S. HRG. 110–739

REAUTHORIZATION OF THE SMALL BUSINESS INNOVATION RESEARCH PROGRAM: HOW TO ADDRESS THE VALLEY OF DEATH, THE ROLE OF VENTURE CAPITAL, AND DATA RIGHTS

ROUNDTABLE

BEFORE THE

COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

OCTOBER 18, 2007

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ONE HUNDRED TENTH CONGRESS

FIRST SESSION

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REAUTHORIZATION OF THE SMALL BUSINESS INNOVATION RESEARCH PROGRAM: HOW TO ADDRESS THE VALLEY OF DEATH, THE ROLE OF VENTURE CAPITAL, AND DATA RIGHTS

THURSDAY, OCTOBER 18, 2007

U.S. SENATE,
COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP,
Washington, DC.

The committee met, pursuant to notice, at 10:10 a.m., in room 428–A, Russell Senate Office Building, Hon. John F. Kerry (Chairman of the Committee) presiding.

Present: Senators Kerry and Tester.

OPENING STATEMENT OF HONORABLE JOHN F. KERRY, CHAIRMAN, SENATE COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP, AND UNITED STATES SENATOR FROM MASSACHUSETTS

Chairman KERRY. Well, thank you all. We will come to order and I appreciate everybody's patience. I am sorry to be a little late, but I had an off-campus meeting this morning and Washington traffic seems to be getting worse, not better. I think every road is under repair and every detour is closed, so it is fun.

Let me just say up front that we are going to run this as we have in the past, and the staff will principally drive the discussion. This is not because of our lack of interest or anything, but I have a competing transportation hearing down in the Commerce Committee which I need to be at because of Massachusetts interests, and also we have a new Congresswoman being sworn in in about 40 minutes, so I need to attend to that.

However, let me try to focus this conversation, if I can. I want to start by thanking Kevin Wheeler for her terrific efforts with these roundtables, which I think are enormously productive. I can't tell you how helpful they are to the committee because they allow for a back and forth discussion. There are a lot of faces around the table that have been here many times, and as I have said before roundtables are just so much more effective than the hearings in many ways, and the discussions are really helpful to us and provide a very strong record in the process.

For those who aren't here who wanted to participate, we will accept their thoughts and comments in writing, and the record will remain open for a couple of weeks in order to adequately do that

and to help us build our base of knowledge as we move forward with the reauthorization process.

As you all know, the SBIR program, the Small Business Innovation Research Program, for those new to it, expires next year on September 30, and this is now the second roundtable in this Congress that we have held to think about its reauthorization. The first was held during the summer, in August, and it focused on the National Academy of the Sciences study, and I am pleased to say that the conclusion of the National Academy of the Sciences was that the SBIR program is working well and should be reauthorized, which is an important contribution to our discussions.

Senator Tester, welcome.

If you will forgive me for singling him out, I would particularly like to welcome Dr. Fanucci of Kazak Composites, Mr. Mehra of Scientific Systems, and Mr. Haber of the Infocitex. Kazak Composites and Scientific Systems are both based in Woburn, Massachusetts, and Inofcitex is located in Waltham. I am proud that they are here and pleased that they will share their experiences. Their firms are examples. They are conducting very exiting research in defense and health and alternative energy, and I know it is going to help the committee to understand the real world dynamics to be able to hear what they have to say, particularly about venture capital and the whole venture capital issue.

The venture capital issue is probably the most controversial, but it is not, I don't think, the most difficult. The more difficult issue is this "valley of death" issue and how you work through it, and we want to hear people's thoughts, descriptions of exactly what the valley of death is, how it works, and how we can move through it.

But, obviously, over 25 years, this program has built a pretty impressive track record of small businesses that have grown, of small high-tech firms with very important technologies, but we are still struggling with this issue of commercialization and where and how you make that seamless transition, which we want to be seamless but it doesn't always prove to be so, hence the valley of death issue.

So we must really look at this question of whether or not it is reasonable, or where is the reasonableness of expectation with respect to Phase II, the end of Phase II and the beginning of free-standing commercial enterprise.

We are also going to have an opportunity to talk about the issue of small firms that are owned and controlled by venture capital firms and their access to the SBIR program. That will be the second portion of today's roundtable.

However, let me start out by saying that there is a lot of frustration on some of our parts with some of the misleading statements that have so often guided this debate, and I think it is important that the debate at least operate on the basis of fact. I am referring to the myth that venture capital firms are not allowed to participate and that this is a choice where you take VC and lose SBIR eligibility or you don't and remain eligible. It isn't. That isn't nor has it ever been true.

In fact, GAO did a study of the awards at DOD and NIH, the two largest SBIR agencies, looking at a 2-year span before the SBA clarification of who was eligible to receive an SBIR award and then the 2 years after that clarification. They found that the number of

awards and the number of dollars going to firms with venture capital actually increased in the two years after the clarification. So there are firms with venture capital participating in SBIR, and they can participate so long as VC ownership does not exceed 49 percent. Now, can you improve? Can you do a better job and still maintain SBIR in a small business program? Obviously, we need to look at that. GAO is here, I think, and we can draw on GAO to clarify their study if people need that clarification as we have this discussion.

Let me also emphasize, and I really want to emphasize this, that this is not a question of whether some members of the committee are pro venture capital or con venture capital. I want to make that very clear. I think everybody on this committee is 100 percent supportive of venture capital efforts, and that is evidenced in our own efforts on the committee in a number of different areas to facilitate venture capital and capital movement into small business and small business endeavors. Futher, in the full Senate we have created tax incentives to help those firms and others to conduct R&D and to attract capital. We have supported stem cell research and so forth. So there have been a lot of examples of the members of the committee embracing venture capital.

The final issue is the question of data rights. SBIR firms are often pressured by the agencies as well as by prime contractors to relinquish their intellectual property, and that struggle often results in a duplication of effort. It is a waste of money as well as time for people to spend thousands and thousands of dollars on attorneys to fight to keep data rights when they enter into a contract, and in many cases, other people spend the time just duplicating the work. So there ought to be a way to try to resolve this and that is something that I hope will be discussed here today.

So let me ask, Senator Tester, do you have any opening comment you would like to make?

STATEMENT OF HONORABLE JON TESTER, A UNITED STATES SENATOR FROM MONTANA

Senator TESTER. I do. Thank you, Senator Kerry. I want to welcome Dr. Busch from Missoula, Montana, to the roundtable today. Welcome. You have had a lot of experience in SBIR and I appreciate you making the long trek from Montana out, as well as everybody else. Thank you for coming to this roundtable.

I think Senator Kerry has laid out the landscape pretty well and I look forward to the discussion around the table about the valley of death and how venture capital and expanding that may or may not be good. I have my own thoughts on that. And then, of course, the data rights issue.

So with that, I will apologize ahead of time. I am probably going to have to leave early, but I look forward to the discussion and I look forward to reading what is discussed here in the end, because I think the SBIR program in a small business State like Montana is critically important to us so we need to make sure it is viable and it does the job it needs to do and allows for a reasonable level of success.

Thank you very much for being here.

Chairman KERRY. Thank you very much, Senator Tester.

So, Kevin Wheeler, go for it.

Ms. WHEELER Thank you, Senator. I think that we will go ahead and open up the roundtable with the valley of death issue, having each of the firms that would like to make a comment discuss their perspective with the committee so we can build a record about what is happening. What is this so-called valley of death? How do we get from Phase II to Phase III? And is it actually reasonable to expect a firm to be ready to commercialize after Phase II? The committee often hears comments that Phase I and Phase II awards do not allow enough time and that it is not enough money to move a technology to the point of being able to commercialize it. So if you would like to explain, using your company as an example, please turn your nameplate on its side and I will call on you, or the Senators will call on you so that you can explain to us.

Chairman KERRY. Who wants to lead off on that? Go ahead.

Ms. WHEELER Jerry? And Jerry, can you remind us of your company and where you are located and what industry you are in?

Dr. FANUCCI. Sure. My name is Jerry Fanucci. I am with Kazak Composites and we are, I would say, an engineering design firm specializing in advanced materials and automated manufacturing to support cost reduction.

Chairman KERRY. How big are you?

Dr. FANUCCI. Thirty-five people plus probably another 15 to 20 part-time consultants, temps, things like that.

Chairman KERRY. Do you have venture capital?

Dr. FANUCCI. We have no VC, no debt. The company's sales are about $18 million this year.

Chairman KERRY. How long have you been in business?

Dr. FANUCCI. We were founded, basically me sitting on a couch writing an SBIR proposal in 1992 and grown largely with SBIR funding since then to be quite successful at Phase III commercialization. So we are very happy with the SBIR program and owe, in fact, our existence to it in this current state, at least. So——

Ms. WHEELER Jerry, can I ask for one clarification? Can you give us an example of one of your products? I know you described it, but just something in layman terms?

Dr. FANUCCI. Yes. Well, our largest Phase III SBIR success is a piece of a new Navy ship called T–AKE, which is a cargo ship the Navy is building, and through SBIR and the Navy TAP Show, which is the commercialization show, we managed to interest General Dynamics. NASSCO is the company in San Diego that is building this ship, and working with us, actually bringing us into a competition that they had been running for several years to try to supply this particular product and we eventually won it, partly with SBIR technology. So we were able to do that and it is a very large Phase III, two to three ships' worth of 30,000 to 40,000 parts a year. To us, it is many millions of dollars of sales, so it is quite important to us and it is a big commercial success.

Ms. WHEELER And what is the value to the DOD?

Dr. FANUCCI. Well, the value to DOD is the fact that they had no other solution, first of all. They had a ship that needed these things and couldn't do it. These keep the cargo from rolling around inside the hull. That is a bad thing if the ship is moving and the cargo is going with it.

The cost savings, we have learned in the process of working on this that the current cost that we are charging is about one-third the previous cost. So over the run of the ship, we probably saved them maybe about $140 million in cost avoidance, so that is, I think, quite significant. So we get the benefit of the sale and they are not paying $140 million for the next alternative solution, which actually didn't work too well, and which we replaced.

So it is quite a good success story for the SBIR program. It is partly SBIR and partly just the right place at the right time and luck, you know, and lots of things contribute. You can't point just to any one thing, but certainly SBIR allowed us to be at a point where we could even compete, and then to carry the research along to the point where we could win that contract.

Ms. WHEELER And the valley of death?

Dr. FANUCCI. That one actually is the one example we have that didn't have a valley of death because it was so far into the ship design phase that they needed something then and we went straight from SBIR, actually Phase I, to production.

Chairman KERRY. In your case, when you talk about the valley of death, do you refer to it in terms of a specific technology or with respect to the company as a whole?

Dr. FANUCCI. Well, that is a good question and I think that applies both to the valley of death question and the VC question, in a sense. It applies in our case, and I am not familiar with how the health industry works, but certainly in ours, each SBIR is like a little product development project. We do different things for different applications. If you are familiar with DOD's solicitations, they ask for specific things and the winner develops that thing.

A case, for example, where we are in the midst of a big valley of death right now is a very successful Phase I-Phase II SBIR that everyone loves the outcome. It was an end 1999 topic, so it was initiated in 1999. Parts have been on sea trials on carriers and they want to put them on ships, but there is no mechanism that we can find and that even the people in the Navy can easily identify to take that thing that has been tested now on aircraft carriers and they want to put on all the carriers and put it into production and put it on not only carriers, but other ships, as well, so——

Chairman KERRY. Well, are there particular features that can be standardized, or is it completely ad hoc as to when a particular technology actually deserves to be sustained to go into commercialization? Or is there an effort sometimes because it is bread and butter to the company to fit a round peg in a square hole kind of deal sometimes, and so we are sustaining something that may not ultimately succeed. Is there a pressure to do that?

Dr. FANUCCI. Yes. Well, there is a lot of pressure to commercialize because it is becoming the thing to do these days with SBIR and it is important to do that. But I think if you study the topics, at least the kinds that we bid on and materials and engineering high-performance structures, you can tell right away some of these are going somewhere quickly and some of them are just the next step along a long path to moving technology forward.

You know, nano materials would be one. We work in nano materials topics sometimes, along with many other companies. That is not something that at the end of a Phase I-Phase II in SBIR you

are likely to now have a big commercial product, but you might have discovered something that would fit into the next product.

Another case is like this aircraft carrier part. Just reading the topic, you know they have so specifically defined the problem and the solution they need that if you find the solution, they have a use. Now, in this case, we did find the solution and everyone likes the answer and it is very easy, but there is no transition from the R&D guys to the ship maintenance guys, basically in this case.

So I don't know that you can, at least in our kind of products, circle a small specific area and say, that is the problem. That is what we have to address. Each thing that we develop is its own little story like that. We do some UAV work, for example. That is very different than things that keep you from falling down holes in aircraft carriers, which the other thing is. It is a whole different group of people, a whole different technology, so——

Ms. WHEELER Did I hear you say you were financing the testing and evaluation?

Dr. FANUCCI. Well, actually, that is a different—we have talked about this in the past, and yes, that is often a problem. You come to the end. You have something that looks good. It has been through some preliminary tests, but now, in the example that Kevin is mentioning, we need to throw this out of airplanes. That is not covered by the costs and fees to SBIR. You need millions of dollars for that. The Navy—most of our work is Navy, it turns out—is attempting to address that with transition programs, but so far, we haven't benefited from that, at least.

Mr. NECCIAI. Did the communication that you had between your personnel and the contracting officer, in relation to the valley of death, did that ever falter or decrease during that period of time, or did you think it had any influence on——

Dr. FANUCCI. No. No. The contracting officer is interested in the Phase I-Phase II SBIR contract——

Mr. NECCIAI. Right.

Dr. FANUCCI [continuing]. Which doesn't address what happens after the Phase II contract ends. As long are you are performing, they are doing their job and you are doing your job, everyone is happy. But, you know, with the technical people on the program, they realize the cliff is coming up and it depends on who you get. If you have a very involved program person on the Government side, they are very active in trying to move this forward. On the carrier application, that is the case. We have a very involved couple of guys in the Navy who see the value and are, on their own initiative, really, pushing this thing as hard as they can. But it is not the contracting officer.

Mr. NECCIAI. The project manager who saw the value, how to move forward, but in other instances where the project manager didn't either see the value, you didn't feel like that connection was still there?

Dr. FANUCCI. You know, you can run the range of program managers from very interested to guys who got handed this thing and it is just another thing they have to do. That is one of the facts of SBIR life. You deal with who you are dealt with on the Government side. Sometimes they are interested, sometimes they are not. Sometimes there is such a long period of time, I think in some

cases, between writing the topic and getting an award that the person who wrote it is gone. That person's interests are not there anymore and someone else is in the position with different interests, but they have a Phase I to deal with. So you can tell almost right away that it is not going anywhere.

Mr. NECCIAI. Thank you.

Ms. WHEELER Stu, would you like to explain how the valley of death affects your company?

Mr. HABER. Sure. Can people hear me? First, a little background. My name is Stu Haber. I am co-founder, President and CEO of Infoscitex Corporation. We are headquartered in Waltham, Massachusetts. We were funded internally by the co-founders. We have no debt. We had some cash, and we have been profitable since the first year. Next month, we are celebrating our seventh anniversary.

We did not participate in the SBIR program until about two-and-a-half years ago, and since then, we have developed a number of products—I should say, we are developing a number of products—and I might talk about two particular products to give you an idea about how it relates to the valley of death.

One in particular is waste energy conversion systems. What we are doing that is novel is we are, to make a long story short, we are gassifying, essentially shredding, pelletizing, and gassifying trash, and trash being paper, plastic, food, and wood. The gassification connects directly to an institution's grid, a power grid, and creates electricity and heat.

Now, the reason I mention this is that we have received funding from the Army because they have a very specific need to dispose of—to find a less expensive and more environmentally friendly way of disposing of their field waste. In this particular case, we are the point, I would say we are about a year away from actually having a product that we can manufacture and sell, not only to the Army but the real sizable market beyond that is our institutions—hospitals, universities, it could be supermarkets, prisons, I think you get the idea. There is a pretty good market there.

Now, what we require is two things. One is that we require some money to actually build a field demonstrable unit, an implementation pilot program, and we are actually right now working with the University of Massachusetts-Lowell to do just that. And that would require about a million dollars.

Now, down the road, we are expecting we can get the cost down on these systems to $200,000, but the first one doesn't cost $200,000. It is about a million dollars to install and to operate. The payback is 2 years. In order to get the company off the ground, not only do we need the million dollars for the pilot, but we need another $3.5 million to fund the company for working capital, investment, and so forth, and unless we receive the CPP or Commercialization Pilot Program money, we have to go to other sources. We don't have the capital to invest there.

And we have a lot of interest, but it is a major effort, and that is—there is a situation where the Government cannot really—is not in a position right now to fund that value, or as we call it, crossing the chasm.

The other example, a little bit different, where the Government actually has helped us is with a CPP program. We had a Phase I-

Phase II contract with the Air Force to develop a novel cover glass for satellites to protect the satellites against radiation hardening, extend the life. The Air Force felt it was important enough that they issued—it was a little over 1 year ago, 1 year ago August, they awarded us a sizable CPP program and we are working very closely with Schott Glass of Germany, which the Air Force more or less instructed us to work with, who is a big player in the creation of glass, and they are our partner. Two years from now, and everything is on schedule, we will be able to—Schott Glass will be able to go to production and we will receive a licensing fee.

Now, I will tell you that the additional CPP money we received was $5 million over a 3-year period, which is huge. We did not actually market this. The customer came to us and said that this was important enough that they wanted to fund this. Without that money, I suspect nothing really would have occurred. But with that additional sizable amount of money, we are going to be able to go to production in 2 years. In this case, the Government actually did fund.

I think the CPP program is outstanding. It is the only one we have, the only CPP funding we have at this time. But I think it is an extraordinary way to take people across that chasm, through the valley of death, and it can't be done for everything. It has to be selective. But I think it is a great thing to do.

I wanted to ask Kevin, at what point do you want me or others to suggest—make suggestions about what specifically to do about the valley of death in the program?

Ms. WHEELER If you would like to offer a suggestion now, feel free.

Mr. HABER. OK. I would say that I know that there is a lot of discussion about increasing the budget for SBIRs in the future. Whatever that increase would be, I would suggest that I guess really almost all of that, if not all of that additional money go toward CPP. Whether you call it Phase II-B or Phase II enhancements or Phase III or Fred, I think it is important to put the money in there. I think that I would also probably increase the minimum amount of money, the canonical $100,000 to maybe $150,000 on Phase Is. The Phase IIs, perhaps increasing them maybe from $750,000 to $1 million.

But that is not all that critical. What is really critical, I think, is taking the successful Phase I and Phase II programs, I should say successful Phase II programs, and making sure there is money there to meet the Government's needs, to meet the global economy's needs, and I think any increase really should be substantially put toward what I call the CPP.

Ms. WHEELER Thank you. Did anyone else have a comment? Usually people turn their cards on their sides and I haven't seen anyone, so I am not sure if we are missing someone. Kunal, do you want to go ahead?

Mr. MEHRA. Sure. My name is Kunal Mehra. I am with Scientific Systems. We are a small business based in Woburn, Massachusetts. We are about a 50-person company and we focus on developing advanced technologies and solutions, primarily for the aerospace and defense markets. The SBIR program has been critical to our growth and success over the last 15 or so years and I just want

to highlight a number of success stories that we have had in terms of transitioning technology, in our case, into the Department of Defense.

Today, software that we developed, that Scientific Systems developed, is used by troops in Afghanistan on hand-held mine detectors to detect mines that may be underneath the soil. We also have a very large program underway right now to develop a collaborative network of about 50 robots to lower the cost of a DOD operation by probably about 5 percent, so another great success story that draws on a number of our SBIR-funded technologies over the last ten or 15 years.

Third, we have a program underway right now. A major concern within the DOD is that all of their air vehicles, manned airplanes, UAVs, or missiles, are reliant on GPS for navigation, and at the beginning of Operation Iraqi Freedom, we saw that Saddam Hussein had actually bought jammers for $50,000 that he had set up around a lot of the targets, and there is a major concern that in the next war, we could be in an environment where somebody is able to disable the GPS network either by jamming it or by shooting down some of the satellites, as the Chinese did earlier this year. If that were the case, virtually all of our air vehicles would be irrelevant in that type of war.

So we have developed a technology under the SBIR program that enables a missile or an air vehicle to navigate without GPS. Let me just say that this technology would have never been funded, the development of it would have never been possible were it not for the SBIR program and for the incredible support and advocacy that we got from some real thought leaders in the Navy. The technology we developed is software only. It can be implemented onto an existing missile or vehicle that is already in production within 3 years, if we are able to get the funds in place to continue the development. By comparison, the alternative technology is about seven or eight times more expensive.

