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THE NIH/SBIR EXCLUSION IN THE RECOVERY ACT

HEARING

BEFORE THE

COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

JUNE 22, 2009

Printed for the Committee on Small Business and Entrepreneurship

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THE NIH/SBIR EXCLUSION IN THE RECOVERY ACT

MONDAY, JUNE 22, 2009

UNITED STATES SENATE,
COMMITTEE ON SMALL BUSINESS
AND ENTREPRENEURSHIP,
Rockville, MD

The Committee met, pursuant to notice, at 12:59 p.m., in the 7th Floor Hearing Room, Stella B. Warner Montgomery County Council Office Building, Hon. Benjamin L. Cardin, presiding.

Present: Senator Cardin, Representative Van Hollen, and Representative Edwards.

OPENING STATEMENT OF THE HONORABLE BENJAMIN L. CARDIN, A UNITED STATES SENATOR FROM MARYLAND

Senator CARDIN. Well, let me welcome everyone to this hearing of the Small Business and Entrepreneurship Committee of the United States Senate. I particularly want to thank Senator Landrieu and Senator Snowe, the chairwoman and ranking member of the Small Business Committee, for permitting this field hearing to take place and allowing me to chair the hearing today in Montgomery County.

I want to thank my colleague, Donna Edwards, who is joining me today. Congresswoman Edwards sits on the Science Committee as a very active member on these issues, and we very much appreciate her attendance today. We expect to be joined by Congressman Chris Van Hollen, who also represents Montgomery County in the Congress of the United States, does a fabulous job with people of this region, and serves on the Ways and Means Committee.

So I appreciate my colleagues being here, and I understand the schedule and expect that they may have to leave during the hearing, and I thank you very much for being here.

I see Councilman Michael Knapp is here. First of all, let me thank Phil Andrews and the full Council for allowing us to use this facility. And I want to thank Councilman Knapp for his interest in this issue. I had a chance to meet with the Council last week, and it was Councilman Knapp who pointed out to me one very obvious reason why we are so concerned about research funds getting to small businesses. And he made the very valid point that one of our objectives in getting our economy back on track is to energize companies to bring products to market, and that is an issue that we think was sensitized by the SBIR program. So that is another reason why we are pleased to convene this hearing today.

Earlier this year, Congress passed the American Recovery and Reinvestment Act. We did that to help bring our economy back on track from this recession. My colleagues mention frequently that in order to get our economy back on track, we have to stimulate small businesses, and that most of our job growth will come from small businesses. Small businesses are very suited for innovation and moving forward in creating new job opportunities. And that is true generally. It is also true with the SBIR program.

As the ARRA, the American Recovery and Reinvestment Act, worked its way through the Congress, in the Conference Committee, there was language that was added. Let me point out that during the consideration of the Recovery Act, there was an amendment that increased the funds to NIH from about three and a half billion to about $10 billion, a significant increase to say the least, in NIH funding. And as the Conference Report was being considered, language was added to the Conference Report that said, "the funds provided in this Act to NIH shall not be subject to provisions of 15 U.S.C. 638 and 15 U.S.C. 638(f) and (1)".

I welcome my colleague, Congressman Van Hollen, who I acknowledged earlier and thank him for joining me here.

What that meant was that the allocation of the funds to go through the SBIR program and STTR program, that is required under statute, was waived by the language added to the Conference Report.

I can assure you that we were unaware of that language being placed in the Conference Report. Senator Landrieu and Senator Snowe sent a letter to NIH, encouraging them to comply with the allocations because of the importance of the SBIR program to small businesses. Along with Senator Feingold, I also sent a letter to NIH, encouraging them to comply with the spirit of law. They could still allocate the money. There is nothing in the conference report that prohibits them from making funds available to small business. And to date, we have not received an adequate reply.

Now, I know that NIH is going through some transition and we certainly understand that, with a change in the administration. I strongly support, as do my colleagues, NIH in its mission and its budget, and I have worked very hard over the years to make sure that it can be the premier facility of its type in the world, located right here in Montgomery County. We are very proud of NIH, and we will continue to fight for their mission.

But I am puzzled as to why they are not responding to our request as it relates to the small business community and I am disappointed. We had hoped to have a representative from NIH with us today on this panel. I do not believe that someone will be here. Certainly, I think my colleagues would acknowledge it would not be too far from their job, right down the street, so it is certainly not a geographical problem. This is certainly a convenient location.

We are going to pursue this. This is a matter that is too important. We are going to make sure that NIH responds to our inquiries. We believe this matter can be adequately addressed if the will is there at NIH to make sure that there is a fair allocation of the research funds to the small business community. So we are going to continue to work on that, and I do not want the absence of NIH here today to impart anything other than that.

The SBIR program is 27 years old. It was established to stimulate technology innovation related to each participating federal agency's goal and mission, use small businesses to meet the federal research and development needs, and increase private sector commercialization of innovation that is from federal research, the point that Councilman Knapp was referring to.

The Small Business Technology Transfer program was originally created as a pilot program in 1992 to stimulate partnerships through small businesses and nonprofit research institutions, such as our universities, a partnership that we think makes a great deal of sense. But though departments with an annual external research and development budget of more than $100 million are required to allocate two and a half percent of that amount to the SBIR program, a rather modest sum, and departments with external R&D budgets of more than a billion must allocate 0.3 percent to the STTR program–so these are modest allocations but important allocations—11 different departments have SBIR programs and five have STTR programs. According to the Small Business Administration, the largest share awards is attributable to the Department of Defense and the Department of Health and Human Services.

Since the two programs were created, more than 100,000 awards have been made for a total exceeding $24 billion. In addition, small businesses receiving SBIR awards employ more than 1.5 million people, so funding for these programs is a major source of job creation. Between 2005 and 2009, Maryland companies received 1,004 SBIR awards, and the SBA reports that SBIR firms have received more than 84,000 patents.

This past Thursday, the Small Business Committee in the United States Senate, by a unanimous vote, reported out a bill reauthorizing both of these programs for the next 14 years.

The bill would increase gradually the SBIR program's allocation from two and a half percent to three and a half percent and double the STTR's allocation from 0.3 percent to 0.6 percent. The bill would also increase awards guidelines from $100,000 to $150,000 for phase one, and $750,000 to a million dollars for phase two. It also strengthens the Office of Technology at the SBA so it has the authority and resources to carry out its duty overseeing SBIR and STTR across the Federal Government.

I am pleased that a couple amendments that I authored were included. The first clarifies that small businesses with cooperation, research and development agreements with federal labs, can participate in the SBIR program, and the second clarifies that the allocations are not ceilings, with regard to the amount of funds that can be made available by NIH and other agencies. They can supplement SBIR and STTR awards with other funds for small businesses. We want to make that very clear, that we do not expect this to be a firewall with other programs of support for the small business community.

We are pleased that we do have a very distinguished panel that we will be hearing from as to the importance of these programs and the impact on economic recovery from the inability to release adequate funds under the ARRA. But before I turn to our panel, I will give my colleagues an opportunity to give an opening state-

ment. We will start with Congressman Van Hollen, who, I pointed out earlier, serves on the Ways and Means Committee and as part of the leadership in the House of Representatives. He is a close colleague and friend, and he does a great job representing the people of Montgomery County and Prince George's County.

OPENING STATEMENT OF THE HONORABLE CHRIS VAN HOLLEN, A UNITED STATES REPRESENTATIVE FROM MARYLAND

Representative VAN HOLLEN. Thank you, Senator Cardin. I want to start by thanking Senator Cardin for his leadership on a whole range of issues important to both Maryland and the country and for organizing this gathering, hearing, today on this very important subject. It is also great to be here with my colleague, Congresswoman Donna Edwards. And Mike Knapp, always good to see you, joining us from the County Council, and others here.

I am not going to be long. In fact, if I could just have my statement included in the record, I will not go through the whole thing.

[The prepared statement of Mr. Van Hollen follows:]

Statement of Representative Chris Van Hollen

Senate Committee on Small Business and Entrepreneurship

Rockville, Maryland Field Hearing

June 22, 2009

I'd like to thank Senators Cardin and Landrieu for convening today's hearing on the important subject of NIH's SBIR program and the Recovery act. I want to also thank them for the opportunity to join them and to participate.

According to the Bureau of Labor and Statistics, the number of unemployed Americans increased in May by 787,000 to 14.5 million. Since the start of the recession in December 2007, the number of unemployed persons has risen by 7 million, and the unemployment rate has grown by 4.5 percentage points.

Congress passed, and the President signed, The American Recovery and Reinvestment Act to help reverse this trend by quickening economic recovery with shovel-ready projects that would precipitate job growth in both the near and long term.

The National Institutes of Health, which is located in my district, received over $8 billion dollars in Recovery Act funds, but in an ironic twist, the act prohibited NIH from using those funds to support any of its SBIR program projects.

Small businesses drive the U.S. economy and are responsible for most of the country's job creation. The SBIR program is the typical route by which many small companies compete for funding support from NIH. Denying small businesses access to this important source of funding, given current economic conditions and the difficulty small business are having accessing private investment capital, could harm America's growing biotechnology industry and potentially curtail the industry's ability to continue to create sustainable job growth at a time when the country needs it most.

I look forward to hearing NIH's assessment of the SBIR program and the role it plays in advancing innovation. Again, I thank Senator Cardin for the opportunity to participate in today's hearing and I look forward to the testimony of our witnesses.

Representative VAN HOLLEN. I just want to underscore the importance of two things. Number one is when you passed the Economic Recovery Bill, it was designed to try and get the economy moving again. As all of us know, the economy was in a tailspin, and I think there are some promising signs that things have begun to at least flatten and end the downward spiral. But it will take some time for the economy, of course, to recover.

As part of that effort, we did substantially increase our investment in the National Institutes of Health. I am proud that they have their home in the 8th Congressional District because we believe there are lots of researchers out there with great ideas that have not been able to be funded. In fact, there is a big backlog of proposals out there that have already been deemed to be promising proposals that have not been adequately funded. So we want to make sure that the funds provided that increase for NIH.

We also need to recognize that small businesses are the engine of our economy and that the whole idea behind the SBIR grants is to take advantage of small business entrepreneurship and innovation with respect to the areas of scientific endeavor and technological breakthrough. So I believe it was very short-sighted for that provision to find itself in the Economic Recovery Bill to essentially say that the NIH portion of the funds were no longer subject to the requirement that that percentage go to SBIR grants, and that the Senator made that known to the Department of Health and Human Services as well as NIH.

We look forward to working with Senator Cardin and his colleagues as we do the reauthorization of SBIR in both the House and Senate to ensure that going forward, the SBIR program is not just saved but it is enhanced and strengthened going forward, because I think the results speak for itself. The National Academy of Sciences report indicated that this was a good investment for the country, and I am, like the Senator, disappointed that there is not a representative from NIH. If it was not due to inadvertence on their part, I think that means that we will have to let them know very clearly that we are disappointed and we will be following through and taking further action.

Thank you, Senator.

Senator CARDIN. Thank you very much.

Congresswoman Edwards represents also Prince George's County and Montgomery County.

OPENING STATEMENT OF THE HONORABLE DONNA F. EDWARDS, A UNITED STATES REPRESENTATIVE FROM MARYLAND

Representative EDWARDS. Thank you, Senator Cardin. And in their absence, thank you to Senator Landrieu and Ranking Member Snowe for enabling us to be here this afternoon, where it is always very important, I think, to be out in the field and among the community of people who share an interest, as we all do, in NIH and the small business program.

I have the responsibility in the Congress, I serve on the Science and Technology Committee, and it has oversight responsibility for the NIH. And on April 23rd, really just a few weeks ago, we held

a hearing about this very issue and both the challenges and opportunities of the SBIR program.

Mr. Glover, you testified before our committee that day. And also present was the deputy director from NIH, and we had an opportunity to explore the way that NIH views the program. I have to say that coming out of that hearing, that was somewhat surprising to me, that although supportive of the SBIR program, there seems to be a bit of, at least unexplained, reluctance about the program, about expanding it, providing more opportunities for small business. And I think it is important for us both on the Senate and the House side to come and get to the bottom of that.

Like my colleagues, I share the concern that, especially with NIH—and, of course, Prince George's and Montgomery County have the great benefit of being home to some of the best federal laboratory and research facilities in the country in addition to our education institutions. Both, internally, the programs within NIH and our other laboratories, as well as the supporting industry infrastructure is really important to our economy here in this region but also to our economy in this state.

So when we passed the American Recovery and Reinvestment Act, while it is important across the country to create—and all of us heard that—this notion of shovel-ready jobs, here in a state like Maryland, for us, in addition to the roads and infrastructure projects, infrastructure and shovel-ready means investing in research and technology and science. I mean, it is a backbone for our state.

So all of us in the delegation and with our colleagues in the Congress, we are pleased to be able to support increased funding for programs at NIH and NIST and NOAA and NASA, and all of the science and research facilities here, but disappointed about the inclusion of this exclusion in the legislation with respect to the SBIR program. And it seems very unfortunate because, as my colleagues have described, small businesses are really the engines and innovators, the creators, places where experiments can take place, and sometimes cannot take place, in a larger business setting, where we need to make investments in the early stages of research and science, not because you are ensured of success but because you are experimenting with the opportunity for success. And that is really important in science and investigation.

As some of you know, I started off my early days at the National Aeronautics and Space Administration at Goddard Space Flight Center, systems engineer for the Spacelab program, at a time when we were making investments in science, and people just said, "What are they doing over there?" But the fact is that making those investments now, 20 years hence, has proved to be the bedrock of what we are doing with our space telescope program and a range of other programs. And so, I deeply understand the importance of investing in technologies early and experiment. And you are nodding. I think that is great value of the SBIR program.

One of the questions that we released in the April 23rd hearing on the House side was also, in addition to small business, what the agency is doing with respect to incorporating the needs and the reach to minority businesses, to women businesses and entrepreneurs. I think that these still remain really important questions

in the context of the program, and partnering with institutions that are not your obvious larger educational institutions to invest in science technology and research.

So I look forward to your testimony today. I, like my colleagues, am disappointed that NIH is not here represented today, but I know that both from our delegation as represented here and our respective committees, that we will have increased opportunities over the next several weeks and months to probe a little bit more deeply of NIH about where it sees the direction of this SBIR program and how it will make the greatest use of resources to really support small business innovation and the range of those innovators in whom the NIH can invest. And so, I thank you very much for being here. And thank you, Senator Cardin, for your invitation, and I look forward to your testimony.

Senator CARDIN. Well, let me thank both of my colleagues for being here. As I pointed out earlier, I know the schedule today is difficult, so we just appreciate your being here as long as you can. It is certainly helpful.

Ms. Penny Pickett, representing the Small Business Administration, Acting Associate Administrator for Entrepreneurial Development, it is a pleasure to have you with us.

I might point out to all of our witnesses that your entire statements will be made part of record, and you may proceed as you would like.

STATEMENT OF PENNY PICKETT, SENIOR ADVISOR TO THE ADMINISTRATOR, ACTING ASSOCIATE ADMINISTRATOR FOR ENTREPRENEURIAL DEVELOPMENT, SMALL BUSINESS ADMINISTRATION

Ms. PICKETT. Thank you. Good afternoon, Senator Cardin, Representative Van Hollen, Representative Edwards. Thank you for the opportunity to speak with you today about a very important program for the Small Business Administration. Many of America's most powerful innovations start with small business. A study by the SBA's Office of Advocacy showed that small firms produce 13 to 14 times more patents per employee than do large firms, and these patents were cited more often than the average patent.

For decades, SBA has worked to harness that innovation through programs like the Small Business Innovation Research program. Since 1982, SBIR helped to push small business innovations into the marketplace. The SBIR program's focus on commercialization turns small business innovation into jobs.

