

And finally, Dr. Matthews, what role does the SBIR program have in Cincinnati that creates companies, that project and any other programs or projects that you would like to mention?

Mr. MATTHEWS. Thank you.

First of all, I am very impressed by the testimony and the wide range of issues that have been brought up here because I am more at the early, early, early, early, early, early—did I get six in there?—early stage.

[Laughter.]

Mr. MATTHEWS. I live in the ideation/conceptualization world more than a lot, but I completely support what Mr. Heesen is saying in terms of venture capital backed ventures, and that is where Cincinnati Creates Companies came into play. We identified this gap that exists at that early stage, very early stage, where we have individuals who are extremely interested in moving forward science and technology, but just do not know how to do it, do not know what to do or how to go about it.

We conceived Cincinnati Creates Companies around that very notion, and it is a three-part program. The first part is a very rigorous ten-week educational program. We put them through their paces. It is kind of an advanced boot camp, if you will, over ten weeks; a 15-week structured mentor relationship. So we actually have a mentor come in and work with them oftentimes from the Angel or VC community on a volunteer basis.

Then we have a competition because nothing motivates people like getting together and trying to compete against each other in these situations because that is what they are going to be doing from that point forward.

And so they compete and they get some funding from that what I call trouble money because it is not enough to really do anything with but get them in trouble, but that is a good thing because that really propels them forward.

SBIR becomes a critical component of that as they move through that process, as they become aware of it, especially as I mentioned for some of our BIO life]science companies that are at the BIOSTART incubator. This has been particularly critical for them, and some have been very successful at moving from the bench forward, which again I apologize. I think it was Mr. Heesen or Mr. Greenwood said that people are not rushing to fund a lot of these things at that early, early stage. So SBIR is critical at that point to make that happen, and I certainly saw that with Cincinnati Creates Companies.

Now, we had NSF funding for that program over three years, and we had a one-year extension. We put four cohorts through that program. We are trying to keep it going at CincyTech. CincyTech now is trying to use some of their Third Frontier money in Ohio to keep that program alive and moving forward.

So I would very much like to see SBIR play a key role in that, and I keep in touch with the 47 graduates of the program very extensively and just was in conversation with one, Dr. George Weber, who is working on a molecule for cancer, a very good example, and I see him as prime, prime to get an SBIR to move his process forward.

He just competed very successfully at the Purdue Life Sciences Business Plan competition. So, yes, critical, just very critical.

Chairwoman VELÁZQUEZ. Would the gentleman yield?

Mr. CHABOT. I would be happy to yield.

Chairwoman VELÁZQUEZ. Dr. Matthews, we created a program for Phase 1 and 2 primer that will provide technical assistance for Phase 1 and then on Phase 2, for those, you know, Ph.D. researchers that have something really good, but they do not have the skill in terms of how to run a company. So you will be supportive of that?

Mr. MATTHEWS. Absolutely. Again, in the academic world you have professors who are very adroit and adept at the science side, and you have those that are very adroit and adept at the business side, but they rarely exist in the same space So getting those folks together or getting one trained on the other side is critical.

A great case in point, in my graduate MBA class I often have engineering students. Four or five years ago I had an engineering student show up in my spring quarter class. He is an engineer through and through. You know, business was not in his vocabulary, but he was a co-patent holder on some type of MEMS-based technology that was very promising in the liquid cooling side of the house for electronic applications. He went through my regular MBA program. He graduated and actually applied to and was part of our Cincinnati Creates Companies Program, and he has moved that program forward tremendously at this point.

Now, he is being incubated out at the Siemens Business and Technology Park in San Francisco. He will probably be applying for an SBIR in the not too distant future. I would be a little concerned that now he has gotten a little bit of backing that he would be excluded from that, but you know, without that training, he would not be in the position that he is in now.

Mr. CHABOT. Yes, Mr. Greenwood.

Mr. GREENWOOD. There is a point that I failed to make in response to Mr. Chabot's question, which is why our industry is so particularly reliant upon venture capital. If you are a small business and you make widgets, it is not a very long period of time until you can start selling your widgets, and then you derive revenues from those sales, and you can become completely self-sufficient.

In the biotechnology world, once you get a patent for your molecule, let's say, you have a ten to 12 to 15-year long period for you to develop that to the point where you can test it in animals and then do Phase 1 clinical trials in humans and Phase 2 and Phase 3 and take it to the FDA.

And throughout all of that period, throughout all of that time, and by the time you get to the FDA you have spent hundreds of millions of dollars, you have to raise all of that money usually without a penny of revenue from sales, and you cannot get there without at some point becoming more than 50 percent owned by venture capital. There is just no other way to do it.

And that is why this rule is so nonsensical.

Mr. CHABOT. Thank you.

Madam Chair, I want to commend you for putting together such a fine panel here, and it was extremely informative, and we appreciate the testimony of all the witnesses, and I will yield back the balance of my time.

Chairwoman VELÁZQUEZ. Thank you.

I have two more questions or maybe three. Mr. Greenwood, the draft bill includes provisions that require federal agencies to establish an SBIR advisory board that includes private sector representatives. The bill also requires agencies to release regular research solicitations and to issue a final decision on an SBIR application within 90 days after the agency received the application.

How will these provisions impact the small research firms that are members of your organizations?

Mr. GREENWOOD. Well, I think it would be useful. I think the one sensitivity I would raise is that in some of these agencies already have peer review panels, and so what you want to do is be careful to avoid redundancy there, but I like the idea that you would have two representatives from small business there to make sure that the review gets that perspective, and I certainly think anything that gives you certainty with regard to the turnaround time of your application would be very helpful.

Chairwoman VELÁZQUEZ. Thank you.

I want to ask the question that I engaged the Administrator regarding the use of one percent of funds set aside for SBIR research to pay for administrative costs associated with commercialization programs, and current law authorizes the Department of Defense to use it.

The draft legislation takes a different approach, and I would like either Mr. Leahey or Mr. Greenwood to comment on this.

Instead of re-purposing scarce research dollars, it authorizes an appropriation to the SBA equal to approximately one percent of the set-aside for a fund that federal agencies can draw on to support new commercialization initiatives. Do you support this approach to funding federal agency efforts to help small firms commercialize SBIR funded research?

Mr. LEAHEY. Madam Chairman, yes, we do. I think it is an important mechanism. Again, it supports the overall objective of the SBIR Program. So to the extent that these funds could be used to administer or provide additional commercialization or training activities to help educate these entrepreneurs, I think, is consistent with the overall objective of the program, and certainly something we could support.

Mr. GREENWOOD. I think very straightforwardly, if the Congress is able to authorize the appropriations of these funds to cover the administrative costs, it is more money left for R&D, and that is what the program is all about.

Chairwoman VELÁZQUEZ. Yes. Well, I want to thank all of the witnesses. It has been quite an insightful hearing today, and we will continue to work on this reauthorization and expect to mark up the bill soon and in consultation with, of course, the minority, Mr. Chabot.

And I ask at this point consent that members will have five days to submit a statement and supporting materials for the record. Without objection, so ordered.

This hearing is now adjourned. Thank you.

[At 12:21 p.m., the Committee hearing was adjourned.]

NYDIA M. VELAZQUEZ, NEW YORK
CHAIRWOMAN

STEVE CHABOT, OHIO

Congress of the United States
U.S. House of Representatives
Committee on Small Business
2361 Rayburn House Office Building
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STATEMENT
of the
Honorable Nydia M. Velázquez, Chairwoman
Committee on Small Business
Full Committee Legislative Hearing to Examine the "Small Business Innovation Research Program Reauthorization Act"
Thursday, March 13, 2008

Today we will examine legislation modernizing and extending the Small Business Innovation Research program. SBIR is one of the government's largest sources of funding for innovation. It awards more than $2 billion dollars in research grants every year, which enables the work of thousands of America's most inventive small firms. As science and technology evolve, however, so must this initiative.

The authors of the program had great foresight. 25 years ago they recognized early stage firms could make important contributions regarding technological development. SBIR made it practical for these small and innovative companies to conduct research on behalf of the Federal government. This has yielded groundbreaking advances, including: unmanned aviation, needle-less insulin patches, and a promising malaria vaccine.

SBIR awards have supported R&D that strengthens our country's national security and public health infrastructure. In the process, it has helped launch leading technology companies such as Amgen, Qualcomm and Symantec – employing thousands of Americans.

From the Committee's perspective, continuing this success is dependant on three primary issues. First, the number of small firms that apply for SBIR awards must increase. Second, awardees must have access to financing of all types, including venture capital. Third, the commercialization of SBIR-funded research projects must be more of a priority.

The draft legislation we will consider this morning seeks to address each of these elements. In order for more small firms to apply for SBIR, it doubles award sizes, providing more capital for important research projects. It also establishes a 90-day period for a decision on applications. These provisions will enable small firms to get <u>more</u> capital <u>more</u> quickly – and reduce the time it takes for research to go from the lab to the marketplace.

Emerging economic sectors—including women, veterans, and minorities—are also brought into SBIR. This is achieved through the reauthorization and expansion of the Federal and State Technology Partnership program. FAST will increase competition for federal research dollars—giving the taxpayer a better value.

While SBIR has been a successful program, one of the critiques we have heard is that it is difficult to take the next step. The legislation addresses this by establishing a new PRIMERS initiative, which will provide the technical "know-how" and assistance many small firms need.