The weapon that we are focused on right now is the Tomahawk cruise missile. Our technology could be on the platform across 2,500 or 3,000 missiles for $40 million from today. The alternative technology will cost about $300 million and will take another five or 6 years, because it requires some substantial hardware modifications to the platform.

I think in talking about the valley of death, I think one has to consider a number of things. The first is that not all SBIR technologies are the same. There are some technologies that are very narrowly defined. They might be software-only and therefore you can take them to a higher level of maturity with the $750,000 that you would ordinarily get in a Phase II.

We have seen other technologies, and the program that I mentioned that we have, it is actually with DARPA to develop these robots. This is an accumulation of SBIRs that we have done over the last ten or 15 years, and it has taken a very long time to get that technology to maturity just because of the breadth of the capability that we are developing.

So there is really no one-size-fits-all over here. It is possible to take some technologies to a TRL of five or six. Other ones, you can't get beyond a readiness of three or four.

But I think one of the big challenges we face is: who the program manager is. We have the GPS navigation example I gave you. We are lucky enough that we are working with a person who is responsible for engineering within the Tomahawk acquisition program at NAVAIR, so he is very well plugged into the needs of the program. He is able to help us shape the direction of the technology development in a way that nobody else could.

In other examples, I have had technical monitors who are in labs and they are as disconnected from the acquisition program and the user as we are. In many cases, they have told me, oh, you are too worried about commercialization. Don't worry about that right now. Let us develop some cool technology and we will think about that later on.

So I think education and fostering better collaboration between the labs and the acquisition programs is just absolutely critical, and it won't only help SBIR technology, it will help every single other form of technology development that is sponsored by these labs. I think that is really critical and it is just very important to get a higher return on investments that are to be made in technology development.

Ms. WHEELER Michael from DOD, did you want to comment on any of this about the valley of death, since many of the examples have been from DOD?

Mr. CACCUITTO. Sure. I would be happy to say a few words. I first want to second what was just said. I mean, one of our biggest challenges in DOD is that collaboration. We are institutionalized—we tend to be institutionalized in such a way where our technologists, our real experts, generally reside in laboratory functions and where most of the procurement, and indeed, most of the R&D money resides are in our buying activities, or developing and buying activities, or acquiring functions. And they tend to be very separate institutions—tend to be—and it differs from service to service how much they collaborate, the degree to which they are either collocated or not, how they are set up to operate.

So that is indeed one of the challenges that CPP is supposed to address, is to find new ways to effectively connect our technologists with our weapons developers and buyers, or weapons systems support systems and logistics and maintainers. That challenge, I see as perhaps the biggest, and indeed, if we crack that nut, then we bring value to the broader institution, not just to SBIR. We can help ourselves do a better job across the board.

I want to make a couple of other comments, too. I think it is important that we recognize that we want some amount of failure in the program. Failure in a sense is a measure of success, and we need as we are thinking about this to recognize that we can't expect every technology we invest in to be a huge success in the marketplace. That is just not the nature of scientific exploration and technology development. Some are going to rise to the occasion via circumstances, or good forward thinking by the part of the Government, or excellent execution on the part of companies, and some will not and that is good.

So in a sense, what we need to get comfortable with is what is the right balance, what is the right expectation to have for the pro-

gram as a whole, if we are looking at it as a whole. What is the right transition rate, if you will. What is a reasonable expectation.

And then we need to look at what we can control in the context of what is that proper way of viewing transition, and what we can control on the Government side is how we institutionalize, how we govern the program, the processes that govern the program, and CPP is another one of the governance mechanisms that we are looking at now. And I think that is where we need to focus our effort, is to continually evaluate how the program governance mechanisms are operating, how effective they are being, and at the same time not—we need to be very careful not to, I guess the term is throw the baby out with the bathwater.

We need to be careful we don't turn the program into what amounts to a procurement program. We need to be sure that we are taking risks and accepting a certain amount of failure in the context of a smart institutional design. From where I sit, that is our biggest challenge, is balancing that risk spectrum, if you will, in the institutionalization of the program.

Ms. WHEELER Senator Kerry feels the same way. He has always said that this is not an acquisition program and that there needs to be a balance, that we shouldn't expect every project to commercialize and that we want an element of risk because there are certain technologies that the private sector simply will not take on. And so I am sorry he is not here to hear you say that because, for the 9 years I have worked for him, that has been his goal for the program. Thank you.

Jo Anne—oh, wait a minute. Senator Tester, did you want to hear Dr. Busch's——

Senator TESTER. That would be fine, either way. I will be here.

Ms. WHEELER OK. Jo Anne, did you want to go ahead, since your card was up first?

Ms. GOODNIGHT. Sure. I kind of wanted to give a perspective from another Federal agency, but one where we are typically not the Phase III customer. It may happen that our intramural scientists are buying, and it does, in fact, happen that the intramural scientists are buying some of the products being developed, but by and large, the NIH SBIR, and STTR awardees are looking externally for that Phase III partner.

And so we have thought long and hard, how can we help companies over this proverbial commercialization valley of death, recognizing, A, that this is not a linear process. When Roland Tibbitts conceived of this program as Phase I, Phase II, and Phase III, it was laid out linearally, but in fact, at least in the biosciences area, it is anything but.

And so we offer Phase I, Phase II, Phase II competing renewals for those projects that need to go through the FDA regulatory process, and then we go further to offer a Commercialization Assistance Program to our Phase II awardees whereby this program is focused on attracting third-party financing, be it licensing partners, strategic partners, venture capital. There is a mix of exit strategies for our companies.

So this program, the CAP, is now in its fourth year. It is very much individualized entrepreneurial training, because just as you

just mentioned, this is not one-size-fits-all. Different companies are going to need different things to help them cross that valley.

We bring them through a 10-month fairly rigorous process, and we actually lose some companies in the beginning because there is a little bit of attrition, that they are not ready to go through that rigor. But for those who go through and for the more than 300 Phase II awardees who have participated, we are starting to see some positive outcomes.

And so part of my comment here is: is there something that is broken? Because, given what we have been doing and will continue to do, based on using the currently allowable SBIR funds, as well as some of our own administrative funding, we have got that nice mix within the current set-aside. For example, 50 companies in our 2004 and 2005 through 2006 participants have received $136 million in equity investments. Sixteen companies received $73 million in strategic partner investments. These are now just the value of a program that provides that very important early stage funding for really high-risk projects and seeing that leveraged into some very real dollars for getting drugs and devices to the marketplace.

One other thing. We also offer a Pipeline to Partnerships, because after the venture forum is over, everybody goes home and deals are definitely not made overnight. So we offer this Pipeline to Partnerships, or P-to-P opportunity, which is a virtual space for Phase I and II SBIR and STTR awardees to showcase their technologies to an audience of potential investors—again, licensing partners, VCs, and strategic partners. We offer that, as well, to our NIH licensees, and that is starting to gain some real momentum. We just launched it in July, and we have already heard from Genzyme, and from some other companies, that this is exactly what they are looking for—a one place stop where we can look at who is working in cancer diagnostics, who is working in autoimmune diseases, and what phase are they in with regard to clinical studies. Is it Phase II? Is it Phase III? So we are going to continue that endeavor, as well.

Ms. WHEELER Erik, did you have a question?

Mr. NECCIAI. It sounds like the partnership was very successful and I wonder if there are any other agencies—I know that we have got the pilot program that has had success at the DOD, and I know that NIST has a program that they are working on, and I imagine that that is going to be a success, as well. But are there any problems with the program? There is always success, and that is fantastic, but what things can we do to make them better?

[No response.]

Mr. NECCIAI. No comment, OK.

Ms. WHEELER Erik, I think both Jo Anne and Kunal wanted to respond.

Mr. MEHRA. Well, I think in the Department of Defense, I think one has to realize there is a big difference between the Department of Defense and the NIH in that products developed for the NIH, by and large, have a very large commercial market you can go after. Most of the—I don't want to say most, but many of the products developed under the DOD SBIR program have a very narrow niche market which is pretty much the Department of Defense. Outside investors are often not interested in that.

I am a member of the Small Business Technology Council and last week we had a large conference where a venture capitalist said, if you can't show me a commercial application for your technology, I am not interested in funding it because the Federal Government market is so narrow and it is so hard to navigate that we don't want to invest in it.

So for companies like mine that are developing products to really enhance the Nation's security, CPP is the only alternative, and I just want to echo Mr. Caccuitto's points, which are I think the CPP program is excellent. The legislation is exactly the right direction. I think if there is a problem with it, the only problem is that there is not enough funding there.

The funding required to go from a promising technology out of the end of the Phase II to where we are all trying to get, which is being credible enough that the technology is approved, that a program officer will put you into their budget, what they call the POM, the Program Operating Memorandum, where the technology is proven. That can be ten to 15 times the amount of money that you got in the Phase I or Phase II. So you are talking about going from needing $100,000 to $750,000 to $10 to $15 million and there is just not enough money in the CPP program to support that.

So I agree with Mr. Haber's points also, I think we should look—any increases in the SBIR program should be directly channeled to enhancing the transition of technologies through programs like CPP.

Ms. WHEELER Jo Anne, did you want to answer?

Ms. GOODNIGHT. I guess the only other point I would offer, because, again, we are a very different agency, I think getting that involvement very early on. It is not looking for these avenues to cross the valley at the end of Phase II. All of these concepts need to be thought of even prior to submitting the Phase I.

And to the extent that States can help—I mean, there are a lot of, again, for our agency, the State assistance can help companies address some of their manufacturing issues and scale-up issues, to the extent that Federal agencies want to model after Pipeline to Partnership. We have had a couple of agencies talk to us. There is no need for them to reinvent the wheel and maybe there is an opportunity for us to partner on this just like we did for the I-Edison System, where it is a multi-agency system for companies to report their inventions.

And then for the companies also to take on some of this, as well, not that you are not, but it has got to be a shared activity for really getting across that valley.

Senator TESTER. Dr. Busch?

Dr. BUSCH. Thank you. Thank you for being here, Senator Tester. I appreciate it.

Just a short, brief background. I had a small business a long time ago. I started in 1975, before the SBIR program. When the SBIR program came into being in 1982, we focused on it as a target of opportunity and it was very good to us, benefited our company a lot. I personally benefited a lot from it.

We sold the business in 1986 and in 1993 moved back to my roots, which are in the Northern Rocky Mountain States. I now live in Missoula, Montana. And when we got there, I became involved

in this so-called SBIR outreach activity, basically working with small businesses in Montana, mostly the Northern Rocky Mountain States, but other regions, as well, helping them compete in the SBIR program. So that is a quick summary of my background.

On this valley of death issue, what I wanted to say is that I think the agencies have done a wonderful job in supporting transition to Phase III and commercialization. The programs that Jo Anne has, NSF, DOD, perhaps all of them, are laudable and have been very helpful. I do think, though, sometimes perhaps too much help is offered to the small businesses to try to guarantee a successful transition through the valley of death. I think the true entrepreneur needs to, in some cases, at least, fend for himself and weave his own way through the hurdles and through the valley of death and shouldn't depend too much on the SBIR program, should seek other sources of funding, from industrial partners, other agencies, non-SBIR R&D funds, venture capitalists, and angel investors and so forth.

As far as SBIR assistance and getting through the valley of death, I think what Jo Anne said is certainly true. It is not a linear process. I know of very few cases, if any, actually, where there has been a linear process where you go from Phase I to Phase II to a successful Phase III program. It is a parallel process in virtually—certainly it was true in my case, and virtually all the companies I work with, it is a parallel case. Multiple programs are underway. They dovetail with sources of funding from other sources, other R&D sources, other commercial sources. So I just wanted to underscore what Jo Anne said about the parallel process.

Senator Kerry mentioned the distinction between the valley of death for a specific technology and the valley of death for the business as a whole, and I think that is an important distinction to make. The SBIR program is set up so that some technologies don't get through the valley of death. If every technology funded by SBIR gets through the valley of death, there is a question of whether enough risk is being funded. Some technologies should fail, should stay in the valley of death. So that distinction, I think, is important.

I appreciated the comments about the CPP program at the DOD. I think that is a great opportunity. We didn't have that when I was in the program, obviously. But again, what Jo Anne said, not all agencies are set up to have a CPP-type program. In fact, probably most of them are not. So other opportunities are needed there.

Again, I am kind of echoing all the things Jo Anne said, but I think the cases that I have been involved with since I have been involved in this outreach effort where businesses get into trouble is where the business personnel and resources are top-heavy on the technology side and low on the business savvy side. You know, it is all about doing research, it is all about solving this technical problem or that technical problem, and by the time it comes to commercialization, they are just not either mentally or culturally or in other ways, financially, prepared to cope with the rigors that come with commercialization. So early access and early provision of mentoring, commercialization mentoring by the agencies, I think, and encouraging small businesses to begin thinking about it, is really vital.

Ms. WHEELER Because we are running to the end of the one hour I had allotted for this topic I want to give everyone a chance. Could we just go through and maybe give everybody 2 minutes to weigh in here. Dr. McGarrity, I see your card has been up.

Dr. MCGARRITY. Thank you. I am with a biotech company in Maryland known as VIRxSYS, and I just wanted to give a different perspective of the real life of a biotech company.

We started in 1998. It was technology that came out of Johns Hopkins University, and so the company was started. It got initial funding and we went into our first clinical trial in 2003. Presently, VIRxSYS has about 65 employees. We have raised about $85 million from investors, very little of it, frankly, from VCs. We have had a couple of SBIRs and probably more SBIRs from a company that we just acquired recently, and I will talk about some of those experiences in the VC section.

But to give you a snapshot, in our Phase I trial, it is for AIDS, and you say, what is the new approach in AIDS? We are doing gene therapy in AIDS so hopefully those patients can take one treatment and then do not have to take daily pills for six or 8 months and you circumvent the problem of drug resistance in these patients.

So the trials have been going reasonably well. We had a Phase I at the University of Pennsylvania. Our Phase II trials are occurring in Connecticut, Kentucky, Florida, New York, and we will start a clinical trial in Harvard before the end of the year. So to date, we have treated about 52 patients.

However, if you look forward as to where we are going, we are in a Phase II clinical trial. We hope to start a Phase III clinical trial next year and that is going to require about $50 million to do. Also, the requirement on us is that we have to meet the same standards in our Phase III trial as a Genentech or a Merck or anything else like that. So the anticipation, if all of this goes successfully, we will go to market in 2010, 2011.

So I wanted to contrast the experience of a biotech company that started in 1998 and it will take 13, 14 years before we have any sort of reasonable revenues, and it is an enormous amount of money. The SBIRs that have been helpful have been not so much in the AIDS program but in smaller programs and smaller disease states, like cystic fibrosis and in hemophilia. So that is where that attraction of SBIR's grants is concerned.

But it is a stark contrast between the biotech and the emerging biotech companies and what I have been hearing around the table today. In fact, sitting here this morning, I have realized that I have been living in the valley of death for the past ten or 15 years and didn't know it.

[Laughter.]

Dr. MCGARRITY. Thank you.

Ms. WHEELER And your valley of death was on an SBIR grant?

Dr. MCGARRITY. No. No.

Ms. WHEELER No?

Dr. MCGARRITY. The SBIR grant is now when we are finishing our Phase II clinical trials and now we are going to a Phase III that we are going to have to have 250 to 300 patients and either—will our original investors stay with us and invest more money, or

can we find a partner in the form of a large pharmaceutical company to share that burden and provide money and expertise to get us to commercialization.

Mr. NECCIAI. Dr. McGarrity, just to distinguish, you are talking about Phase I, Phase II, Phase III in a medical trial——

Dr. MCGARRITY. In a medical setting.

Mr. NECCIAI [continuing]. Not in SBIR phases.

Dr. MCGARRITY. That is right. That is right. And as I said, we have used the SBIRs, but not in our main program of AIDS but in programs with smaller capital markets like cystic fibrosis.

Ms. WHEELER Kunal, did you want to go ahead?

Mr. MEHRA. I just want to summarize. I mean, I think we all agree on two points. One is that not every technology should be transitioned. It is probably a low percentage. I think we all agree that the yield right now is lower than it ought to be.

I think the second thing is that all the programs are quite different. The NIH is different than the DOD and a one-size-fits-all approach will not fit.

But I think the improvements that we seem to all agree on are kind of three-fold. The first is certainly there needs to be more education of the entrepreneurs themselves so that they understand how to cross the valley of death and how to market to the acquisition programs or to the drug companies in the case of a former organization.

The second thing is I think more collaboration between the technical monitors and the labs and those on the acquisition side of the house will only help to kind of foster the kind of information transfer that we need.

And then third, once those two things are done, you have got people who understand how to cross the valley of death, you have got advocates who can help them cross the valley of death. The thing that is missing is the funding in place to be able to support a company through that process. So that is kind of my summary of what I have heard and what I agree with.

Ms. WHEELER Thank you. Mr. Sarich?

Mr. SARICH. Hello. My name is Ace Sarich. I am the founder and Vice President of Voxtec. We do research, development, manufacturing, sales, software, after-market support, and training of a hand-held one-way translation device. It started off as an SBIR program back in Phase I in 2000. Phase II, 2001, the first prototypes September 10, 2001. And then from that time on, it went from an R&D prototype to now we have about 25 employees and are doing $12 to $15 million in revenue this year.

The program, first of all—our company would not exist if it wasn't for the SBIR program. But a couple comments I just want to make. We were talking about some of the challenges. First of all, there is no free lunch, but the SBIR program certainly does help out a lot. We still—we have three owners. The company has been all bootstrapped. It is our three owners of the company have mortgaged our houses to the hilt to be able to make this work, but at the same time, if we didn't have the Government revenues, it wouldn't exist.

Regarding the incubation period or the valley of death, I call it the incubation period. It took longer than I expected. We had a

working prototype, but it took a while before it was what I would consider good enough. So this has been aided quite a bit through the Phase III program. We have had a number of our military customers using, customers around the world, Afghanistan, Iraq, are using our products to communicate with the indigenous population and we have been using the SBIR grants.

But the challenge has been in the past working through various contracting agencies. They just don't understand what the Phase III is, and we weren't smart enough to be able to a lot of times tell them how to do this. We just recently got a Phase III IDIQ with NAVAIR for $45 million over 5 years, so that should help us quite a bit over the next few years.

I would also like to say that a lot of times, our biggest challenge has—one of our biggest challenges has been working through contract officers. If you get the wrong one, it can be the kiss of death. It has taken like 6 months to get paid on some, and for a company that lives from hand to mouth, you can't wait 6 months to get paid because of the slowness of the contracting process.

Ms. WHEELER Thank you. Dr. Abramson?

Dr. ABRAMSON. Hi. I am Fredric Abramson, founder and CEO of AlphaGenics. Our business is to commercialize genetics into the consumer world for everyday life with a series of products dealing with weight control, physical performance, and influenza prevention.

But I come here really with a different background. In addition to being a scientist, I have got 40 years in the computer IT field, 20 years in the retail segment, as well, and I teach in the Master's Program of Biotechnology at Johns Hopkins and I teach three courses, Financial Management, Creating the Biotech Enterprise, and the Economics of Biotechnology.

We have heard three comments here about the difference between bio or a life science from the DOD kinds of technologies. I want to reiterate this. There is a structural problem in the life sciences which is deeper than SBIR. Very few people who are scientists have any business background. In fact, their ability to get an SBIR depends upon their qualifications and their knowledge of science, not business. And as Ms. Goodnight said, many of these people come into the program unprepared even to think commercialization.

I have many conversations with companies in the incubator in Rockville. We are in the Maryland Technology Development Center. And frankly, very few of them can even understand what it means to define a market in concrete terms. So it is difficult for them to think of commercialization when they can't think through the steps of even who it is they are going to sell to.

There is a tendency in the field to live as in the film "The Field of Dreams." If you build it, they will come. But the fact of the matter is, they do need a great deal of expertise and insight on the business side. Dr. Busch pointed this out. Whether that is in the purview of an SBIR program, or as Ms. Goodnight said, maybe it is something they need to get in advance as they are coming to the table, and maybe that needs to be something that is put into the system as part of their development through Phase I and Phase II so they can better understand what they need to do to begin mov-

ing through the long process, as Dr. McGarrity said, eight to 12, 13 years. So it is not just, I think, an issue that SBIR can solve at the NIH level, for example. Thank you.

Ms. WHEELER Thank you. Edsel?

Mr. BROWN. He stole my thunder.

[Laughter.]