A comprehensive study of SBIR by the National Research Council of the National Academies concluded that the SBIR program is sound in concept and effective in practice, meets its major congressional objectives, and is a driver of innovation and commercialization for small businesses.

The SBIR program has been able to reach many committees, contributing innovation, commercialization, job creation and revenue growth. From 1992 to 2005, nearly 15,000 Phase II awards have been granted. With respect to innovation, one-third of NIH's SBIR projects generated at least one patent. Moreover, from 2002 to 2006, approximately 25 percent of R&D Magazine's top 100 annual innovations came from companies that had received SBIR funding.

In terms of commercialization, half of SBIR's Phase II awardees reported bringing their innovations into the market place. And finally, in terms of job creation and revenue growth, a 1996 study found that SBIR awardees generate four times as many jobs and nearly four times as much revenue when compared with firms that do not receive SBIR funds.

There are many SBIR success stories right here in Maryland, home to approximately 440,000 small businesses. Since the start of the SBIR program, Maryland small businesses have received over 4,000 awards, for a total of $1.2 billion. In fact, in Fiscal Year 2007, Maryland ranked number 4 in total SBIR awards and number 7 in total award dollars.

The SBIR program covers all agencies with extramural R&D budgets in excess of $100 million, and SBA believes that full agency participation by all 11 qualifying agencies provides significant benefits. But at the same time, the SBA recognizes that its 11 partner agencies have different program missions and R&D needs, so maintaining program flexibility is critical to the SBIR program's continued success. The SBA believes that both full participation and agency flexibility are invaluable.

With the SBIR program scheduled to sunset on July 31st of this year, it is urgent that Congress take action now to reauthorize the program. First and foremost, the nature of the SBIR program makes long-term reauthorization necessary. Uncertainty associated with a short reauthorization period would adversely affect program planning efforts and increase uncertainty for entrepreneurs and small businesses seeking SBIR funding.

Second, the SBA supports funding the SBIR program's administration cost to improve oversight and enhance small business outreach. We recommend that 3 percent of the program's set aside be available to agencies for program administration. We support a rigorous competitive process for the SBIR grant program, and we want to continually reach out to more small businesses and enhance the quality and quantity of proposals. In addition, SBA wants to track the performance of the program more effectively and is driving to develop fact-based metrics-driven analyses of the program.

Finally, the administration is committed to increasing federal investment in R&D with a 2.5 percent SBIR requirement and 0.3 percent STTR allocation in these agencies. This will increase the total funding available to the programs.

In this challenging economic environment, small business research and innovation is critical, not only to our economic recovery but also to our nation's ability to remain competitive in the global marketplace. This administration is committed to working with all our partner agencies to strengthen this program that helps small businesses commercialize their innovations. Thank you and we look forward to your questions.

[The prepared statement of Ms. Pickett follows:]

SBA Testimony for
Field hearing ("*Missed Opportunities: The ARRA and the NIH/SBIR exclusion*") of the U.S. Senate Committee on Small Business and Entrepreneurship in Rockville, MD
Monday, June 22 at 1:00 p.m.

Many of America's most powerful innovations start in a small business. One study by the SBA Office of Advocacy of firms that produced more than 15 patents over the period from 2002 to 2006 showed that these small firms produced 13 to 14 times more patents per employee than large firms, and that these patents were cited more often than the average patent.

For decades, the SBA has worked to harness that innovation through programs like the Small Business Innovation Research program. Since 1982, the SBIR has helped to push small business innovations into the marketplace. **The SBIR program's focus on commercialization turns small business innovation into jobs.**

Any federal agency with over $100 million in extramural research and development funds must set aside 2.5% of that money to SBIR grantees. In FY 2007, that translated to about 5,500 Federal R&D grants to small businesses, totaling nearly $2 billion.

A comprehensive study of SBIR was conducted last year by the National Research Council of the National Academies. It concluded that the SBIR program is sound in concept and effective in practice, meets its major Congressional objectives, and is a driver of innovation and commercialization for small businesses.

The study said specifically that SBIR is "increasing innovation, encouraging participation by small companies in federal R&D, providing support for small firms owned by minorities and women, and resolving research questions for mission agencies in a cost-effective manner." The SBIR program has been able to reach many small businesses, contributing to innovation, commercialization, job creation and revenue growth.

- From 1992 to 2005, nearly 15,000 Phase II awards were granted (National Academies).
- With respect to innovation, surveys conducted by the National Academies found that one-third of NIH SBIR projects generated at least one patent.[1] Moreover, from 2002 to 2006, ~25% of *R&D Magazine*'s top 100 annual innovations came from companies that had received SBIR grants.[2]
- In terms of commercialization, the National Academies study found that half of SBIR's Phase II awardees reported bringing their innovations into the marketplace.
- Finally, in terms of job creation and revenue growth, a 1996 study by Joshua Lerner found that SBIR awardees generate four times as many jobs and nearly four times as much revenue when compared with firms that do not receive SBIR funds. On average, they generate $4 million in additional revenue and 26 more employees after they receive SBIR funding. The study did add that job and revenue growth tended to diminish for multiple award recipients and that a subset of firms located in certain geographic areas exhibited superior performance.[3]

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[1] The National Academies received responses from 1,239 firms out of 4,085 surveyed.
[2] Block and Keller (2008). "Where Do Innovations Come From? Transformations in the U.S. National Innovation System, 1970 – 2006", *Information Technology & Innovation Foundation.*
[3] Josh Lerner, 1996. "The Government as Venture Capitalist: The Long-Run Effects of the SBIR Program," NBER Working Papers 5753, National Bureau of Economic Research, Inc.

There are many SBIR success stories right here in Maryland, home to approximately 440,000 small businesses. Since the start of the SBIR program, Maryland small businesses have received over 4,000 total awards totaling nearly $1.2 billion. In fact, in FY 2007 Maryland ranked #4 in total SBIR awards and #7 in total award dollars.

One success story is Celadon Laboratories Inc. in Hyattsville, which received an SBIR award from the NIH. SBIR grants allowed Celadon to advance their flagship software product substantially, which helps scientists both identify genes that are involved in disease and identify new drugs.

Techno-Sciences, Inc. (TSi) in Beltsville is another SBIR awardee. TSi used its SBIR grant from the Department of Defense to develop an automated scheduling system that improves naval aviation unit operational readiness and mission effectiveness. This system minimizes schedule turbulence, reduces mission risk, and allows Navy personnel to respond to aviator scheduling requests, to view and archive aviator status information, and to automatically schedule and reschedule aircrews.

The SBIR program covers all agencies with extramural R&D budgets in excess of $100 million, and SBA believes that full agency participation provides benefits. At the same time, the SBA recognizes that its 11 partner agencies have different program missions and R&D needs, so maintaining program flexibility is critical to the SBIR program's continued success. The SBA believes that both full participation and agency flexibility are valuable.

With the SBIR program scheduled to sunset on July 31 of this year, it is urgent that Congress take action now to reauthorize this program.

First and foremost, the nature of the SBIR program makes long-term reauthorization necessary. Uncertainty associated with a short reauthorization period would adversely affect program planning and undermine integration of SBIR into agencies' acquisition and technology development efforts. Perhaps most importantly, long-term reauthorization would reduce uncertainty for entrepreneurs and small businesses interested in SBIR funding as a tool to help them research, develop and commercialize their innovations.

Second, the SBA supports funding for SBIR Program Administration to improve oversight and enhance small business outreach. We recommend that 3 percent of the program set-aside be available to agencies for program administration. We support a rigorous, competitive process for the SBIR grant program, and we want to continually reach out to more small businesses and enhance the quantity and quality of proposals.

In addition, the SBA wants to track the performance of the program more effectively. As part of the SBA's drive to develop fact-based, metrics-driven analyses of its programs, the agency is currently implementing cross-agency performance measures for these programs. It is also working with SBIR partner agencies in building data collection and reporting systems to measure and analyze program effectiveness.

Finally, the Administration is committed to increasing federal investment in R&D overall by doubling the budgets in the Department of Energy's Office of Science, NIST, the National Science Foundation and cancer research at the NIH. With the 2.5% SBIR requirement and the 0.3% STTR allocation in these agencies, this will increase the total funding available to these program.

In this challenging economic environment, small business research and innovation is critical not only to our economic recovery but also to our nation's ability to remain competitive in the global marketplace. The SBA is committed to working with all our partner agencies to strengthen this program that helps small businesses commercialize their innovations. Thank you and I look forward to answering your questions.

Submitted by Penny Pickett, Senior Advisor to the Administrator and Acting Associate Administrator for Entrepreneurial Development.

Senator CARDIN. Well, thank you very much for your testimony. We very much appreciate it.

Mr. Jere Glover is well known to all of us for small business issues. He is executive director of the Small Business Technology Council. It is a pleasure to have you here.

STATEMENT OF JERE GLOVER, EXECUTIVE DIRECTOR, SMALL BUSINESS TECHNOLOGY COUNCIL

Mr. GLOVER. Senator Cardin, Congresswoman Edwards, Congressman Van Hollen, it is a pleasure to be here with you. I represent the Small Business Technology Council and the National Small Business Association, 150,000 members across the country.

The purpose of the American Recovery and Reinvestment Act is to create jobs and stimulate the economy. NIH has chosen to ignore the nation's job creator and innovator. There are three areas that I would like to discuss today, and I was careful to footnote the sources of a lot of this information since, apparently, some of the folks at NIH either do not know about it or have chosen to ignore it.

The SBIR program is by far the most successful federal program for leading age innovation, commercialization of advance technologies and job creation. SBIR creates four times as many important innovations as universities. Twenty-five percent of important U.S. innovations come from this one small program. Four times as many jobs are created by SBIR companies as other companies; four times as much revenue as other companies.

The average sale per SBIR award is $1.2 million. The average outside investment, additional investment, beyond the SBIR money, is $850,000 per SBIR award. Fifty percent of all SBIR Phase II awards are commercialized. SBIR makes four times as many awards to minority and women-owned businesses as do venture capitalists. It is broad—small business outreach to over 15,000 different firms have received Phase II awards.

Small business today employs 38 percent of all scientists and engineers in America. That is up from 8 percent just before the SBIR program was put into law. Small business itself creates virtually all of the net new jobs in America and especially after a recession. Between 35 and 45 percent of all companies winning SBIR awards develop sufficient technical knowledge to be worth the time and expense to file a patent application and awards. That is quite impressive, according to the National Research Council.

Unfortunately, either the NIH does not realize small business and SBIR successes or they chose to ignore it. The NIH has a long history of lack of support for small business going back over 30 years. NIH's efforts to exclude the SBIR program from ARRA funds should be reversed.

When we talk about federal R&D, it just has not kept up with what has really been happening in the marketplace. As scientists and engineers have gone to work for small businesses, the federal R&D going to small businesses is just 4.3 percent. That is barely up over 30 years from when the SBIR bill was first passed, and half of this number is the SBIR program. If it were not for the SBIR program, the R&D share of small business would have actually gone down.

Let's talk a little bit about the history of the SBIR program and the National Institutes of Health staff. In 1978, before the SBIR law was passed, congressional studies found that NIH awarded no contracts to small business, not one single contract, and they testified that there was no small business that could satisfy their requirements. Today they list 69 current success stories on their Web site. They are quite impressive, which belies the original argument no one could do it.

In 1996, NIH asked Congress to exempt them from part of the SBIR program, citing low scores and lack of quality by SBIR proposals. Director Van Hollen later provided a clarification letter to Congress and the Office of Advocacy, correcting some of the misinformation provided by the NIH staff to the Congress. Dr. Varmus pointed out that the NIH scoring system for the SBIR system was on a scale of 100 to 500. The evaluations scores for everybody else from universities was 100 to 300. So guess what? Small business did not do as well on their scoring system. They went on to point out this, and because of the scoring differences they would resist making side-by-side comparisons on the quality of proposals.

Recently, when the National Research Council was doing its study, they again used the same mischaracterization of 500 versus 100 to 300.

Now, concerning the information that they used after the fact to justify this exclusion, it is interesting to note that the analysis that we conducted shows that the program is 1.7 to 3.6 times more competitive than other NIH programs. And there are two reasons for that misinformation. One is it is a two-step process. The SBIR program is a two-step process. You compete for Phase I and you compete for Phase II. All the other NIH programs are a one-step process. So they compare competition at each of those phases, so they, in effect, double count and thereby reduce the amount of the scoring.

They also failed to point out the fact that if you go back a few more years from the number of awards, what you find is it is cyclical. Every few years, the number of awards drop down, the success rates drop down, and the number of applications drop down. We saw it happen back in the '80s, it happened in the '90s, and now it has happened again. So this is not a real unusual phenomena that justified them running to Congress and asking for that.

So I think that when you look at these issues, what you see is that people at NIH just have not been educated outside their small universe of things. Small business has done a remarkable job. Large firms have contracted out much of their research. It is recognized by them, this is where they should be doing better research, but the Federal Government still lags behind.

So I wanted to just point out that the commercial success of the SBIR program is truly phenomenal. I mean, you have got licenses. You have got sales over a million dollars, additional funding of 850,000. It is the most remarkable success story that you could ever want under commercialization. That is why I get upset when some people criticize the program and say, oh, well, we need somebody else to come in the program, like venture capitalists or others. The success rate is truly remarkable and we do not want to lose sight of that.

So just in conclusion, let me just say that this program has worked extremely well. NIH should be putting more money in the nation's job creator, not less.

[The prepared statement of Mr. Glover follows:]

Testimony of

Jere W. Glover

Executive Director

Small Business Technology Council

Washington, DC

REGARDING THE SBIR PROGRAM AT NIH

BEFORE THE

SENATE COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP

ROCKVILLE, MD FIELD HEARING,

SENATOR BENJAMIN L. CARDIN, MARYLAND, CHAIRING

22 June 2009

On behalf of

The Small Business Technology Council and The National Small Business Association

(202) 785-4300 *(202) 293-8830*
www.sbtc.org *www.nsba.biz*

SBTC is the nation's largest association of small, technology-based companies in diverse fields, and represents more companies that are active in the federal Small Business Innovation Research (SBIR) Program than any other organization. SBTC is proud to serve as the technology council of the National Small Business Association.

Founded in 1937, the National Small Business Association (NSBA) is the nation's oldest nonprofit advocacy organization for small business, serving more than 150,000 small companies throughout the United States.

Senator Cardin, thank you for holding this very important hearing on the Small Business Innovation Research (SBIR) program at the National Institutes of Health (NIH) and for offering us the opportunity to present our findings and recommendations today. I am Jere Glover, Executive Director of the Small Business Technology Council of the National Small Business Association. I appear here today on behalf of the more than 150,000 small business companies that SBTC and NSBA represent across this Nation.

There are three items I'd like to discuss today:

1. The SBIR program is by far the most successful federal program for efficient, leading-edge innovation, commercialization of advanced technologies, and for job creation in new technology-based industries. Even with its proven success over more than 26 years, the SBIR program still receives only 2.5 percent of the Federal extramural research and development funding. This should be expanded.
2. Unfortunately NIH either doesn't realize the SBIR successes documented by their own reports and the recent National Academy of Sciences Report, or they chose to ignore it. There has been a long history of lack of support for small business innovation at NIH going back over the 30 years that I've been involved in this effort. Their efforts to exclude the SBIR program from the ARRA funds should be reversed.
3. Changing the fundamental definition of small businesses to permit large venture capital firms to access the SBIR program does not serve the taxpayers, the research and innovation agenda of our Nation, or small businesses. It only serves the VC industry itself, and we don't believe they deserve a "bail-out" using funds that Congress allotted to this highly-successful program.

Item #1: The SBIR program is the best Federal program for converting research to products in the market and creating jobs.