The draft bill also ensures companies can choose from a wide array of external financing sources – and that the SBA does not make this decision for them. We have included a provision that is identical to the amendment offered by Ranking Member Chabot on the House floor last fall. This gives certainty that businesses can make their own financing choices. It also frees them from worrying about being second-guessed by the government.

SBIR-funded research needs must reach the consumer – whether it is the government or the private sector – and this legislation places a greater emphasis on commercialization. The changes consolidate the existing fragmented effort and expand it government-wide, which benefits all research sectors, including health care, energy, and agriculture.

These improvements will entice, enable and permit more small companies to advance the innovations that have made our economy so diverse and vibrant. They will help ensure that SBIR awards remain competitive, fund top-notch research, and produce cutting-edge breakthroughs.

As a result, the SBIR program will keep pace with the very innovation that it seeks to promote, and will continue to foster next-generation technologies and therapies. That also means it will solidify our efforts to increase U.S. competitiveness worldwide. I look forward to today's hearing and I want to thank all the witnesses in advance for their testimony.

U.S. House of Representatives

SMALL BUSINESS COMMITTEE

Thursday, March 13, 2008

Subcommittee on Contracting and Technology

Opening Statement of Ranking Member Steve Chabot

Legislation to Reauthorize and Modernize the Small Business Innovation Research Program

Good morning. Thank you, Madam Chairwoman, for holding this hearing to review a Committee Print of legislation reauthorizing and modernizing the Small Business Innovation Research 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 and especially to Dr. Charles H. Matthews, who holds a Doctor of Philosophy in Management from the University of Cincinnati. Dr. Matthews is a professor of entrepreneurship and strategic management at the University of Cincinnati's College of Business. He is also the founder and executive director of the university's Center for Entrepreneurship Education & Research and the director of the College of Business' Small Business Institute. Welcome, Dr. Matthews.

Today's hearing is the third in a series designed to collect information and data to help this committee draft legislation reauthorizing the SBIR program. On January 29, we held a hearing that reviewed how well the SBIR program is performing. On February 13, this committee's Oversight and Investigations Subcommittee held a hearing to review the SBIR program's role in the development and commercialization of innovative healthcare technologies. At each of these hearings, the committee received valuable information from academics, small businesses, and trade associations on the performance of the program.

Based on this input, the committee developed draft legislation for the SBIR program's reauthorization. We are working toward developing legislation that modernizes and strengthens the SBIR program.

The draft we have before us goes a long way toward achieving those goals. As the National Academies of Sciences noted in its report on the SBIR program, there are not adequate measures of performance in the SBIR program. The draft legislation before us addresses that issue by requiring agencies with an annual SBIR program of 50 million dollars or more a year to create an SBIR advisory board to review the program quarterly and recommend improvements in that agency's operation of the program. The creation of these advisory boards and the annual report to Congress will allow for greater oversight and better management of the program.

The draft bill also mandates that agencies required to have an SBIR advisory board must complete evaluation of competitive SBIR proposals within specific timeframes. Additionally, the legislation doubles the authorized SBIR Phase I and II award amount, and makes numerous other technical, but important, changes to the program.

That said, I do have some concerns with a few of the provisions in the draft before us. I am certain that the Chairwoman and her staff, as she and her staff have done since the beginning of this Congress, will work with me and my staff in a bipartisan manner in an attempt to hammer out any differences that may come up as we continue with this process.

Today, we have excellent witnesses here to provide us with discussion on the draft legislation. Thank you Madam Chairwoman. I look forward to working with you on the improvement and reauthorization of the SBIR program. I yield back.

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Statement of Rep. Jason Altmire
Committee on Small Business Hearing
"Legislation to Reauthorize the
Small Business Innovation Research Program"
March 13, 2008

Thank you, Madam Chairwoman, for holding today's hearing to review legislation to reauthorize the Small Business Innovation Research Program (SBIR). Since its inception in 1982, SBIR has been a catalyst for some of today's most successful enterprises that began as a small business. For over twenty years, SBIR has allowed innovative small businesses to partner with the government for the development of some of today's most cutting-edge goods and services.

SBIR is a program designed to spur American innovation, and while Congress did make some modifications to the program when it was reauthorized in 2000, some have expressed concerns that SBIR has fallen out of step with the realities of today's technology-centered world. This committee, along with the House Committee on Science and Technology, will have the opportunity to examine the challenges that today's small businesses face to ensure that reauthorization will keep pace with the technological changes and advancements of today.

The region I represent in western Pennsylvania has produced a number of SBIR success stories, ranging from new medical therapies developed by CardiacAssist to computer technology created by Inteligistics. I look forward to the timely reauthorization of SBIR and the continued success of the small businesses that participate in the program.

Madam Chair, thank you again for holding this important hearing today. I yield back the balance of my time.

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U.S. Small Business Administration
Statement of Administrator Steven C. Preston
House Small Business Committee
Reauthorization of the Small Business Innovation Research Program
March 13, 2008

Chairwoman Velazquez, Ranking Member Chabot and members of the Committee, the Small Business Innovation Research (SBIR) Program has helped small business to access federal research and development funding.

The SBIR Program was created in 1982 and has been used by small firms to fund research that has fostered technological innovation and commercialization of products. Every federal department with an extramural research and development budget of $100 million or more participates in the SBIR Program. There are currently eleven federal departments that participate including Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, Transportation, the Environmental Protection Agency, NASA and the National Science Foundation. SBA is responsible for promulgating regulations and policy directives to govern the program, while other federal agencies utilize the program to foster innovation.

Eligibility Rules

As a brief background, for a business to be eligible for participation in the SBIR Program, on the date of award they must (1) be organized for profit; (2) 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 at least 51 percent owned and controlled by one other for-profit business that is itself at least 51 percent owned and controlled by individuals who are citizens of, or permanent resident aliens in, the United States; and (3) have, including its affiliates, not more than 500 employees. The purpose of these requirements is to ensure that benefits reach only the small business entrepreneurs and that the research and development advances resulting from the SBIR Program remain in this country and benefit the United States.

In 2003, SBA proposed a rulemaking to modify the ownership requirement for SBIR awardees. The Proposed Rule was to add a specific flexibility in the requirements to allow SBIR awardees the option of conducting their innovative SBIR work through a wholly owned and controlled subsidiary. Cases had been brought to SBA's attention where small businesses formed research and development subsidiaries to pursue innovative research with SBIR funding. However, the subsidiaries were unable to receive the funds directly because they were more than 49 percent owned and controlled by another firm. The Proposed Rule was open to public comment from June 4, 2003 to July 7, 2003. Most of the comments were in favor of the proposed change. Some comments argued that the rule need not require 100 percent ownership and control—that less than 100 percent ownership and control by another concern should be allowed.

After reviewing the public comments, SBA published a Final Rule on this issue in the Federal Register on December 3, 2004 (69 FR 70180). In the Final Rule, SBA made one modification to the ownership requirement set forth in the Proposed Rule. It changed the proposed requirement that the subsidiary be 100 percent owned and controlled by another for-profit business to the requirement that it be at least 51 percent owned and controlled by another for-profit business. Based upon the comments received, the SBA considered its original proposal to be unnecessarily limiting. The Final Rule therefore provides that an SBIR awardee must meet the following requirements: it must be either (1) a 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 (as the pre-existing regulations required); or (2) a for-profit business concern that is at least 51 percent owned and controlled by another for-profit business that is itself 51 percent owned and controlled by individuals who are citizens of, or permanent resident aliens in, the United States. The Final Rule became effective January 3, 2005.

During the period that SBA was developing the proposed rule, SBA's Office of Hearings and Appeals (OHA) received an appeal from a company that was found ineligible for the SBIR Program because it was not majority owned by individuals. During the appeal it was argued that the term "individual" in the program's 51 percent ownership requirement should be interpreted to include non-corporate institutional investors such as Venture Capital Companies (VCCs). On May 29, 2003, OHA denied the appeal maintaining the long-standing interpretation that an "individual" is a natural person. This decision reaffirms the eligibility requirements set forth for the SBIR Program.

The 51 percent requirement is there to distinguish between individual owners and owners that are institutional entities to ensure that SBIR funds go only to small, independent U.S. firms. It is important to note that the OHA decision constituted neither a new eligibility rule, nor a new restriction on venture capital financing within the SBIR Program. In fact, based on the new final rule SBA believes this provides further opportunities for venture capital involvement under the SBIR program.

Venture Capital Participation

SBA wants to ensure that the integrity of the program is maintained and that it remains a program for small businesses. VC participation has been allowed and encouraged since the inception of the program. Currently, more than one venture capital company may invest any amount of money into small businesses that receive SBIR awards, with the only restriction that they cannot in concert own more than 49 percent and/or have the ability to control the SBIR awardee. In addition, if a VCC is for profit and is owned at least 51 percent by one or more individuals who are U.S. citizens or permanent resident aliens, it may own more than 49 percent of the SBIR awardee so long as the awardee and its affiliates (including the VCC and its affiliates) have no more than 500 employees in total.

The option of expanding VCC participation raises a number of issues. For example, exempting VC or other institutional investors from affiliation in size determination could affect the transparency needed to determine program eligibility as well as the intent of the program to benefit businesses that are small. Further, any changes to SBA's size standards could potentially affect SBA's other programs. SBA is unaware of any meaningful distinction between VCCs and other business entities that would allow greater VCC participation in the SBIR program without affecting important ownership restrictions in other SBA programs.