Mr. BROWN. Again, on behalf of SBA and looking out for the best interests of small business, he hit the nail right on the head in addition to what some of the other commentors have already said, CPP, enhancements to Phase II. But again, we are making these as to highly technical, organic companies, but again, we need to look at the ability of these companies from a business standpoint. They are so focused on moving this technology forward, they may not have the necessary infrastructure in looking long-term to commercialize it. So even if they had the technical expertise to move it forward, just how much do we know about the actual management skills, et cetera, that the principals of the firm have?

And again, one of the other issues facing us as we move toward reauthorization, we talk about administrative costs for the agencies. They get the funding, but we are looking at administrative costs for the agencies to move the funding to the firms, and the same could be said for the small businesses. Yes, they get an award, but be careful what you ask for. They may not be able to handle it.

Ms. WHEELER Thank you. Erik? I am sorry. Ron, did you want to go ahead?

Mr. COOPER. Ron Cooper with SBA. First of all, I would like to thank the committee. We find these hearings and these roundtables extremely helpful in trying to understand the aspects of the program.

Just stepping back a bit, the valley of death is essentially a market failure that we are addressing in financing early stage and innovative activity. As such, that is the rationale or a key rationale for having the SBIR program in the first place. My work has shown that there are five dimensions to this market failure and it is quite complex, including information gaps as well as the size of financing that the private market is able to or willing to invest, and the degree of risk, and also the geographic areas that are—there is a gap there or a valley of death geographically.

So our task with SBIR is to focus the program, to target the program to this valley of death, trying to address the market failure, and so we are very interested in how this gap is changing over time and developing.

I just wanted to mention the way that we target. The targeting mechanism for the program is the eligibility requirements and that is, I suppose, a segway to our next section, so we can talk about that more. But that is the way that I view this, is that we have to continually reevaluate the nature of that gap and use our eligibility requirements to target it effectively.

I wanted to just also echo what has been said before about the fact that this valley of death has a very different shape for different industries. The best example of one that is quite different is the biotech firm that has this long lead time and has, in essence, not just a valley of death, but at the end of that, a long canyon of

thirst or starvation or whatever you want to call it, but it has got an additional issue. So there are unique profiles to this funding gap. Thanks.

Ms. WHEELER Thank you. Jerry, and then Stu, and then we will go on to the venture capital piece of this.

Dr. FANUCCI. Something I guess a little different that hasn't been said. I have been told by some of our technical managers on the Government side that the SBIR management process is basically out of their own time and hide. They are not funded to support a SBIR company. When we look at the projects of our company that have been the best commercial successes or have at least a possibility of commercial success, one of the things that is always true is we have had an involved program manager on the Government side.

Maybe some of the money that we are talking about giving to the small business should be directed to support the Government program manager so that he can be more actively engaged in the program from the beginning, you know, trips to the company, trips to the customer, who is not usually the program manager but someone on the ship side of the Navy, for example.

Ms. WHEELER But you are saying program manager that is in the field, not program managers of SBIR, like Jo Anne or Mike?

Dr. FANUCCI. I am talking about we interact on each SBIR with a different technical person in the Government who either wrote the topic or has been handed this topic to deal with in some way, and if that guy is interested in the result of that program, you find that that correlates highly with eventual commercialization of that part. He knows—he is actively involved enough to tell us where we are going wrong, to talk to people who would eventually use it, who isn't the person who is the technical person but someone else in the Navy, and really help to guide us along this two-and-a-half-year SBIR path to something that at the end looks useful to someone else in the Navy, which is hard for a company on its own to do.

So maybe some of the money—I don't know if it is true or not, but I get the impression that those guys don't have funding really to support real active participation in the SBIR process.

Ms. WHEELER Thank you. Stu, do you want to make a comment quickly?

Mr. HABER. Yes. Thanks, Kevin. I wanted to respond to something that Jo Anne said earlier, and I think, Jo Anne, you were making the case for not needing a CPP because NIH has been successful in seeing some of the companies who have received SBIRs gain a fair amount of venture capital and what not. I want to argue that I think NIH actually has a built-in CPP program, because often, the awards made by NIH are two-and-a-half to three times the size of those that are made by DOD.

Ms. GOODNIGHT. Do I get to have one final——

Ms. WHEELER Sure. Go ahead.

Ms. GOODNIGHT. I am sorry. That will make the second hour go more rapidly.

Ms. WHEELER Yes.

Ms. GOODNIGHT. Right. And I think that we have some type of CPP-like program built in. We have multiple programs built in.

But I just want to come back also to a comment that Chris highlighted and I just think that it is very, very important that we think about—I need to even articulate this right—small companies to succeed are going to need to have the right team in place. It is going to be management. It is going to be market development. It is going to be the commercial guy. It is going to be the PR gal or guy. You are going to have to have that team, and it doesn't matter how much money the Federal Government puts into this program. If that team is not there to see those products move across that valley, it won't ever happen, OK.

Ms. WHEELER OK. Go ahead.

Mr. MEHRA. Just a very quick closing point. I could not agree more with the importance of having business skills in the company. I think that is something that most people overlook. But unfortunately, the way that the program is structured right now, I think it is not companies with great business and technical skills who are necessarily being rewarded. It is companies with great political skills, because most of the Phase III success stories that I am aware of involved a congressional plus-up at some point, and I just think that that is not the process that we want in place right now, where you have to go get a congressional plus-up to be successful to cross through the valley of death.

Ms. WHEELER Well, that is an excellent point and we have been concerned about that, that plus-ups, as you said have often been relied upon. Then can we get around this inefficient process of requiring people and the money that it involves for them to chase those plus-ups?

One final question before we go on. Well, I will turn to Erik, but my final question is to DOD and to NIH. On your Phase II-B-pluses or your CPP, where does the money for these extra grants come from? Is it coming from the 2.5 percent? Where does it come from? Michael?

[Laughter.]

Mr. CACCUITTO. Not by much. You have Phase II enhancement, we call it. It otherwise sometimes manifests itself as Phase II-plus or Phase II-B at NSF and other places. The matching funds for those programs tend to be matching fund programs where we require the companies to secure external funds to match our additional money. That additional money that we provide does, in fact, come from the set-aside, and what you are seeing happening right now at CPP is the same way. It is Phase II enhancement with a new governance mechanism attached to it. It is really the same old program that has been around for 8 years, just being used in a more aggressive way, in a different way. But it does limit our ability to influence outcomes because we are drawing that money from the same pool, that same set-aside pool.

Ms. WHEELER OK. Thank you. Jo Anne?

Ms. GOODNIGHT. Our Phase II competing renewal awards are made using the SBIR or STTR set-aside. But I should also mention that sometimes actually the companies are bringing State funds to that project, as well. For example, Kentucky offers Phase I and Phase II match funds, and there are certainly other States who provide some match funds, so that if they see we are funding a

Phase II or Phase II competing renewal, they can bolster that a little bit.

Ms. WHEELER Thank you. Erik, did you want to add anything before we go on to the VC portion?

Mr. NECCIAI. My questions will lead into that, especially considering the various forms of funds either increasing the percentages or outside VC funding or State funding, et cetera. So I will reserve my questions for that time.

Ms. WHEELER You are OK? Michael, your card.

Mr. CACCUITTO. Just an addendum. Often, the contracts are modified with non-SBIR money, even unilaterally. We will call it mission funds, DOD funding that is not set aside for SBIR and apply that to SBIR contracts if there is interest to do so. So that does happen quite frequently——

Ms. WHEELER OK, but——

Mr. CACCUITTO [continuing]. In addition to——

Ms. WHEELER [continuing]. For both of you, it is coming from the 2.5 percent right now? OK. Thank you.

Well, with that, if Senator Snowe's staff is OK, we will move on to the second portion of the panel and discuss the role of venture capital. The easiest way to lead into this is to just start with the firms and get them to explain to us how they feel about the possibility of changing the eligibility rules to allow firms majority-owned and controlled by venture capital firms to participate in the program.

You know what? Someone just asked if we could take a break. Could we take a break and then we will come right back, let us say in a couple of minutes. Is that all right? OK.

[Recess.]

Ms. WHEELER I am sorry to interrupt, but could we ask everyone to take their seats and we will start the second panel on the role of venture capital. Thank you.

At least one of our participants has to leave within 30 minutes, and so I would like to get started and we will open up with the SBA. An important part of this is to try to get the facts straight. As Senator Kerry has said, we continue to see articles and documents that suggest, for some reason, that firms with venture capital are not allowed at all to participate in the SBIR program, and that is not accurate. So we will start this with SBA giving us the definition of eligibility for SBIR and answering whether firms with venture capitals are allowed, and then I am going to turn to Stu Haber before he runs out to an airplane, and then, after that, it will be first come, first served. SBA?

Mr. BROWN. OK. I don't want to bore everybody, but to make sure I get right on point in terms of the development of the eligibility criteria, especially as it relates to potential venture capital participation, I have a prepared statement.

Ms. WHEELER OK. Two minutes?

Mr. BROWN. Well, I will tell you what. I will wind it down to the basic criteria and I will pass it on and then we can get reaction to that.

Ms. WHEELER OK. Can everyone hear? Do you want to pull your microphone a bit closer?

Mr. BROWN. OK. This definition is basically right out of our amended SBIR policy directive, and I am probably going to get on a roll anyway. It was most recently amended back in December 2004 and it became effective in January 2005 with the latest amendment.

The basic definition is that the firm must be for profit, it must be at least 51 percent owned and controlled by one or more individuals who are citizens of or permanent resident aliens in the United States, and have, including affiliates, not more than 500 employees.

The latest amendment added an additional provision on the 51 percent. It added, or 51 percent owned by another concern that is also 51 percent owned by individuals that are U.S. citizens or permanent resident aliens, and that was expanded to allow for subsidiaries of a small business.

And, of course, where we stand at now is are we going to expand upon that definition that is already out there, so I will just leave that there.

Ms. WHEELER OK, but before I turn to Stu, I want to make clear that firms with venture capital investment are eligible to participate in the SBIR program.

Mr. BROWN. Yes. Under that definition, and again, that is what comes up time and time again at SBA, is an understanding of exactly what that definition that I just outlined means, and it means—I don't want to say it this way, but it means exactly what it says. And the fact that the firm happens to be a venture capital firm as opposed to any other type of business, the criteria is the same. So the venture capital firm can have 49 percent ownership in the company as we speak. So there is no prohibition against venture capital participating in our program as we speak.

Of course, the issue is where do we go from here? Is additional ownership going to be allowed? Could you have a minority interest, say two or three venture capital firms owning 20 percent, participating in the program? But what we have to also look at, and I am glad that we have Gary Jackson here from our Office of Size, is it is not just ownership, it is control. It is potential control of a firm. So I will just leave it out there with that broad stroke.

Ms. WHEELER And tell us what the affiliation rule is.

Mr. BROWN. The affiliation rule is if a firm has an interest in a small business, that control could be inferred, that that would be lapped into the firm that is under consideration and the firm may possibly not be considered small.

Ms. WHEELER But I think my question is, are the employees of affiliates counted in the 500?

Mr. BROWN. Right. Right. That is what would put them over the 500. So if you had two or three companies that are considered affiliated with one another, even though they have less than 500 employees individually, the total would be included for the firm that is being considered for eligibility, the SBIR firm, and they, in turn, would not be considered small.

Ms. WHEELER OK. Let us turn to Stu and then we will go to Gary on size standards.

Mr. HABER. Thanks, Kevin. I would like to make four points, and one is to quasi-quote the regulations, which says that the SBIR

program protects small businesses and enables them to compete on the same level as large businesses. If you think about what that means, what do large businesses have that small businesses don't have, I would say it is resources. I would argue that a company, a small business that has millions of dollars invested in it has resources. And so I think to change the regulations to include—to modify the regulations to give VC-backed companies more opportunity, I think would be contrary to really what the program was designed for.

My second point is I have heard it mentioned a few times that, you know, why would VC-backed companies ever be interested in $100,000 Phase Is and $750,000 Phase IIs, and I don't believe they are. I think DOD is—my opinion is DOD is out of the picture from a VC perspective for two reasons. No. 1 is DOD issues topics and companies have to respond to those topics, and I don't imagine that a VC-backed company is going to operate that way. I would imagine that a VC-backed company is going to submit their own topics, and to my knowledge, NIH is the only agency where that can be done.

So No. 1 is I don't think it fits for VCs to go after DOD SBIR, and I don't think they will. The second thing is I think they are really focused on NIH because they can submit their own topics, plus the size of the awards, as I mentioned before, are much larger, two-and-a-half to three times the size.

The third point I want to mention, and I guess I will—this is from speaking with many VCs, trying to raise funds from them for our own products, and also something Jo Anne said earlier, and that is VCs really are focused on betting on the horse. They are focused on investing in management, not really technology. Sure, there has to be a market there, but I think they are really focused on bidding on management, and it would seem to me that if they have already made an investment and they believe in a company and that company has one more product that they want to move forward, I don't understand why they wouldn't invest if they really do believe in the management, why they wouldn't invest some additional money at the early seed stage level.

And the fourth point I wanted to make was actually to respond to the slides that Mr. Eisenberg sent to us. Slide No. 8, depicts four companies. One is a public company with 300 employees who would be eligible. Another one is 475 employees that has $150 million in revenue. It is also eligible. Company C, a $200 million company with 400 employees, eligible. And then the fourth case of an ineligible company with only 20 employees, very small, $50,000 in revenue, very tiny, but yet $8 million in VC funding.

I think this is a good chart, but I don't think it argues for company A, B, and C to receive SBIR funding. I think what it argues is that perhaps the 500-employee threshold is too high. So I think a company that has received $8 million in capital, I think has resources and I think that would—I think it would place small businesses without those resources in a competitively disadvantaged situation.

But even though that is not your point, I would go along and argue that maybe the 500 is too large. I have always thought of a company with 500 employees as not being small. Maybe it should

be half that. That is open for discussion. But it seems to me by the time a company gets to that size, I think they do have the resources and they really don't need—just like VC-backed companies, I don't think companies with 300 or 400 or 500 employees need to be nor should they be entitled to go after SBIR funding.

Ms. WHEELER We have here Gary Jackson from the SBA, who is an expert in size standards, and I wonder if you could speak to that 500-employee number. Can you tell us the history, why we have that number?

Mr. JACKSON. There is a relatively simple history of it. Basically, for R&D activities under the North American Industry Classification System, we set a small business standard. We look at the characteristics of R&D firms in that industry to come up with that level. And since the SBIR program is focused on R&D-type companies, or at least R&D activities, SBA historically has just applied that size standard for the SBIR program.

There have been some discussions saying that there is some legislative history that supports that. I can't cite anything to say that, but it is mainly to be consistent with our other size standard that we apply for R&D activities.

Ms. WHEELER SBA several years ago put out a rule on this issue. In fact, SBA is still in the middle of that rulemaking. You can give the dates of when you did this, but SBA went all around the country and solicited comments. Did the 500–employee number come up?

Mr. JACKSON. It did come up in a few instances, not very often. It wasn't raised by either members of the public that testified at our hearings, which were in June of 2005, or during the public comment period on our December 2004 Advanced Notice of Proposed Rulemaking. So a few people have raised that issue, as Mr. Haber has, but not—again, it has been few in number.

Ms. WHEELER And what is SBA's position on changing the eligibility rules relative to venture capital firms?

Mr. JACKSON. OK. At the moment, we have looked at a lot of information on comments that we have received. There are a variety of issues. One thing that I think I have learned from working in size standards for many years is there is rarely a consensus on these issues, and within the question about how to address the question of VC companies that are majority owned by VCs, we have the same situation. We have some very good arguments on both sides of the question.

So when we are looking at that issue, we are very concerned about a number of things. One, what does the public feel about this? That is a consideration. Again, we have mixed views on the appropriateness of allowing companies that are majority owned by VCs to participate in the SBIR program as small businesses. Mr. Haber has reflected some of those concerns on reasons against that. I am sure we will hear reasons that we ought to do that or allow those companies to also qualify.

I wanted to just follow up briefly with Edsel's remarks and just point out that when we look at small business status and what is a small business, there are really two aspects of it, and this is driven from the Small Business Act. One, there is a size dimension,

and that is where the numerical size standards come into play in terms of some type of measure of what is a small business.

But there is also the aspect of one that is independently owned and operated, and that is more of a qualitative assessment. What that provision is trying to focus on is whether a business is controlled by another organization, especially large businesses, and Mr. Haber kind of stole my point, too, that part of the concern there is that you do have access to different resources. If you are part of a much larger organization or you have overcome some of the disadvantages of being a small business, you have access to resources. You have access to managerial advice and other forms of assistance. That is a consideration, not just the numerical aspect of size.

So I think that is something to keep in mind as we look at that whole issue. How does that play into it? How does that change the nature of a firm and how does that VC backing give more competitive advantage to one firm over another that is in a similar situation.

Mr. NECCIAI. You mentioned the VC's competitiveness. What benefits do VCs bring to small businesses?

Mr. JACKSON. Well, first of all, quite obviously is the use of capital to pursue investments. We have already talked about that during the discussion of the valley of death. But also VCs quite often bring in very knowledgeable and experienced management talent. We have already talked about that, too, and the need that it is not just getting the capital, but it is also having the business expertise to be able to follow through and market a product.

Ms. WHEELER Mr. Doerfler, do you want to comment?

Mr. DOERFLER. I would like to tell the story about our company. I would also like to talk, maybe at another time, about how important this industry is, the biotechnology industry, but let me tell the story of MaxCyte.

I formed the company in 1999. It is a biotechnology company. I financed the company through, I like to say now, unfortunately, ex-friends and family——

[Laughter.]

Mr. DOERFLER [continuing]. Over the course of the first four or 5 years, and we raised about $10 million through that group.

We are working in an area that is really exciting. It is technology that uses a patient's own cells to treat disease, and our major product right now is in clinical development and it is for treating people who have severe lung issues, where we are actually regenerating lung tissue. So it is the only treatment of its type that is available. It is truly a really fascinating product.

When we started to see some progress on that—I have a very unique situation. I am still under 49 percent from the venture capital perspective because I have an angel that has been investing in the company who has a personal interest in the work that we are doing.

As we began to raise more money, we got around $10 million and he said to me, he said, "Doug, this is a really complicated area you are in and I think you need help. You need to bring in some people to," he called it smart money, because he is smart money himself, but he doesn't understand the work that we are doing.

So we went out and we met with scores of potential investors. In these investors we had to find their interest in the product that we are developing, which is a cell-based product, very unusual, and we wanted to find people who had expertise, to Mr. Jackson's point, because they had networks of physicians and they had been through this a number of times and they could give us more discipline in terms of how we should be thinking about developing these products because they are so risky.

In biotech, there is a valley of death and the valley of death is perhaps hundreds of millions of dollars. And then you get to a cliff at the end of that point and the FDA can turn your drug down or put it back up just like that, and all that investment goes down the drain.

There is also a number of instances where clinical trials have been stopped because of a single patient having adverse effect that you can't prove that your drug wasn't the culprit. It is hard to prove a negative, but sometimes you are forced to do that. And again, those trials can completely go upside down on you.

So this is a very risky business and you have to find people who understand the business and who have the financial ability to do so. So we are under 49 percent. We have been the recipient of a Phase I SBIR for about $90,000 through NIH and it was for a completely different use of our technology in an area that I didn't feel we had enough understanding of before we wanted to make any investment in, so we went to NIH and we went into a large study section. I believe there were 18 people. These are just top-notch scientists that really took us through the wringer to make sure that we had the right science behind what we were trying to do.

We got the Phase I and we are about to move into a Phase II submission for about $800,000, which we hope to get sometime in the near future. So that is a sideline of our business. It is very exciting. It opened up a new area for us, which is in actually a vaccine for treating these same kind of diseases.

The issue here is that when we are successful in this clinical trial, I have to raise a lot more money, probably around $35 to $40 million to take this product through the next phase, and that money is going to go to nursing staff. It is going to go to paying for the hospital for the patients that are on this drug, paying for the drugs that the patient takes, as well, because the insurance companies won't pay those. So these are very expensive trials.

I need to raise that money. I am not going to have those resources. I need to raise money for the next two or 3 years that is going to be dedicated to those kind of operations. I am not going to be flush with cash. Although I have cash, it will be very well committed to the hospitals that we are going to be using.

I talked to my lead investor, my angel, if you will. It just so happens that my angel has more capital at his disposal than all the venture capitalists that I have invested in my company combined. He said to me, he said, "I want to go this next step, but I need help. I need more smart money into your company to make this work." So I will be faced very soon with a situation where I will undoubtedly have to go above 49 percent and in the 51 percent range in order to go after the product that the company has been focused on.