The recent SBA Fact Sheet on the SBIR program states:[1]

"Small businesses are the driver of innovation in America. One study, by the SBA Office of Advocacy, of firms that produced more than 15 patents over the period 2002-2006 found that the small firms in this group produced 13 – 14 times more patents per employee than did the large firms, and these patents were cited in applications more often than average patents. ***The SBIR program's focus on commercialization turns small business innovation into jobs.***

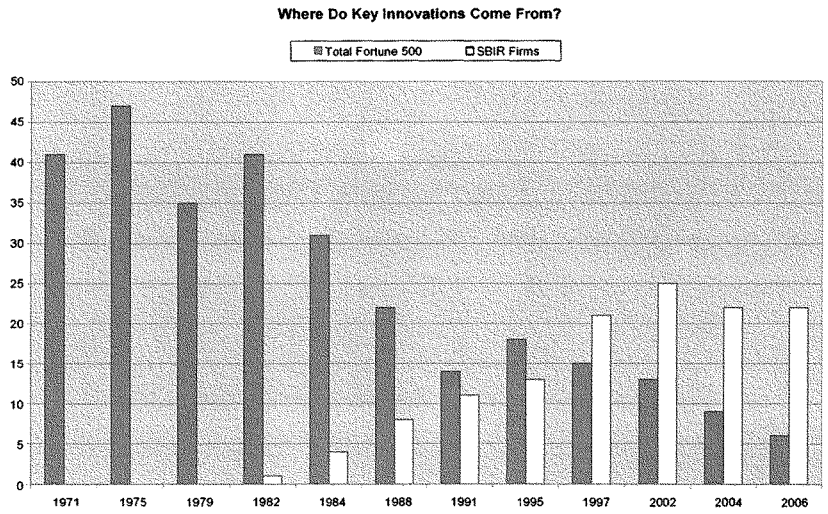
According to the 2008 National Academies study, SBIR 'is increasing innovation, encouraging participation by small companies in federal R&D, providing support for small firms owned by minorities and women, and resolving research questions for mission agencies in a cost-effective manner'. Some highlights of the SBIR program are:

- ***Job and Revenue Growth:*** *SBIR awardees generated four times as many jobs and nearly four times as much revenue as comparable firms that did not receive SBIR funding (Lerner 1996).*
- ***Commercialization:*** *The National Academies found that about half of Phase II awardees responding to its survey reported bringing their innovations to the market place.*
- ***Innovation:*** *One-third of NIH SBIR projects generate at least one patent (National Academies). Moreover, from 2002 to 2006, about 25% of R&D Magazine's top 100 annual innovations came from companies that received SBIR grants.*
- ***Broad Small Business Reach:*** *From 1992 to 2005, nearly 15,000 different firms received at least one Phase II SBIR award (National Academies)."*

Expanding on the SBA report, just the SBIR Program – with 2.5 percent of extramural R&D at eleven federal agencies – has been delivering about 25 percent of the nation's most important innovations every year for the past decade as shown in the chart below, according to a recent study by the Information Technology and Innovation Foundation. [2]

Large companies, which had been delivering about 40% of these top innovations when SBIR started in 1982, now account for less than 5% of them, even with their far greater access to capital.

Universities, which receive more than 10 times the Federal R&D funding than small businesses, only account for around 8% of the key innovations.



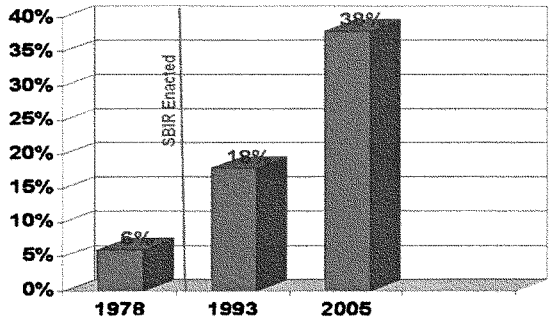
But federal R&D procurement does not reflect this reality. Overall, just 4.3% of R&D goes to small business, and SBIR is over half of that. **The small business share of federal**

R&D has gone up by less than 2% in the last 30 years. If not for SBIR, the figure would actually have *declined*.

(1) **38% OF SCIENTISTS AND ENGINEERS WORK FOR SMALL BUSINESS**

SBIR Program was set up at the time when small businesses employed about 6% of the nation's scientists and engineers. Now there are over six times as many scientists and engineers choosing small business – 38% altogether. More scientists and engineers work for small companies than for any other sector – large companies, universities, nonprofits, or government.

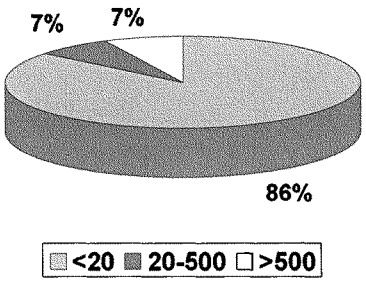
Percent of U.S. Scientists and Engineers Employed by Companies with Fewer than 500 Employees[3]



(2) **SMALL BUSINESSES CREATED 93% OF THE NET NEW JOBS FROM 1989 TO 2005)[4]**

Small businesses are by far the most effective instrument for helping the nation grow new jobs. From the time that the Bureau of Census and the SBA Office of Advocacy started tracking net new job creation by company size in 1989 to the most recent data in 2005, small businesses created 22.9 million of the total of 24.6 million net new jobs over these sixteen years.

Total US Net New Job Creation
By Company Size
(1989 to 2005 Cumulative = 24.6 Million Jobs)



In the periods following a recession, the job creation by small business is even more dramatic. In the three years after the 2001 recession, small businesses created 4.8 million of the total of 3.9 million net new jobs (large businesses continued to shed jobs and ***lost*** 950,000 jobs over these three years).[5] The very small businesses of the SBIR type (<20 employees) created 3.1 million (79 percent of the total).

Conclusion: The SBIR program has been proven effective as documented by GAO and NRC in converting Federal R&D funds to commercially available innovative new technologies faster than other R&D programs, and multiplies job creation in new industries. It is meeting the goals established by Congress and should be expanded.

Item #2: At NIH the SBIR Program is working quite well – but does not get the credit or support it deserves.

In the earliest 1978 Congressional studies of the percentage of Federal R&D dollars going to small businesses, we found that NIH had ***NO*** contracts with small businesses.[6] In subsequent hearings they testified that there were ***NO*** small businesses that could satisfy their requirements. That was empirically proven wrong by an industry witness at the hearing, and has been abundantly proven wrong by the successful history of the SBIR program at NIH. The NIH SBIR – STTR Success web site[7] lists 69 current success stories where SBIR/STTR companies brought urgently needed health technologies to market quickly and efficiently.

There is a history of inaccurate information about SBIR by members of by NIH staff.

(A) In 1996, the NIH Director, Harold Varmus, MD, provided a clarification letter to Congress and to the Office of Advocacy at SBA correcting some misinformation provided by NIH staff to Congress and to *Science Magazine.* Dr. Varmus pointed out that the NIH scoring system for the SBIR program used a "100 to 500 Scale" for evaluation, versus a "100 to 300 Scale" for R01 programs, and that claims by NIH staff that SBIR projects had worse scores did not accurately reflect lower research quality (at NIH a higher score means a worse score)[8]. As Dr. Varmus stated, "Because of these scoring differences, the NIH resists making any side-by-side comparisons of the quality of a proposal based on the priority scores alone."

(B) In recent discussions with the National Research Council staff preparing the Congressionally mandated National Academy of Sciences report on the SBIR program at NIH, the NIH staff again misstated the differences between SBIR (100 to 500) and R01 (100 to 300) scoring as reported in the NAP report:[9]

"Low relative scores. *From discussions with staff, it appears that the paylines for SBIR awards at the different IC's are substantially higher than for RO1 awards, and these gaps have grown recently. This implies that projects funded through SBIR are receiving worse peer-review scores than projects funded through other mechanisms.*

NIH management decided not to share scoring data with the research team, so it is difficult to determine whether or to what extent reality matches perceptions in this area. However, it seems likely that these different scores may well be the result of using a selection process that is primarily aimed at selecting academic applications for basic research and adapting it for use with SBIR, which has different objectives and indeed different selection characteristics. For example, commercialization plans are supposed to play an important role in selection for SBIR, but not for other NIH awards. It does not appear that program staff has undertaken research either to substantiate this perception or to investigate possible alternative explanations for differential scores between RO1 and SBIR applications."[page 133]

Need for increased staff and management support: The NAS report also recommended additional support and management attention to the SBIR program at NIH:

"III. SUMMARY OF KEY RECOMMENDATIONS ...

A. The NIH should retain its distributed management structure for the program while increasing evaluation efforts, improving data collection, obtaining

additional resources, and encouraging upper management attention."[page 6]

(C) Misinformation on SBIR Competitiveness at NIH:

Within the past few months, additional misinformation has been provided to Congress regarding the lack of competitiveness of the SBIR program. This misinformation was used to argue that the SBIR Program should not receive ***any*** of the billions of dollars in windfall funding that NIH received from the American Recovery and Reinvestment Act (ARRA). SBTC performed an analysis of the comparative competitiveness of the SBIR and the R01 programs at NIH.

That analysis shows that the SBIR program is from 1.7 to 3.6 times ***MORE*** competitive than NIH's comparable R01 program. See the chart below:[10]

Year	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
R01 Competitive Ratio	(3.2:1)	(3.1:1)	(3.1:1)	(3.1:1)	(3.2:1)	(3.3:1)	(3.8:1)	(4.3:1)	(4.8:1)	(4.2:1)	(4.3:1)
SBIR Phase I Competitive Ratio	(3.6:1)	(3.6:1)	(3.8:1)	(3.3:1)	(3.7:1)	(4.2:1)	(5:1)	(5.5:1)	(5:1)	(4.2:1)	(3.6:1)
Combined Phase I & II Down-select Competitive Ratio	(7.3:1)	(7.5:1)	(10:1)	(6.3:1)	(7.6:1)	(9.4:1)	(13.5:1)	(15.4:1)	(12.2:1)	(9.9:1)	(7.5:1)
Most Competitive Program	**SBIR X 2.3**	**SBIR X 2.4**	**SBIR X 3.2**	**SBIR X 2**	**SBIR X 2.4**	**SBIR X 2.8**	**SBIR X 3.6**	**SBIR X 3.6**	**SBIR X 2.4**	**SBIR X 2.4**	**SBIR X 1.7**

Information about SBIR provided by NIH to Congress typically omits a number of metrics on which SBIR excels. This omitted information includes:

Commercialization: The highly competitive SBIR program has been proven at NIH (and other agencies) to provide very high commercialization of the research work, compared to other Federal Research programs. According to the NAS study of the SBIR program at NIH, 30.3 percent of the NIH SBIR research projects reached the commercial market, almost the same as DOD's 31.6 percent.[11] A more recent NRC study found that non-VC

SBIR awardees reached the market 55% of the time and VC owned reached the market 38% of the time.

Additional investment: The NRC report at page 55 indicates that SBIR projects generated over $850,000 each.[12]

Patents: The result that between 35 and 45 percent of all companies with SBIR awards developed sufficient technical knowledge to be worth the time and expense of a patent application (and award) is impressive.[13]

Outreach to women- and minority- owned businesses: The NAS report also showed that in the NIH SBIR program, women- and minority-owned businesses received a considerably higher percentage of the awards than the approximately 2 percent provided by the Venture Capital industry.[14,15] [page 57].

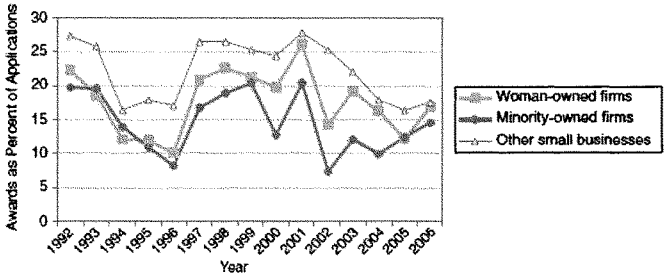


FIGURE 3-11 Success rates for Phase I awards by demographic, 1992-2006.

National reach compared to the venture capital industry:

The NIH SBIR program has participation by almost all states as shown in the NRC report. [Table 3-3, Page 47] Compared to the concentration of the VC funding in California, Massachusetts, New York, Texas and Pennsylvania (63.8 % of all VC investments from 1995 to 2005), the NIH SBIR program is providing much needed high-risk capital for advanced research across the United States. (Maryland obtained only 1.9% of the nation's VC funding.[16])

TABLE 3-3 Phase I Success Rates—By State (Winning applications as percent of total applications)

State	Phase I Success Rate	State	Phase I Success Rate	State	Phase I Success Rate	State	Phase I Success Rate
MA	30.8	WY	25.4	NH	21.2	VA	18.2
UT	30.5	HI	25.1	FL	21.2	MS	18.2
MO	29.7	AZ	24.3	RI	21.0	NY	18.0
WA	29.2	NJ	24.2	MI	21.0	NC	17.8
KY	28.5	LA	24.2	TN	20.8	AR	16.9
TX	27.9	NV	24.2	IL	20.4	MD	16.5
IA	27.2	PR	24.0	IN	20.3	NE	15.4
CT	26.2	PA	24.0	OK	20.2	AL	15.4
MT	25.8	SC	23.8	DC	20.2	WI	14.1
DE	25.8	MN	23.5	OH	19.7	GA	9.8
KS	25.8	ID	23.2	VT	19.3	ND	7.8
CA	25.8	ME	21.6	CO	19.1	OR	7.7
WV	25.7	NM	21.6	SD	18.6	AK	0.0

SOURCE: NRC calculations base on National Institutes of Health data.

Conclusion: The SBIR Program at NIH is succeeding even according to the metric that NIH has cited, competitiveness. A broader range of metrics shows that SBIR outperforms comparable programs at NIH on a number of criteria. Overall, NIH's SBIR program is highly effective and competitive. And as the NAS study noted, NIH's SBIR program is meeting the goals established by Congress. NIH's legislative ploy to exclude SBIR from the agency's ARRA funds should be reversed. Congress should encourage NIH's senior management and Congressional relations staff to become better informed about the SBIR program. NIH should develop the additional support recommended in the NAS study.

The Venture Capital Issue

SBTC understands the desire of the venture capital and biotechnology industries to participate in the SBIR program. Many successful SBIR companies graduate to venture investment and acquisition or licensing to large biotech or pharmaceutical companies in Phase III of the SBIR program. We support this and actively work to help make these linkages.

However, we strongly disagree with the VC / biotech proposal to completely change the definition of small business. Companies that are more than 51 percent owned by large VC's are not small businesses. To permit large biotech and pharmaceutical companies (or any large organizations) to use new or existing venture capital companies to obtain over 51 percent ownership of a company in Phase I or Phase II of the SBIR Program would completely debase the program.

SBTC believes that the following VC issues should be brought before the Committee members:

(1) The SBIR program is focused entirely on pushing the research boundaries to solve critically important national problems – that is why the solicitations specify the problems that are important to NIH. The VC industry has a sole fiduciary responsibility – to provide the highest return to their Limited Partners (their investors – usually very wealthy individuals, pension funds, insurance companies, and similar large financial organizations).