SBA is particularly concerned with possible changes to its affiliation provision. Affiliation is a key concept in defining a small business. Along with a numerical measure of the size of business, the Small Business Act includes the criteria that a small business must also be "independently owned and operated." Without a consideration of affiliation, Federal assistance targeted for small businesses could be inappropriately provided to a business concern that is part of a large business. Accordingly, SBA advises Congress to proceed with the utmost caution in this key concept of defining a small business.

Proposed Legislation

The Administration is concerned with the proposed legislative change to the definition of small business for the purposes of venture capital investment. While recognizing that venture capital investment is crucial to small business growth, the Administration is nevertheless concerned that the committee print offers too broad a definitional change to the affiliation standards. SBA is currently reviewing these rules, and believes that the current change may not reflect the appropriate balancing required in development of size standards. In particular, any redefinition that alters the elements of independent ownership and control that identify small business ownership under current law has the potential for great harm to all small business programs.

It is also of concern that there are certain potential conflicts in the proposed legislation. For instance, SBA has noticed that there is a conflict between the definition of a VCOC which includes patent and licensing organizations affiliated with institutions of higher education and the clause requiring that VCOCs not be controlled by any business concern that is not a small business concern. Under the Small Business Act institutions of higher education are generally not considered small business concerns. Such definitional conflicts present potential inequities and SBA would hope we could work with the committee to clarify this language, consistent with what we believe is a mutual overarching objective: appropriately define the term "small business" in a manner that effectively minimizes *ineligibility* of actual small businesses while also minimizing the *eligibility* of large businesses.

Despite our differences of opinion on the affiliation rules, SBA is committed to the continued improvement and expanded monitoring of the SBIR program. In particular, the Administration would like to work with the committee to create performance goals for the program. These goals and metrics will provide useful information on the successes and strengths and weaknesses of the program in its goal to support innovative research.

For example, the Administration would like to develop quality metrics that can assist agencies in developing standards to limit the perceived effect of so-called "SBIR mills". In order to understand the issue surrounding multiple award winners it is necessary to have clear data on the issue. Successful awardees should not be penalized provided there is a solid basis for their awards and a clear understanding of the nature of the research's potential for advancement.

Likewise, the Administration would support efforts to study the commercialization and implementation of research to develop a better understanding of the needs of the Phase III process. While recognizing the historic goal of commercialization in the SBIR program, we believe that further expenditures and programmatic changes should be based on performance data, and we caution Congress to avoid re-focusing the program in a manner that involves direct support for commercialization activities more appropriately performed by the private sector.

The Administration's clear goal is to further quality research which produces significant results for the Nation. SBA looks forward to working with this Committee as legislation moves forward prior to the sunset date on September 30, 2008.

I appreciate the opportunity to share the administration's position on the SBIR programs and I look forward to answering any questions you may have.

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

HEARING TESTIMONY
THE HONORABLE JAMES C. GREENWOOD
PRESIDENT AND CHIEF EXECUTIVE OFFICER
BIOTECHNOLOGY INDUSTRY ORGANIZATION

BEFORE THE HOUSE OF REPRESENTATIVES COMMITTEE ON SMALL BUSINESS

"REAUTHORIZING THE SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM"

MARCH 13, 2008

Good morning Chairwoman Velázquez, Ranking Member Chabot, Members of the Committee, ladies and gentleman. I am Jim Greenwood, President of the Biotechnology Industry Organization (BIO). I am privileged to be here this morning on behalf of BIO.

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in 50 U.S. states and 31 other nations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The overwhelming majority of BIO member companies are small, early stage research and development oriented companies pursuing innovations that have the potential to improve human health, expand our food supply and provide new sources of energy.

The historical role of the SBIR program in bringing breakthrough therapies to the American public is a matter of public record. There are 252 FDA approved biologics that have been developed by 163 companies and affiliates. Thirty-two percent of those companies and affiliates have received at least one SBIR/STTR award. It is clear the SBIR program has played an important role in helping small biopharmaceutical companies obtain critical funding at early stages of research and development. However, I am here today to discuss the future of the SBIR program, not its past. Unless the SBIR Reauthorization updates the program to address the current realities facing small, innovative American companies, the ability of the SBIR program to provide critical funding for therapies and treatments that have the most potential of improving the public health is hampered.

I want to start by commending the Committee for recognizing that SBIR Reauthorization is an appropriate vehicle to foster the important linkage between early-stage R&D funding and new medical breakthroughs. Congress created the SBIR program in the early 1980's in order to utilize the capabilities of small, innovative, domestic companies to fulfill federal research and development needs. Congress recognized that some early stage, promising scientific research failed to be funded by private-sector capital because it was viewed as too high-risk. This failure of the markets is often referred to as the "valley of death". In biotechnology, the "valley of death" delays potential therapies for HIV, cancer, and infectious diseases from reaching patients, who often lack other comparable alternatives. For twenty years the program worked well for U.S. life sciences companies engaged in high-risk, cutting-edge medical research.

However, in 2003 the Small Business Administration (SBA) Office of Hearings and Appeals (OHA) arbitrarily ruled that a biotechnology firm, Cognetix, did not meet the SBIR size standard because multiple venture capital investors, in the aggregate, owned more than 50 percent of the company's stock. This new interpretation of the SBA's SBIR regulations has denied medical research funding to an untold number of small biotechnology firms over the past several years. The ruling is not based on the SBIR statute, in which Congress specifically encouraged private-sector investment in SBIR applicants.

The ruling ignores the realities of the biotechnology marketplace. Small, emerging biotechnology companies have high and intense capital needs that rely on the involvement of venture capital investment. The Tufts Center for the Study of Drug Development estimated it takes between 8 and 12 years to bring a biotechnology therapy to market and costs between $800 million and $1.2 billion. The majority of small biotechnology companies are without any product revenue for a decade or more. They 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. Companies generally begin fundraising for lead products in development and raise between $5 million and $15 million in their first round of venture financing, an amount that usually results in multiple venture capital companies collectively owning more than 50% of the companies. However, it is typically the case that no single venture capital company will own more than 25-35% of the equity.

Despite the extensive fundraising a biotechnology company must undertake for the lead products, these funds are not interchangeable to fund the other more early stage research projects. It is for these other projects, in the earliest stage of development but with tremendous potential to benefit the public, that SBIR funding has been critical. Funding from the SBIR program helps to create a path from the spark of an idea to scientific validation and development, and ultimately becoming available to the public.

The ruling is a misinterpretation of the SBA's regulations to ensure that SBIR applicants are U.S.-owned, domestic companies, a goal we fully support. However the use of capital structure as proxy for determining domesticity and the subsequent OHA ruling has had the unintentional consequence of excluding a sizeable portion of the biotechnology industry that would otherwise be eligible to participate in the program. These are companies that have participated in the SBIR program for 20 years prior to this ruling and were a fundamental part of the aforementioned success of the SBIR program. Moreover, these small companies are solely based in the United States and are majority-funded through a combination of U.S.-based venture capital companies and citizens.

Since implementation, this ruling appears to be negatively impacting the competitive pool of SBIR applicants and the program's ability to award projects based on scientific merit and commercialization potential. In fact, applications for SBIR grants at NIH have declined by 11.9 percent in 2005, by 14.6 percent in 2006, and by 21 percent in 2007. Additionally, the number of new small businesses participating in the program has decreased to its lowest proportion in a decade.

Numerous BIO member companies have shared examples with this Committee of promising discoveries that have been shelved or delayed as result of being ineligible for the SBIR program. The Director of the National Institutes of Health, Dr. Elias Zerhouni, said it best in a letter to SBA Administrator Barreto in 2005: *"NIH believes that the current rule undermines the statutory purposes of the SBIR program...It undermines NIH's ability to award SBIR funds to those applicants whom we believe are most likely to improve human health."*

The reauthorization of the SBIR program presents an opportunity to restore the program and ensure the most competitive pool of U.S. small business applicants. The reauthorization presents an opportunity to ensure that grants are awarded on scientific merit and potential to improve public health, and not on capital structure.

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 (even if only it only owns a minority share), not only are the employees of the venture capital company included in the size determination, but so are the employees of all 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, just because the companies share a common investor.

For these reasons, among others, I commend Chairwoman Velázquez, Ranking Member Chabot and the Members of the Committee for their foresight in including a remedy to the eligibility issues affecting small biotechnology and medical device companies in the reauthorization legislation soon to be introduced It is the right thing to do and this is the right time to do it. On behalf of America's biotechnology companies, I look forward to working closely with you to see this much-needed change enacted into law this year.

BIO also supports the proposed provisions in the reauthorization that provide agencies with the flexibility and authority to determine amount of awards and number of times a project can be awarded under Phase II. BIO concurs that one of the great strengths of the SBIR program is that Congress provided the affected departments and agencies with flexibility in establishing the program. Agencies should maintain 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. Agencies should be the best judge of how to use their SBIR funds to advance science and commercialize new innovations.

I would also like to commend the Committee for drafting legislation that re-affirms and fosters the original goals of the SBIR program, namely the commercialization of new technologies by small, innovative American companies. Specifically, BIO supports the modernization and reauthorization of the Federal and State Technology (FAST) Program that will assist agencies in their outreach efforts to areas traditionally underserved by the SBIR program. And secondly, BIO supports the authorization of funds for agencies to develop and expand commercialization programs. These programs will enable the SBIR program to attract the most innovative science companies and provide assistance in the early stages of the process, as well as better equip these small businesses with the tools necessary to achieve commercialization of a new therapy or treatment.