It is interesting, though. If I become a public company and I am very successful, I can go back into the program. But under the existing SBA rules, I can't participate during that time when my capital structure is more than 51 percent, but I can when I go back to being a public company and have even more resources than I would in the future.

The size of my company, we are 14 people. I expect when we raise the next major round we will balloon to about 25 people. I don't expect it to be any larger than that. So we are a small company. We absolutely are a small company.

We are in a very high-risk business and we are in a business that is unique, and I think we have heard that today, that perhaps this is an industry that is really different than most industries in the U.S., and perhaps this is the only industry of its type where the venture capital community plays a major part in its success.

And biotech, we are still the leaders in the world in biotech, I think in large part because of the role that SBIR played in some of the early formations of companies with venture capital and with public financing.

Ms. WHEELER We have a question for SBA. Mr. Doerfler is saying that if he were to go public, he would still be eligible. What would be the rationale for them being eligible if they are public as opposed to if they are majority-owned by entities? You are saying that these will be entities, they will not be individuals?

Mr. DOERFLER. It could be individuals. They could be—it depends on——

Ms. WHEELER Well, then you would be eligible. But if they are entities, then you would not be.

Mr. DOERFLER. Right.

Ms. WHEELER So let us just say that they are majority-owned and controlled by entities.

Mr. JACKSON. Right. That is correct. Within the SBIR current regulations, that publicly traded company still would have to satisfy the requirement that 51 percent of the stock was owned by U.S. citizens or permanent residents of the United States. It comes back to an issue of control, that if you have a certain amount of ownership, there is control that you can exercise. But when you distribute ownership widely or by various institutions, the question of control comes up. It is somewhat of an anomaly, this situation that you bring up, because it does say that in some cases, a very small company may not qualify but a very large one may relative to the other. But I think the issue becomes one of control, where that public company is still under the control of the individuals.

Ms. WHEELER Who would control your company?

Mr. DOERFLER. This is my third company. The first two were venture majority-owned companies, investor companies. We have an independent board of directors. In each of the three companies I have been involved in, we have an individual board of directors, and the board is made up of a majority of non-investors, which isn't unusual in this business.

We went out and we found the venture capital investors. They did not put together their own group. We find these people based on our interests and their capability to invest in us. So it is not like we are going to a club or it is not like we are going to a group

that is investing in our companies. We are responsible for bringing in these investors.

Frankly, I don't want to have an investor that has more than maybe 20 or 25 percent in it for any influence whatsoever, but they don't have control. We have an independent board. We vote on all matters concerning the management of the company. I have complete control of that company on a day-to-day basis. So I don't see the connection, frankly, from my experience in my third company that your ownership structure infers some sense of control by a group or a number of investors.

Ms. WHEELER So if they have the majority, they do not control your company? They don't exert control?

Mr. DOERFLER. They don't, no. I mean, I can't—I don't want to be glib about this, but it is hard enough to get them to agree on lunch and location. It is very difficult for them to agree on a business strategy. It is very uncommon for there to be unanimity around what their interests are because they are all in different aspects of their funds. They have different portfolio pressures. Their need to invest in the company is based on their return, but they also have their own internal payback requirements and time lines that are different from investor to investor.

Ms. WHEELER Dr. McGarrity, your name plate was up.

Dr. MCGARRITY. Thank you. I also wanted to add my experiences from biotechnology, and I told you about my present company. I want to talk to you about a company that I was formerly CEO with until about a year ago and that company was ENTRON. It was very similar to the beginning that Dr. Fanucci mentioned. The basic technology was invented in the scientist's living room. They started out with one to two employees. The first grant that this company had was from the Cystic Fibrosis Foundation, so it was taking a highly innovative technology, trying to apply it to this disease setting.

The company applied to NIH for a Phase I SBIR grant and it was approved. In fact, the same kind of review committee that Doug had mentioned, 18 to 20 national scientists actually gave the company more money than we requested, and when is the last time you heard a Government budget grouping doing something like that? We fulfilled the objectives of that Phase I.

We went into a Phase II application. A different expert committee of 18 to 20 scientists approved that and they said, quote, "This is one of the most innovative, thoughtful, and exciting applications" they ever read. So that really psyched us. We thought we were highly valid, we had something to contribute.

We then got an addition, an extension of that SBIR grant that was awarded in June of 2003. In August of 2003, NIH contacted us and said there is a new interpretation of the eligibility rules. We want to look at your funding. And on the basis of our Phase II grant, that highly innovative application, we went out and raised venture capital funds, and that was—the SBIR award was our credibility and our credentials.

So suddenly, 3 months into this grant, the grant was rescinded and we had three people working on cystic fibrosis. We had to terminate those people. We canceled that program and we could never restart that. So on the one hand, NIH invested probably $3 million,

$3.5 million in all of these studies and we will never really know whether that would have any potential to help or cure cystic fibrosis.

And so I am sitting in my office and I am saying, you know, I have 20 employees and I am told I am not a small business and there is just something wrong with this picture, because I read the legislation of the SBIRs and it was to stimulate and help small companies and it was to stimulate innovation in American companies. So, I thought, we are really doing that, and as an entrepreneur, as a manager, as a scientist, I am perfectly willing to compete with anyone in the country on the quality of my science and the quality of my program, and if I don't get the award, it tells me I have to go back and work harder, and that is really the American way. That is what competition is all about in this country.

So I see there is a disconnect there, and I think if I apply this even to this setting, if you allow me to be McGarrity Venture Capital this morning just for the sake of illustration, and let us say all of the people around this table are biotech companies, and let us assume that the ownership requirements are fair and the total number of employees around the table total 450 employees total in affiliated companies, well, that means we are all fine, we are all eligible for SBIR.

But let us assume Mr. Jackson's company hits a breakthrough and there are great things going on in the country and he has to hire 50, 60, 70 employees. Well, then suddenly we are over the 500-employee limit and his success means you are ineligible for SBIRs. There is just something wrong with that equation for me.

And when I look at that, and I have recently in the past 6 months been to Europe and to Japan and then to Australia and I am meeting with other biotech companies around the world. I want to point out, and I think you are well aware of this, but I want to say it for the record. What happens here really has a direct impact on biotechnology in the United States and in international competition. I would say, please let these companies, especially these early stage biotech companies, compete for the most innovative idea, the most innovative science, and allow them to prosper, to create jobs, create economies, and also to bring cures to patients, especially those that are in those markets that are perhaps underserved or where there is no alternate therapy available.

I would just close by saying if you are developing a therapeutic, if you are developing a drug, it is basically going to be the same cost of development whether your market is $10 million, $100 million, or $1 billion. So where is the emphasis going to go? It is generally going to go, all things equal, to the larger markets.

And one final point. I read that if this goes through, well, large pharma is going to get in and have access to SBIR funds. I was with a small biotech that was purchased by Novartis about 12 years ago and I can tell you, that just doesn't happen. When I am inside Novartis and a scientist comes to me with a new and innovative idea, do you think I am going to take two people and tell them to work 2 months to write a grant application to NIH and then wait 9 months to get an answer back? If it is worth doing, we are going to do it today and I am not going to wait ten or 12 months

to do it. So I think that type of argument just doesn't reflect the reality. Thank you.

Ms. WHEELER May I ask you a question?

Dr. MCGARRITY. Sure.

Ms. WHEELER When you had that Phase II that had so much promise and the company attracted the venture capital that then made you ineligible, why would a round one of investment eat a majority ownership of a company?

Dr. MCGARRITY. Because they were approximately 60 percent ownership.

Ms. WHEELER But isn't that highly unusual? I was under the impression that first rounds are usually a smaller amount, and then as you go on, you receive more investment and VCs take control of a larger percentage of your business.

Dr. MCGARRITY. No. I think there is a tremendous variation there, and typically in an early stage biotech company, you will reserve a certain amount of stock for the owners and the founders, the scientific founders of the original team. You will set a certain amount of stock aside for stock options. And it is not atypical at all for the VCs or a VC to end up with more than 49 percent.

Ms. WHEELER And so why did the company still need the SBIR money if they had just attracted all of that venture capital?

Dr. MCGARRITY. That is a great question, and it goes to what I had said. The VC money that came in, there was a cardiovascular program, a large, large market, a lot of potential. There was a cancer program, again, large market, a lot of potential. Cystic fibrosis, and I have done the clinical trials in cystic fibrosis, they are really tough clinical trials to do. I mean, kids are sick, they are mucousy, and even to get the medicine in, it is very difficult. And the markets are much more modest.

And that was my point, that for all of these so-called orphan diseases or the diseases that do not have large and attractive markets, that is where you need the help of a thing like this to get it off the ground and to go through the early stages. As I say, large markets, the capitalist system works very well. If you say, I have great data, great technology, and I am going into atherosclerosis, you get a lot of attention on that.

Ms. WHEELER But I don't understand. I thought that project, the one for multiple sclerosis, had attracted the VC. So you had the money.

Dr. MCGARRITY. No. The—well, the actual technology was what attracted the VC. I mean, getting down into the detail, we had a cystic fibrosis program and it was the innovative technology that was being applied to cystic fibrosis. So how we pitched the VCs was, look, this is working and we have proof in animal models that it is working in cystic fibrosis. We want to take the same technology now and apply it to cardiovascular and cancer, and so they liked the combination that it was this highly innovative technology applied to a major market disease.

Mr. NECCIAI. You mentioned cystic fibrosis. And that it unfortunately got cutoff at that time. Are you familiar with any other programs that got cut? It seems like every time the funding is taken away, that these programs just get dropped and that there are po-

tential cures for, you know, X-number of different things that unfortunately don't come to fruition.

Dr. MCGARRITY. Yes, and the unfortunate thing is, as I said, we will never know whether this could have been effective. As I said, we had to terminate the three people that were doing this program and scale back and drop that program. And then you asked, well, could you go back and try to restart that? You could, but it is very difficult to do on a day-to-day basis because the team and the cohesiveness and everything else has left. It is very hard to restart something like that.

Ms. WHEELER So those venture capitalists who said they were interested in cystic fibrosis, once they found out you weren't eligible for SBIR, they decided not to give the company money?

Dr. MCGARRITY. No, no, no, no. No. We had data on cystic fibrosis using this innovative, I call it smart technology. So they said, hey, this is really slick, and we always got high marks from people on the technology. They said, this is really nice, but gee, you are applying it to cystic fibrosis. That is a long clinical path, it is a modest market, and they are tough clinical trials to do. We said, it will also apply to atherosclerosis, which are much easier trials to get through and you could potentially attract the interest of large pharmaceutical companies.

So they said, all right. We will pay you for this—we will invest in you for this innovative technology if you are applying this into atherosclerosis or into cancer. But to cystic fibrosis, they said that is such a challenging disease, a difficult disease, and a small market. We don't want to fund that aspect of it.

And I think that is what is happening with a lot of biotech companies, that they are using SBIR grants as a model or as a proof of concept into often diseases that are underserved by the markets, and often these orphan diseases, or you look at the list of people who have signed this letter, the patient advocacy groups, and we would get a lot of questions, can you use your technology for spinal muscular atrophy? Can you use them for Duchenne muscular dystrophy? So that is more typical than not.

Mr. NECCIAI. Dr. McGarrity, how was the business model for biotech firms different pre-SBIR than it is with the restrictions currently in the SBIR program?

Dr. MCGARRITY. Well, I think if you look over the past 10 years, a number of things have happened because it is difficult to try to put a stereotype around venture capitalists because that model is changing for a long time. When I went to my first biotechnology company in the early 1990s, it was high risk, high reward, and they were willing to take much more risk. If you look what has happened over the past five to 8 years, venture capital firms want less and less risk, and that is why I think the vacuum created by not having access to these SBIRs is really starving early stage biotechnology companies.

I mean, I want to point out, right now, my present company, VIRxSYS is eligible for SBIR, so I don't have an axe to grind. And you could say, well, why don't you keep your mouth shut and you will have a better chance at competition, but I think that is not what the country is about and I don't think that is what the spirit of the SBIR legislation is about.

Ms. WHEELER Did you have another question? If not, we will move on to Kunal.

Mr. NECCIAI. Sure.

Mr. MEHRA. My comments are kind of over three different parts, but I would just say, I mean, I think one thing we really need to talk about are the unintended consequences of any form of legislation, and there are a lot of, I believe, unintended consequences from the proposed legislative changes to the small business size standards.

The first is the two examples that Mr. Doerfler and Dr. McGarrity just gave are, I think, riveting examples of companies that are clearly doing things to save lives, but these are companies that are also clearly in the development and testing phase. They are not in the early stage innovation phase, which is what programs like SBIR and other things are intended for.

And I understand there is this kind of disparity. On the one hand, they are developing a drug that is for a particular set of applications, and then they see a separate application on the side that they might want to apply it to and maybe that is innovative.

We need to figure out a way to distinguish between those two different types of companies, and one way that you can do that is you can actually spin out the application of the technology for this new market, have a different capital structure with it, and then you don't worry about the company that is further down the road in the development and testing from being—as not eligible for SBIR because you have got this new small entity that just has that license, has a different capital structure, and could take advantage of an SBIR if it has the technology.

So I think there is an element of kind of robbing Peter to pay Paul in this, which to me is kind of concerning.

The second thing I want to talk about was the control issue, because I think this is an extremely complex issue. Quite frankly, I think boiling it down to something black and white, like if 51 percent of the equity sits with one entity, then it is no longer controlled by the entrepreneur, I just don't think it is that black and white.

I was a strategy consultant with McKinsey and Company and then I actually worked in a venture-backed company, so I think I have some unique insight into this, and I have seen examples where the venture capitalist will give $5 or $10 million to a small business in the form of debt that is equitable at some point in the future, OK. They basically control that company. The entrepreneur literally has a gun to his head. If he does not perform, his equity will be wiped out because in some kind of liquidity event, all the money is going to first go to the VC who is holding debt before the entrepreneur is allowed to benefit at all. So that would not show up on any of the control standards that have been suggested by the SBA, but I think clearly is in direct opposition to what people intended under SBIR. So there needs to be a very careful study of this.

Second, you know, venture capitalists can structure their investment in preferred stock, so again, even if they only own 20 percent of the equity, if that is a preferred type of equity vehicle, they can still have control over the company.

Third, the question of independent versus non-independent boards, well, that only matters depending on how rigorous your governance structure is. I have seen companies that have entirely independent boards, but guess what? Their board has really no control over the company because of the way the governance is set up. It is a particular set of shareholders that control, again, preferred equity or control a convertible debt note that might be exercised at some point in the future.

So I just think this requires very careful study. There is no easy demarcation to make here, and what I worry about is every one of these companies are going to have to be a unique case and then the SBA is going to be overloaded in terms of studying these examples.

And when I talk about unintended consequences, let me give you the extreme example. The way that the legislation has been reworded by the House, the Carlyle Group, which is a private equity firm that I am sure most of us in this room are aware of, which owns several multi-billion-dollar defense companies, could go out and hire Phil Condit, who used to be the CEO of Boeing. They could go put $100 million into a new small business. They could compete for SBIRs. They could go out and get small business set-asides.

And why would they want that? Well, because of the sole source authority that you are given in SBIR and other types of awards. And they could go out and they could use that as a front to sell products from some of their other portfolio companies. That would be allowed underneath the current regulation. It just seems completely ridiculous that we would allow a loophole like that to compete with a company like what Mr. Sarich has talked about, which is bootstrapped by three guys who mortgaged their houses and are clearly disadvantaged and don't have access to those kinds of resources.

Ms. WHEELER Thank you very much.

Erik, did you have a question on any of that? No?

Mr. NECCIAI. No.

Ms. WHEELER It sounds to me that what this argues for is what SBA has said all along, which is that there is no easy way to get at this structure when you look at venture capital firms, and that is why they have stayed with the basic definition of independently owned and controlled, because it is so hard to get at these individual cases. Is that accurate?

Mr. JACKSON. Unfortunately, yes, that quite often we have to look at these situations on a case-by-case basis. The overriding principle is the power to control, who really controls, who benefits, and that can vary under the circumstances. We have seen situations where a small share of ownership coupled with other types of assistance leads to control, and again, it is very difficult to give general guidance on what is acceptable and not. We try to keep our size ranks simple, but again, this is an area that you do have a lot of complexity.

Ms. WHEELER OK, thank you. Dr. Abramson, did you want to make some comments?

Dr. ABRAMSON. Yes. Thank you. I think the points being made here revolve around business decisionmaking. The bottom line for

me is, there is no need to change the current rule. So make that clear right up front.

I think we just heard Dr. McGarrity discuss a business decision not to pursue a particular line of research by his investment group. That is a legitimate business decision. Doug Doerfler gave a similar discussion, that his investors don't want to pursue a certain line of research or development in contrast with other more valuable or opportune opportunities.

For an individual business—by the way, we have no SBIR funding. We have applied three times and were turned down. But fundamentally, on an individual business basis, any funding program that is available should be sought. So there is no question that if I had an opportunity to get funding, I would go after it. But what is good for an individual business doesn't make good public policy. We can find individual examples where a particularly meritorious type of research would have, could have, should have been funded, but that doesn't mean as a general rule that we should change the basic structure of the rule system.

Very few early stage life science companies have any funding at all from the outside. It is very difficult even to get angel funding, let alone VC funding. As Dr. McGarrity pointed out, they have to prove some success, some traction somewhere to attract the kind of investment to move forward.

For many SBIR companies, many small bio companies that I know personally, the SBIR funding is their lifeblood. Without it, they die. If the rules are changed and other companies who are not now eligible enter the game, it will eliminate the opportunity for these smaller companies to prove themselves.

Another point that needs to made is that the SBIR community, the representatives of SBIR, say quite candidly to the small business community, apply, get turned down, then you can improve your proposal until you can be approved. But the science isn't changing. So what that says is that there is a part of the SBIR process is the quality of the writing of the proposals, and we already heard the comment that resources that can be dedicated to writing a proposal can provide a better quality proposal.

Now, we can argue about whether that should or shouldn't be the way it is done, but the fact is that is how it is done. So the small person who struggled for 2 months, who is a scientist, who is facing the valley of death, doesn't have the business background, isn't a very good writer, will get turned down. If they can't compete for that, where they could get a good enough score, the chances of them surviving to even demonstrate that what they want to do could have a benefit to society disappears. That means, ultimately, in my view, the pipeline begins to dry up, and in fact, we will lose the opportunity to sustain our world leadership in biotech if we change the rules.

Ms. WHEELER Thank you. Chris, did you want to make a comment, or did you have a question?

Dr. BUSCH. Yes. The discussion we are having largely deals with why certain entities should be excluded. Exclusion was the name of the game from the very beginning of the SBIR program. When it started in 1982, it excluded not-for-profit entities. It excluded universities. It excluded large businesses, big businesses. And they

all screamed and hollered when this program was being put into place. What it was restricted to is a very small part of the R&D pie of 2.5 percent today. It started smaller, but 2.5 percent today that is dedicated and established just for for-profit small businesses. So there is nothing new or unusual about excluding entities.

The second point is, ownership and control matters. Several folks have talked about situations where VCs or angels own a majority of the company, but they don't have control of the board. Well, that might be true today, but I have been involved in a number of these situations where that transitions to the situation where the outside owners take control of the board. So ownership and control really does matter.

And in the H.R. 3567, in principle, takes that away from the SBIR program. It limits, if I have it correctly, any individual venture capital company can own up to 50 percent, but there can be multiple VC firms owning a company so that the small business people, the entrepreneurs, could own less than 50 percent and the company could still compete for SBIR.

It is hard for me to understand, especially being from Montana, how one can view that as a small business. If the big companies own and control the entity, it is just common sense to me that it is no longer a small business, and outside the original intent of the SBIR program and the intent of the rules and regulations that are promulgated by the SBA policy directive. So that was that point.

The third, if the H.R. 3567 goes forward, it seems to me that it really lends the SBIR program to folks gaming the program, just exploiting the program, which I think would not be in the best interests of either small businesses or the technologies that they look to bring forward.

As I indicated in my previous comment, I grew up in and now reside in a rural State region where the SBIR program provided and provides the fertile bed for high-technology companies to take root. I think I may have mentioned before that before SBIR, there were virtually no high-tech companies in the rural States like Montana. Today, there are not as many as some of the States that you are from, but there is a fairly healthy high-tech community that has evolved, not due exclusively to SBIR but enabled in large part by SBIR.