(2) The Venture Capital industry has fallen on difficult times in the recent years. This is not a reason to provide them with a "bail-out" using scarce small business research funds. The following chart from a June 10, 2009 report by the Kauffmann Foundation provides a summary of the VC performance in the past 1, 5, and 10 years.[17]

Venture Capital Performance

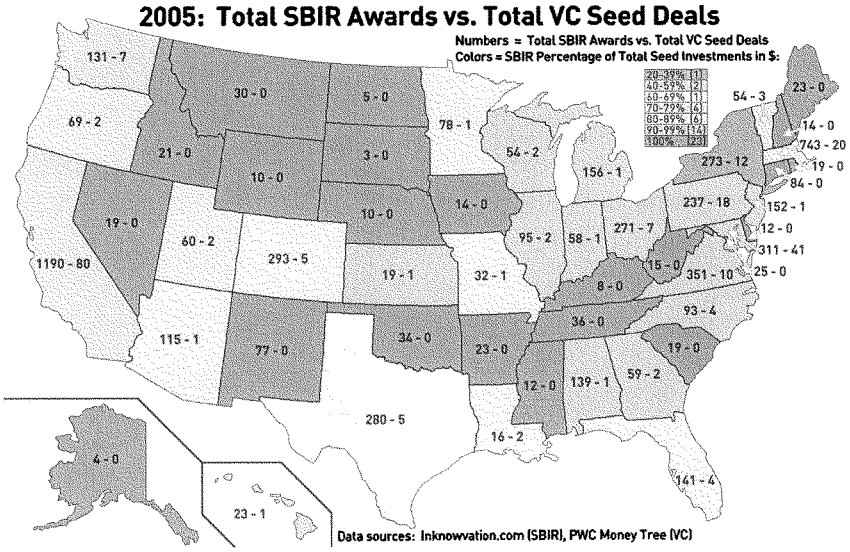
Period*	Venture Capital	Russell 2000	S&P 500	NASDAQ
1-year	-21%	-34%	-38%	-41%
5-year	6%	-10%	-19%	-21%
10-year	16%	18%	-26%	-27%

*Ending 12/31/2008
Source: National Venture Capital Association /Thomson Reuters, author calculations

According to the author of this report:

> *"Note that this ten-year period includes the dot-com episode, thus materially inflating the venture industry's trailing performance. (The combined value of venture-backed public offerings in 1999 and 2000 was more than the aggregate value in all other years between 1994 and 2008 inclusive.) According to Cambridge Associates data, the nine-year venture capital performance is negative, which means that ten-year venture performance will almost certainly turn negative at the end of this year when the bubble venture exits of 1999 are excluded. As a result, the venture industry's current returns are already challenged and set to become considerably worse."*

(3) The VC industry is not very effective in the "seed" investment in the few million dollar amount appropriate for SBIR companies. **The map below shows how few VC "seed" investments are made across the United States in 2005 compared to the SBIR awards.**



(4) VC Managing Directors are highly compensated, as reported in the study ***2006 VC Compensation***.[18] This study shows that the average 2006 total annual cash compensation for a Managing Director (the currently legally popular title for "Partner") is about $843,000 (base plus bonus), and the average value of their "Carry" (which is their compensation in their ownership) of the portfolio is $9.5 million (taxed at Long-Term Capital Gains and conservatively stated by VCComp to be equal to a 2X return). For a typical 10-year fund, this means **the average annualized compensation (taxed at lower long-term capital gains rates) is $1,793,000 per Managing Director. For the typical 10-year period this equates to a total average compensation of $17.9 million.**

The SBTC does not see a value to the taxpayer to subsidize these wealthy individuals by effectively certifying them as "small businesses."

Summary and conclusions:

1. Two general conclusions flow from this.

(a) The overall design of the SBIR Program should not be changed. It's working. As the recent series of NAS and GAO[19] studies concluded, SBIR is sound in design and effective in practice. The SBIR program has worked so well that large

wealthier companies and even non-profits are trying to join small business in the SBIR program.

(b) The share of federal R&D going to small business should increase, and SBIR is the single best way to do it. The federal government addresses public needs. Absent an increase in the SBIR allocation, the federal government is in effect starving these public needs of the nation's largest pool of science and engineering talent – and its demonstrably best source of innovations.

Attachment 1: Correspondence from NIH Director, Harold Varmus, MD, August 1996, correcting misinformation provided by NIH staff to Congress and *Science Magazine*.

Attachment 2: SBTC Recommendations for the SBIR and STTR Programs.

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[1] Small Business Innovation Research Program June 8 2009, SBA

[2] Fred Block and Matthew Keller, *Where Do Innovations Come From? Transformations in the U.S. National Innovation System 1970-2006*, Information Technology and Innovation Foundation, July 2008. http://www.itif.org/files/Where_do_innovations_come_from.pdf

[3] National Science Foundation, *Science and Engineering Indicators*, 2007.

[4] SBA Office of Advocacy, from data provided by the U.S. Bureau of the Census, Statistics of U.S. Business. See: http://www.sba.gov/advo/research/dyn_b_d8905.pdf. This data series runs from 1989 and is currently available through 2005 only. The 2006 data will be available in the Fall.

[5] Source: Office of Advocacy, US Small Business Administration; See: http://www.sba.gov/advo/research/dyn_b_d8905.pdf and *Small Business Profiles for the States and Territories*; published November 2008

[6] 1978 joint House and Senate Small Business Committee hearing on Federal R&D allocations to small businesses.

[7] http://grants1.nih.gov/grants/funding/sbir_successes/sbir_successes.htm

[8] Dr. Harold Varmus letter to Jere Glover dated August 29, 1996, included as Attachment 1 to this testimony.

[9] An Assessment of the Small Business Innovation Research Program at the National Institutes of Health http://www.nap.edu/catalog/11964.html

[10] Data from: (http://report.nih.gov/nihdatabook/Charts/SlideGen.aspx?chartId=115&catId=13) and from the NIH Data Book, from NIH Research Portfolio Online Tool (RePORT) (http://report.nih.gov/index.aspx)

[11] From: An Assessment of the Small Business Innovation Research Program at the National Institutes of Health http://www.nap.edu/catalog/11964.html, page 83, Figure 4-1.

[12] Venture Funding and the NIH SBIR Program, NRC 2009

[13] Ibid.

[14] Yago, Glenn and Pankratz, Aaron, The Minority Business Challenge: Democratizing Capital For Emerging Domestic Markets (September 25, 2000). Available at http://purl.access.gpo.gov/GPO/LPS6842

[15] Brush, Candida, et al., An Investigation of Venture Capital in Women- and Minority-led Firms (January 2002). Available at: http://www.sba.gov/advo/research/rs214.pdf

[16] NASVF report, *Seed and Venture Capital, State Experiences and Options, May 2006;* www.nasvf.org.

[17] *RIGHT-SIZING THE U.S. VENTURE CAPITAL INDUSTRY*, Paul Kedrosky, Senior Fellow, Ewing Marion Kauffman Foundation, June 10, 2009, at: http://www.kauffman.org/newsroom/venture-capital-industry-must-shrink-to-be-an-economic-force-kauffman-foundation-study-finds.aspx

[18] From the web site: http://www.vccomp.com/old/VCComp2006survey.pdf

[19] *Federal Research: Assessment of Small Business Innovation Research Programs*, GAO Report RCED 89-39, January 23, 1989; *Federal Research: Small Business Innovation Research Program Shows Success But Could Be Strengthened*, GAO Report T-RCED 92-3, October 3, 1991; *Federal Research: Interim Report on the Small Business Innovation Research Program*, GAO Report 95-59, March 8, 1995; *Federal Research: Observations on the Small Business Innovation Research Program*, GAO Report RCED 98-32, April 17, 1998; *Small Business Innovation Research*, GAO report 06-565, April 2005; *Federal Research: Observations on the Small Business Innovation Research Program*, GAO Report GAO-05-861-T, June 28,2005.

Senator CARDIN. Thank you very much for that testimony. Particularly, for some of the history, which I found very, very helpful.

We will now hear from Mr. Jonathan Cohen, who is president and CEO of 20/20 GeneSystems, based in Rockville, Maryland, and has been very helpful in trying to explain how these programs work to this senator.

STATEMENT OF JONATHAN COHEN, PRESIDENT AND CEO, 20/20 GENESYSTEMS

Mr. COHEN. Thank you, Senator, for your leadership in convening this panel this afternoon. And I also want to thank Representatives Edwards and Van Hollen for taking the time to come out and hear from us on this very important issue.

I am Jonathan Cohen, president and CEO of 20/20 GeneSystems, based here in Rockville, Maryland. We are a small biotechnology company focused on developing innovative diagnostic products for both cancer and biodefense. We hope to commence marketing of a first generation blood test for the early detection of lung cancer as early as this fall. Moreover, our patented BioCheck product for screening suspicious powders is now routinely used by more than a dozen federal agencies and more than 500 fire departments throughout the United States.

That product was developed by us following the 2001 anthrax incidents with the support of only about $100,000 of government grants, both state and federal. And since then, it has likely saved tens of millions of dollars to the U.S. economy when banks, post offices, government facilities and other places of business can reopen and continue operations following a suspicious powder incident. And if I am not mistaken, I believe the building that we are in today may have been one of those buildings that was reopened with our product a number of years ago.

Now, as Congresswoman Edwards pointed out in her remarks, a lot of the Recovery Act funding has gone to so-called shovel-ready projects, road repair, bridge improvements and so forth. Though important, it is important to keep in mind that permanent job creation really requires new products and technologies that can be made, sold and improved upon for years after they develop. The shovel-ready projects typically create jobs only as long as the government money continues, and once that funding stops, very often, more cases than not, the jobs stop.

On the other hand, when you have an innovative product, like the BioCheck product that I had mentioned, it is like the economic gift; it keeps on giving. The jobs continue long after the government funding ceases. For example, less than $100,000 for this product has created more than a half dozen jobs, six to eight jobs, over a 20-year time period, which is typically about the life of an innovative product, patented product. And I think that is the point that is often missed, even by economists and certainly policymakers, and I think it really needs to be underscored. So, again, it is really sustainable job growth that we are after, not temporary job growth.

Now, more specifically to the NIH, it is important also to understand that no amount of academic research will ultimately deliver products to patients and doctors without the considerable invest-

ment, considerable effort, of companies. And very often those are small companies.

In my nearly 20 years of experience in the biotech industry, I have yet to come across an academic technology or an NIH-funded piece of intellectual property that was further than about 10 percent of the way that it needed to go. And I think that is something that I think a lot of policymakers also may not be aware of. I, frankly, was not aware of that until I really got into this business.

So, in essence, we have often been asked to do 90 percent of the development work with what is now about 3 percent of—more or less, 3 percent of the grants budget, at least to NIH, plus whatever one can, of course, supplement by the capital markets. Now, that is tough in a robust economy, to be frank. I mean, and we all know the tremendous efforts that go on, the long time frames that so many biotech companies have to go through. But in an economy like we have today, it is virtually impossible.

Now, typically, biotech companies are funded through either institutional investors, particularly venture capitalists, or individual investors, which we refer to as angels. And our company is primarily the latter; we raise money from individuals and have done so for a number of years. We have been very active in this for the last couple of months. We, like a lot of Maryland companies, tend to tie our fundraising around something called the Maryland Biotechnology Investor Tax Credit, and it is truly an effective and important program. And the deadline is coming up next week, so I wanted to get in this state's fiscal year.

I can tell you, it is, from my own personal experience and from talking to a lot of colleagues, five to ten times harder to raise capital today than it was two years ago. I have to work as hard to raise—it takes me as long to get 25,000. Two years ago, I could have gotten probably 250,000 for virtually the same amount. So that is really what is going on here. And in light of that, frankly, I think it justifies an increase in SBIR and programs like SBIR, and certainly not an exclusion.

Ms. Pickett referred to a study we are doing, 100 Awards, and I think it is a very important piece of research. And I have produced a bar graph in my testimony. I do not know if you have a copy of it, but I can certainly provide that to you after the hearing. I think it is a remarkable study. Last year, it was published. Two researchers at the University of California analyzed over the last—since I think 1960, something called the R&D 100 Award, which is no less than the Academy Awards for science and technology, in all fields, not just the life sciences.

What they found was that there is a remarkable increase in the percentage of those awards going to small SBIR awardees. And you can see the climb. It is now about 25 percent of those, whereas Fortune 500 companies, there has been an equivalent decline in those awards. And with the universities, it has been about flatline. So I think this provides some very empirical evidence of the value that small business in general and the SBIR program in particular is playing in our innovation economy. And in my mind, it justifies a significant increase in SBIR.

Just to conclude, I would respectfully urge, and suggest, we propose, in light of the economic downturn and in light of the record

that SBIR—the demonstrated record of SBIR contributing to the economy, an emergency doubling of the SBIR set aside for at least a two-year period, FY10 and FY11. In other words, take it from 2.5 percent to 5 percent, and then it can be reassessed at that point.

But I feel very strongly that until we get through this downturn, we really need to protect the good companies. Because what happens is when a company downsizes or goes out of business, all the R&D, all the technology, all the intellectual property essentially just drops down. And we simply cannot—in addition to creating jobs, we cannot afford to lose what could be important cures and advancements in Alzheimer's disease and various cancers and so forth.

Just to conclude, Senator mentioned the bill that passed the Senate Small Business Committee last week, Senate Bill 1233. I want to just commend the Senator and others on that committee for passing it unanimously. There has been an ongoing difference in opinion within our own community over the years on the extent to which venture capital should be permitted into SBIR. I think that that bill is a very good balance and a very good compromise.

Regrettably, the legislation coming out of House, at least in my opinion, I do not believe has achieved that balance. And I would encourage the House of Representatives to look at that bill and model their legislation after that. Thank you very much.

[The prepared statement of Mr. Cohen follows:]

Testimony of Jonathan Cohen*
Committee on Small Business & Entrepreneurship
United States Senate

NIH Funding for Small Businesses

Field Hearing—Rockville, MD--June 22, 2009

Thank you Senator Cardin. I am Jonathan Cohen, president and CEO of 20/20 GeneSystems, a small biotechnology company based in Rockville, Maryland focused on developing and bringing to market innovative diagnostic tests for cancer and biodefense.

20/20 hopes to commence marketing of a first generation blood test for the early detection of lung cancer this Fall. Furthermore, our patented *BioCheck®* field test for screening suspicious powders is routinely used by nearly a dozen federal agencies and hundreds of fire departments and other first responder organizations nationwide. That product was developed by us after the 2001 anthrax incidents with the support of only about $100,000 in government funding. Since then it has likely saved tens of millions of dollars to the U.S. economy when banks, post offices, government facilities, and other places of business can reopen and continue operations following a suspicious powder incident.

SBIR & the America's Economic Recovery

Much of the Recovery Act funding is going to "shovel ready" projects like road improvements, building construction, etc. While important, these projects will expand employment only temporarily. Once the federal dollars stop flowing, most of the jobs will be lost. Permanent job creation requires the creation of new products and technologies that can be made, sold, and improved upon for years after they are developed. This is primarily the domain of entrepreneurial companies. For example, the 20/20 *BioCheck®* product that I mentioned will have created 6-8 new jobs each year over a 20+ year timeframe with the support of only about $100,000 in government assistance.

As this example illustrates, increasing federal investments in small biotech firms would pay both immediate *and* long-term dividends for our economy. Biotechnology companies receiving these funds would immediately make new hires and procure needed supplies and services in the same manner as firms tasked with improving our nation's infrastructure. However, as innovative products are launched this creates a new jobs multiplier in manufacturing, sales, marketing, etc. that does not occur to the same extent when roads are repaved or buildings enhanced. In other words, technology innovation creates economic "gifts that keep on giving" years after the federal subsidies end.