Before I close today I would also like to discuss recommendations that would help ensure taxpayer funds are being used in an efficient and effective manner. The SBIR program is not a basic research program, it is about developing new products for the benefit of society. There have been concerns expressed over the number of grants an individual company may receive from the SBIR program. While BIO supports agency flexibility, we would support reasonable limitations, such as capping the number of awards per company to 5 -10 awards per year/per company. The bill does contain some provisions addressing these concerns by requiring the SBA to release the names of firms that have received multiple Phase I grants and zero Phase II grants and promulgate rules for the agency to address these awardees. We support this effort but are concerned these provisions may not fully address "gaming the system" concerns. For example, a single company that has over 40 Phase I awards and 1 or 2 Phase two awards over a five year period would not be included in this oversight.

No company should make SBIR grants the basis of its business model. SBIR exists to fill the funding void for companies that are raising private capital to do their research and development. Any company that receives excessively large numbers of SBIR grants year after year, without commercializing technology, is probably not the type of company in which the federal government should be investing taxpayer resources. We look forward to working with the Committee to ensure the intent of these provisions is fully realized.

The 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.

Again, thank you for the opportunity to testify today. I would be happy to answer any questions Members of the Committee might have.

House of Representatives Committee on Small Business
March 13, 2008
"A Hearing to Review Legislation to Re-authorize the Small Business Innovative Research (SBIR) Program"

Testimony of:
Mr. Mark G. Heesen
President
National Venture Capital Association
Washington D.C.
Final

Introduction

Chairwoman Velazquez, Ranking Member Chabot and Members of the Committee, my name is Mark Heesen and I am president of the National Venture Capital Association (NVCA). The NVCA represents more than 480 venture capital firms in the United States and advocates for policies and legislation that are favorable to American innovation and entrepreneurship. In 2007, venture capitalists invested approximately $30 billion into small, high-risk, emerging growth companies in areas such as life sciences, information technology, homeland security, and clean technology. The goal of our members is simple – to bring the best and most innovative new products and services to market in the most efficient manner.

I would like to thank the Committee for the opportunity to contribute to the discussion regarding the reauthorization of the SBIR program which expires in September. I hope my comments today will effectively capture the NVCA's unwavering support for the draft Committee Print, which includes a provision that will allow small businesses backed by professional venture capital investors to once again participate in the SBIR program. When put together, SBIR funding and venture capital investment is a proven and effective way to bring a steady stream of innovation to the market and support small businesses.

Yet, it is important to articulate the venture capital industry's utmost frustration with the Administration's campaign to exclude small, venture-backed companies in this important program. These are among the most talent-rich entities in the United States and they are focused on solving very important problems. To preclude them is a disservice to our country. To that end, if the provisions which guarantee a level playing field for venture-backed companies are removed or compromised in any way, NVCA will not support the re-authorization of this program. The program can not continue to precisely exclude the small businesses that offer the most promise in assisting the government in commercializing truly innovative technologies. In this extremely budget conscious environment, the appropriateness of such a program under such circumstances can and should be questioned.

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 seven years since an administrative law judge redefined an "individual investor" to mean a "natural person," thereby opening the door for the Administration 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 Small Business Administration (SBA) has used this interpretation in recent years to deny grants to many of our country's most worthy small businesses. Over the last seven years SBA's policies regarding SBIR eligibility and how they determine if an entity qualifies as a small business have been inconsistent, discriminatory, and based on serious misconceptions which they appear to have absolutely no interest in re-examining.

In contrast to the SBA, 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 and into the marketplace, into the healthcare system, into our military and into developing alternative energy. The venture capital community is committed to contributing significantly to this endeavor. We have consistently asked the Administration to join us. In absence of their willingness to work with us, we urge Congress to reauthorize the program with provisions that ensure venture-backed companies have a fair chance to thrive under the SBIR program alongside of their non-venture-backed counterparts. Doing so will only strengthen the future success of the program.

Venture-Backed Companies are Small, Fragile Businesses

I would like to spend some time debunking the myths employed by the SBA when they argue against venture-backed business participation in SBIR programs. The first myth is that venture-backed companies do not need SBIR programs because they are strong, fully funded entities. Make no mistake: the venture-backed companies that apply for SBIR grants are the epitome of small, fragile businesses. These entities typically employ less than 25 people, and are comprised of just a few individuals who have developed a promising innovation that they wish to bring to market. Like all small businesses, they face many obstacles unique to young innovators including clinical trials and beta tests, regulatory approvals, competition from larger players, human capital needs, and, of course, financing. The only distinction for a venture-backed company is that it has demonstrated enough promise to attract an investor whose business it is to find and fund opportunities ready for commercialization.

Even with venture capital investment, the road is long and difficult. These companies are extremely high risk and have the same chance of failure as their non-ventured counterparts. Contrary to the SBA's premise, venture-backed companies do not have access to a bottomless pit of funds. In fact, the financial controls at a venture-backed company are perhaps more stringent than those without this oversight. Venture dollars are earmarked for very specific development activities. They are focused on exclusive projects with narrow trajectories. Venture-backed companies must also consistently meet or beat agreed upon milestones to continue to receive funding. Perhaps SBA believes venture funded companies have unlimited cash because they believe venture firms have unlimited cash. That too is a fallacy. Venture firms raise capital in a closed-end process. Once the fundraising cycle is complete, venture firms have a contractually finite pool of resources with which to help grow a dozen or more companies—and those resources have to last 10-12 years.

When a small business receives venture capital, there are no "extra" funds to support early stage basic research projects. Venture capital dollars are not available to these companies for this purpose. Venture capitalists support applied research and commercialization. Small venture-backed companies are also extremely unlikely to win government R&D dollars, which are targeted to specific programs and large corporations. To wit, only 0.4 percent of the NIH extramural grants went to businesses with most monies directed to higher education and research institutions. Just last week this Committee heard compelling testimony from small businesses across various industries about the difficulty they face in competing for government procurement dollars. For many venture-backed companies, the SBIR program is their only funding mechanism for critical early stage projects. Both venture capitalists and entrepreneurs by their very nature are opportunity seekers. If there were other avenues to obtain these much needed funds, after seven years of being discriminated against by the SBA, they would have found it by now.

Venture Capital Firms are Not Large Corporations

The SBA also wrongly assumes that venture capital firms are equivalent to large corporations, and therefore the companies that they fund should be excluded from consideration from SBIR grants. On September 6, 2007 Steve Preston, SBA Administrator, testified before the House Small Business Committee, where SBA went on the record opposing a provision in HR 3567 that would include venture-backed companies stating that, *"While SBA encourages venture capital investment in small business we must object to this provision. The basic premise of small business size status (independent ownership and control) is circumvented by this provision, which would allow a* ***large business*** *(emphasis added) to own and control several small businesses without affecting the size status of the businesses."*

We agree that large corporate owned businesses should not be allowed to participate in small business programs. But venture capital firms are not large corporations with deep pockets and ulterior motives. They are almost entirely private partnerships that are typically comprised of less than a dozen professionals. And if the SBA considers a dozen professionals to be equivalent to a large corporation, then almost every business they support is out of compliance.

In reality, the SBA knows this, which is why they have gone to great lengths to manipulate the system and concoct a nonsensical formula to justify their position. In September of 2007, one of our members testified before this Committee and described a situation in which one of its small portfolio companies was denied a small business waiver from the SBA for a $900,000 FDA application fee. While the company employed just 7 people, the SBA affiliated every employee from not only the venture capital firm (in which there were less than 10) but also every company in the venture portfolio, to exceed the 500 employee threshold. Aside from this maneuver being absolutely irrational and unjustified, the SBA hurt a very small business and delayed a very promising drug discovery.

H.R.3567, the Small Business Investment Act, which passed the House with an overwhelming bipartisan margin, incorporates the appropriate safeguards to ensure large corporations cannot participate in small business programs. The draft Committee Print to Reauthorize the SBIR incorporates the same safeguards. By definition and practice, venture capitalists are financial investors who share the same goal as the SBIR program, i.e., the desire to generate successful small business innovation and build these small businesses to stand on their own. Venture capital firms are small businesses growing small businesses.

Venture Backed Companies are not Controlled by Venture Capitalists

The SBA also wrongly assumes that venture backed companies are controlled by venture capitalists. While venture capitalists as investors typically have Board participation (usually two or three seats of a five to seven member Board), they do not exert day-to-day control of a company for several reasons. The partners at venture funds work with a number of portfolio companies at once. Their time is divided between all investments of the venture fund and it would be impossible and impractical to spend that limited time on the 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 capitalists 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, more often than not, the venture capital firm does not have 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.

Ironically, SBA's policy particularly hurts the very regions that the SBIR program was designed to support, like mid-America where only about four percent of all venture capital is invested. The scarce venture capital dollars available in this region must cover a greater geographic footprint than 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.

SBIR and VC Have Worked Well Together

In discriminating against venture-backed companies, the SBA has tried to "fix" a situation that was never broken. Throughout the SBIR program's history, and prior to the current controversy, majority venture-owned small business have applied for and received SBIR funding. This historical precedence strongly suggests that their participation has caused no harm to the program or to other small businesses. To wit, the recent National Academies of Sciences study on the SBIR program offered no evidence that other small businesses have ever been crowded out by the participation of venture-backed businesses.