So I really worry about the impact of changing the rules and the impact that that will have on the competitiveness of small high-tech businesses in the rural States, because there are virtually no venture capital resources available in the rural States and I think the GAO study of DOD and NIH awards, the one that came out about a year ago, pointed that out. If you look at the State-by-State information that GAO compiled, in the rural States, there is virtually no venture capital-funded SBIR projects, either on a minority or a majority scale. So the rural State impact, I think, is a big time concern for myself, and Senator Tester mentioned that this morning.

Ms. WHEELER Thank you, Chris.

Edsel, did you want to make a comment? I see your card up.

Mr. BROWN. Yes. A couple of quick points. First of all, for purposes of clarification from my earlier statement about our defini-

tion, as most of you around this table probably already know the facts, but our definition really hasn't changed much since 1980. The change I spoke of in 2004 broadened our definition and it was basically a follow-up for a clarification of individuals that came out from the Cognetix case back in, I believe, 2003. So I just want to point that out there, that the program really hasn't changed and the definition and consideration of individuals really hasn't changed and the 2004 change, which was effective in 2005. We wanted to provide a little bit more latitude to firms because of concerns like those expressed here at the table.

Now, having said that, I would like to elaborate on a few things. First of all, from my perspective at the Small Business Administration, having been there for 3 years, and I can tell you that in my brief tenure there, I can see how this program is really maturing. Now, 3 years may not sound like much, but I can look at that back to 2004 and see the type of issues we were entertaining versus where we are today, and we are really moving forward.

One concern that I have is we are talking about possibly changing the eligibility criteria, not just for SBIR, as outlined by Dr. Busch for H.R. 3567, we are talking about changing the standards for all of SBA. And again, there are pros and cons on this issue, obviously. But I think we really need to look at what the implications of this change will be, not just on our program, but for all small business programs.

And the question that I ask is, where do we draw the line? If we change it now, and there are some very good arguments here, let me say that now. I know Jo Anne is probably going to speak on a lot of the issues from the NIH and through the proposed rulemaking process that we went through a couple of years ago when we got hundreds of comments in the Federal Register, there are a lot of very good arguments. But again, I ask, where do we move the line as we move down a continuum? And as we move down that continuum, more firms are going to be coming into focus as we move upstream. What happens to those firms that were downstream in terms of what the program was originally put together for? So I think we need to look at that.

The other thing is, and this is beating a dead horse, but if we do change it, what are we doing in terms of looking at the risk and the creative technologies that we are looking to fund? Are we looking to fund less creative technologies by changing our eligibility standards? Again, I think that needs to be looked at.

This is a key point, again, from the SBA's standpoint, is as there has been greater concern about whether my firm is small or not, because that is what is happening. A lot of firms, they have heard there was a change, and that is why I made the point earlier that SBA is changing standards, and a lot of people—we have received hundreds of calls. We heard you changed the eligibility standard, and, of course, we have to explain to them that the standard did not change, that there has been feedback relative to that Cognetix case and we just provide clarification.

But if there is a change, there will definitely be an impact on SBA, as Gary has touched upon already. We will be an eligibility office, because once you get into the more sophisticated organizational structures, we are really going to have to look at these. I

don't want to put out there the lessons learned from other SBA programs, but we have programs like the 8(a) program, where you have an eligibility office that they actually look at things. I am not saying we are going down that road, but that would also have to be considered.

The other thing I want to point out is, again, there are some very good arguments for venture capital participation. As we have already said, that participation can be up to 49 percent in terms of pure ownership without getting to the control issues. But what impact will the potential exit strategies of the firms have on the program, because there are a little bit different interests involved when you are looking at someone looking to get a return on their investment versus to develop a cutting-edge technology, and as we are saying here, we shouldn't just be focused on commercialization. It is very important and we want to keep our commercialization rates up, but it is a balance. It is not all or nothing.

And last but not least, I want to touch upon what Dr. Busch said, as well, that we need to keep this out front and in focus. We are talking about 2.5 percent, not 97.5 percent. Thank you.

Ms. WHEELER Thank you, Edsel.

Ron, did you want to make a comment? And, I am sorry, we are just going to have to keep everyone a little briefer here so we can explore this a little more.

Mr. COOPER. Yes. I was just going to—I won't repeat what Edsel said, but with the—I just wanted to clarify that the rule, the last rule change that we did make, which was in 2004, and it took effect in January 2005, that I call the subsidiary rule because it is allowing a subsidiary, a firm to set up a subsidiary to receive the SBIR. We had been approached by SBIR firms that wanted to just set up an R&D subsidiary to pursue their SBIR work and we were not thinking of venture capital when we were making this rule change. It has implications, of course now, for venture capital. A small venture capital company that qualifies as 51 percent owner controlled by individuals can own and control a SBIR awardee so long as, looking at the affiliation web, it does not include—does not go over the 500-employee mark.

Now, the comments that we received during that rulemaking procedure led us to the Advanced Notice of Proposed Rulemaking which went out in 2004, and this is our process for making adjustments to the SBIR eligibility requirements, is we go through this rulemaking procedure. We received a significant amount of public comment during this advanced rulemaking.

We did not overall receive a clear, compelling argument or rationale to change the program eligibility requirements for the entire program. It was clearly demonstrated that there are unique innovation financing problems for small biotechs, which we are very concerned about and are very interested in trying to address. We also did not receive a clear quantitative measure of the extent of the problem that existed or that was being claimed.

So I just wanted to emphasize that this is, as we have been hearing, an extremely complex issue. We are still analyzing this and we would request your input.

A couple of issues that I think Edsel touched on, when we are looking at eligibility requirements, we need to be sure to maintain

the transparency of the applicant, and that is for identifying the control issue. This can easily get very complicated as we try to address some of the specific cases, say, that we have heard today in a rulemaking. For a small business program, it is important to keep the eligibility requirements simple and easy to self-certify. We don't want the Rube Goldberg solution, even though that is what may be necessary to—we could all point to cases that we think should be allowed. We need to keep these rules simple.

And then my last point is that we want to avoid shifting the program down toward—out of our focus of this market failure gap toward activities that the private market would probably fund anyway. Thank you.

Ms. WHEELER Thank you, Ron. Those are very good points.

Mr. Eisenberg, did you want to go ahead and make some comments?

Mr. EISENBERG. Sure. Thank you. I wanted to make a couple points that I think are important to make here. The first is much of the concern from the biotech industry is not about venture backing, it is about majority venture backing, and there is a difference here and it is important. Most of our companies have majority venture backing. There are about 1,400 biotech companies in the U.S. and 75 percent of them are private. Of those that are private, the vast majority have more than—have 50 percent or greater, are majority venture backed.

The average company that is out there right now today, be it in Maryland, be it in Massachusetts, be it in North Carolina, be it in Texas, be it in California, all over the country, the average company has five products in development, one in Phase II, not Phase II SBIR-speak, Phase II being FDA-speak, that is efficacy testing, small-scale efficacy testing. They have another product that is in small-scale safety testing. And they have three products that are somewhere in pre-clinical.

And the value of SBIR is, as has been discussed, really in helping to move products that are otherwise sitting on the shelf down the road through some proof of concept, early proof of concept testing that would not otherwise generate venture backing. When a company receives venture capital backing, those funds are generally dedicated toward the achievement of certain milestones with a particular product, and normally it is going to be the product that has the least risk, that is the product that is furthest along.

And so it is important that the SBIR provides the opportunity to take products, or applications of products, or new products that you otherwise have on the shelf and move them out into—down the road for proof of concept testing sooner than you otherwise would have. That is good from a public health standpoint. That is good from a patient standpoint. And it is good from a public policy advantage.

The basic fact is that biotech companies participated in the SBIR program for 20 years, and there are many of the success stories that SBA publishes on its own website, that we are happy to publicize, as well, about the biotech industry. Many of the companies that participated have had SBIR backing. Synagis, a product from Medimmune that takes care of—Medimmune out here in Maryland that takes care of kids that—premature infants that have lung in-

fection, that is an SBIR success story. There are wonderful success stories from this, and the basic fact is, for 20 years, companies participated regardless of capital structure.

Ms. WHEELER But I think the point is there that they weren't supposed to.

Mr. EISENBERG. Well, the SBA clearly knew who it was going to, and what is further, Congress reauthorized the program twice during that period, and if they weren't supposed to, Congress could have, but clearly didn't, make a change to the rules.

Ms. WHEELER But we did not know that firms majority-backed by multiple VCs were participating until there was a ruling from the SBA when the issue of size standards came up. I would prefer that you would focus on why we should change the rules rather than on whether it was a change because we disagree on that.

Mr. EISENBERG. So we can turn then to why should companies be able to participate.

Ms. WHEELER OK.

Mr. EISENBERG. Take a look at the decline—what has happened since the rule change has occurred? Slide 5 of the slides I provided to the committee shows what has happened to the applications at NIH in terms of SBIR grants.

OK. What is more, our companies are not taking—don't take advantage, it is not a question of taking advantage of the other 97.5 percent. The NIH grant structure is intended—the vast majority of them are intended toward hypothesis-driven, research-oriented grants. Those are intended to further science and do wonderful things for public health, but are not oriented toward commercializing technology.

And as a result, what is appropriate are the SBIR grants. And so you see the fall-off in the application. The companies—so what you have is a reduction by 12 percent in 2005, another 15 percent in 2006. So there is a fall-off and that doesn't help produce the best science. The best science helps when you have as many applications as possible, reviewed by world-class scientists organized by the NIH to review that science, and then awarded to the best science to produce the best outcomes that we can find.

Mr. NECCIAI. Could you repeat those statistics again you mentioned in 2005 and 2006?

Mr. EISENBERG. Sure. In 2005, you had a fall-off in SBIR base application rate of 12 percent, 11.9 percent, and 15 percent, 14.6 percent. Meanwhile, there is an increase, a continued increase in the R01. That is the largest program at the NIH, which is for hypothesis-driven research that really is not oriented toward commercializing technologies. So you have had a fall-off in scientific applications.

Mr. NECCIAI. And do you think that these fall-offs are attributed to the lack of venture capital funding?

Mr. EISENBERG. Sure, and that is why you see, if you take a look at the next slide, the letter that was sent by Dr. Zerhouni, the head of the NIH, specifically making the point that it is not receiving the best possible scientific applications, that the NIH believes, and you can read this to yourself, the NIH believes that the current rule undermines the statutory purpose of the SBIR program to stimulate technological innovation and to increase private sector com-

mercialization of innovations derived from Federal research and development, thereby increasing competition, productivity, and economic growth. Furthermore, it undermines the NIH's ability to award SBIR funds to those applicants whom we believe are most likely to improve human health, which is the mission of NIH.

So that is why there should be—you have lost some of the scientific competition and you have lost the opportunity to more quickly advance products out to patients sooner.

Ms. WHEELER May I ask you a question? Why is it that you think that this drop in applications correlates to the rule change?

Mr. EISENBERG. Because you have fewer companies that are able to participate, and therefore those companies that would otherwise participate are not submitting applications. When you ask our companies, would they participate in the program if they were eligible, over 80 percent of them say, yes, we would submit applications. We want to be able to compete for these grants because we have products that may work.

Ms. WHEELER But that is assuming that this entire 12 percent and almost 15 percent is only made up of companies majority-owned and controlled by VC firms, and do we know that? It is impossible to know that. Furthermore, I had more than 20 meetings this summer with the SBIR program managers and we have pulled the data from SBA also, and there are at least four other agencies that have seen a drop. I don't think you can say at the Department of Agriculture that they have seen a drop because of venture capital owned and controlled firms suddenly realize they can't compete in the Department of Agriculture.

So I think for the purposes of the committee, in looking at legislative solutions, it would be better to focus on how we could identify those firms which require a lot of venture capital backing but that legitimately are still small businesses. We could make them eligible, but I think the blanket approach is not working, and I think that some of these arguments that suddenly science has stopped or that there is a correlation to the drop in applications or that VCs get no money, are very hard to substantiate.

So I think a more constructive conversation would be for all of us here to say, is there some agreement that there is a sliver of these firms that legitimately should be participating in this program, how do we define eligibility and how do we stay within these terms that Ron identified? We must keep it simple. The firms must be able to self-certify. Also, how do we keep SBIR dollars going toward the early stage projects instead of those that are further along.

So can you speak to us in those terms?

Mr. EISENBERG. Sure, and as far—I guess a couple points on that. Point No. 1, as far as keeping it simple, one of the things that needs to be addressed are the affiliation rules as they presently stand, because as Dr. McGarrity pointed out, not only is that information not public, a venture capital firm could be investing in companies in California, Boston, Michigan, Florida, Texas. Those companies don't know each other, don't have any interaction with one another, but yet if they are supposed to apply for an SBIR grant, they are supposed to ask their venture capitalist non-public information.

How many employees do these other firms have? And then if one of them happens to all of a sudden be successful, that knocks me out of the program, even though I am in a totally different field and have never even met those companies? That doesn't make much sense. So that certainly gets away from, as you just pointed out, the intent of keeping it simple and making it straightforward. That certainly gets away from that sort of stated intent.

So in terms of addressing it, and we would be more than happy to come back and talk with you about potential ways to look at this, but that certainly strikes me as not in the spirit of keep it simple.

Ms. WHEELER I think you are right. This 500-employee number is not really applicable to the biotech industry because, in general, most of the firms are fewer than 50 employees anyhow. And so do you think that there should be a consideration of looking at the biotech industry and the actual numbers—you seem to know what that market looks like—and saying, OK, we are going to say that a small biotech firm is 20 employees. Would that be fair?

Mr. EISENBERG. I don't know that it makes sense to speculate on numbers. The average is 50 or fewer. We can certainly have discussion about that. But to suppose that a company is able to ask its investor, well, how many employees do all of your other portfolio companies have, and that is not public information, and then ask several of the venture capital firms that have invested in it, and how many do all of yours have, doesn't get at it. What is more, investors in venture capital firms, some venture capital firms invest across multiple industries. Some invest exclusively in health, but some invest across multiple industries where the average size may be larger than that.

So again, if you are trying to stay within what the spirit of the SBA is saying, which is that affiliation is important, that still gets you sort of—it can get you off in a couple of different areas that don't make sense relative to, I think, the public policy that the committee is trying to get at.

Ms. WHEELER But my point is, if the industry is seeking to be exempt from the affiliation rules, what would be the alternate suggestion that you are bringing to us to help identify what would be a small firm?

Mr. EISENBERG. As I said, we would be more than happy to talk with you and have a conversation with the committee staff and Chairman Kerry and so forth about possible outcomes and possible constructs in terms of how we would move that forward. I think we would welcome the opportunity to have that discussion with you. I didn't come in here today with a proposal to put down about what makes sense, and we are obviously very pleased that the committee is holding this roundtable to have a good discussion about these issues and certainly appreciate Chairman Kerry and Senator Snowe's interest in moving this issue forward. But there are—we wanted to have the discussion on the broader issue, and if there are specific areas that the committee would like to discuss in terms of different constructs, we would welcome that conversation.

Mr. NECCIAI. And Alan, we appreciate you taking the time to come today and discuss these issues. That goes for everyone here.

It is very important to have this conversation to get all aspects, a nice balance of varying different views.

Mr. EISENBERG. Sure.

Mr. NECCIAI. I wanted to ask you a quick question just for a moment and then we can move on about the graph that you provided here. You have this zone where the 2003 case was illustrated, and then later 2004 and 2005 where the SBA regulation changed, and then the grants drop-off here, and we were talking about the lack of venture capital and how that could have a great effect in the lack of NIH grants, et cetera. And then Kevin pointed out that there was a lack in other agencies at the same time. Since we don't for sure know what caused the lack of awards, couldn't it be possible that the lack of NIH, SBIR awards in addition to the lack from other agencies, are directly related to the lack of venture capital?

Mr. EISENBERG. I am not sure I fully followed you.

Mr. NECCIAI. The same association of the lack of having these NIH grants dropping and that other agencies who also receive venture capital firms, that the lack of those awards is also attributed to the lack of venture capital.

Mr. EISENBERG. It is reasonable. What we have received from our companies, our membership, is that many of them stopped making application to the program because they were under the—they were told that they were no longer eligible to participate, and as a result, many of them said, we would have otherwise applied or we would be happy to apply in the future if we are again eligible. That suggests to us that that is the sort of—the correlation is that companies that were otherwise eligible and no longer were have stopped making application to the program. So that is where our impression has been from our company feedback.

Mr. NECCIAI. So in other words, there is potentially a direct correlation between the lack of NIH awards and the lack of venture capital funding?

Mr. EISENBERG. Potentially.

Mr. NECCIAI. OK. Thank you.

Ms. WHEELER But then I think we would need to look further. That is why I think it is hard to look at these graphs, because then we have something that contradicts that when we look at the GAO study, which found that 2 years after the clarification, actually the number of awards to firms with VC went up and also the dollars.

Mr. EISENBERG. The GAO study, though, the GAO study, just to be clear, didn't do a terribly good job in terms of looking at majority venture-backed companies as opposed to venture-backed companies, I think.

Ms. WHEELER Those are two separate issues. We are talking about venture investment, not majority owned. In fact, we invited the GAO here for this purpose because we know that in this discussion, some people have tried to undermine the only unbiased study that there is. We requested the GAO study because we really felt like we needed to get data.

And so, again, I think that the constructive conversation here is not to argue over everyone's interpretation but for us to really try to identify if there is a way to get these legitimately small firms into the program or if there should be a change at all.

Mr. MEHRA. Could I make a suggestion for how we could do that?

Ms. WHEELER Yes.

Mr. MEHRA. I think the mechanism exists currently, which is if you are a small business and you are developing some revolutionary technology in the biotech space, you want to go into these Phase II clinical trials, you need to raise a whole slug of venture capital money to do it, which will dilute you, what you could do, which is the same approach that PSI, who is in this document, has done is you spin that out into a separate entity. You let venture capitalists invest in that entity, which is solely focused on the clinical trial, and you keep the core technology in the parent company which is still majority owned by the entrepreneurs and you can continue to apply for SBIR grants.

If you have already gone down the road of being diluted by your VCs, then you could say to them, hey, let me carve out this technology and put it in a separate entity that I will capitalize and fund myself. But that seems to me like a good mechanism that doesn't create any more administrative burdens for the SBA, stays on the existing rules, and achieves all the objectives that Mr. Eisenberg just talked about.

Ms. WHEELER Mr. Doerfler or Dr. McGarrity, does that model work for you?

Mr. DOERFLER. The amount of SBIR funding that we would go after is relatively low. I look at Slide 7 where there are companies in here that receive tens of millions of dollars a year in SBIR funding. This isn't the biotech way in any way. I mean, the companies—we need to provide the data, but the averages are quite small. They may have two or three SBIRs going at one time. It is a very small part of our business, but it is important because it allows us to try out new science. I was trained as an engineer. Engineering is very different than basic science. You cannot predict what is going to happen, so you have to give it a shot and maybe a one in 20 chance of being successful. You have got to give it a shot, and that is what these SBIRs are.

So I personally wouldn't set up a separate company to go after half-a-million dollars or a million dollars of funding. It is more complicated. There are governance issues. It just would be—if I had to do that, I wouldn't go after—in our industry, bio sciences, I would not go after SBIR if the only way I could do it was to set up a separate subsidiary or separate company for that sole purpose. I just wouldn't do it. That is my opinion.

Ms. WHEELER Which, as Dr. Abramson would say, is a business decision, no? That would be a business decision.

Mr. DOERFLER. So my business decision would be to not pursue the creation of any innovative new science, which is an interesting business decision but one that I think many in the bio science would completely disagree with, because again, we get up in the morning to create new medicines and we want to have as many chances as we possibly can to do that.

So again, the question was posed, would we do it? I wouldn't do it, and therefore I wouldn't participate in the SBIR program.

Ms. WHEELER OK. Thank you. I am sorry. I know that Jerry and Jo Anne are waiting to talk, but go ahead, Dr. McGarrity.

Dr. MCGARRITY. My comments would really reflect what Doug just said, because, one, it is an awful lot of work to set up a managerial structure to handle a relatively modest type of investment. On the other side, while you can say it makes sense from a managerial standpoint, you are asking your present investors to say, look, we are going to take some stuff that we kind of took out of the mainstream of the company and that you invested something in and we are going to spin this out and you are not going to be in the control that you have now. You are going to have to give up something. The investment market just doesn't work that way. Investors are not going to say, yes, I would be happy to spin this out into a free-standing entity and I will take less for my investment.

Ms. WHEELER But what I don't understand about that argument is that, on one hand, they say that they are not going to put money in the SBIR technology because it is too nascent, but then when you say you are going to take it out, they say, hey, wait a minute. You are taking something that I have interest in. Did I understand that?