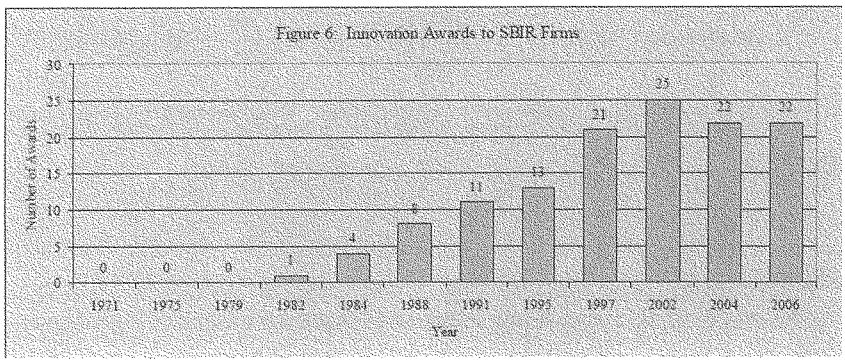
Regarding the NIH, no amount of academic research will advance cures for most diseases unless this is followed by significant investment by private firms. While NIH funded

* Jonathan Cohen is President & CEO of 20/20 GeneSystems, Inc., Rockville, MD (www.2020gene.com). The views expressed herein are his own and do not necessarily represent those of the company or its shareholders. He can be reached at jcohen@2020gene.com or 240-453-6339.

university research often provides a foundation for new biotechnology that research almost always ends very early in the development process with a scientific publication. Last week the Science Editor of *Newsweek* had a column lamenting the failure of the NIH to meet its promise to translate more medical research "from bench to bedside." (See article attached) This has been a chronic problem with NIH funded academic research. In my nearly 20 years of involvement of the biotech industry I cannot recall coming across any university research that was more than 10% along the development pathway no matter how much funding the project has received. Thus, companies are typically left with the burden and expense completing nearly 90% of the R&D required to bring a safe and effective drug, medical device, or diagnostic test to market.

Emerging biotech companies typically finance their R&D through two sources: private capital and government grants. Private capital comes from either institutional sources—venture capital—or more commonly from individual investors known as "Angels." Unfortunately the economic downturn has dramatically reduced available capital from both venture capitalists and Angel investors. NIH grants therefore play a critical role for biotech companies during this recessionary period. However, less than 3% of the NIH's external grants budget is dedicated funding R&D by business who, as stated, typically must undertake nearly 90% of the R&D effort to bring a biomedical product to market. This gross imbalance in funding priorities must be rectified if we are ever to defeat cancer, Alzheimer's disease, and other diseases.

Numerous studies by the National Academies of Sciences and others have concluded that SBIR has been extremely effective in advancing the R&D missions of the agencies and in developing innovative technologies. Last year researchers at the University of California analyzed *R&D Magazine*'s top 100 innovations of the year over the last four decades.[†] (See bar chart below)



[†] Block and Keller, *Where do Innovations Come From*, Information Technology & Innovation Foundation, July, 2008.

The study revealed a significant growth in recent years in the number of award winning inventions coming from small businesses with SBIR grants relative to those coming from Fortune 500 companies and universities. The authors conclude that "SBIR-nurtured firms consistently account for a quarter of all U.S. R&D 100 Award winners—a powerful indication that the SBIR program has become a key force in the innovation economy of the United States." That SBIR funded companies could constitute a quarter of award winning innovations while receiving a mere 2.5% of federal R&D grants strongly suggests that the program is giving taxpayers more "bang for their buck" and that Congress should substantially **increase** this set aside significantly, perhaps to 5% or more. This increase is particularly important during recessionary periods when private sources of venture capital are significantly curtailed.

Remedying the Exclusion of the SBIR Set-Aside from the NIH Stimulus Funding

ARRA provided an additional $10 billion to the NIH. Not enough of this is going to support small biotech companies despite the enormous decline in private equity financing. Rockville Maryland is home to one of the largest biotech clusters in the country. Yet biotech companies here and in other regions are downsizing everywhere. "Lab space available" signs are visible all around us. This will not only eliminate jobs but will kill lifesaving innovations that have been in development for years. Many of these products would not only improve patient outcomes but can reduce healthcare costs by tailoring treatments to patients in a more personalized manner. *While AIG may have been too big to fail, America's biotech industry is* ***too important to fail.***

To avert or mitigate these unacceptable losses to our healthcare system and to create sustainable new jobs I respectfully urge that Congress pass emergency legislation to double the NIH SBIR set aside for FY 2010 and 2011 to five percent (5%). This would not increase the federal deficit at all since it would require no new spending. Furthermore it would not necessarily result in a reduction in university research if it were accompanied by a mere 1% reduction in overhead (indirect costs) by NIH grantees over this two year period.

I also urge the full Senate to pass S.1233 (SBIR Reauthorization) in its present form which is a much more balanced and well conceived bill than its counterpart bill in the House of Representatives, especially in connection with the long-simmering dispute over access to the SBIR program by VC owned firms.

Thanks for considering my testimony this afternoon.

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Attachment: "From Bench to Bedside: *Academia Slows the Search for Cures*"
http://www.newsweek.com/id/200599

Senator CARDIN. Thank you very much, Mr. Cohen.

Ms. Aprile Pilon is the CEO of Clarassance, Inc. It is a pleasure to have you here.

STATEMENT OF APRILE PILON, CEO, CLARASSANCE, INC.

Ms. PILON. Thank you for the opportunity to speak today, Senator, for setting up this hearing. Thank you, Representatives Van Hollen and Edwards for taking the time to be here.

I am Dr. Aprile Pilon. I am president and CEO of Clarassance and APC Biotech Services, Inc., two small biotechnology companies based in Rockville, Maryland. Clarassance is developing protein biologic drugs, and APC Biotech provides consulting lab services and it is also developing a novel production platform for biologics under a current SBIR grant.

Both my companies are located in a Montgomery County business incubator. I watched many companies, fellow biotech companies, shrink, contract, lay off employees, sell assets and move out. Investment capital is not available, and small biotech companies are in dire need of economic assistance.

I have significant experience utilizing the SBIR program at NIH to build healthcare technology assets and facilitate their commercialization. I have personally written and submitted 23 SBIR grant applications since 1995, of which eight have been funded, for a total of over $2 million. These grants were submitted on behalf of three different small businesses located here in Montgomery County.

My lead drug candidate in Clarassance has attracted over 9 million in equity financing to fund two Phase I clinical trials, is currently poised in our Phase II clinical trials, and was partially funded in the pre-investment early stages using 1.1 million in SBIR funding from the NIH. These SBIR grants add value to my companies, more than just a dollar amount. And what I mean by that is that they provide third-party opinion on the technology and the research plan by qualified experts facilitating investment by angels and small-institutional investors who do not necessarily have the resources to do their own technical due diligence.

Basic discoveries made at academic institutions, government labs, or even in small companies must be evaluated for reproducibility, product feasibility and de-risked to the point where institutional investment and corporate partnering are possible. A significant amount of high risk, specialized R&D must typically be performed in order to evaluate and reproduce basic discoveries and to explore product ideas to assess their commercial potential. Typically, small companies are the only ones willing to take these risks. This is an especially long and expensive process for the development of healthcare related technologies.

The NIH/SBIR program therefore shows a vital huge stage of funding gap between basic discoveries and commercial enabled healthcare technologies. The SBIR program and NIH, and the small businesses that it supports, are essential components of the food chain in the biotech industry that now develops more healthcare technologies and creates sustainable jobs. Early stage commercially directed R&D is thus complementary to the basic re-

search conducted at academic and government labs and a necessary stage in the commercialization process.

The NIH basis for requesting the SBIR program exclusion from the stimulus package and the position that the SBIR program is underutilized and that poor quality applications, so-called junk science, would receive funding under the SBIR program at the expense of higher quality academic applications is unfounded. NIH's position is based on its funding criteria established for academic institutions and does not take into account the situation with small businesses.

It has grown increasingly difficult to obtain grant funding through the NIH/SBIR program. According to the SBIR program funding data, provided by the NIH itself in the table attached to my testimony, the number of SBIR applications and the success rates have both decreased between 2004 and 2007. The decrease in the number of applications can be directly attributed to the decrease in the application success rate.

The preparation of a grant proposal requires an enormous amount of time and energy, representing both an economic and an opportunity cost that significantly depletes the resources of a small business. Small businesses must carefully select and plan high quality scientific projects. Before considering writing and submitting a grant proposal, the economic cost of failure to receiving grant funding can be lethal to a small biotech. I, therefore, believe that the higher investment of small businesses in proposal writing and the higher cost of failure to secure grant funding justifies a significantly higher success rate for the SBIR program compared to other grant mechanisms tailored for academic institutions.

A recent NRC report, in which survey responses were obtained for nearly 400 NIH/SBIR award recipients, stated that the decrease in the number of SBIR proposals between 2002 and 2005 was directly attributed to three primary causes, including the high level of competition translating to decreased success rates; concerns about the selection mechanism; issues about the quality of the reviews; and funding delays. I am personally aware of two companies that have funding scores—grants that have received funding scores and have not received funding yet for no particular reason. I personally experienced each of these three primary issues during my 14 years of submitting grants to the SBIR program at NIH.

When the competition is high and the success rate decreases, small businesses are not able to devote resources to these unproductive activities. NIH review committees are comprised primarily of academics who, in my experience, generally resent the intrusion of small business in what they consider their domain of NIH funding, and they often do not consider translational research conducted by small businesses to be either innovative or meritorious. Given these prejudices, the NIH's position that small businesses are eligible to compete for non-SBIR awards under most of the other RFAs planned under the ARRA is disingenuous. Therefore, set asides for small businesses are essential to ensuring that R&D funding flows to companies. Moreover, the SBIR program is significantly more efficient at directing R&D funds towards actual R&D spending when high academic institutional indirect cost rates, up to 175 percent, are taken into account.

We have an economic stimulus to support NIH-mediated development of healthcare solutions that completely excludes small businesses. There is no question that small businesses are more efficient at converting research dollars into economic growth under the SBIR program. Small businesses are the principal vehicle for the development of technology into marketable healthcare products and services, sustainable new jobs, and sustainable economic growth.

I urge the NIH to recognize and embrace the SBIR program as a catalyst for transforming basic biomedical research into healthcare solutions and to offer more opportunities like the new RC3 mechanism to fund translational and clinical research. I urge the Senate to pass S.1233 in its present form and to expand the SBIR program to 5 percent of the NIH R&D budget, and if possible, to reverse this exclusion of the NIH–SBIR program from the economic stimulus funding. Thank you for your consideration.

[The prepared statement of Ms. Pilon follows:]

Testimony of Dr. Aprile L. Pilon, Ph.D.*
Committee on Small Business & Entrepreneurship
United States Senate

Field Hearing – Rockville, MD – June 22, 2009

Thank you for the opportunity to speak today, Senator Cardin. I am Dr. Aprile Pilon, President and CEO of Clarassance, Inc. and APC Biotechnology Services, Inc., two small biotechnology companies based in Rockville, MD. Clarassance is developing biologic protein drugs to treat respiratory and immunologic disease, focusing on a new treatment to prevent chronic lung disease in premature infants. APC Biotech provides consulting and laboratory services, and is also developing a novel manufacturing platform for the production of biologic drugs and vaccines under a current NIH SBIR grant. My companies are located in the Montgomery County Business incubator, in which over 40 small businesses reside, over half of which are biotechnology companies. For months, I've watched fellow biotechnology companies give up space, lay off employees, try to sell their equipment, move out, and finally close their doors. Investment capital is not available and small biotechnology companies are in dire need of economic assistance in order to survive.

I have significant experience utilizing the SBIR program at NIH to build healthcare technology assets and facilitate their commercialization. I have personally written and submitted 23 SBIR grant applications since 1995, of which 8 have been funded for a total of over $2 million. These grants were submitted on behalf of 3 different small businesses and supported a total of 8 full time scientists and 6 part time scientists during the funding periods over a period of 14 years. Our lead drug candidate in Clarassance attracted over $9 million in equity financing to fund 2 Phase 1 clinical trials, is poised to enter Phase 2 clinical trials, and was partially funded in the pre-investment early stage using $1.1 million in SBIR funding from the NIH. These SBIR grants added value to my companies beyond simply the dollar amount of the grant award in that they provide a third party opinion of the technology and research plan by qualified experts (reviewers), thus facilitating investment by angel and small institutional investors who may lack the resources to perform technical due diligence on their own.

Basic discoveries made at academic institutions, government labs, or even in small companies, must be evaluated for reproducibility and product feasibility and de-risked to the point where either institutional investment or corporate partnering is possible. A significant amount of high-risk, specialized R&D must typically be conducted in order to evaluate and reproduce basic discoveries and to explore product ideas to assess commercial potential. Typically, small companies are

*Aprile Pilon is President & CEO of Clarassance, Inc., Rockville, MD (www.clarassance.com) and APC Biotechnology Services, Inc., Rockville, MD (www.apcbio.com). The views expressed herein are her own and do not necessarily represent those of the companies or their shareholders. She can be reached at aprile.pilon@clarassance.com or 301-452-2899.

the only ones willing to take these risks. This is an especially long and expensive process for the development of healthcare technologies. The NIH SBIR program, therefore, fills a vital intermediate seed-stage funding gap between basic discoveries and commercially-enabled healthcare technologies. The NIH SBIR program, and the small businesses that it supports, are essential components of the "food chain" that develops new healthcare technologies and creates sustainable jobs in the biotech industry. Early stage, commercially-directed R&D is thus complementary to the basic research conducted at academic and government labs and a necessary stage of the commercialization process.

The NIH basis for requesting the SBIR program exclusion from the stimulus and position that the SBIR program is underutilized and that poor quality applications, so-called "junk science", would receive funding under the SBIR/STTR program at the expense of higher quality academic applications is unfounded. Indeed, the reverse may be the case. The NIH's position is based on its funding criteria established for academic institutions and does not respect the very purpose of the SBIR program, nor take into account the situation with small businesses. It has grown increasingly difficult to obtain grant funding through the NIH SBIR program. According to the SBIR/STTR program funding data (see attached table), the number of SBIR applications decreased by 41% from 2004 to 2007. This is no surprise, since the SBIR Phase 1 success rate decreased from the 30% range in 2001-2002 to about 20% in 2005. Likewise, the Phase II success rate decreased from the 50% range in 2001-2002 to 35% in 2005.

The decrease in the number of applications can be directly attributed to the decrease in the application success rate. The preparation of a grant proposal requires an enormous amount of time and energy, representing both an economic cost and an opportunity cost, that significantly depletes the resources of small businesses. Also, the relatively small seed-stage amounts of the NIH SBIR awards ($100,000 for Phase 1 and $750,000 for Phase II) is also taken into account in the company's decision to allocate resources to grant preparation and some decide that their resources are better spent trying to secure other types of funding. Therefore, small businesses must carefully select and plan high quality scientific projects before considering writing and submitting any grant proposal. Often the basic research has been done, to provide some measure of confidence in a successful outcome, and the technology to be developed has already received some form of limited financial support other than grant dollars (ie. founder investment, etc.) The economic cost of failure to receive grant funding can be lethal to a small biotech business. I, therefore, believe that the higher investment of small businesses in proposal writing and the higher cost of failure to secure grant funding justifies a significantly higher success rate for the SBIR program compared to other grant mechanisms tailored for academic institutions.

A recent National Research Council report[1] in which survey responses were obtained from nearly 400 NIH SBIR award recipients, stated that the decrease in the number of NIH SBIR proposals between 2002-2005 was directly attributed to 3 primary causes, including;

1. the high level of competition,
2. concerns about the selection mechanism (ie. qualify of reviews), and
3. funding delays.

I have personally experienced each of these three primary issues during my 14 years of submitting SBIR grants to the NIH. (As an aside, the issue of venture ownership (of more than 51% of the small business) accounted for just 3% of companies that abandoned the SBIR program between 2002-2005.)