The NAS report also found that there are useful synergies between venture capital investment and SBIR funding in terms of selecting the most promising companies. During the first two decades of the program, when participation of venture funded firms was not at issue, some of the most successful NIH SBIR award winning firms were able to perform at high levels because they were allowed to receive venture funding as well as SBIR awards. By discriminating against venture-backed firms, the SBA is removing some of the most worthy applicants from consideration. This behavior isn't helping anyone and, in fact, is hurting many.

The Current Situation is Untenable

Venture-backed businesses have been fighting this battle for too long. And many of the best have already given up on the promise of SBIR and for good reason. They are being put in a position of choosing one type of investment over the other – when, in reality they need both. It is a terrible message to send to small businesses and innovators.

Given the extreme actions of the SBA, it is very difficult under current circumstances for small venture-backed businesses to understand the rules of the game. In fact, SBA's policies have become so inconsistent and unpredictable that top law firms have sent out advisories to clients warning them of the perils created by the SBA. In January of this year, Cooley Godward Kronish published an alert to clients saying that there is a significant risk for venture-backed companies to participate in the SBIR program under the False Claims Act. This law firm is one of the top legal advisors to venture-backed start ups and they are broadcasting to the venture capital and entrepreneurial community that there are now legal liabilities associated with the brightest companies seeking government funding.

A Public/Private Effort is in Everyone's Best Interest

The SBA's discriminatory 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 innovations that are too early in their development for the venture capitalists to cover. SBA is cutting off the innovation pipeline so the most promising projects never see the light of day – and it is denying our government scientists the opportunity to collaborate with some of the most talented private sector engineers and researchers in the world.

If it is still the intent of Congress that the SBIR program generates significant commercial impact, it makes no sense to exclude any class of venture-backed small businesses because they are empirically among those most likely to have significant commercial success. New technologies developed by venture-backed small businesses are a critical source of innovation essential to accomplishing the missions of NIH, DoD and more recently the interest within the Department of Energy to work with the venture capital industry to develop alternative energy sources. Excluding such business from SBIR participation will do nothing to help advance the goals of these agencies at a time when we need as much access to innovation as possible to solve serious issues around homeland security, energy dependence, and quality healthcare.

Case in point: the Department of Defense (DoD) Office on Innovation recently concluded that the SBIR program could have the additional benefit of being a mechanism to provide early access to venture-backed technologies the government wouldn't see otherwise. Programs such as the Defense Venture Catalyst Initiative (DeVenCI) focus on increasing DoD awareness of emerging commercial technologies developed by non-traditional DoD procurement sources. During this process, the DoD may come across a promising venture-backed technology that could solve a significant national security challenge. However, the technology may require additional research that a venture capital firm can not afford but the SBIR program could. Yet the SBA's policy would preclude an SBIR grant and deny government access to cutting edge technologies. These technologies exist across all the areas that venture capitalists invest -- life sciences, information technology and alternative energy. Yet, without SBIR support, these projects will not take place and will never be developed to the point that the government or general public can use them.

Conclusion

The venture capital industry is known for its patience when it comes to investing. And as an industry we have been extremely patient as the problems I've recounted are brought up again and again. We are extremely appreciative of the lawmakers who support the inclusion of venture-backed businesses in the SBIR program. But we have lost a great deal of time and innovation in the last seven years as we have allowed the Administration to discriminate against an entire subset of promising candidates – simply because others think they are promising too. In the mind of the SBA, venture backed companies should be penalized for succeeding. The SBIR program is a wonderful mechanism for the government and private sector to come together and do what everyone in this rooms wants us to do– innovate! We are asking Congress and the SBA to let us do just that. We support this bill and reauthorization wholeheartedly but only if we have an opportunity to contribute to its success. With venture capital working with government we have nothing to lose and everything to gain.

Thank you for your time.

Testimony of:

Mark B. Leahey, Esq.
Executive Director
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"

March 13, 2008

Introduction

Chairwoman Velázquez, Ranking Member Chabot, 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 Executive Director 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 current efforts to reauthorize the SBIR program.

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 and by 14.6 percent in 2006. 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.

Legislation

MDMA was very pleased that the House of Representatives voted to proactively address the individual ownership requirement by passing H.R. 3567, the Small Business Investment Expansion Act of 2007, in September of last year. In short, H.R. 3567 amends the Small Business Act to provide that, for purposes of determining whether a small business is independently owned and operated or meets specified small business size standards, the Administrator shall not consider a business to be affiliated with a venture capital operating company (or with any other business that the venture capital operating company has financed) if: (1) the venture capital operating company does not own 50% or more of the business; and (2) employees of the venture capital operating company do not constitute a majority of the board of directors of the business. The legislation further 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: (1) that owns 50% or more of the business; and (2) the employees of which constitute a majority of the board of directors of the business.

The clarification of the ownership requirement made in H.R. 3567 is a critical step-forward in returning to the envisioned level of public-private partnership in the development of innovative technologies under the SBIR program. Furthermore, the combination of investment from both SBIR and venture capital is vital to the further development of life-saving medical devices.

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 similar to those passed in H.R. 3567, 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 $200,000 and $1.5 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.

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.

Statement
of
Mark Skinner

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Before The

United States House of Representatives
Committee on Small Business

Full Committee Hearing on "Legislation to Reauthorize the Small Business Innovation Research Program"

March 13, 2008

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Madam Chair, Ranking Member, and Members of the Committee on Small Business:

Thank you for the opportunity to appear today to present the views of the State Science & Technology Institute (SSTI) on the importance of reauthorizing the Small Business Innovation Research Program (SBIR) program and the Federal and State Technology Partnership (FAST).

What is SSTI?
Before I begin, unlike the distinguished organizations with which I'm sharing the panel today, I presume SSTI may require a little introduction. I serve as vice president of a national nonprofit organization based outside Columbus, OH, that is dedicated to leading, supporting, and strengthening public-private efforts to improve regional economies through science, technology and innovation. SSTI was created with funding from the Carnegie Corporation of New York 12 years ago to serve as a clearinghouse of best practices in state and local technology-based economic development and as the professional development arm of the then-emerging field of tech-based economic development. Our membership consists of the 39 leading science & technology organizations and agencies within 35 states as well as 150+ additional regional, university and non-profit tech-based economic development organizations.

For the broader public, SSTI publishes a free e-newsletter entitled the *SSTI Weekly Digest*, which has a readership of approximately 75,000 individuals across the globe. The *Digest* reviews the top state, local, federal and international news for the tech-based economic development community. Subscription information and the complete 12-year archives of the newsletter are available on our website: ssti.org.

Part of SSTI's mission is to serve as a neutral convener for discussion and advancement of key issues to further state and federal cooperation on science and technology. It is this role that led SSTI to be chosen to prepare a report in 1999 on *State and Federal Perspectives on the SBIR Program* for the U.S. Innovation Partnership, a task force of the now-defunct Technology Administration within the Department of Commerce. For *Perspectives*, SSTI conducted extensive interviews with the SBIR program managers at all of the participating federal agencies as well as 51 state-level officials who managed state SBIR programs in 46 states. Many of the findings of that report helped frame the original design of FAST.

With the reauthorization of SBIR required for the highly successful program to continue, our state members asked SSTI to explore ways to support the program's continuation and to improve and reauthorize FAST.

Who Am I?
Personally, my experience with SBIR extends over two-and-one-half decades. I was the designing manager of Ohio's SBIR Program for its first six years. We had a budget of $2.4 million and provided grant writing assistance and bridge funding directly to small tech firms in the state. With SSTI, I was a lead author with Marianne Clarke on *State and Federal Perspectives on the SBIR Program* and helped draft the initial FAST program legislation. In addition, more recently I served on the Committee of Visitors for the National Science Foundation SBIR Program. That experience provided me a behind-the-scenes understanding of some of the challenges federal agencies face in implementing the SBIR program – even an agency with as efficient and effective an operation as NSF's SBIR shop under the very capable direction of Kesh Narayanan.

The Importance of SBIR to State Innovation Strategies
SBIR over the past 25 years has evolved into a state-federal-industry partnership in ways that I do not believe are fully realized by the federal agencies and perhaps even Congress. I will spend the balance of my testimony explaining why SSTI holds this position and exploring the opportunity to strengthen the state-federal element of the partnership through the important piece of legislation under consideration today – reauthorization of SBIR and FAST.

States Have Been SBIR Partners since Nearly Day One
Two of the greatest barriers to growth for small technology companies are 1) access to early stage capital and 2) adequate technical and managerial expertise to carry an innovation into commercial success. Over the past 25 years, the SBIR program has proven to be a valuable financial tool for small technology firms during the high risk stages of research feasibility and proof of concept.

Recognizing this and hoping to ensure successful SBIR participation by more of their local technology companies, within a year of SBIR's first government-wide implementation in FY 1983, states began developing programs to provide outreach and technical assistance to current and prospective SBIR award recipients. I was part of Ohio's initial efforts, beginning in early 1985 through the Ohio Department of Development. Similar activities were underway in the mid-Eighties in Michigan, New Jersey, New York, North Carolina, Oklahoma, and Pennsylvania, to name just a few of the early SBIR partners.

Today nearly every state has some form of SBIR-related outreach or assistance on its books, has localized SBIR assistance programs, or both. In fact, as has been the case for more than a decade, SBIR assistance remains one of the most widely applied state strategies to encourage technology-based economic development. I've attached a list of many state and local SBIR efforts as evidence.