Dr. MCGARRITY. Well, because we are paying for the superstructure. We are paying for all of this. And to say, let us take this and just go off and either not give you anything for all of the years of support that you have given or to give you less than what you think may be fair market value. And I think that this whole point comes back to what we were saying about the VCs are going to control the entity or they are going to be—you know, I could make an equal scenario that if you have a sole investor that is going to be putting up $5 million, an individual can be just as demanding as a VC. There is nothing in the VC criteria that says they are going to be controlling and an individual investor is not going to be as controlling.

Mr. MEHRA. I think that is a key point behind the SBIR program, though. It is intended to support entrepreneurs, entrepreneurially controlled companies to do innovative activities. It is not intended to support VC-controlled companies to go after these really innovative ideas. And so exactly the issues that were just brought up, I think that is a great argument for why they should not be participating in SBIR.

Mr. DOERFLER. I am not a policy person, but I did read a little bit of this and I didn't think that venture capital was included in the original SBA law. It was around, I think, creating innovative science, and that is what we are talking about here. And the issue is, is the bio science business a different business than perhaps the other ones around this table, and what might work for the concern that you have, Mr. Mehra, around unintended consequence of someone raising $100 million. That is not the bear in the woods that we see in the bio science area. There is no evidence of support that that has ever happened. I think when we have worked on this bill, we tried to prevent that from happening by ensuring that someone who owned 51 percent of the company and controlled the company wouldn't be participating in this program.

So again, I am going back to the business decision of would I set up a separate company, create a rather complicated licensing agreement between A and B in order to get—which is another complicated issue and probably would also have some control tests

around that licensing agreement—would I set that up to go after SBIR in a bio science company? I would say, absolutely not because of the size of the awards.

Ms. WHEELER Thank you. Dr. Fanucci, and I am really serious, 2 minutes. I am sorry but we have to move on to the next topic very soon.

Dr. FANUCCI. Well, I guess one question I have, it seems that there is a, unless we have a skewed sampling of people here, that biotech people all would like to see VC participate and everybody else wouldn't. Can't you split the rule so NIH has a different set of rules? That is just a question.

The other, I think it would be an extraordinarily bad idea to allow VC to participate in the DOD, maybe NASA, other hardware-oriented SBIRs. In our experience, DOD primes now create a lot of the SBIR DOD topics. They write them. This is research they would like to be doing and often participate with the small business, in our case always actively in the program. If they could do it themselves, I am sure they would. So if the rules were changed in some way that created a possibility for them to position themselves as a small business-eligible program participant, they would do that and exclude companies like Kazak because they wouldn't need to have us involved.

An unstated benefit here of the rules right now is that those guys, the GE or Boeing and the large companies, are motivated to work with the small businesses, which even when you don't get the award, you have now made contacts in that company that remember what you talked about and it is a great marketing benefit for other things not related to SBIR that really wouldn't be easy to match without the program and the motivations and the big companies to work with us.

Ms. WHEELER Thank you, Jerry.

Jo Anne?

Ms. GOODNIGHT. The fun of going last.

Ms. WHEELER And Joan is running the timer here, if that is helpful to anybody, with the green and red lights.

Ms. GOODNIGHT. Great. I just want to start by emphasizing that NIH shares SBA's commitment, it shares all of these small companies around this table and other small business advocates around the table's commitment to ensuring that only small businesses receive SBIR and STTR support. It is a very important point for me to get across this preface.

I also want to say we absolutely appreciate the rule change that SBA put into effect in January of 2005 that did, in fact, open the door ever so slightly for subsidiary firms to participate.

When you look at the reality and the profile, the real profiles of companies who are being determined ineligible, the data show, in fact, that most companies are not just owned by another, a single other business concern. When they get to the stage of getting through their Phase II clinical studies, when they get to the stage, and I am speaking more specifically to drug development and medical devices, of needing that additional financing, which often will come from VCs, not solely, it may be coming from strategic partners. It may be coming from others. So we can't just totally focus on that.

When they get to that stage, then the small business is often owned by multiple VCs. We have data to show that, happy to share it, because every time a firm is determined to be ineligible, I ask them, tell me what your ownership structure is. When GAO did their study, as much as the information was useful in there, some very important points. It went from 2001 to 2004. Well, our downward spiral of the applications has been since 2004.

Ms. WHEELER Right, but the study ended in 2005.

Ms. GOODNIGHT. There is data——

Ms. WHEELER If you would like us to ask them to update it, we will.

Ms. GOODNIGHT. Their data ended with the 2004, so it is since 2004 we have seen an overall 25 percent reduction. Is it solely because of VC? Absolutely not. I won't sit at this table and say that.

We do have another unbiased study and that is the National Academy of Sciences study. You know, they found that 25 percent of the 200 NIH Phase II award winners between 1995 and 2005 received the highest number of SBIR awards, also obtained VC funding. They also found that new lines of research that are, indeed, high risk that VCs cannot or will not fund are perfectly ripe for SBIR and STTR funding. Hence, there is a synergy there that nobody here is really talking about, where——

Someone keeps raising the comment that we will be funding even later stage research. There are no data to show that. We have data to show that these firms have been in the program. The GAO study didn't explain when they received the VC or what their percent ownership is, but the Academy's report probably speaks more to the fact that they did receive it, and it is those early, early stage ideas that aren't downstream in the Phase II to Phase III stage that we are actually looking at funding for——

Ms. WHEELER But the issue is not whether any VCs should participate. Nobody has a problem with that. What we are struggling with here is how much.

Ms. GOODNIGHT. How do we identify small business? I can't tell you how to fix it. What I can say is, you know, thought could possibly be given to if a company is, in fact, owned by multiple venture capital firms, then perhaps some thought as to what percentage do you own of that company? And if you can be under some X-percent that the policymakers decide is the appropriate amount and certify that, on a day-to-day operational basis you are doing the R&D to get that project to the stage where it is going to then attract venture capital or other resources, that may be the approach to take to keep it simple, because while part of me is pained by we are talking about keeping the rules simple, I also understand that small businesses need to understand the rules and be able to self-certify. So we don't want to make them too complex.

But for a community such as ours where small businesses have these high and intense capital needs, we want to see all four goals of the program realized to the extent that Phase II is a successful endeavor. We want to see life extended and health improved. These are some of the same firms who were participating and who no longer are eligible, and there can be some simple fixes.

Ms. WHEELER OK. Thank you. Jere, did you want to make some comments?

Mr. GLOVER. Yes. I want to make several comments. One, putting this all in context, 40 percent of all scientists and engineers work for small business and are self-employed. We still only get 4.3. So there is a clear problem. And when you talk about, for example, in the House bill that was passed, you have to be very careful about how definitions change because, for example, they want to include nonprofits and universities. They already get 44 percent of Federal dollar R&Ds. I don't think they need a bigger share of the Federal R&D dollar. Small business with 4.3 probably does need a bigger share. So it is fairly clear and fairly obvious on that score.

There is also a lot of discussion recently about SBIR mills. Let me simply say, no one is talking about the huge number of contractors in the Defense Department who get the lion's share, nor are they talking about the fact that, for example, Johns Hopkins gets 1,299 awards in 2005 for $607 million. The University of Pennsylvania got 1,157 for $471 million. So the mill issue, I think, is really a non-issue since the National Academy of Sciences study came out, definitively looked at it, and said that those companies do a better job of commercialization and did the evaluation.

Let me just point out a few other things quickly, because I know the hour is late. We surveyed all NIH winners and asked them the specific question of should VCs be included. At an 8-percent response rate, which is fairly good by survey standards, 92 percent of small businesses involved in the SBIR program who had won at NIH do not want the VC-controlled firms in. We did an objective study. We referenced BIO's website, our websites, and you can read it and figure it out.

No matter where we cut the definition off, there is always someone complaining. Women-owned businesses, 49-51, they complain why shouldn't it be 50-50? You get—no matter what SBA definition it uses, there is always someone who are hurt on the other side of the things.

The other thing is every venture capital-owned company that receives an SBIR award takes money from some other small business who are eligible. On average, there are six companies that don't get an award for every one that does under the SBIR program. Those numbers basically have stayed the same for a good while.

The unintended consequences and definitions are something you have to be very careful about because what seems to be a minor change turns out to be a huge change. Little things like, for example, the VC company has to be domiciled and incorporated in the United States. A Chinese company that sets up a U.S. subsidiary that is domiciled in the U.S. and incorporated in the U.S. suddenly becomes eligible to take Federal Government money offshore.

No matter how you define this, you have got to be very careful and you need SBA's career staff to look at any definition, any change that we make, to make sure that we don't open Pandora's box and do things that we don't seem that should be done.

Ms. WHEELER Thank you. Dr. McGarrity?

Dr. MCGARRITY. Thank you, and I will be very, very quick. I just want to speak from my experience, 20 years in the biotech industry in four different companies, and I appreciated all of the comments from the different industries and from the Small Business Adminis-

tration. From my take or my conclusion from what I have heard here today, I think that the biggest stumbling block and the biggest obstacle for early stage biotechnology companies is the concept of the affiliated companies, and I think that is what is really having a strong negative impact and potential on the early stage biotechnology company.

I would just say that I would welcome and we would all welcome the opportunity to work with you and the committee to see if we can somehow modify this so that the United States will be able to maintain its international lead in the biotechnology field, because I think if this continues, I strongly believe that this is going to have a strong negative impact on international competition and the whole technology industry in terms of jobs, economic development, and more importantly, cures and better lives for our citizens. Thank you.

Mr. NECCIAI. I agree with you. I don't think it seems quite fair with the affiliation or with the 49 percent, with certain aspects. In more of the contracting aspect, Administrator Preston sent out a letter asking that if you are a large business and you have small business—in other words, a small business who grows and has a contract and goes over, they maintain that contract until the life of the contract. They just can't get any more contracts as a small business because they are no longer a small business.

It doesn't seem fair that a small firm who has an SBIR grant goes over a number of employees and all of the sudden loses its grant. So there is job loss, there is NIH funds that are lost, there is a potential cure that was lost, versus being able to maintain that SBIR award until the life of the award——

Dr. MCGARRITY. Well, I believe——

Mr. NECCIAI [continuing]. That only seems reasonable.

Dr. MCGARRITY [continuing]. And I would defer to Ms. Goodnight, I believe your eligibility is determined at the time the grant is awarded.

Ms. GOODNIGHT. Correct.

Dr. MCGARRITY. So if I am eligible today and I get the award today, if I grow tomorrow or next week, then I still maintain that award. But it still will mean that I——

Mr. NECCIAI. But you cannot get a Phase II award? You are only limited to that Phase I award.

Dr. MCGARRITY. That is right, but see, with the affiliated companies, I am not in control of my own destiny because I can be a 20-employee company. If another company from that VC hits it big, then suddenly I am being punished for something that I had no control over at all.

And I think the statements that, gee, you have access to all these other management and these other companies, I think that is grossly overstated. I think that doesn't happen, because, as Doug said, generally, it is not the same—the other companies, the other companies in the stable, the portfolio, are not in the same specific business and there is very minimal interaction, as a matter of fact.

Ms. WHEELER Erik, do you mind if we just give everybody 60 seconds, and then we will move on to data rights. We will have to figure out a different way to keep this conversation going after this

roundtable so maybe we can get something concrete, or just not agree. I don't know.

Dr. ABRAMSON. Sure. Absolutely.

Ms. WHEELER Sixty seconds.

Dr. ABRAMSON. Sixty seconds. I think the issue that the committee has to grapple with, the way I would summarize the discussion, is the majority of VC investment-owned firms want to shift the business risk over research to Government. That is it in a nutshell. And the policy question is, should that take place or should the program be continued as it is, which would not allow them to shift that risk. Thank you.

Ms. WHEELER Thank you. Ron?

Mr. COOPER. Let me see. Yes. The one thing that we have heard a lot about is what Dr. Mehra was mentioning, the spin-offs and the ways in which SBIR firms are using spin-offs and asset sales to pursue this in spite of the—once they become VC-majority owned, so I am very interested in your comments and further discussing that.

I just wanted to mention that the—well, you have to be careful with the statistics on the grant applications. That is a, what was it, a 4-year window. If you zoom out a little bit, then you see that there is a broad trend of increasing applications with these cyclical events and it could be due to our rise and fall in our outreach or other economic conditions.

The way you were phrasing the question, how can we make these firms eligible for the program, I would maybe rephrase that as what is the best kind of public policy, what is the best program vehicle that we can think of at this point for assisting these bio firms that are faced with this long lead time due to—that are in drug development, because it is what appears to be a narrow segment of that industry, the ones that are requiring FDA approval.

Ms. WHEELER I think that is an excellent point, and we are going to move on to the data rights section, but you are right. There was a proposal to take these firms and set up a separate pot of money so that they could compete for that since they did look a little different, but we can debate that a different time.

Now we are going to move on to data rights. Unfortunately, because we are already 10 minutes over, I am going to say we have 20 minutes for this and basically we just want the firms—I know that Dr. Fanucci is an example, I don't know if anybody else is to explain to us what is happening. As we see it, Congress intended for firms to keep their data rights, their intellectual property rights in Phase III, but it seems that they are running into the prime contractors as well as the agency that will often fight them on their rights. It means that they have to go to expensive lawyers to fight for what we intended for them to have already. And then an unintended consequence is that it is a waste of money, because if they don't use the SBIR, then they are going to end up duplicating the research, which wastes time and money.

So can you give us your example?

Dr. FANUCCI. Sure. We have lots of examples, but one good example is the big commercialization success we talked about earlier about with the ship cargo support. There, we developed that clearly under SBIR. There really was not argument about whether it was

done under SBIR by anyone, but both the prime contractor—in this case, it happened to be NASCO, which is a General Dynamics company, and the Navy contracting people, either or both didn't understand, or did understand—either way, it doesn't matter—they actively worked not to allow those rights to pass forward, which in our case would have meant someone else would be building these things, not us. In other words, nothing special once you see what it is to go out and have someone else make it.

So long story short, after 6 months of negotiating, and to the credit of the General Dynamics people, they finally did agree that it was appropriate for us to call this an SBIR Phase III and retain the data rights to them.

And there are many other examples of that, I guess we won't go into, that Kazak has been involved with where companies really don't understand the rules. It is a complicated rule. They don't encounter it much. And actually, the Clause 718, the DFAR clause, is in opposition to the one that is in their prime contract, 713. They really say the opposite thing.

So one issue that always comes up from the primes is, well, how can we protect your data rights as a subcontractor when our prime contract doesn't say anything about that? So somehow—I don't know what the right way to do this is—they have to be either made to understand, which our attorney, David Metzger, will say is it is inserted, not flowed down, but it might be just easier to put that in the prime contract, that if you are dealing with an SBIR company, you can give them SBIR data rights. Once they understand that, that seems to be at least one part of the pie that needs to be solved here.

Before that can happen, there needs to be the education process, the contracting people both in the Government and in the primes understand what SBIR data rights are in a simple page or two that even I could read and understand. It is not simple to understand all of the subtleties there. But really it comes down to the definition, which is derived from—extends or logically concludes SBIR-initiated technology. We have had large contracts dropped by prime contractors with us because they refused to either admit—or I guess they would admit, but they refused to grant those data rights.

One argument that they sometimes will use is that, well, this isn't a Government contract, it is our own IR&D, but if it is a missile on a ballistic missile defense application, the ultimate user is the Government, so I believe that somehow something has to be done to make it clear that even though they might be using $50,000 of their own IR&D money, it really is a Government application after all and the data rights should apply to that kind of deal.

Time is short. I guess that really summarizes. It is an understanding issue on the side of the Government people, an education problem, and then also an attitude that why should these small businesses have these special rights that the big companies don't get.

Ms. WHEELER Thank you, Jerry.

Kunal?

Mr. MEHRA. Just very quickly, we have had experiences on both sides. I have had a number of program managers basically tell us either drop your data rights or we are not going to give you an award, which is, again, like holding a gun to the entrepreneur's head.

On the other hand, you know, we have kind of very nicely explained to prime contractors, listen, the only reason why these data rights are there is to make sure that the small business retains a stake in the game, and that has worked well for us, also.

So in general, I think there just needs to be much better education throughout the DOD of what the small business data rights are, what they are intended to protect for and what they are not, so that people are not paranoid when they come up and they don't try to basically pressure the companies into giving up their data rights.

But I think the second issue also is how do you exercise your data rights. What has happened in the DOD is it is almost like program managers are conditioned that the only thing they ever have to pay for is hardware, and the reason is that so much software is developed under Government funding that there is no direct cost associated with it, so they almost believe that if it is software, it is at no cost. Well, if the small business retains the data rights to it, then the free market takes over and they should be able to pay for it. What I have found is that Government sponsors don't understand that concept whatsoever.

So as a taxpayer, what disappoints me is that smart small businesses just take software, put it into hardware, and it ends up costing the Government five times as much as it would have if they had sold it as software, and sell it to the Government that way. It is just a waste of money. So I think there needs, again, to be better education about why small businesses have this right and why the Government needs to honor it, and in the end, it will just save money for everybody involved.

Ms. WHEELER Mike, since you are representing DOD, would you like to comment on how DOD looks at these data rights, if they have heard that there are issues with this, and if there is anything we can do to educate the acquisition managers and various employees?

Mr. CACCUITTO. I am not quite sure what to say. I am not a lawyer. I am not a contracting officer. Education is great. More would be better. I mean, I am not familiar with the specific examples that were cited here, but I have heard about them. Our contracting community is huge. We are spread out all over the country, indeed, all over the world. Educating them is perhaps something we need to look at.

Ms. WHEELER Is DOD aware that firms sometimes run into this problem through their contracts and they are pressured to give up these rights or that they are frustrated that the folks within the agency don't know the rules? Has that come to your attention?

Mr. CACCUITTO. Yes.

Ms. WHEELER OK.

Mr. MEHRA. I will just say, I think the SBIR program within the DOD has done a tremendous job of trying to protect the interests of small businesses. The issue is not on the SBIR side of the house,

it is in the general contracting side of the house that has not educated their staff on how to deal with this.

Ms. WHEELER Thank you for that clarification.

Now, SBA, would you like to explain to us what your role is, because as Jerry has pointed out, sometimes they just need an advocate. So what is the appeals process or the grievance process that the businesses have when they feel that their rights have been violated?

Mr. BROWN. Yes. We have authority via the SBIR policy directive to intervene on behalf of a small firm that has concerns, and as you well know, we have come forward to the committee via a couple of instances with small firms. I am not going to name the firms.

Again, they can provide us what took place. In most instances, it has been cases, and I will call it a backhanded way of dealing with the data rights issue, and that is that the firm is alleging that it is a Phase III and they were not awarded the Phase III and they contact us to look into it with the agency and they are saying it is a follow-on and it naturally follows up or extends technology that was developed in Phase II. And we contact the agency and let them know we have a notice of appeal. They have 5 days to follow up with us in terms of, you know, why it is a different technology or the grounds for them to make the award above and beyond the fact that it is a Phase III.

That is a hole in the policy directive, because even worst-case scenario, as we have been talking, and this is a whole another discussion, is even in the worst-case scenario, if it is a follow-on in terms of the technology, we really don't have any way to follow up with it. I mean, even if it was, you know, no question about it, there is really nothing we can do. The agency could say that in the interest of time or in the best interests of the United States, we must proceed on this, so it is wide open.

But, of course, there are concerns about the firm losing out on the data rights and ability to move the technology forward, and again, it is very difficult, as all the program managers here know, as well, to define exactly what is a Phase III. We get this all the time. Is this a Phase III? So——

Ms. WHEELER Does SBA think that the agencies are reporting when they don't give Phase IIIs to these businesses? Do we have accurate data?

Mr. BROWN. I will say—I will put it to you this way. In the time that I have been there, the 3 years that I have been there, I believe we have received two instances where an agency met their regulatory requirement to let SBA know ahead of time that we are going to go ahead and make this award. It is a Phase III. Or is it not a Phase III and for the following reasons. If you have any questions, please come back to us to open up discussion as to why or why not this is a Phase III.

In most instances, it winds up being an SBIR award recipient that has already received two or three other awards, and this has happened multiple times. It is not the first time it has happened. It has happened two or three other times with other agencies and they have had enough and they come forward to us and we move it forward.

So again, I will predict that—again, I really wouldn't have any way of knowing what the numbers are, but the numbers are a lot greater than what we receive because the firms are concerned about being blackballed, obviously.

Ms. WHEELER And who is the employee at the agency who is supposed to be reporting it? Is it an acquisition manager? Does it vary?