When the competition is high and the success rate decreases, small businesses are not able to devote resources to unproductive activities. NIH review committees are comprised primarily of academics who, in my experience, generally resent the intrusion of small business into what they consider their domain (ie. NIH funding) and often do not consider translational R&D conducted by small businesses to be either innovative or meritorious. Given these prejudices, the NIH's position that small businesses are eligible to compete for non-SBIR grant awards under most of the other RFA's planned under the ARRA is disingenuous. Reviews of SBIR grants are often unfairly negative, academic reviewers are often uninformed about the SBIR review criteria (versus academic review criteria) resulting in applications being rejected for erroneous reasons, and inconsistency from review panel to review panel (ie. recommendations to change the research plans from one panel are criticized and rejected by the next panel that reviews the grant). Another issue that is difficult to manage and results in lower grant scores for small businesses is the fact that the company may not be able to reveal all of its technical rationale and data to justify pursuing a particular line of research, due to the confidential nature of the information, especially before a patent is filed. Most academic reviewers have little patience for missing information and will downgrade the application on that basis. This is a significant problem when the academic review process is applied to the SBIR program so poorer scores under these conditions do not necessarily correspond to poorer science. Therefore, set asides for small business are essential to insuring that some R&D funding flows to companies. In addition, while the small business community applauds the new RC3 mechanism aimed at enabling small businesses to conduct pivotal translational research, recently announced by NIH, the $40 million allocation is a far cry from the ~$230 million that would have been allocated to small businesses if the funding had gone to the SBIR program.

1. Venture Funding and the NIH SBIR Program. Prepublication copy. Charles W. Wessner, Editor, The National Research Council of the National Academies. The National Academies Press, Washington, DC. 2009.

Moreover, the SBIR/STTR program is significantly more efficient at directing R&D funds towards actual R&D spending. Nearly every dollar of R&D grant funding awarded to a small company is spent directly on the R&D, whereas academic institutions typically receive between $1-$1.50 for every $1 actually spent on R&D to cover their overhead. Indirect cost rates for small businesses are often not tolerated by SBIR budget review committees, and if they are, they are typically less than 25%; while NIH tolerates indirect cost rates of up to 175% from academic institutions.

Thus, we have an economic stimulus to support NIH-mediated development of healthcare solutions that completely excludes small companies and subsidizes low risk product development for large companies. The purpose of the ARRA is to stimulate the economy and stimulate job growth, primarily through supporting the health and growth of small businesses. There is no question that small businesses are more efficient at converting research dollars into economic growth under the SBIR program. Small businesses are the principle vehicle for the development of technology into marketable healthcare products and services, sustainable new jobs, and sustainable economic growth.

I urge the NIH to recognize and embrace the SBIR program as a catalyst for transforming basic biomedical research into healthcare solutions and to offer more opportunities like the RC3 mechanism to fund translational and clinical research.

I urge the Senate to pass S. 1233 in its present form and to expand the SBIR program to 5% of the NIH R&D budget, and to reverse the exclusion of the SBIR program from the NIH economic stimulus funding.

Thank you for your consideration.

NIH Data

Statement of Request:

Update table of FY 1995 - 2007 SBIR applications by FY and phase

FY	All SBIR				Phase 1				Phase 2			
	Number Reviewed	Number Awarded	Success Rate	Amount Awarded	Number Reviewed	Number Awarded	Success Rate	Amount Awarded	Number Reviewed	Number Awarded	Success Rate	Amount Awarded
1995	3,744	831	22.2%	$131,554,136	3,200	619	19.3%	$58,508,040	544	212	39.0%	$73,046,096
1996	3,316	696	21.0%	$111,804,628	2,808	524	18.7%	$50,998,428	508	172	33.9%	$60,806,200
1997	3,108	1,023	32.9%	$177,545,919	2,568	742	28.9%	$72,425,919	540	281	52.0%	$105,120,000
1998	2,964	928	31.3%	$155,251,782	2,503	703	28.1%	$69,474,761	461	225	48.8%	$85,777,021
1999	3,758	1,153	30.7%	$210,168,503	3,173	874	27.5%	$94,944,070	585	279	47.7%	$115,224,433
2000	4,171	1,177	28.2%	$215,876,258	3,582	946	26.4%	$113,468,347	589	231	39.2%	$102,407,911
2001	3,629	1,230	33.9%	$262,655,129	2,972	885	29.8%	$112,826,747	657	345	52.5%	$149,828,382
2002	4,095	1,265	30.9%	$279,031,110	3,411	930	27.3%	$124,423,577	684	335	49.0%	$154,607,533
2003	5,135	1,370	26.7%	$307,181,916	4,384	1043	23.8%	$151,079,961	751	327	43.5%	$156,101,955
2004	6,109	1,334	21.8%	$319,429,001	5,299	1032	19.5%	$161,415,416	810	302	37.3%	$158,013,585
2005	5,380	1,118	20.8%	$289,911,889	4,511	806	17.9%	$126,216,067	869	312	35.9%	$163,695,822
2006	4,580	1,080	23.6%	$309,217,486	3,723	725	19.5%	$119,285,839	857	355	41.4%	$189,931,647
2007	3,613	975	27.0%	$266,131,441	2,947	696	23.6%	$118,796,366	666	279	41.9%	$147,335,075

Senator CARDIN. Well, thank you very much for your testimony. I appreciate it very much.

Mr. Joe Hernandez is president and CEO of Innovative Biosensors, Inc. It is a pleasure to have you on our panel today.

STATEMENT OF JOE HERNANDEZ, PRESIDENT AND CEO, INNOVATIVE BIOSENSORS, INC.

Mr. HERNANDEZ. Thank you, Senator Cardin. I appreciate it. Congresswoman Edwards, Congressman Van Hollen, I appreciate the opportunity to share a little bit about my experiences as it relates to biotechnology in general. I am here on behalf of the Biotechnology Industry Association. We represent 1,200 companies and related groups in 50 states. I am also a member of the MD Bio Division of the High Tech Council, and also it is in that capacity I am here.

I have been involved in three biotech companies, three early stage biotech companies; one in Silicon Valley, a company by the name of Affymetrix. And we were able to put the human genome on a computer chip and interrogate the human genome. And that technology is added to really the knowledge we have in the genomics to a great extent. I was involved in a local company by the name of Digene, developed the human papilloma diagnostic test, that I would argue has revolutionized the way we treat cervical cancer.

My current company is the name of a company by the name of Innovative Biosensors. We are a company of 20 employees. We license the technology out of MIT, technology that was originally funded by DARPA and developed under the auspices of the Department of Defense. The technology as well is in Science, and we have been able to product-tize the technology in the area of bioweapons detection. We have created sensors, small box sensors, that we deploy out in areas of interest. Our primary application is actually one of the most critical buildings inside the National Capital Region. Obviously, I cannot disclose where it is for obvious reasons, but it is a deployed technology. We are very proud of the work we have done, this company of 20 people.

We have been successful in raising venture capital. We have raised $20 million in venture capital and numerous rounds of financing. I can tell you that the capital markets right now are something I have never seen in my very long—and I look older—I am older than I actually look—my very long career in the biotech sector. The value that we provide as an industry I think is quite evident. We provide significant value in terms of innovation, knowledge, jobs, and also changing the health care of our society. But we also have a very important impact on the economy. And Maryland is a very good example of this.

I am very proud to say that the economy in this state has a significant impact on the wages we provide to our employees. I can tell you from a personal perspective, the average salary in my company is $110,000. Now, I do not say that because I want applications, but I am just saying that to really illustrate the fact that we are really an industry that really pays our employees really well, and it is important that we maintain this industry strong.

It is a tough market. There is no question about it. Biotech typically is the highest risk investment in a normal market. In a market like this, it is considered an ultra high investment, an ultra high-risk investment. The typical liquidity events that exist in companies such as the IPO markets are non-existent. Our investors cannot exit out of these companies. It is a very, very significant issue, one that we cannot lose our perspective of.

VCs. While there are a number of VCs both in the area, and, really, throughout the country, they are really not making currently new investments, and that is clear in the marketplace. What you see in venture capital occurring is that they are actually maintaining the companies and allowing them to survive this market in hopes that it will change. There are no new investments coming out of—I would argue that they are ranking their companies and really dropping the ones that are at the bottom of that list, which is a significant issue.

The M&A activities slowed down. There is no M&A activity. The M&A activity you see is really what I call the middle-tier, larger companies that are consuming each other up because the market requires that they do that. And small companies, such as the one represented here today, really have a hard time existing in an M&A environment.

So survival is key for us, and this is why we believe it is important that additional capital come into the marketplace via federal vehicles. Bio has urged the NIH to include small biotech in the American Recovery and Reinvestment Act. It has been a position that I think Bio has been consistent about. The American Recovery and Reinvestment Act does not require the NIH to direct the SBIRs. In some ways, we are frustrated like everybody else is about that notion. But I would argue that it is more important to focus on how do we get those dollars out quickly to the community.

I would argue that it does not really matter what we call it. It can be done in the format of recovery vehicles or recovery grants, the RC1s, RC2s and RC3s that are currently being solicited by NIH, some of which, though, lend to the past. So in some ways, these are a moot point. I think that what we really need to do is just get this capital out there.

In some ways, I would argue that the current RC vehicles are better because they are faster. They turn around more quickly. They are suggesting at least—the grants that I am familiar with are suggesting 30- and 60-day turnaround times in terms of response, which is really critical in this market. We really need that capital and that decision really quickly. And they are larger in size, which is I think quite helpful as well.

So it is important that we get this capital out there. It is easy to throw eggs at the NIH, but I would argue that the NIH has played a very critical role in the development of these technologies. They play a very important role in our society, and all we are asking for is that these dollars that are really part, and intended to be part, of the Recovery and Reinvestment Act, that they be deployed and they be deployed quickly.

So I thank you for your time, and I would be delighted to take any questions you have.

[The prepared statement of Mr. Hernandez follows:]

HEARING TESTIMONY

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

ON BEHALF OF THE

BIOTECHNOLOGY INDUSTRY ORGANIZATION

BEFORE THE SENATE COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP

June 22, 2009

Good morning, Senator Cardin. Thank you for holding this hearing today in Rockville. I am Joe Hernandez, President and Chief Executive Officer of Innovative Biosensors, Inc also known as IBI. I am appearing before this Committee on behalf of the Biotechnology Industry Organization (BIO). BIO represents more than 1,200 companies, academic institutions, state biotechnology centers and related organizations in all 50 states.

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

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

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

As we develop the next-generation of biosensors and treatments for diseases that would have been considered unapproachable just a decade ago, it is incumbent on our system to find ways to

support these risky but transformational discoveries that could improve the lives of children and adults suffering from genetic disorders, infectious diseases, cancer, and autoimmune diseases, among others. We want to take advantage of the ground-breaking scientific discoveries in basic research that have been achieved in the last decade at the NIH, in academic centers, and in industry and translate them into tangible treatments as rapidly as possible to improve the lives for patients. This has personal and economics benefits, both to the individuals affected, the organizations and companies working on these initiatives, and our society in general.

Small biotechnology companies have high and intense capital needs (over $1 billion) and an unusually long development time of 5-12 years. The impact of the current economic crises on small biotechnology companies has been and continues to be severe. According to the latest available data,:

- 16% of the 394 public U.S. biotech companies that were active at the beginning of 2008 ended the year either in bankruptcy, restructuring, or suspended operations, or were acquired.
- Since January 2008, over 125 biotech companies have laid off more than 10,000 employees to save cash and over 35 companies have shelved promising development programs with positive clinical data. These programs include therapies for HIV, cervical cancer, Multiple Sclerosis and diabetes.
- 40% of the currently active 330 public U.S. biotechs have less than 1 year of cash
- 23% of the currently active 330 public U.S. biotechs have less than 6 months of cash.

The total capital raised by the biotech industry in 2008 has seen a steep decline, down 55 percent compared to 2007. A recent study by BIO and Thompson Reuters found that the current economic crisis has forced over 80% of biotech investors to change their investment approaches. They can no longer afford the high risk that is characteristic of investment in biotech. In just the last seven months, at least 40 U.S. public biotech companies have either placed drug development programs on hold or cut programs all together. These programs include therapies for HIV, cervical cancer, Multiple Sclerosis and diabetes. The decline of the biotech industry jeopardizes not only America's patient population, but also America's competitive edge in the 21st century global economy.

While these projects tend to be high-risk, they are also high-reward, both economically and socially. The total employment impact of the biosciences sector is 7.5 million U.S. jobs, taking into account the direct and indirect jobs created in the economy. These are high-paying jobs that are on average 68% higher than the average private-sector job.

It is imperative that we find better ways to treat chronic diseases. A 2007 study by the Milken Institute found that the U.S. could save about $900 billion in indirect costs (lost productivity) by 2023 by reducing the rate of chronic disease through improved prevention and disease management. Innovative treatments are an important component of reaching this goal. Currently there are more than 400 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDs and arthritis. The importance of fostering innovation by small U.S. biotechnology companies has never been clearer.

BIO has urged NIH to include small biotechnology companies in American Recovery and Reinvestment Act (ARRA) funded grant programs. It is important that there are ARRA funding opportunities for small companies that will assist them in continuing their research and development programs over the next two years while the economy recovers.

The vast majority of NIH grants have historically been targeted toward hypothesis-driven basic research, not the development-oriented endeavors small biotechnology companies purse. Other than the very successful and vital NIH Small Business Innovation Research Program (SBIR), almost all NIH research funds are awarded to non-business entities. For example, in 2006, NIH awarded 54,773 extramural grants, of which 79% were awarded to higher education institutions, 8% to research institutions and 8% to independent hospitals. Outside of the SBIR/STTR grant program, businesses (of all sizes and fields) received a total of 0.04% of the 2006 awards. Unfortunately, even within the SBIR program there exist barriers to funding of biotechnology research, primarily due to the exclusion of small companies that are venture-backed. Hopefully Congress will fix this problem as a part of the SBIR reauthorization process and the funding level of the NIH SBIR program will become even more important for our industry going forward.

The ARRA does not require that 2.5% of the extramural research funds allocated to NIH be directed to the SBIR program, as would normally be the case under existing law. Rather, ARRA exempted NIH from this requirement, meaning that there are fewer dollars in the NIH SBIR program than would have otherwise been the case. However, it is my hope that NIH will recognize the importance of providing ARRA funded grant opportunities for small biotechnology companies, so that work on developing cutting-edge treatments and therapies that would be beneficial to the American public can continue. BIO has written to NIH urging them to do so, as I imagine have other groups and companies in the life sciences arena.

While NIH's primary role has been - and should continue to be - funding basic research, today's economic environment argues for a much more aggressive effort to sustain the small biomedical companies which will ultimately commercialize the scientific breakthroughs made at NIH and NIH-assisted research universities. Making these ARRA grant funds available to small biotechnology companies and having an expedited review process would enable these small companies to continue work on promising drug development programs beneficial to the public health. This would serve to meet two of NIHs stated missions: 1) To foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to advance significantly the Nation's capacity to protect and improve health; and 2) To expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research.

I commend NIH for including small businesses as eligible entities for the Challenge and GO grants. Preliminary information indicates that there were an overwhelming number of applications for both of these programs. I would especially like to commend NIH for creating the Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Pilot Program and the Small Business Catalyst Awards for Accelerating Innovative Research Program (SBCA-AIR). These two small business-focused

competitive grant programs are exactly what is called for to ensure the continued development of next-generation discoveries, treatments and therapies.

We urge NIH to consider creating more small business competitive ARRA-funded grant programs. As long as the financial markets are frozen, it will remain difficult for small biotechnology companies to secure capital to fund high-risk, long-term projects. Access to NIH's ARRA-funded grant programs would provide substantial assistance to small biotechnology businesses' research and development program over the next two years while the economy recovers and the capital crunch eases, thus providing long term benefits to public health and ensuring that a whole generation of America's life sciences companies and their research is not lost. Furthermore, providing economic recovery funds to small biotechnology companies would help ensure that economic development associated with investments in biomedical research is maximized.