As a result of states seeing such economic development value in the federal SBIR program, states now:

- **Serve as *de facto* marketing and outreach partners for the federal SBIR programs.**
The dozens of state and local SBIR outreach efforts in place around the country are serving as the *de facto* marketing arms of the federal SBIR programs. And rightly so, as these state initiatives are on the ground and in the trenches with the small tech firms, the university researchers and the individual innovators on a daily basis. State and local technology-based economic development programs are positioned to identify the right firms to compete for federal SBIR funding and the right SBIR research topics for their client bioscience and technology companies to exploit.

- **Filter potential applicants for appropriateness and likelihood of Phase I success.**
State and local technology-based economic development organizations interact with thousands of industry and university researchers across the country each day. As they work with their client firms, tech-based economic development initiatives are able to assess the company and technology strengths – most often using the technical and market skills of private and academic experts – to outline individualized strategies that increase the likelihood of commercial success. Alternately these customized paths toward entrepreneurship can be beneficial by avoiding unnecessary failures and wasted resources. SBIR is just one of the financial tools available to firms, but is not the right fit for all technologies or companies. By this triage service, states are reducing the number of unqualified and ineligible SBIR Phase I proposals submitted to the federal agencies and the administrative costs for the federal agencies.

- **Move SBIR technologies closer to commercialization.**
Nearly every state invests significant funding toward other technology-based economic development initiatives to ensure greater success of small technology and life science businesses – including more than $1 billion in new commitments made by states legislatures last year along. State portfolios to support small tech businesses include direct financial assistance, research financing, entrepreneurship services, incubator facilities, and linkages to private equity and manufacturing sources research financing, entrepreneurship assistance and public/private equity partnerships. These programs are so valuable and numerous that BIO regularly publishes a directory of state programs, incentives and tax policies that support

life science and medical device R&D to the tune of several billion dollars annually (see: http://bio.org/local/battelle2006/).

States are not spending millions of dollars, collectively, toward furthering the goals of the federal SBIR program out of philanthropic sympathy for the R&D missions of the federal agencies. It is solely because states recognize SBIR serves an important and vital economic development function for knowledge-based economic prosperity. It must be continued. It must be reauthorized.

A seldom recognized benefit of such intense state interest in SBIR has been to help broaden the geographic and demographic reach of the federal SBIR program – explicit goals of the legislation under consideration by the Committee today. Because so many states engage in SBIR outreach and Phase I assistance, ranging from simply broadcasting the solicitation openings and annual conference to Phase Zero grants for proposal, more companies are aware of the opportunities presented through SBIR.

Strengthening the Partnership: Reauthorizing and Improving FAST

Better linkages between the federal SBIR program and the cadre of state and local tech-based economic development programs are vital for maintaining the greatest flow of research-based innovations through America's small businesses and into the global marketplace. In SSTI's 1999 interviews with the federal program managers, SBIR outreach and commercialization were viewed as the most fruitful areas of state-federal cooperation. They remain so. Fortunately those are the two areas that are most fruitful for state economic development goals as well.

I respectfully recommend the Committee consider including language in the reauthorization bill that leads to the timely release of information regarding federal SBIR program applicants and award recipients. The result would be more small businesses receiving technical and financial assistance at earlier stages in developing SBIR-funded research and future SBIR applications, increasing the likelihood of commercial success.

Another suggestion is the development and implementation of an intensive training and certification program for state and regional SBIR assistance efforts. The training program would address the skills that federal agencies desire in state SBIR efforts and the educational needs identified by small technology businesses and state SBIR assistance providers. The result will be more unified and higher quality technical assistance being provided everywhere in the country, helping to level the playing field for small tech firms located in areas and within populations that do not perform as well historically in the SBIR program. Participation of the federal SBIR program managers and SBA in an advisory and coordinating council would be valuable in designing and implementing the training program.

The Federal and State Technology Partnership can prove a useful vehicle for implementing these suggestions. However, simply renewing FAST as it was originally structured would miss a great opportunity to improve the program's impact.

To prepare its recommendations for improving FAST, SSTI convened two conference calls of the lead science & technology organizations for the states. Representatives of 25 of the 35 member states were able to participate on calls – a strong indication of the states' enthusiasm for SBIR reauthorization and improving FAST. Several were multiple-time FAST recipients.

Participants on the calls shared stories regarding how FAST was originally implemented, identified challenges that impeded service delivery to client small businesses, and suggested solutions for inclusion in the SBIR reauthorization bill. I developed and circulated a consensus email for the group's revision and approval. The recommendations below flowed from this process.

Recommendations for Improving FAST

- The Reauthorization level should be increased to $20 million per year to allow more useful multi-year grants to a greater number of states - increasing the opportunity to expand SBIR participation and speed the commercialization of SBIR developed technologies. The previous authorization level was $10 million.
- A FAST Advisory/Oversight Council should be established to insure the FAST program is reaching its goals. Representation should include:
    - The Small Business Administration (chair of council)
    - Each of the federal agencies required to participate in the SBIR program
    - Small businesses who are current or past SBIR recipients or their representative organizations
    - SBIR outreach and assistance service providers or their representative organizations
- The current requirement should remain that each state is limited to submitting only one FAST proposal per year. While the services to be performed through a FAST proposal may be provided by public, private and/or nonprofit organizations, the proposal is to include written endorsement by the governor of the state to help to ensure the FAST effort is integrated with the balance of the state's portfolio of investments to help companies commercialize technology.
- FAST should include a requirement that proposals from states address one or more of the following goals for FAST:
    - Increasing applications and awards from underperforming geographic regions (measured by the number of SBIR awards);
    - Increasing applications and awards from underrepresented population groups, such as women- and minority-owned firms (measured by the number of SBIR awards); and
    - Improving commercialization success for technologies developed with SBIR funding.
- Multi-state proposals should be acceptable but must include endorsement letters from each participating state governor. States should not be able to simultaneously submit an individual proposal and be part of a multi-state proposal.
- FAST awards should be for multi-year periods of no less than three years. Milestones or performance goals should be reviewed prior to disbursal of year 2 and year 3 funds.
- Awards should be selected competitively through peer review. Reviewers should include federal SBIR program managers as well as private individuals and organizations knowledgeable of SBIR, the innovation process, technology commercialization, and state and regional technology-based economic development programs.
- To ensure the FAST Partnership is of optimum value for the federal SBIR agencies and the state TBED programs, FAST should include educational, training and networking initiatives developed cooperatively among the federal SBIR agencies and state TBED programs.
- Strong consideration should be given for the FAST Partnership to be administered by the Office of Industrial Innovation and Partnerships within the Directorate of Engineering at the National Science Foundation (NSF).
- In development of the FAST selection criteria, NSF and the FAST Advisory/Oversight Council should consider requiring applicants to convincingly demonstrate the following:
    - That the proposed services and activities will reach either an underperforming geographic area or underrepresented population group (measured by number of SBIR awards) AND/OR improve the commercialization success of technologies developed with federal SBIR funds;
    - How the services to be offered complement and are integrated into the existing public-private innovation support system for the targeted region or population; and

- How the applicant will measure the effectiveness and impact of the proposed services and activities.

I know these final recommendations will cause some consternation and will require involvement of additional committees in the House and Senate with oversight of NSF programs. Nevertheless, I believe strongly, based on the experiences of the vast number of FAST recipients during its initial and only three funding cycles, that moving FAST from SBA and to NSF would ensure the partnership is of greatest value for the states, the federal SBIR agencies and, most importantly, the small technology businesses SBIR is intended to serve.

Thank you again for the opportunity to appear today. I hope as the Committee considers SBIR and FAST reauthorization, these suggestions may be taken into consideration. SSTI will be happy to assist the committee further as it works through reauthorization issues.

State Initiatives Supporting SBIR

State	Program

Alabama

Procurement Technical Assistance Program of Alabama, Alabama SBDC
http://www.asbdc.org/program.htm
SBIR advising

University of Alabama Huntsville SBDC
http://nearsbdc.uah.edu/counseling.htm
SBIR advising

Alaska

trend Phase 0, Alaska SBDC
http://trendalaska.org/node/1
Phase 0 financial and technical assistance, SBIR advising

Arizona

Arizona Technology Enterprises
http://www.azte.com/ForFaculty/Startups/Startupservices/tabid/87/Default.aspx
SBIR advising

AZFAST Grants, AZ Dept of Commerce
http://www.azcommerce.com/BusAsst/Technology/AZFAST.htm
Grant for preparing applications

SBIR Phase I & II Workshops, ASU Technopolis
http://www.asutechnopolis.org/programs_details.cfm?program_id=43
Phase I & II Proposal Writing Workshops

Arkansas

Arkansas Science and Tech Authority - Technology Transfer Assistance Awards (TTAA)
http://www.asta.arkansas.gov/ttagp_guidelines.html
up to $5,000 to offset costs of SBIR Phase I applications, including travel

California

SBIR Workshops, Office of Technology Licensing, USC
http://www.usc.edu/academe/otl/events.htm
SBIR workshops