Mr. BROWN. Well, really, it is supposed to be the contracting officer when they make the award. And as I think Mike has already alluded to, some of this, they don't know. I mean, I will say this right now. Some of them, and some of the program managers are here and they can jump in, but some of them really don't know. So on behalf of SBA and the program managers in general, I and we can take some of the blame. But again, when you get out of the SBIR program and you get to the point of the award being made and it is in contracting, a lot of times the agendas are different and it is out of the SBIR program and it is now meeting the mission, et cetera, so——

Ms. WHEELER Thank you.

Mr. NECCIAI. I think you hit a really good point there. It seems that 1102s or contracting officers only refer to the FAR. And you mentioned the SBA directive. It actually specifically says contracting officers representing the Government are prohibited from exerting pressure or coercion, which is kind of what we talked about before, with primes on SBA companies and that the directive expressly states that the agency must not in any way make assurances that the SBIR Phase III award is conditional on data rights. But that is in the SBA directive, and then there is the FAR and the contracting officers are looking at the FAR. So there seems to be a disconnect or a lack of either education or just understanding that these both apply, not just one. Would you agree?

Mr. BROWN. Yes, I agree, and I think this all gets back to part of the reason why we are here today. The program is really evolving. We are a greater than $2 billion program now and we are getting a lot more attention and a lot more sophisticated issues than we did this time in the last reauthorization. And a lot of the issues that we are discussing now were barely on the radar screen the last reauthorization. So again, we need to do the best that we can to fine-tune it.

But again, we also have to be honest when we look in the mirror. It is not a panacea. There is no way we are going to be able to be everything to everybody. There is just no way. So we have to do the best job that we can with what we have to maintain propriety of the program as we move forward.

Ms. WHEELER Jere?

Mr. GLOVER. Yes, just some of our Government officials are somewhat modest. Mike Caccuitto has been working internally on getting regulations and reforms and improvements with his bosses and I think that is to be commended. That will help make the process work better. The Commercialization Pilot Program is a great leap forward, and certainly the amendment that Senator Kerry and Senator Snowe sponsored this year is going to, assuming it passes the House, is going to be very helpful in encouraging incentives in reporting on Phase III. And to Edsel's credit, he just got a "stop

work" order on a specific contract while the SBA procedure is going through.

So there are things in place. Good things can happen. They are happening on the Phase III and the issue and the data rights. But clearly, it would help if we didn't call this the SBA policy directive or policy guidelines, we called them SBA regulations, because that is legally what they are. It is just people choose to ignore them because they think they are less than what they really are, and there is an educational challenge each time it comes up.

Mr. MEHRA. First of all, I want to just echo what Jere said. The SBIR program and the SBA are two of the greatest friends for small businesses working in the DOD, so thank you both for everything that you have done. They are tremendous advocates throughout all the services, both within the SBIR program and outside the SBIR program for small businesses.

But just to the quote that you just read about how acquisition officers should not make awards conditional on data rights, I can send you numerous broad agency announcements where at the end, when they list criteria for making an award, No. 1 is technical, No. 2 is cost, and No. 3 or four is that the Government gets full data rights to all of the IP. I mean, that is pretty shocking.

Ms. WHEELER Thank you. Erik, did you have a question?

Mr. NECCIAI. No.

Ms. WHEELER I had one last point. Last year, Senator Snowe's staff tried to address some of the data rights issues regarding the night vision case. Can somebody just tell me very quickly what that night vision case was? Are you familiar with that, Jere?

Mr. GLOVER. Yes. The night vision case is a case in which the small business did virtually everything procedurally wrong that they should do. They didn't avail themselves of any of the rights, that they went—my understanding is they probably did not contact either SBA or the Small Business Office at DOD to try to preserve their rights.

Having said that, the Air Force bullied the small business, did about everything a Government shouldn't do to a small business, and the court ended up saying the Air Force could get away with it. We don't know what would happen had they actually exercised their rights and challenged it at SBA or gotten DOD at the senior levels involved in that, but the law in that case, which came out of U.S. Circuit for the District of Columbia, did say that SBIR data rights are preferences, but not requirements, and that the DOD was permitted to go forward.

The issue of the policy directive was not really in play because it was done after that procurement occurred, and, quite frankly, they never exercised those rights under that. So that is the thrust of what was there.

Ms. WHEELER Thank you. And Michael, are these some of the steps that they are taking to make sure that that doesn't happen again? Jere had given you credit for what you are doing internally. Is that partially in response to what happened with the night vision case? Or are you taking that initiative on your own?

Mr. CACCUITTO. I think Jere might have been referring to some efforts we are making to improve reporting and data collection on activity.

Ms. WHEELER I see.

Mr. CACCUITTO. Program activity is—getting good data that characterizes that is difficult, particularly difficult in Phase III because much of it happens at subcontract levels. More than 50 percent of it happens in the commercial marketplace, not our direct or subcontract marketplace. And our systems aren't set up to actually collect it. So we are taking steps to improve that, and I think that might have been what he is referring to. We have also had some engagements with our procurement policy folks to address a host of issues, one of them being this Phase III issue.

But relative to night vision in particular, the courts have, in a sense, spoken here. I mean, I could go through all the facts of that case. It happened well before my time and involvement with this program. And again, outside of our awareness at this level.

I don't think I have answered your question. What was your question?

Ms. WHEELER Well, I think the main thing is that we are worried about the night vision case and we would like to know, even though we hear that the SBIR people at DOD are doing everything they can, if you are aware of other things that DOD is doing to prevent this from happening again, such as reporting to SBA, justifying why they didn't give that firm a Phase III if, indeed, it was their technology and they had the right to it.

Mr. CACCUITTO. Are we doing anything specifically right now? I can't say we are.

Ms. WHEELER OK.

Mr. CACCUITTO. I unfortunately can't.

Ms. WHEELER Thank you. Edsel, did you have one final comment before we wrap up?

Mr. BROWN. Just real quick. Jere already got into the particulars for night vision, but night vision was a really bad case, and unfortunately, it turned on the facts of that case and that facts of that case got applied to the whole program. It involved a prototype, and SBA is considering—let me underscore considering—possibly changing our policy directive, but we are still looking at it because it is more than just making that little minor change. What impact will that have on other things if we make that change about prototypes?

Ms. WHEELER And you could do that regulatorily? That is not something you would need our committee to do as part of SBA reauthorization?

Mr. BROWN. I don't believe so, but that is one of the reasons why we are going easy, because we have to go through our legal counsel before we do that. So that is why I am not committing that we are going to do that definitely, but it is under consideration.

Ms. WHEELER OK. Thank you.

Erik, did you have any final comments before we wrap up?

Mr. NECCIAI. No, just to reiterate if anyone has any other additional comments, of course, the record will be open.

Ms. WHEELER Well, thank you, everyone. On all of these issues, particularly on the VC issue there is never enough time to come up with a solution and to air all the facts, I think what we will try to do on the VC issue is come back to you and take one more run at this and see if there is any common ground we can find be-

tween the two sides that would protect the goal of the congressional intent of the program. So thank you, and I look forward to talking to you and I am sure Erik does, too. Thank you.

[Whereupon, at 1:32 p.m., the committee was adjourned.]

APPENDIX MATERIAL SUBMITTED

1

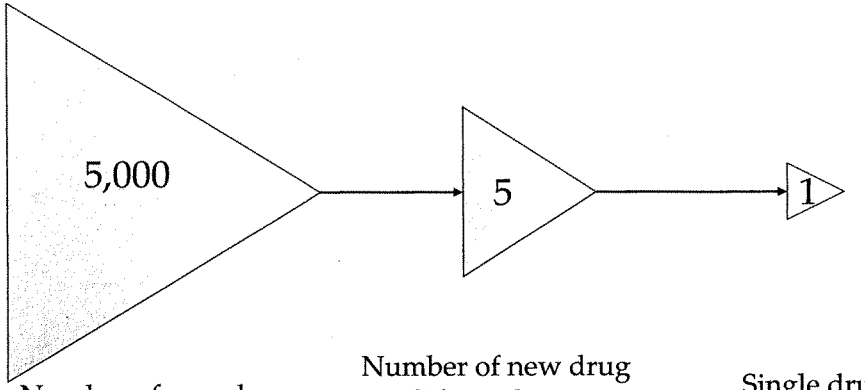
Biotechnology Industry Organization (BIO)

- Characteristics of biotechnology industry
- Impact of SBA ruling on NIH SBIR program
- Who is eligible?

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

2

Risk of Failure



Number of new drug candidates identified

Number of new drug candidates that progress to being tested on humans

Single drug approved by the FDA

Bio
BIOTECHNOLOGY INDUSTRY ORGANIZATION

Average Time and Cost Associated with U.S. New Drug Development

3

	Early Research	Clinical				
Phase of FDA Submission		Phase I (Safety)	Phase II (Efficacy)	Phase III (Side Effects)	Phase III (Long Term Use)	Post Market Testing
Time (Year)	3.5 *		6.6**		1.4***	Total = 11.5 years
Cost	$868 Million ($2004)					

*figure interferred from Tufts Center for the Study of Drug Development (CSDD) data on mean time from synthesis to FDA approval (2000-2005)
**mean clinical development time for NCEs approved in 2000-2005 (Source:Tufts CSDD)
***mean approval time for 2000-2005 approved NDAs

Bio
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Typical BIO Emerging Company

- No FDA approved product on the market
- Private company
- Fewer than 50 employees
- Less than $150,000 in annual revenue
- 3 or more years away from having product revenue
- Completed a Series A round of venture capital financing
- 5 products in development, with a lead product in Phase II clinical trials, a secondary product in Phase I clinical trials, and 3 pre-clinical products.

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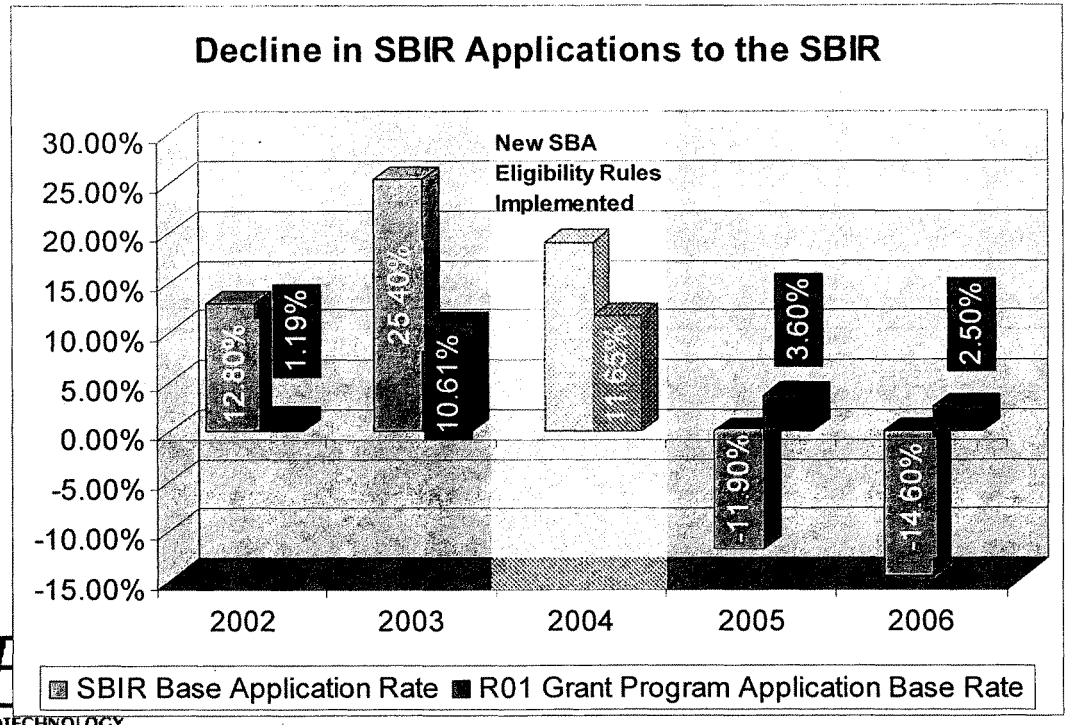
INDUSTRY ORGANIZATION

5

NIH SBIR Statistics



BIOTECHNOLOGY INDUSTRY ORGANIZATION

NIH SBIR Statistics

- The number of *new* small businesses participating in the program has decreased to the lowest proportion within the last decade
- The top 100 award recipient companies continue to receive a higher proportion of grants.

"NIH believes that the current rule undermines the statutory purposes of the SBIR program to "stimulate technological innovation" and to "increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity and economic growth." Furthermore, it undermines NIH's ability to award SBIR funds to those applicants whom we believe are most likely to improve human health, which is the mission of the NIH."—Dr. Zerhouni, Director, National Institutes of Health, June 28, 2005

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Examples of Frequent Award Winners

Radiation Monitoring Devices, Inc. (RMD)

- 363 SBIR/STTR grants
  - Prior to 2003: 309 SBIR/STTR grants
  - Post 2003: 54 SBIR/STTR grants
- Totaling $93,278,936
  - Prior to 2003: $70,889,162
  - Post 2003: $22,389,774

Physical Sciences, Inc.

- 552 SBIR/STTR grants
  - Prior to 2003: 467 SBIR/STTR grants
  - Post 2003: 85 SBIR/STTR grants
- Totaling $123,849,791.70
  - Prior to 2003: $96,785,639
  - Post 2003: $27,064,152

Cybernet Systems Corporation

- 181 SBIR grants
  - Prior to 2003: 157 SBIR/STTR grants
  - Post 2003: 24 SBIR/STTR grants
- Totaling $41,565,490
  - Prior to 2003: $37,986,375
  - Post 2003: $3,578,815

Bio
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Company A

- Public
- 300 Employees

Eligible

Company B

- Private
- 475 employees
- $150 million in annual revenue

Eligible

Company C

- Private
- $200 million in VC raised from multiple VCs, equaling 49% equity
- Significant angel investment
- 400 employees

Eligible

Company D

- Private
- 20 employees
- $50,000 annual revenue
- $8 million in VC raised by multiple VCs, equaling 56% of equity

Ineligible

BIOTECHNOLOGY INDUSTRY ORGANIZATION

Regulatory Not Statutory Requirement:

"Moreover, the legislative history of the Small Business Innovation Development Act of 1982 Pub. L. 97-219, 96 Stat. 217, and the Small Business Research and Development Enhancement Act of 1992, Pub. L. No. 102-564, 106 Stat 4249, which amended the Small Business Act to establish and expand the SBIR program, discuss only generally the need to reverse the decline in American technological innovation and competitiveness. See S. Rep. No. 97-194 reprinted in 1982 U.S.C.C.A.N. 512; HR. Rep. No. 102-554(I), (II), (III) (1992). Although these reports clearly support U.S. ownership of SBIR awardees, as opposed to non-U.S. ownership, they do not discuss individual ownership of SBIR awardees, as opposed to entity ownership." CBR Laboratories, Inc., No. 4423 (January 10, 2001) (http://www.sba.gov/aboutsba/sbaprograms/oha/allcases/sizecases/SIZ4423.txt)

Regulation Actually Meant to be a Proxy for Domesticity:

"The SBA believes that requiring that the business concern with the controlling interest be at least 51% owned and controlled by U.S. citizens or permanent resident aliens (note that SBA does not consider entities to be individuals or citizens or permanent resident aliens) supports the intent and purpose of SBIDA that the research and development (R&D) advances resulting from this program remain in this country and benefit the United States. Specifically, SBIDA was enacted because "the rate of productivity increase in the United States ha[d] been well below that of all the leading industrial nations, most notably Japan and Germany. While this relative decline in American productivity [wa]s due to many factors, a major one [wa]s certainly the slowdown in our technological innovation." S. Rep. No. 194, 97th Cong., 1st Sess. 1 (1982)." SBA SBIR Small Business Size Regulations 13 CFR Part 121

BIOTECHNOLOGY INDUSTRY ORGANIZATION

BIO Supports:

- Allowing small, domestic companies that are majority venture capital backed to compete for SBIR grants.
- Limiting eligible venture capital investment to exclude:
  - Corporate venture capital companies
  - Foreign venture capital companies
  - Majority ownership by a single venture capital company

Bio
BIOTECHNOLOGY INDUSTRY ORGANIZATION

CHRISTOPHER S. BOND
MISSOURI
COMMITTEES:
APPROPRIATIONS
SMALL BUSINESS
ENVIRONMENT AND PUBLIC WORKS
INTELLIGENCE

United States Senate
WASHINGTON, DC 20510-2503

November 1, 2007

The Honorable Steven C. Preston
Administrator
U.S. Small Business Administration
409 Third Street, S.W.
Washington, DC 20416-0001

Dear Administrator Preston:

This letter is concerning an October 18, 2007 news release from the Small Business Administration (SBA) entitled *"Frequently Asked Questions on SBA's Small Business Innovation Research Program and Venture Capital Investment."* This publication was released the same day that the Senate Committee on Small Business and Entrepreneurship held a roundtable discussion which focused on, among other issues, the role of majority venture capital (VC) backed companies in the Small Business Innovation Research (SBIR) program.

First, thank you for contributing to the productive discussion over potential changes to the SBIR program. However, I believe your October 18th news release did not address a number of questions which have been at the very heart of the committee's deliberations over SBIR and the role of majority VC-backed firms.

With the goal of fostering discussion and further clarifying some of the points of misunderstanding regarding the SBIR/VC issue, I would appreciate your answers to the following questions. I hope you will be as thorough as possible in answering these questions, as I believe your answers can contribute enormously to the committee's efforts regarding SBIR reauthorization.

1). The SBA news release, and SBA officials, have stated that VCs can invest in companies up to 49% of the company's equity, "as long as the venture capital company or companies do not control the SBIR applicant." Current SBA affiliation rules as they relate to "affiliation based on stock ownership" (CFR 121.103(b)), state that a shareholder is deemed affiliated where the shareholder owns or controls "a block of stock which affords control because it is large compared to other outstanding blocks of stock." It is not stipulated that this block of stock must constitute a majority of a company's equity. In these instances, how does the SBA determine "control" in the case of VC investment?

2). How should a small company with limited resources evaluate if a VC investor will be determined by SBA to exercise "control?" For example, if a company has 35 employees and 10% of its stock is owned by VC1, 15% is owned by VC2 and 20% is owned by VC3, can the company be assured that it is eligible for the SBIR program (assuming it meets all other applicable requirements) or should the company be concerned that VC3 might be deemed by SBA to "control" the company? What would the result be if the equity distribution were instead: VC1 – 5%, VC2 – 10%, VC3 – 30%?

3). How would SBA conduct an analysis of affiliation in the two hypothetical ownerships structures presented in Question 2? Specifically, would VC3 in these examples be considered affiliated with the small business for purposes of determining the number of the small business' employees?

4). The SBA's news release states that the SBA is currently "examining whether the SBIR program should be changed to reflect the concerns of the biotechnology and venture capital industries." Is the SBA currently undertaking a rulemaking regarding size standards, specifically relating to the treatment of majority VC-owned companies under the SBIR eligibility rules? If so, when does SBA expect to complete such rulemaking?

Thank you in advance for your thorough and insightful answers to my questions, as I am confident they will assist me and other members of the committee as we consider changes to the SBIR program as part of SBIR Reauthorization.

Sincerely,

Christopher S. Bond
United States Senator

CSB/mw

U.S. SMALL BUSINESS ADMINISTRATION
WASHINGTON, D.C. 20416

OFFICE OF THE ADMINISTRATOR

November 30, 2007

The Honorable Christopher S. Bond
United States Senate
Washington, DC 20510

Dear Senator Bond:

Thank you for your follow-up letter regarding the U.S. Small Business Administration's (SBA) participation in the Senate Committee on Small Business and Entrepreneurship roundtable discussion of October 18, 2007. Your letter asked several detailed questions about the issue of venture capital (VC) eligibility in the Small Business Innovation Research (SBIR) program. I have provided answers to each of your questions in an enclosure to this letter.

SBA is currently addressing the issue of VC eligibility for the SBIR program through the public rulemaking process. We continually monitor the program for improvements, to include modifying eligibility requirements when appropriate. The issues involved are complex and technical. I urge you to have your staff meet with my staff at your convenience to ensure you have a clear understanding of the facts and latest analysis.

I hope this information will be helpful. Should you have any additional questions, or wish to arrange a briefing on the topic, please contact me directly.

Sincerely yours,

Steven C. Preston

Enclosure

Federal Recycling Program Printed on Recycled Paper

SBA Answers to Questions from Senator Christopher Bond

Question 1. The SBA news release, and SBA officials, have stated that VCs can invest in companies up to 49 percent of the company's equity, "as long as the venture capital company or companies do not control the SBIR applicant." Current SBA affiliation rules as they relate to "affiliation based on stock ownership" (CFR 121.103(b)), state that a shareholder is deemed affiliated where the shareholder owns or controls "a block of stock which affords control because it is large compared to other outstanding blocks of stock." It is not stipulated that this block of stock must constitute a majority of a company's equity. In these instances, how does the SBA determine "control" in the case of VC investment?