BIO is and will remain a strong supporter of NIH. As the nation's premier research agency for the study of human health conditions, diagnostics, and treatments, a properly-funded NIH is vital to the ability of small biotechnology companies to improve technology and develop innovative treatments and cures.

Thank you for the opportunity to testify.

[The prepared statement of Ms. Sally J. Rockey follows:]

Testimony
For the Committee on Small Business and Entrepreneurship
United States Senate

Opportunities for Small Business Participation in NIH ARRA Research Programs

Statement of
Sally J. Rockey, Ph.D.
Deputy Director for Extramural Research
Office of the Director
National Institutes of Health
U.S. Department of Health and Human Services

Submitted for the Record
Monday, June 22, 2009

Madam Chairman and Members of the Committee:

I am pleased to provide the following statement regarding the American Recovery and Reinvestment Act (ARRA) and the opportunities for small businesses to participate in National Institutes of Health (NIH) ARRA research programs.

As you know, the funds provided to the NIH under ARRA are exempted from the statutory set-aside requirements for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs; therefore, the NIH is not required to provide a set amount of its ARRA funds to those programs. The NIH continues to comply with the statutory requirement to set aside 2.8% of its other Fiscal Year (FY) 2009 appropriated extramural budget toward the SBIR/STTR programs.

Although the NIH is not required by ARRA to provide a set amount of the funds toward the SBIR/STTR programs, it is important to note that NIH is committed to the small business community and small businesses are able to, already have, and will receive NIH ARRA funds. NIH has been encouraging small businesses to apply for stimulus funds through various funding opportunity announcements that have been released to assure that small businesses receive an adequate share of the ARRA funds appropriated to NIH.

Outreach efforts have been stepped up to alert small companies of ARRA opportunities. In the last two months, seven SBIR/STTR presentations have been given throughout the country at life science or SBIR/STTR conferences in Indiana, Kentucky, New Jersey, New York, Maryland and Washington, D.C. NIH's 11th Annual SBIR/STTR Conference is to be held next week, with typical attendance in the hundreds; this will be another excellent opportunity to disseminate information about targeted ARRA opportunities to a national small business audience.

During the past few months, NIH has released several funding opportunity announcements (FOAs) that were supported by ARRA, for which small businesses were strongly encouraged to apply. These include:

- The *NIH Challenge Grants in Health and Science Research* or "Challenge Grants"
  http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-09-003.html
  This opportunity focuses on specific knowledge gaps, new technologies, data generation or research methods and would benefit from an influx of funds to quickly advance the area in significant ways.

- *Research and Research Infrastructure "Grand Opportunities"* or "GO Grants"
  http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-09-004.html
  This opportunity focuses on developing and implementing critical research innovations to advance their research enterprises, stimulating future growth and investments, and advancing public health and health care delivery.

More than 500 applications were submitted by small companies in response to the Challenge Grant announcement, and over 370 applications were submitted for GO grants.

As recently as June 2, NIH released two additional announcements that explicitly target the private sector commercial research community. These include:

- *Recovery Act Limited Competition: Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Pilot Program*
  http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-09-008.html

  This FOA is a pilot program that focuses on the funding gap between promising research and development and transitioning to the market by contributing to the critical funding needed to pursue the next appropriate milestone(s) toward ultimate commercialization. Any U.S.-owned, for-profit enterprise/commercial organization is encouraged to apply for this funding, and although not explicitly limited to small businesses, most of the applications are expected to be submitted by small businesses. Please note that applications received under this funding opportunity may be given funding priority if the applicant is associated with an enterprise/commercial organization that is of small size and/or of limited resources.

- *Recovery Act Limited Competition: Small Business Catalyst Awards for Accelerating Innovative Research*
  http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-09-009.html

  This opportunity specifically targets the SBIR research community and focuses on accelerating innovation through high risk, high reward research and development that has the commercial potential and is relevant to the NIH mission. It seeks to encourage fresh research perspectives and approaches and focuses on early-stage ideas that promise to lead to major leaps forward rather than incremental improvements of existing technologies. Only U.S. small

business concerns are eligible to submit Phase I SBIR applications, and first-time applicants to NIH may receive funding priority.

In March 2009, NIH offered three administrative supplement and competitive revision opportunities for those with active research project grants (including SBIR and STTR). The supplements provided additional funding to accelerate the tempo of scientific research on active grants. Revision awards support a significant expansion of the scope or research protocol of approved and funded projects. Administrative supplements were also offered to provide summer research experiences for students and science educators. SBIR and STTR projects successfully competed. At this time, nearly 20 SBIR/STTR grantees have been selected to receive administrative supplements to provide summer research experiences for students and/or science educators.

In addition to releasing these funding opportunity announcements, the paylines at various NIH institutes and centers have been extended to reach more meritorious research grants, including those submitted by small businesses.

As evidenced, NIH has afforded small business with a large variety of opportunities to compete in the NIH ARRA program in keeping with the President's agenda to revitalize America's innovation engine. NIH has used ARRA funds to support small businesses in new and unique ways that are likely to advance biomedical science and quicken the development of products and services that benefit the health of the nation.

Thank you for the opportunity to present this information to you.

Senator CARDIN. Again, let me thank all of our panel of witnesses for their testimony. I think there is a general consensus of the importance of the SBIR program, that it will create jobs much more efficiently than the other recipients; that it will help in innovation, and the numbers and statistics and the leveraging appear to be pretty conclusive.

We are also in a recession, as many of you have pointed out; therefore, it is very difficult for these small companies, innovative companies, to get capital necessary for their normal businesses, let alone the expansions that we would like to see.

Mr. Hernandez, I agree completely with you and other witnesses that NIH could rectify the problem with that amendment. There are plenty of opportunities they have to get money out to small businesses. And they have been reminded of that by Senator Landrieu and Senator Snowe and Senator Feingold and myself, and we will continue to do that.

I just want to hear first from Ms. Pickett so that we are clear on this. Regarding the waiver that was included in the American Recovery and Reinvestment Act to the allocation, I just want to get on record your view that this was not something that the SBA had requested and something that you think is particularly not helpful in this recovery.

Ms. PICKETT. Senator, it was a surprise to us as well.

Senator CARDIN. I just want to make sure we were not alone on that particular issue.

Ms. PICKETT. No.

Senator CARDIN. I want to talk about the current economic climate and how urgent it is for us to try to get some relief to innovative small companies. The $10 billion is a lot of money at NIH alone. And if we could get SBIR allocations up to that $230 million level, or somewhere around there, which we thought was going to be allocated to small businesses, how important that would be. Has there been any sign of help from NIH to small, innovative companies under any of their opportunities?

Have we seen much happening?

Mr. HERNANDEZ. If I can just make a personal comment.

Our company looked at some of what are called RC1s and RC2s, which are part of the Recovery Act, dollars and granting vehicles that the NIH had put forth. The RC1s appeared to us—and, again, we are sort of making a judgment call here—appear to us that they were pretty selected in terms of the topic areas that they were seeking dollars for. It just seemed quite tight in terms of the topics that they wanted applications for. So we actually dismissed the RC1s for not being really broad enough to justify us investing the time to really write those grants. The RC2s were, I would argue, a little better mechanism, and the RC2s seem like a lot better mechanism to be able to, in fact, apply for these dollars.

The time that they had proposed to get back to us in these grants, some of those have come and gone, so I do not know exactly what is happening in terms of the time line and so forth. I understand they received an overwhelming amount of applications, so that is probably part of the reason. But I would argue that the RC1 vehicle was not of any help to at least companies I am involved with.

Senator CARDIN. My point is, do you see any special effort by NIH today to reach out to small, innovative companies to try to make sure that they are included in the Recovery funds?

Mr. COHEN. Hard to say. There has been—to be fair, you should not conclude that none of the Recovery funds are being used for small business. And, in fact, as the NIH will say, we are permitted to compete for virtually everything. We are not excluded from competing. As a practical matter, the likelihood of a small business winning a grant that is normally geared for universities is extraordinarily low.

Furthermore, there have been some SBIR initiatives within the Recovery Act. In fact, our company has competed for one. What I do not know, and what I doubt, is whether they have set aside the required typically 2.5 percent. I suspect it is considerably less than that, but it is not zero.

Furthermore, a couple weeks ago they came out with an interesting program. The acronym is BRDG–SPAN. It is an interesting program for valley of death. It is not an SBIR program. In other words, companies of all sizes are permitted to compete. But I will say I think it was a very well thought out program, still relatively small. I think only $40 million was set aside for that. So there are some signs of interest and some signs of progress. I just do not think it is enough and it is not fast enough.

To the first part of your question, urgency, I can tell you I have had meetings—I have had companies that have come to us over the last couple of months, companies that have literally weeks of capital left. What I think is hard for the NIH administration to really fully grasp—because they are typically from academia; they have that mind-set. We do not have tenure, unlike the university, our university counterparts. For us—people, when you cannot make payroll, your best assets, which are your scientists, they have feet. They have to leave. So it is extremely urgent, and I do not see that urgency, regrettably, in terms of the NIH and the programs that they are going forward with.

Senator CARDIN. Let me just point out my concern. Mr. Glover's testimony particularly underscores this, that there has been an historic hostility at NIH to allowing special allocations to small businesses within the innovative research program. And then during the reauthorization of SBIR, we know the difficulties we had with NIH increasing it from two and a half percent to three and a half percent. There was hostility from NIH.

Now, I want to point out, it was done by our committee and the bill passed unanimously by our committee. So there is strong support in Congress. And it seems to me that NIH is still resisting an effort to allow small businesses an even chance to get in the door. Without the allocation amounts, it is going to be very difficult to see these other programs at all filling the gap that the SBIR program has been able to do.

So moving forward, we are going to have a reauthorization of SBIR. We are going to hopefully get it up to three and a half percent. We are going to get that done. But on these stimulus dollars, which are significant funds, we are not there yet. We are not there yet.

Yes?

Ms. PILON. I just wanted to address that, first, I have been in the trenches for a long time, rubbing elbows with people who review grant proposals, fellow grant applicants from universities and other institutions, as well as companies. There is a tremendous bias against applications from companies. By and large, the academic attitude is that they are throwing—the government is throwing its money away by funding poor science in companies. And it is an ingrown prejudice that has been there since the inception of the SBIR program.

That said, I believe, as I stated in my testimony, that I do not believe that small businesses would receive any significant portion, less than a percent, of federal R&D spending if it were not for the specific set aside. And secondly, for your earlier questions, I follow these things fairly closely. There has been nothing from the stimulus for business specifically, except for the RC3 mechanism allocating $40 billion to fund approximately 10 large grants, targeted at business. And it is not focused on small business; it is any for-profit entity. So small businesses like mine would be competing with Merck or Pfizer, potentially, if they decided they wanted to go for these grants, which is not particularly helpful.

Senator CARDIN. Just one final observation before turning to my colleagues. I support research funding for our universities. I think that is important research. I am not trying to suggest that NIH is not doing a service by these contracts. But the point that was raised earlier on commercialization, getting the innovation out in the marketplace, creating jobs, in those areas the SBIR program has been extremely valuable.

So I really cannot figure out the hostility here. We are going to have to overcome it, because we need to make sure that NIH continues its extremely important mission, that the universities can do the work that they are doing, and the small, innovative companies have the capital they need, particularly in this recession, to get the job growth and our economy back on track.

Congressman Van Hollen.

Representative VAN HOLLEN. Thank you, Senator.

I just wanted to follow up on some of the questions and comments related to these new programs that NIH has apparently developed. And, obviously, it is unfortunate that we do not have a witness from NIH here. But before I do that, let me underscore the point that I think all of you have made, which is none of these are a substitute for the SBIR program, and we all want to work together to increase the set aside, whether it is three and a half percent, Mr. Cohen made the proposal 5 percent for two years. But whatever it is, I think that increasing that, based on the National Academy of Science's study and the observations you have all made with respect to the data showing that so much innovation comes out of the small business community in this area, is warranted.

But I would like, to the best we can, get some sense of what the NIH claims it is doing. I am looking at a letter of response to a letter that Senator Cardin had written, and this is the response from NIH, dated May 28th of this year, where the NIH says, "You may be aware NIH has released several funding opportunity announcements."

Is that what you are referring to by RC1, 2 and 3?

[Witnesses nodding affirmatively.]

Representative VAN HOLLEN. Okay.

And I assume number 1 was then these challenge grants, and number 2 was the grant opportunities of GO grants, and RC3 you are referring to is the BRDG–SPAN?

[Witnesses nodding affirmatively.]

Representative VAN HOLLEN. Okay. If we could just take each of those and get some sense of how much funding NIH is allocating to these grants, to what extent we know small businesses are currently or may participate in those. Because another thing we may want to look at as we go forward, if these have merit—Mr. Cohen you mentioned—the valley of death issue is one we have all discussed a lot. So if NIH is on to something here with the BRDG–SPAN, maybe as part of reauthorization, we would actually look at further developing that idea and maybe putting it in a more concrete and sustainable framework going forward.

So to the extent they have come up with some good new ideas, maybe it is an opportunity for us not to substitute those ideas for some set aside, whatever percent it may be, but to build on them. So I would be interested in your, at least, preliminary observations based on what you know about each of these three programs, both in terms of the magnitude of the funding and whether you think that they make a good investment.

Mr. HERNANDEZ. If I may go ahead, and my colleagues here, we have the experience that we have applied for the RC1s and the RC2s, and so we know at least some of those vehicles pretty well. The RC1, if I recall correctly, is a $1 million program over a two-year period. The RC2 was a $2 million program over also a two-year period. RC3s are a little bit larger in size, but to Dr. Pilon's point, there are a very, very small number of those. So we are not going to compete simply because we think it is just not even worth our time.

The RC1s, those dollars—those grants seemed that they were previous programs that were not funded, and they were, in essence, re, what is the word, characterized——

Ms. PILON. Recycled.

Mr. HERNANDEZ [continuing]. Recycled grants is the terminology we use, the sophisticated terminology that we use in the industry. I would argue that the vehicles themselves actually make some sense. And what I mean by that is, the turnaround time is quite impressive. I remember when we were writing these grants, or our scientists were writing, they were astonished that the NIH can turn around the grants in such a period of time. So maybe there is sort of a positive thing there.

The other thing is the size. I think, from our perspective, we have always argued and we made this testimony—I myself made testimony in front of Congress previously related to the size of the Phase I and Phase II grants. They are really small, relatively speaking. A hundred thousand dollars is a very, very small amount of dollars for our industry. It just, unfortunately, does not get us a whole lot. So the fact that these are larger grants actually has some positive things that I think we should not overlook. But I just felt the first elements of these grants look like they were predetermined.

Ms. PILON. They were. I support Joe's comments. The RC1s in particular are the challenge grants. The topics—there were something like 400 topics to fund 200 $1 million grants. And from what I understand, the NIH received upwards of 12 or 15,000 applications for that, for 200 grants. There were single universities putting in 500 grants for one solicitation, for one RC1 or RC2 opportunity. So those kind of numbers and that kind of competition—and particularly in the RC1, the topics were very academic. They were not—they were not projects, topics that had a commercial objective. The GO grants, the RC2s, were a little bit different. Here again, that is 200 grants they were going to fund, and I believe the cap was also $200 million with 100 grants. It is a small number.

Between RC1 and RC2, I understand that 23,000 applications were put in. I know that small businesses are competing in that, but they are vastly outnumbered. The turnaround time is excellent but remains to be seen, if they can do it and do a good job. NIH has been requesting reviewers who are volunteers from both the academic and business communities to help handle this load. There are significant issues where people in small companies, to serve as reviewers because of conflict of interest issues and what you might be reviewing. I personally—although I have gotten a lot of grants from NIH, I do not serve as a reviewer. I serve as a reviewer for National Science Foundation, where my conflict of interest issues are much reduced.