State	Program
Colorado	
	SBIR Colorado http://www.sbircolorado.org SBIR advising
Connecticut	
	ctsbir.com - Connecticut Center for Advanced Technology, Inc. http://www.ccat.us/sbir/ coaching, reviews Phase I and Phase II proposals
Delaware	
	Delware EPSCoR - Phase 0 Seed Grants http://www.epscor.dbi.udel.edu/funding.php up to $10,000 to offset costs of SBIR Phase I applications
Florida	
	Enterprise Florida Phase 0 SBIR/STTR Program http://www.eflorida.com/ContentSubpage.aspx?id=872 up to $3,000 to offset costs of SBIR Phase I applications
Georgia	
	SBIR Assistance Program for the State of Georgia http://innovate.gatech.edu/Default.aspx?tabid=1717 consulting/advisement for companies looking for SBIR assistance
Hawaii	
	SBIR Matching Grant and Assistance http://www.htdc.org/sbir/matching.asp SBIR financial and technical assistance, matching grant for Phase I
Idaho	
	Idaho Small Business Assistance Fund, Idaho Dept. of Commerce http://technology.idaho.gov/Portals/33/documents/SBIR%20brochure%20Feb2007.pdf up to $4,000 to offset costs of SBIR Phase I applications, SBIR advising

State	Program
Illinois	
	DECO Innovation Challenge Grant & Matching Grant Programs http://www.commerce.state.il.us/dceo/Bureaus/Technology/Technology+Grants+Programs SBIR advising, up to 50% of the funds awarded through the federal SBIR Phase I award
Indiana	
	21st Century Fund Program, Indiana Economic Development Corporation http://www.in.gov/iedc/166.htm SBIR financial and technical assistance, matching grant for Phase I
Iowa	
	Iowa State University Research Foundation http://www.techtransfer.iastate.edu/en/sbir_sttr_assistance/ SBIR advising
Kansas	
	Kansas Bioscience Matching Fund for Phase I & II Grants http://www.kansasbioauthority.org/how_we_can_help/Matching.aspx up to 50%, for a maximum of $50,000 for Phase I; up to 50%, for a maximum of $375,000 for Phase II
Kentucky	
	SBIR Matching Funds Program, Kentucky Science and Technology Corporation http://www.thinkkentucky.com/dci/sbir/ Matching grant for Phase I & II, Phase 0 grant
Louisiana	
	Louisiana SBIR/STTR Phase 0 Part I Program (through LSU) http://www.bus.lsu.edu/research/lbtc/CapAccess/Phase0PartI.htm up to $3,000 to offset costs of SBIR Phase I applications
Maine	
	Maine Technology Institute - SBIR/STTR Phase 0 Proposal Assistance Program http://www.mainetechnology.org/content/306/SBIRSTTR_Phase_0/ up to $5,000 to offset costs of SBIR Phase I applications, SBIR advising

State	Program
Maryland	
	Maryland Minority R&D Initiative & Rural Business Incubation Initiative, TEDCO http://www.marylandtedco.org/tedcoprograms/ SBIR advising
Michigan	
	SBIR Emerging Business Fund http://michigan.org/medc/ttc/sbir.asp SBIR financial and technical assistance, matching grants for Phase I
Minnesota	
	Minnesota SBIR/STTR Assistance Program (through DEED) http://www.deed.state.mn.us/sbir/MNAssistancePgm.htm consulting/advisement in preparing and evaluating applications
Mississippi	
	Mississippi Phase 0 Program & MS-Fast, Mississippi Technology Alliance http://www.technologyalliance.ms/MSFast/services.php up to $3,000 to offset costs of SBIR Phase I applications, notification of SBIR program news
Missouri	
	CET SBIR Training Program http://www.emergingtech.org/services.html hosts two-day grant workshops, consulting/advisement in preparing applications
	Missouri Federal and State Technology Partnership (MoFAST) http://www.missouribusiness.net/fast/about.asp consulting/advisement in preparing and evaluating applications
	Missouri Univ. of S&T SBIR/STTR Program http://ecodevo.mst.edu/info/ceo_es_sbir.html consulting/advisement/connect to univ. researchers in preparing applications
Montana	
	Montana SBIR, MT Dept of Commerce http://sbir.state.mt.us/ SBIR advising, Phase 0 grants

State	*Program*

Nebraska

SBIR/STTR Counceling through Nebraska Small Business Centers (NSBC)
http://www.nbdc.unomaha.edu/SBIR/
consulting/advisement in preparing and evaluating applications

New Hampshire

New Hampshire SBDC
http://www.nhsbdc.org/service/OEI.html
SBIR workshops

New Jersey

SBIR Bridge Grant Program, Commission on Science & Technology
http://www.state.nj.us/scitech/entassist/sbir/
Bridge grant, SBIR advising

New Mexico

SBIR Outreach Center at Technology Ventures Corporation (TVC)
http://techventures.org/news/index.php?releaseID=047
grant writing assistance and instruction

New York

NYSTAR New York SBIR Outreach Program
http://www.nystar.state.ny.us/sbir/outreach.htm
consulting/advisement in preparing and evaluating applications

North Carolina

One North Carolina SBIR Matching Funds & Phase I Incentive Program
http://www.ncscienceandtechnology.com/
Matching funds for Phase I & II, SBIR advising, Phase 0 grants

North Dakota

North Dakota SBIR/STTR (NDSS)
http://www.techconnectnd.com/
consulting/advisement in preparing and evaluating applications

State	Program
Ohio	
	Ohio SBIR/STTR Office through Ohio Dept. of Development http://www.odod.state.oh.us/tech/SmallBusinessInnovationResearch.htm consult/advise/connect university researchers in preparing applications
Oklahoma	
	OCAST SBIR Program http://www.ocast.state.ok.us/Programs/SBIRSTTR/tabid/58/Default.aspx SBIR financial and technical assistance, Phase 0 grants, Bridge grants
Oregon	
	Oregon SBIR State Summitt http://www.oregonsbir.org/ held in Portland, March 2008
	Oregon SBIR/STTR Matching Grant Program through OECDD http://www.bizcenter.org/Services/7530/6198/7572 up to $3,000 for writing consultant; up to $500 for travel; of to $500 for proposal review
Pennsylvania	
	Innovation Partnership's MicroVoucher, MicroGrant, Travel & Training program http://www.innovationpartnership.net/microvoucher.html up to 50% for proposal assistance and travel
South Carolina	
	SC EPSCoR/IDEA Phase 0 Program http://www.scepscor.org/solic/home.html up to $6,000 to offset costs of SBIR Phase I applications
	SC Launch Phase I Matching Grant Program http://www.sclaunch.org/apply_sbir_sttr.shtml 100% of the Federal SBIR/STTR Program Phase I award, not to exceed $100,000.
South Dakota	
	SBIR Workshops, Dakota State University http://www.sbir.dsu.edu/ SBIR workshops

State	*Program*

Tennessee

Phase I Proposal Writing Workshops through Univ. of Tenn.
http://www.cis.tennessee.edu/government/research_grants/sbir_news.shtml
training for preparing SBIR applications

Tennessee Technology Development Corporation Phase 0 Program
http://www.tntechnology.org/sbirsttr.html
up to 50% of costs, for a maximum of $4,000

Texas

SBIR Conference, Texas Office of the Governor, Economic Development and Tourism
http://www.texasone.us/site/PageServer?pagename=nat_conference
SBIR conferences

Utah

Technology Commercialization Office, USU
http://research.usu.edu/
SBIR workshops

Vermont

Vermont SBDC
http://www.vtsbdc.org/technology.cfm
SBIR advising

Virginia

CIT SBIR Workshops and Phase I and Phase II Assistance
http://www.cit.org/programs/entrepreneur/federal_funding-04.html
suite of programs, including funding assistance and patent review, SBIR workshops

Washington

Washington Technology Center's Business Consulting Services
http://www.watechcenter.org/index.php?p=SBIR+Program&s=376
offers 4 free hours to help with SBIR/STTR consulting

West Virginia

WVSBDC Research and Commercialization Assistance Grant Program
http://www.sbdcwv.org/research.php
Grant for preparing applications

State	*Program*
Wisconsin	
	Wisconsin SBIR-Fast One on One Assistance http://www.wisconsinsbir.org/onetoone.cfm consulting/advisement in preparing and evaluating applications
Wyoming	
	Wyoming SBIR/STTR Initiative (WSSI) http://uwadmnweb.uwyo.edu/sbir/news.html offers state SBIR conferences, up to $5,000 to offset costs of SBIR Phase I applications

The Small Business Innovation Research (SBIR) Program: Creating the Future Foundation of Science and Commerce

Testimony before the U.S. House Small Business Committee on SBIR Reauthorization Bill

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13 March 2008

Mr. Chairman, members of the committee, distinguished guests:

It is with great enthusiasm that I present this testimony in regard to the reauthorization of the Small Business Innovation Research (SBIR) grant program. It is not often that one has the opportunity to speak on behalf of a government program that meets and in many cases exceeds its expectations. In short – it works.

Creating a Climate for Small Business Innovation

Quite simply, in order to create the future – to reach the many and considerable goals of enhancing, improving, and moving forward the goals of commerce, science, and society - we must begin that journey today. It is not enough to say that we want a better and brighter future, a more robust economy, a cure for cancer, or an improved quality of life for future generations. We must take positive and proactive steps today in order to reach those goals. We must continue to create an environment that supports the pursuit of not only the foundational science needed, but the translation and application of that science to productive use in business and society.

The Small Business Innovation Research (SBIR) program was conceived for just such a purpose. It creates and supports an environment that encourages the scientific and commercial pursuits needed to advance the applied technologies fundamental to the attainment of goals that benefit the United States and the world. It creates an environment that supports and encourages the nexus of innovation and commerce.