So anyway, the number of grants that are going to be funded so far, specifically out of the RC1, RC2 and RC3, are approximately 410 awards, out of 23,000 applications so far, and we have not even seen the response to the RC3 mechanism.

As John mentioned, the SBIR has received a little bit of attention. The other one that just recently came out was a special program for the next SBIR date, for companies that want to apply for SBIR funding but have never received it before in the past.

Representative VAN HOLLEN. Right, the fourth one coming out.

Mr. COHEN. I do not know the answer to your question. Not surprisingly, if the NIH is not answering members of Congress, certainly they are not telling entrepreneurs what is going on. And beyond the particulars of the Recovery Act, I think what this underscores is the need for more transparency at the NIH and more involvement at the policy level on an ongoing basis, so we can constantly look and relook at whether we are getting it right. AIG, as they said, is too big to fail. Well, the biotechnology industry is too important to fail. America needs this industry to succeed. There are not too many left who are truly ahead of the world, and we still are ahead of the world in biotech.

So I think there are a lot of things that Congress can look at in the long term, beyond the Recovery Act, perhaps designating an assistant director at the NIH for small business innovation, somebody who would be focused on this day in and day out and would have regular interaction with your committees.

As I recall in the Senate legislation, there was an advisory board, a small business advisory board. That is a great mechanism if that is established in the right way, to have ongoing transparency, some fresh ideas, where we really know where things stand, where they should be. Let's get input beyond the academic community. Let's

allow the true customers of the NIH, namely patient advocates, physicians, let them weigh in. What is the right ratio? How much should be going toward translational versus basic?

Obviously, as entrepreneurs, we have a bias, but by the same token, the academic community, who truly own the NIH in every sense of the word, they have a bias, too. So we need to get other voices to the table on an ongoing basis. But in the short run, I cannot give you an answer to your question.

Representative VAN HOLLEN. Ms. Pickett, the SBA's role in monitoring the allocation of SBIR grants, different agencies, do you as the Small Business Administration look at all the different agencies to determine whether they are making their set-aside requirements, or is that just something that is done internally at every agency?

Ms. PICKETT. Well, quarterly reports, annual reports are made to the agencies.

Representative VAN HOLLEN. To the Small Business Administration?

Ms. PICKETT. To the Small Business Administration, yes.

Representative VAN HOLLEN. So let me just ask you, with respect to this NIH issue and the exclusion from the economic recovery funds, the Department of Health and Human Services was not exempted, right? The Department as a whole was not exempted from the two and a half percent requirement?

Ms. PICKETT. It was NIH.

Representative VAN HOLLEN. It was NIH. But the NIH funding would be counted against the full department's, would it not?

Ms. PICKETT. Yes.

Representative VAN HOLLEN. So when you monitor whether or not the Department of Health and Human Services as a whole is complying with this two and a half percent set-aside requirement, will you count that two and a half percent against the funding that goes to the entire department, including the agencies?

In other words, if they do not provide some of these funds for NIH, and we all hope to try and reverse that, are you going to make sure that that two and a half percent still comes out of their entire budget, which, of course, would give them incentive to put more into the NIH on a voluntary basis.

Ms. PICKETT. We just collect the reporting. We really do not have the enforcement tools other than to collect the data and report to the House and Senate committees on the reporting. Our administrator can work closely with officials there, and the intent of Congress can be made clear. Right now, we are just collecting, making sure the money is being spent and that award is being made.

Representative VAN HOLLEN. But when you make your report to Congress this time, with respect to the Department of Health and Human Services set-aside money, will you—I assume you are agreeing that they have that two and a half percent requirement that goes department-wide, and the funds that came to NIH are included in the department-wide funds.

Isn't that right?

Ms. PICKETT. I will have to check on what the reporting is. I do not know that NIH specifically—that HHS has the entire program,

whether it is all focused in NIH or it goes elsewhere. So I will be happy to get back to you on that.

Mr. GLOVER. If I may, the Missile Defense Agency several years ago tried to do something like this and slip something in. The chairman of the Small Business Committee and ranking member sent a letter to the Secretary of Defense saying, where else are you going to make this up, and requiring the other agencies to make it up. And it was amazing how quickly Missile Defense withdrew—even though they had the statutory permission, they said we do not want to have to fight our friends in the Army and the Air Force and Navy to try and do this. So they actually found money for it. It is one of the unheralded success stories. The Small Business Committee in the Senate did jump right on that, write that letter, and it did have a remarkable result overnight.

Representative VAN HOLLEN. Well, I am hoping the same can be said, Senator Cardin, as others have sent that message to them.

Mr. GLOVER. It is a wonderful suggestion, sir.

Ms. PICKETT. I think that is where the intent of our legislators is helpful.

Senator CARDIN. As this hearing is helpful.

Congresswoman Edwards.

Representative EDWARDS. Thank you, Senator Cardin.

I just have a couple comments, really. Each of you in very different ways actually pointed to exactly the reason that we need investment in the SBIR program and small business in this economic climate. And particularly, Mr. Hernandez, when you spoke about the lack of liquidity in IPOs, you talked about the difficulty and the complexity in this environment of attracting venture capital investment.

All of these things actually highlight why it is a needed investment through SBIR. And so, I hope that NIH takes note of that. I mean, it is very disturbing to hear from Ms. Pilon about, in your testimony, the numbers of small businesses that are essentially having to downsize or close doors because of lack of investment capital. Even on a good day, it is really difficult to attract venture capital into these businesses because they are so risky, and that is in a good economic climate.

I am curious to hear from each of you what you believe the NIH actually could do, even with the exclusion, because as I read the language, I actually think that they could—they say—for example, in the April 23rd hearing, their testimony is, well, the two and a half percent that they have through the regular appropriations process enables them to do what they need to do even now, and especially given the lack of quality. They pointed to a lack of quality in the applicants. And it is hard to know how to read that because on the other hand, you hear from Ms. Pilon and others that this supposed lack of quality, there are a number of different reasons that can be pointed toward the applicant pool.

So I wonder what you believe that they have the capacity to do right now through their regular appropriation and even with the ARRA funds if they were so inclined.

Perhaps Mr. Glover.

Mr. GLOVER. First of all, the SBIR legislation says not less than two and a half percent, so they can go over it very quickly and very

efficiently. In terms of quality, one has to remember they refuse to give the National Research Council the data to evaluate the quality and compare because they did not want anybody else to see it. They still have these funny numbers where they use different things. And when they talk about the competitive ratio, they still count us as having two competitions where everybody else has one.

So their thinking is skewed because of these things, which gets them to different results. And they also have for SBIR commercialization evaluation criteria that does not apply to any other research they do. So there is a difference there. And they can do whatever they want to do if they have the will to do it, and, hopefully the new director will have the will to do it. They can do those things, and there are a lot of other creative things.

When we talk about the valley of death for businesses, it is nothing compared to the valley of death for university research because it still has to get across to a business and then across the valley. So there really are a lot of things that could be done to further streamline commercialization of all of NIH's research, and this would certainly be a wonderful opportunity with the stimulus money.

I would have hoped instead of just giving a lot more basic research, they would have looked for things that would create long-term jobs very quickly. I do not see that they have done that.

Representative EDWARDS. Ms. Pilon.

Ms. PILON. It is my understanding that one of the main uses that the NIH was intending to put the stimulus funding towards is to go back and fund grants that had barely missed or were underneath their funding cutoffs for the past couple of years. These are shovel-ready projects. They have already been reviewed. And they could just go back and fund these projects very quickly.

I am personally aware of a couple of companies that received fundable scores below the cutoff on SBIR Phase II grants, and they have heard nothing about getting funded. So there is this perception, at least for me, that there is a very distinct preference to fund academic research versus small business research, even when they do not have the argument that the scores are inferior to the academic scores. I do not understand that. They should be funded.

One issue that I am acutely aware of because it happened to me several years ago is that, particularly with the smaller institutes, they do not have enough money in their pots to really fund Phase IIs, putting the small company in the situation of waiting two or three years for them to accumulate enough money to get up to that 750K to fund a Phase II proposal. And I would suspect that there might be a backlog of highly qualified, highly meritorious Phase II applications, particularly in the smaller institutes that have not been funded, not been funded in a timely manner. And, of course, waiting two or three years for that kind of money is a death knell for a small company.

Representative EDWARDS. Yes, Mr. Hernandez.

Mr. HERNANDEZ. If I can just make one comment, is really highlighting the chart that you have up here. And that is that it is clear that the number of SBIR applications has been going down year over year. I know this dialogue is not really about the SBIR program in general, but I think it is worthy of looking at why that

is and why companies are not interested in applying for a $100,000 grant. That is the statement I made earlier. It is just too much effort for a company to focus that kind of resources to a $100,000 grant. It is very important to increase competition. Whatever mechanisms we use, I think you have to increase that and increase the competition in general.

I really think that there are some good elements in the Recovery Act that we should not overlook, and that is the expediency of which they are supposedly getting back—we do not know; the jury is still out on this one—that they are getting back to the applicants. The sizes of those grants I think really make it attainable for a company to apply to, and it makes it a little bit more interesting for a company who really has multiple projects in the pipeline.

The last comment I would make about these grants is that, generally speaking, there is an opportunity for us here in August. I think August is the next SBIR deadline. I do not know that we can act that quickly, but I would argue that this is a really, really good opportunity to really have the NIH step up to the plate and allow companies like us to apply to these funding programs. So there is an opportunity. I do not know how realistic it is to expect that they will act.

The one last comment I will make, and that is really in defense of NIH, if I may be the only sole voice here. And that is that we did receive an e-mail from the director of the SBIR program encouraging companies to apply for the Recovery Act grant. So there is an interest, at least based on that e-mail, for companies to apply and to be part of that program.

Representative EDWARDS. Well, again, I just want to underscore—and I know my colleagues feel the same. I mean, this is not—we obviously all were very strongly supportive of the investment funding that went into the NIH and all of our research facilities. And the question is how do you strengthen what is happening at NIH so that it more effectively benefits our small businesses that are actually quite vulnerable in this economic environment, and how do we challenge NIH to live up to the opportunities that are available.

I would just say—and thank you again, Senator, for doing this. And I would just say in conclusion, I have to depart, I think there are a number of ways that we need to look in the future at Phase I and at Phase II, how do you move then from the research and development to really commercializing, through getting a product often out to market, and how can we strengthen the program's ability to do that. And I think from an oversight perspective, many of us are going to be looking at those. And the question is what do we do in this interim period with resources that are available through the American Recovery and Reinvestment Act.

Thank you, Senator.

Senator CARDIN. Well, thank you very much.

I am going to put in the record, without objection, Senator Feingold's statement for today's hearing, and just point out that I am going to concur with Senator Feingold that we are going to continue to try to find out, in specific dollars, how much of the stim-

ulus money that NIH has allocated will end up with small businesses.

[The prepared statement of Senator Feingold follows:]

RUSSELL D. FEINGOLD
WISCONSIN

United States Senate
WASHINGTON, DC 20510-4904

Statement of U.S. Senator Russell D. Feingold at the Senate Committee on Small Business and Entrepreneurship entitled "Missed Opportunities: The ARRA and the NIH/SBIR exclusion"
Monday, June 22, 2009

Thank you, Senator Landrieu, for calling this hearing and for your leadership on this issue, and for inviting my testimony today. I thank you and Ranking Member Olympia Snowe for all the work you both have done on this issue, including your letter to the Department of Health and Human Services (HHS) in March. I also want to acknowledge my colleague, the Senator from Maryland (Mr. Cardin). I have been pleased to work on this issue with him since we learned of this matter.

I am a strong supporter of the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs. Those programs are vital in promoting early stage innovation and ideas. Since the inception of the SBIR program in 1983, through 2006, more than 94,660 projects have been awarded nearly $21 billion. The success of SBIR/STTR has been clearly documented, which is why the SBIR community was so shocked to learn that the National Institutes of Health (NIH) sought and secured an exemption to funding the SBIR program in the $8.2 billion it received in the American Recovery and Reinvestment Act (ARRA) funds. I hope this hearing will shed further light on this matter.

On March 11, 2009, Senator Cardin and I wrote to Raynard Kington, Acting Director of the National Institutes of Health, expressing our concerns regarding the SBIR funding exemption NIH had secured in ARRA funds. We wanted to know to what extent NIH asked for the exemption and the reasons for the exemption. In addition, we asked NIH to explain how HHS, which contains NIH, would meet the requirements to fund the SBIR/STTR program at 2.5% and .3%, respectively, with this exemption in place.

On April 6, 2009, I received a response from Raynard Kington that neither responded to any of our concerns nor acknowledged the SBIR funding exemption. On May 28, 2009, I received another letter from Dr. Kington addressing some of our concerns. While the letter stated that the exemption was provided due to overall declining SBIR and STTR applications and concerns about the ability of eligible firms to produce sufficient numbers of high-quality grants, the question as to what actions NIH took to secure the exemption was not answered.

I am pleased that NIH has developed two new funding opportunities in which small businesses can participate. This is a positive step forward; however I would like to know if funding dedicated to these two new programs will be sufficient to meet the $229

million shortfall in SBIR funding stemming from the NIH exemption, and if not, what percentage of ARRA funds will be provided to SBIR/STTR.

The SBIR/STTR community deserves honest and complete answers from NIH and I look forward to the testimony of today's witnesses. I am confident this hearing will shed more light on this important issue. Thank you, Madam Chairwoman.

Senator CARDIN. Senator Feingold has gotten two responses from NIH. Neither one is satisfactory to his point of view. We still do not have adequate information to understand why NIH took the action they did to secure the exemption. That has not been answered yet. And the fact that it is at least implied by NIH—and, again, it is unfortunate that they are not here so that we could have a complete hearing on this—that the number of applications for SBIR, at least, weighed in somewhat to their concern as to whether the allocation should apply to the stimulus funds.

Mr. Hernandez, you have already pointed out some of the explanations for the numbers. There is also, as Mr. Glover has pointed out, a hostile view toward small businesses. So there is a lot that feeds on this. The bottom line is small businesses, innovative companies are really struggling today to get the type of investments they need so that they can function, stay in business, and, of course, also expand and create the type of job opportunity and innovation in our economy that is so important for our recovery.

So the American Recovery and Reinvestment Act was an effort by Congress working with this Administration to provide tools to help get our economy back on track. We have not taken advantage of the small, innovative companies that are out there that could help us a great deal with a relatively small amount of federal investment. And they are ready to go. That is the frustration for all of us.

So I just really want to concur on Senator Feingold's concern as to how this happened, how this waiver got into this law. We do not know.

Ms. Pickett, you were very straightforward by saying how surprised you were. Believe me, those of us on the Small Business Committee were livid at the fact that this was included without consultation with the Small Business Committee, which is a committee of jurisdiction. That is true also, by the way, in the House. They were unaware of those provisions being placed in there.

So we want to rectify it, and we want to make sure we get funding to the businesses. As I said at the beginning of this hearing, NIH performs an extremely important function, which has had the support of three members of Congress at this hearing, and will continue to have our support, but we want to make sure that there is fair allocation of those funds, particularly to these small, innovative companies. The SBIR program is important as is the attitude within NIH to engage the small business community in accomplishing its mission.

So we will use the information that has been provided today. It will certainly help us in carrying out our mission. If there is nothing further from my colleagues, let me conclude by thanking, again, our witnesses and all of you for being here. I also want to thank the staff of the Small Business Committee for their long drive out from Washington to Rockville. One of the nice things about representing Maryland is that field hearings, which are in close proximity to Washington, allow us to get out into the community, and we thank committee staff very much for making all these arrangements.

With that, the Committee will stand adjourned.

[Whereupon, at 2:30 p.m., the Committee was adjourned.]