Creating a Leveraged Impact

In preparing my remarks for today, I took some time to gather data and input from a number of my colleagues in the both the private and public sectors. In my both research and education activities, I can testify first hand the strong positive impact that the SBIR program has had in Southwestern Ohio. In the four county Region V of Ohio (Butler, Clermont, Hamilton, and Warren counties) in 2004 and 2005, there were a total of 105 Phase 1 and 2 SBIR grants made to a 92 different ventures totaling nearly $27 million dollars, from a low of $67,000 to a high of $981,000. These SBIR's cut across a broad range of scientific and commercial applications including but not limited to biology, chemistry, engineering, health care, nanotechnology, and physics to name a short list.

SBIR funding Region V Ohio (Butler, Clermont, Hamilton, Warren Counties) 2004-2005

# of Phase 1 SBIR	80	# of Phase 2 SBIR	25	Total # Phase 1 and 2 SBIR	105
Total	$ 9,158,890.00	Total	$ 17,819,124.00	Total	$ 26,978,014.00
Avg	$ 114,486.13	Avg	$ 712,764.96	Avg	$ 256,933.47
Min	$ 67,353.00	Min	$ 374,993.00		
Max	$ 499,568.00	Max	$ 981,229.00		

The Case of the Hamilton County Business Center

The Hamilton County Business Center (HCBC) is one of the most successful public incubators in the U.S. It is located in Hamilton County, OH as an integral part of The Hamilton County Development Center (HCDC). Under the skillful guidance of HCDC President, David Main, and the HCBC Director Pat Longo, we can gain a glimpse of the leveraged impact that the SBIR program can have in helping to create an environment the encourages and fosters the progress I mentioned earlier.

Over a dozen current and graduate HCBC companies have been able to advance both scientific and commercial goals as well as grow their business with an assist from the funding, connections, and processes the SBIR program provides. A brief sample of these venture include the **Maverick Corporation** (providing cutting-edge materials technology, setting the industry standard for service and developing advanced materials and technologies to the chemical, industrial, medical, missile, and space industries); **The Modal Shop** (providing structural vibration and acoustic sensing systems to engineers worldwide); **Sheet Dynamics** (whose expertise lies in the field of Mechatronics, the synergistic combination of mechanical and electrical engineering including controls, signal processing, image processing, and vibration); and **Advanced Biological Technologies** (developing a proprietary technology device used in diabetes research and development),

The HCBC not only sees the SBIR program as a strong component of its overall capital strategy for early stage research companies, but also recognizes the value to the stability and vitality of many early stage small business ventures. The competitive process of the SBIR program provides companies with difficult to secure, but incredibly needed funding to enhance the innovation and commercialization processes that early stage ventures need to go through to advance technology oriented products and services to solve market issues.

To quote Mr. Pat Longo, Director of the HCBC, "Without SBIR dollars, a number of HCBC's best success stories would not have made it to being successful product driven, market focused companies." For more information on the Hamilton County Business Center, please contact:

Mr. Pat Longo, Director, Hamilton County Business Center, 1776 Mentor Ave., Norwood, OH 45212, Phone: 513-631-8292, Email: longo@hcdc.com, Web: www.hcdc.com

The Case of the BIOSTART Incubator

In addition to the Hamilton County Business Center, Southwest Ohio is fortunate to have a state-of-the-art lifescience incubator located on the University of Cincinnati campus – BIOSTRART. Under the leadership and direction of BIOSTART President, Ms. Carol Frankenstein, the past ten years bear witness to leveraged success of the creation of an environment that fosters creativity and innovation at the nexus of science and commerce. The SBIR program enables these life science companies to conduct initial proof of concept and pre-clinical and clinical field studies to move their products to market. To quote Ms. Frankenstein, "This is a niche that even early stage funds are reluctant to fill because of the high risk and long time to market." Clearly, the SBIR program is making a strong and sustained difference in advancing these scientific and commercial opportunities. For more information on BIOSTART, contact:

Carol J. Frankenstein, President, BIOSTART, Lifescience Catalyst and Community, 3130 Highland Ave. Third Floor, Cincinnati, OH 45219-2374, (513) 475-6610 phone, (513) 221-1980 fax, email: cfranken@biostart.com.

Cincinnati Creates Companies

After extensive planning over the course of two years by a multi partner, cross disciplinary planning/steering committee, in January 2004, Cincinnati Creates Companies held its first class meeting for aspiring technology entrepreneurs in January 2005. Made possible in part by a $600,000 grant for the National Science Foundation's Partnerships for Innovation, the program is intended to fuel nascent technology entrepreneurship in the Greater Cincinnati and Northern Kentucky area.

Together, the University of Cincinnati, the Colleges of Business, Engineering, and Medicine, the UC Center for Entrepreneurship Education & Research, Children's Hospital Medical Center, Bio/Start, CincyTech USA, and the Hamilton County Business Center put together a hands-on, outcome-oriented program that supports innovation through the development of people, tools, and the infrastructure needed to connect new scientific discoveries to practical and commercial applications and uses. The co-founders of the this innovative technology entrepreneurship program include myself, Dr. Charles H. Matthews, University of Cincinnati; Dr. Dorothy Air, University of Cincinnati; Dr. Ed Grood, University of Cincinnati; Ms. Carol Frankenstein, BIOSTRART; Mr. Pat Longo, HCBC; and Dr. Sid Barton, University of Cincinnati.

Overall, the CCC program provides three modules for the participants. The first module consists of the 10-week intensive classroom portion conceptualized, formulated and executed by Dr. Matthews. The rigorous curriculum includes all aspects of the business planning process and is facilitated by guest speakers, videos, lectures, and group discussions. Sessions are videotaped for inclusion on the class Blackboard web site for later viewing or if someone misses a class. All materials, lectures, PowerPoint slides, videos, etc. are archived on the Blackboard web site. At the end of the 10-week course, all participants present their baseline business plans. The second module consists of a 15-week structured mentor program, including extensive one-on-one feedback from Dr. Matthews on the written baseline business plans complete in the first module. Each participant is assigned an individual mentor to work with them to refine the business plan. Every other week during this module, the cohort gathers to hear a panel present a topic to assist in the development of their business plans. Topics include, networking, financing, organizing, managing technology ventures, and more. The third module consists of a business plan competition. All participants are encouraged to vie for seed grants and in-kind services to help with the launch and growth of their ventures. Over the four years, teams will have the opportunity to vie for over $200,000 in seed money.

The program provides an educational framework for taking participants through feasibility assessment, concept development, business plan development and implementation planning. At the same time participants are learning key principles associated with each stage, they will be applying the information to their own business plan. To enhance successful outcomes, each participant is directly linked to a pipeline of relevant resources to take their idea stage to successful company formation/growth. Participants who complete the program will be eligible to present their business plans before a panel of judges for potential funding and feedback. Any funds received by a participant directly through the program or as a result of external connections are done on a competitive basis. All who participate in the program will have the opportunity to gain valuable exposure and connections through the Cincinnati SoundingBoard and other business groups within the network.

During the three years of the initial NSF grant, 47 nascent technology ventures were selected from over 150 applicants. The inaugural group of 16 ventures, the second cohort of 12 ventures, the third cohort of 10 ventures and the fourth cohort of nine ventures (nearly 100 individual participants in all) met weekly over three academic quarters. In addition to learning necessary skills for launching and sustaining a successful business, participants received personal mentors who actively guided their work on their individual business plans.

Each participant entered the program at a slightly different stage in the business launching process, yet each received significant benefit from the program.

It is particularly noteworthy that the following BIOSTART client companies that participated in CCC are SBIR grant recipients:

Bexion Pharmaceuticals (Xioayang Qi) is a start-up company focused on the development of cures for cancer. The company has a first-in-class biologic product with data-driven potential for treatment of a broad range of human cancers.

PDS Biotechnology (Frank Bedu-Addo) PDS Biotechnology Corporation is a biopharmaceutical start-up company pioneering the development of potent and targeted lipid-based immunotherapies for the treatment of cancer and infectious diseases. PDS utilizes its own proprietary technology to treat specific cancers and infectious diseases for which no cures currently exist.

Satiety Solutions (Randy Sallee) Satiety solutions is positioned as a specialty, platform R&D enterprise, focused on central nervous system drug targets for enhanced satiety through either novel mechanisms of action, or reformulations of off-patent drugs with proven therapeutic utility to enhance satiety and reduce caloric intake.

Spineform LLC (Joe Reynolds) Cincinnati-based SpineForm is working to advance and commercialize less-invasive spinal deformity surgical treatment without fusion.

In today's fast changing, complicated world, it takes a dedicated effort to create and sustain an environment that encourages and facilitates the ideation, conceptualization, formulation, and implementation of technology ventures. The NSF funded program, University and community partners, dedicated volunteers, and willing participants when leveraged with the SBIR program makes for a very power combination.

Creating the Future

In closing, I am reminded of two of my favorite quotes. The first is attributed to Michelangelo:

"The greater danger for most of us lies not in setting our aim too high and falling short; but in setting our aim too low, and achieving our mark." *Michelangelo*

The other is attributed to the Roman orator Seneca, who said, "It is not because things are difficult that we do not dare; it is because we do not dare that they are difficult." *Seneca*

The mission/mantra I wrote for the Center for Entrepreneurship Education & Research is simply, "To remove barriers and create gateways to the next generation of entrepreneurs…"

I encourage you to consider that vital role that the SBIR program plays in removing those barriers and creating gateways that encourages today's entrepreneurs to aim high and dare to create a vibrant future built on the foundations of science and commerce.

Thank you.