When a stockholder (VC) owns up to 49 percent of a small business' voting stock and the next largest block is significantly smaller in size, there is a presumption that this holder of a large block of stock has the power to control it. This presumption can be rebutted by showing that such control or power to control does not in fact exist. See 13 CFR §121.103(c)(1) *Affiliation based on stock ownership.*

Question 2. How should a small company with limited resources evaluate if a VC investor will be determined by SBA to exercise "control?" For example, if a company has 35 employees and 10 percent of its stock is owned by VC1, 15 percent is owned by VC2 and 20 percent is owned VC3, can the company be assured that it is eligible for the SBIR program (assuming it might be deemed by SBA to "control" the company? What would the result be if the equity distribution were instead VC1 – 5 percent, VC2 10 percent, VC3 30 percent?

A small company may contact SBA for assistance with understanding the requirements in this area. This assistance is advisory only and is not binding on the agency. In your hypothetical examples, investments by VCs do not surpass the 49 percent interest in a SBIR company, but this fact alone does not mean there is not an affiliation issue. SBA will look at other conditions of the investment. You will note in 13 CFR § 121.103(a)(5), in determining whether affiliation exists, SBA will consider the totality of the circumstances, and may find affiliation even though no single factor is sufficient to constitute affiliation. If the VC can direct or block the actions of the small business in a significant manner, that leads to control. See 13 C.F.R. § 121.103(c)(3). If the VC can place a manager who can affect the operations of the small business, that can be considered control. If the VC has a voting preference on the board of directors, that can constitute control. See 13 C.F.R. § 121.103(e). All of these forms of potential control are assessed by SBA, on a case-by-case basis, when making a determination.

It should be noted here that, pursuant to SBA's December 2004 rulemaking, a VC firm may own and control an SBIR awardee so long as it: owns at least 51 percent of the awardee firm; is itself at least 51 percent owned and controlled by individuals who are U.S. citizens or permanent resident aliens; and has, including its affiliates, fewer than 500 employees. See 69 Fed. Reg. 70180 (December 3, 2004).

Question 3. How would SBA conduct an analysis of affiliation in the two hypothetical ownership structures presented in Question 2? Specifically, would VC3 in these examples be considered affiliated with the small business for purposes of determining the number of the small business employees?

There are not enough facts to provide an answer. However, if VC3 acquired voting stock with no conditions, then, the investment does not pose a problem for the SBIR company. Generally, the VC investment company has obligations to its investors and will therefore impose conditions necessary to minimize the risk of the investment, so some control and management would be added to qualify the investment. In most analysis conducted by SBA, the reviewer would usually start with the documents that show how the business was organized. The documents that shed light on this would be the Articles of Incorporation, By-Laws, Organizational Charts, Stockholders' Ledger, and Stock Certificates. Other documents of interest would be loan agreements, joint ventures agreements, audits, contracts recently completed, references by customers and other working partners, Dun and Bradstreet Reports, Financial Statements, Tax Returns, Court proceedings and Industry Periodicals. Any other information that would give SBA a better view of the relationship between a VC investment company and the small business would be considered as well, including voting trusts.

Question 4. Is the SBA currently undertaking a rulemaking regarding size standards, specifically relating to the treatment of majority VC-owned companies under the SBIR eligibility rules? If so, when does SBA expect to complete such rulemaking?

SBA is currently examining the issue of greater VC ownership and control in the SBIR program. This examination follows an Advance Notice of Proposed Rulemaking (ANPRM), issued on December 3, 2004, at 69 Fed. Reg. 70197, to solicit information and opinions on the issue.

In June 2003, SBA received suggestions that SBIR eligibility requirements be changed to allow VC company ownership and control of awardee firms. These comments came only from industry organizations representing the biotechnology and VC industries. In response to these comments, and to gather a broader range of views on the issue from the small business community, SBA issued the ANPRM on December 3, 2004 to solicit information and opinions on whether SBIR eligibility requirements should be modified to allow greater VC ownership and control.

The ANPRM comment period was open from December 3, 2004 to April 3, 2005. In addition, public hearings were held between June 2, 2005 and June 29, 2005. Public comments and testimony were predominantly against allowing greater VC ownership and control. Comments and testimony in favor of changing the rules came primarily from members of a small number of biotech and VC industry organizations.

The results of the ANPRM comment solicitation were that SBA received neither a compelling argument to change the long-standing rules concerning affiliation or ownership,

nor information showing the presence and extent of a problem caused by the existing rules. SBA proposes rulemakings to change the SBIR program only when it has this information and is confident a change is in the public interest. At present, this is not the case.

SBA is committed to ensuring that the integrity of the program is maintained and that it remains a program for U.S. small businesses. At the same time, SBA recognizes that some small biotech firms face unique difficulties raising funding for early-stage innovative activity and that there could be a legitimate role for government intervention to subsidize certain innovation-related activities of some of these firms.

It is clear to SBA, however, that the changes to the SBIR program proposed to-date by the industry interest group, such as providing a broad exemption from affiliation or allowing majority ownership, could be harmful to the SBIR program both as a small business program and as an innovation program. Public comments and discourse on the issue have not addressed important complexities involved, and have not provided the information SBA needs to modify a small business program eligibility requirement in the public interest. Furthermore, public assistance vehicles other than the SBIR program, that may be more effective and appropriate, have not yet been discussed. As a result, SBA will continue to evaluate this complex issue in greater depth.

We appreciate your interest in, and support for, the SBIR program, and we welcome your participation in our efforts to maintain the SBIR program as one of the most successful small business programs.

U.S. Senate Committee on Small Business and Entrepreneurship

Roundtable on:

"Reauthorization of the Small Business Innovation Research Program: How to Address the Valley of Death, the Role of Venture Capital, and Data Rights"

18 October 2007

Testimony submitted by:

Chris W. Busch, Consultant & SBIR Advocate
PO Box 16567
Missoula, MT 59808
406-327-0071
cwbusch@aol.com

Senator Kerry, Senator Tester and other members of the Senate Committee on Small Business and Entrepreneurship:

Thank you for the honor and opportunity to participate in this Roundtable, and to submit these follow-up written comments. My comments below focus on the three agenda items for the subject Roundtable:

1.0 Role of Venture Capital in the SBIR Program
2.0 Recommendations for Venture Capital and NIH Technology
3.0 The Valley of Death
4.0 Data Rights

1.0 ROLE OF VENTURE CAPITAL IN THE SBIR PROGRAM

1.1 Retain SBIR Resources for Legitimate Small Businesses

The SBIR Program sets aside a very small part (2.5%) of agencies extramural R&D budget for legitimate small businesses as defined by the Small Business Administration. It is vital that this small set-aside be retained to enable access to federal R&D resources by small businesses, especially in rural and underdeveloped areas, and by minority and disadvantaged persons.

This requires that businesses eligible for the SBIR meet the criteria set forth in the SBA SBIR Policy Directive (Section 3y). A key provision is that the business concern be 51% owned and controlled by individuals, or be a subsidiary of a business concern that is 51% owned and controlled by individuals.

1.2 Retain the Affiliation Rules Governing Eligibility for the SBIR Program

The affiliation rules governing elibility for the SBIR Program must be maintained as presently defined in the SBA SBIR Policy Directive.

Exempting these rules for venture capital operating companies (as articulated in HR 3567) would open the flood gates for venture capital companies to exploit the SBIR Program, and crowd out legitimate small businesses as defined by the SBA SBIR Policy Directive.

See items 1.4 and 1.5 below for additional comments on this issue.

1.3 Retain Historic Role for non-Small Business Investors in the SBIR Program

Since the beginning of the SBIR Program, venture capital groups, angel investors, large industrial companies, universities, not-for-profit entities and other organizations have been allowed to and encouraged to invest in small businesses participating in the SBIR Program. In Phase 1 and Phase 2, investments by these groups can be up to a cumulative 49% of ownership with the remaining 51% ownership and control residing with eligible small businesses. In Phase 3, up to 100% of ownership and control may rest with these investment groups.

It is vital for the integrity of the SBIR Program that these ownership and control limits be retained going forward.

1.4 What HR 3567 Would Allow

HR 3567 would be a disaster for the SBIR Program and the small business community, especially in rural states. Removing the affiliation rule for venture capital operating companies (with less than 500 employees) would allow any one VC firm to own up to 50% of a business eligible for the SBIR Program. Hence, two large VC firms could own virtually 100% of business and it would still be eligible for the SBIR Program.

Very few VC firms have 500 employees or more, and hence the 500 employee limit for the VC firm has virtually no impact.

HR 3567 also would allow nonprofit organizations affiliated with, or serving as a patent and licensing organization for a university or other institution of higher education. This will contribute further to the crowding out of legitimate small businesses from access to

the SBIR Program. Universities already capture a major share of the 97.5% of federal extramural R&D not set aside for the SBIR Program.

HR 3567 would be devastating for small businesses and the SBIR Program if enacted.

1.5 Ownership and Control Has Consequences

It has been argued that entrepreneurs can retain control of a business entity even though they may not have a majority of ownership or exercise absolute control. However, as noted in 1.4 above, two or more VC companies could jointly own and control well over 50% of a business entity (up to 100%), pool their interests, and easily control the business.

Businesses owned/controlled by large venture capital companies have access to a dramatically larger set of assets for SBIR competition than a legitimate independently owned small business. These assets may include people, equipment, experience and resources for travel, proposal preparation and more. Consequently, businesses owned/controlled by large venture capital companies have a dramatic advantage over legitimate small businesses, especially those in rural states and other underperforming regions.

1.6 SBIR Subsidy for Venture Capital Operating Companies???

As noted in 1.4 above, if HR 3567 is adopted and the SBIR Program is required to operate according to its provisions, businesses 100% owned by large venture capital companies would be eligible to compete for SBIR resources. This amounts to subsidizing the venture capital industry with precious SBIR resources.

Venture capital companies invested $7.127 billion in the second Quarter of 2007, or a rate of more than $28 billion annually. This is according to PriceWaterhouseCooper MoneyTree.com.

This amount dwarfs total SBIR annual resources of $2 billion annually. Truly, the HR 3567 provisions would allow the venture capital gorilla into the relatively tiny SBIR Program tent.

It makes no sense for the small SBIR Program to subsidize the relatively huge venture capital industry. Congress must not let this happen!!!

1.7 SBIR Success Story in Rural States

Before the advent of the SBIR Program in 1982, high technology small businesses rarely took root in rural states. Today, most rural states (e.g., Montana, Wyoming, North Dakota and South Dakota) have a healthy and growing high technology small business

culture and presence. This transformation was enabled in large measure (though not solely) by SBIR Program resources and competition.

To achieve this, rural state small businesses have had to work very hard to overcome barriers to their success. These include: lack of familiarity with federal R&D grant and procurement procedures; remoteness from agency personnel; and access to only a small stable of experienced and successful mentors for SBIR competition. Still, most rural state SBIR awards are below national per capita averages.

1.8 Negative Impact of Venture Capital to SBIR Participation in Rural States

Rural states have virtually no access to venture capital resources. For example, in the second quarter of 2007 (according to PriceWaterhouseCooper MoneyTree.com), Montana, North Dakota, South Dakota and Wyoming together had $0 of venture capital investment. In the same period, California, New England and the DC metroplex had a total of $4.134 billion of the total of $7.127 billion invested by venture capital companies for the quarter.

In the past, small businesses in rural states have captured a very small part of SBIR resources, and have had to work very hard to compete with those states with substantial SBIR awards. Allowing businesses owned/controlled by venture capital companies into SBIR competition will make it more difficult for rural state small businesses to compete successfully in the SBIR Program. This inevitably will lead to a reduction in awards to rural state small businesses.

There are no realistic resource alternatives to the SBIR Program for technology based small businesses in rural states. Certainly, venture capital resources are not accessible to them.

1.9 Eliminate Large "Jumbo" SBIR Awards

Venture capital interest in access to the SBIR Program by businesses that it owns/controls is coincident with commencement of the practice by NIH of granting large multi-million dollar awards in Phase 1 and (especially) in Phase 2. This practice started in the late 1990's. While the SBA SBIR Policy Directive specifies $100K and $750K for Phase 1 and Phase 2 respectively, NIH now regularly makes Phase 1 awards in excess of $1 million, and Phase 2 awards approaching $10 million.

The SBA Policy Directive clearly states (Section 7(h)) that "An awarding agency may exceed those award values where appropriate ***for a particular project***." However, NIH now issues solicitations that specifically request proposals for funding amounts substantially over the limits imposed by the SBA SBIR Policy Directive. Clearly, this is contrary to the letter and spirit of the SBA SBIR Policy Direcive.

The GAO Report (GAO-06-565, "Information on Awards Made by NIH and DoD in Fiscal Years 2001 through 2004") points out that awards at funding levels above the SBA SBIR Policy Directive prescriptions accounted for ***70 percent*** of NIH's SBIR dollars. This level can hardly be considered an exception as intended by the SBA SBIR Policy Directive.

The "jumbo" award practice by NIH has encouraged small businesses to "game the system" and to submit SBIR applications for ever increasing amounts of funding. Rather than scoping the statement of work to fit the funds available, savvy small businesses now inflate the funding and work proposed to escalating levels.

The large awards were and continue to be attractive to businesses owned/controlled by large venture capital firms. The past record shows that the smaller awards were not of interest to them. Returning award amounts to levels prescribed in the SBA SBIR Policy Directive would likely reduce the interest of businesses owned/controlled by large venture capital companies.

1.10 Enforce All Provisions of the SBA SBIR Policy Directive

Eligibility for SBIR competition and award funding limits are just two of many important provisions of the SBA SBIR Policy Directive. It is vital to the integrity of the SBIR Program that ***ALL*** provisions of the SBA SBIR Policy Directive be enforced.

Ignoring formal Policy Directives leads to degradation of SBIR Program discipline, different agencies going their own direction with Program implementation, and confusion for candidate small businesses. All of these things are happening, and are continuing to escalate. This direction must be arrested now for the sake of SBIR Program integrity and for the benefit of the small businesses for whom the Program exists.

In order to enforce the SBA SBIR Policy Directive provisions, SBA must be given the resources and make the commitment to do this job with adequate oversight. For example, the SBA Office of Technology now has essentially two full time employees. Research shows that in 1992 with a much smaller and simpler program (e.g., no STTR Program), the Office had approximately 10 full time employees.

1.11 Simplify the SBIR Solicitation Process

The original legislation authorizing the SBIR Program (PL 97-19) directed "simplified, standardized... SBIR solicitations..." Similarly, the current SBA SBIR Policy Directive repeats these words (Appendix 1a).

However, the SBIR solicitation and competition process has become very complex, especially at some agencies, notably NIH. One has only to visit agency SBIR websites to observe the complexity. This complexity discourages newcomers to the SBIR

competition process, especially those from rural states where experienced mentors are in short supply.

Structural changes to the SBIR Program outside the provisions of the SBA SBIR Policy Directive also create impediments to SBIR competition, especially for those unfamiliar with the SBIR Program (e.g., in rural states). These include "Phase 2 Competing Renewals" at NIH, "Phase 2 Enhancements" at DOD; and Phase 1A and 2B, and Phase 2 and 2B at NSF.

My personal experience is that it has become more and more difficult for small businesses (especially in rural states) to compete in the SBIR Program. The more complex the solicitation and competition process is (specifically, NIH), the more difficult successful competition is for small businesses. As a mentor to small businesses engaging the SBIR Program primarily in rural states over the past twelve years, I discourage competition in the more complex programs in favor of those that have retained a greater measure of simplicity and transparency.

While many of the changes are done in the name of agency "flexibility" and some can undoubtedly be justified, they too often translate into "confusion" for candidate small businesses and an impediment to engaging successfully the SBIR Program.

1.12 The Declining Application Problem

At the subject Roundtable, the problem of declining applications for NIH awards was cited. Data presented showed for 2005 and 2006 declines in applications of 11.9% and 14.6% respectively. Presumably, these are year over year percentages. The point was made that the declines started coincident with the implementation of the "new rules."

First, new rules were not implemented. The rules have been a longstanding part of the SBA SBIR Policy Directive. Perhaps enforcement was done more thoroughly beginning at about this time.

Second, no substantive evidence was presented that the cause of the declining application rates was caused by exclusion of businesses owned/controlled by large venture capital firms.

I postulate that the declining application rates at NIH are caused by a) the jumbo awards (fewer applications are necessary for individual small businesses) and b) the complexity of the NIH solicitation and competition process which discourages many small businesses from engaging the competition. As noted in 1.12 above, I personally have advised many small businesses to bypass the NIH SBIR Program for those with more user friendly characteristics.

1.13 Frequent Winners and The SBIR "Mill" Problem

Criticism is frequently levied against the SBIR Program and small businesses that have won a large number of SBIR awards without "sufficient" commercialization of the technology developed. These small businesses are sometimes called SBIR "mills."

In addition, it is claimed that the practice of allowing a few companies with a large number of awards crowds out other eligible small businesses that might otherwise engage and win in SBIR competition. A suggested remedy is placing caps on the number of awards a small business is allowed to win in a specified period of time (say, a year).

However, SBIR award decisions are made by the agencies, and (obviously) small businesses have no voice in selecting winners and losers in SBIR competition. Hence, if there is dissatisfaction with any agency portfolio of SBIR awards (and the consequent commercialization results or awards concentration in too few small businesses), it seems logical to conclude and suggest that the agency should modify its evaluation criteria and procedures accordingly to remedy these problems.

My experience mentoring small businesses provides convincing evidence that a satisfactory remedy for the SBIR "mill" and "frequent winner" problems will be met by:

1) keeping SBIR eligibility requirements as currently prescribed by SBA, and keeping ineligible for SBIR competition large venture capital owned/controlled businesses (see Section 1.1 above);
2) capping Phase 1 and Phase 2 award amounts at levels specified by SBA (see Section 1.9 above); and
3) returning simplicity to the SBIR competition process (as required by statute and regulation, see Section 1.11 above).

SBIR awards should be based on merit and a level playing field. These ends will be achieved by implementing the remedies outlined in the paragraph above. Providing arbitrary caps on the number of SBIR awards to small businesses is not a rational solution to the proposal "mill" and "frequent winner" problems.

1.14 Keep Commercialization in Proper Perspective with Other SBIR Goals

Commercialization of technology developed through SBIR funding has taken on an ever increasing central role in evaluating and charting the future course of the SBIR Program. Technology commercialization should be a key goal of the SBIR Program, and I have worked toward this end through my activities mentoring small businesses in SBIR competition and participation.

However, commercialization is not and should not be the only goal of the SBIR Program. In the original SBIR Program enabling legislation (PL 97-219), the stated purposes of the program were: 1) to stimulate technological innovation; 2) to use small business to meet Federal research and development needs; 3) to foster and encourage participation by minority and disadvantaged persons in technological innovation; and 4)

to increase private sector commercialization innovations derived from Federal research and development.

In its report dated 17 Jun 1999 (GAO/T-RCED-99-198), GAO points out that the different SBIR agencies give varying degrees of consideration to commercialization results. It addition, in this report GAO points out that the emphasis on commercialization raises questions about the role of other goals in evaluating the SBIR Program and companies' performance in it. The report states that other goals, such as innovation and responsiveness to an agency's needs (consistent with the enabling legislation PL 97-219) remain important to agencies when evaluating the SBIR Program.

I strongly support commercialization of SBIR funded research and technology results. However, I urge that it be kept in proper balance with the other goals of the SBIR Program cited in the original enabling legislation as cited above, and highlighted by GAO/T-RCED-99-198.

As stated in Section 1.7 above, one of the great (and infrequently told) SBIR success stories is the nurturing of a high technology small business culture in rural states. These and related achievements of the SBIR Program should not be crowded out by an inordinate quest for commercialization, and concomitant eligibility for businesses owned/controlled by large venture capital companies. If allowed to happen, the rural states and other regions under-participating in the SBIR Program will suffer the consequences.

1.15 Increase SBIR Award Limits Specified in SBA SBIR Policy Directive

The Phase 1 and Phase 2 award limits specified in the SBA SBIR Policy Directive have been unchanged since 1992. In inflation adjusted terms, the award amounts have decreased significantly since that time. Hence it is recommended that the award amount limits be increased when the SBIR Program is reauthorized. Suggested limits are:

Phase 1:	$150,000
Phase 2:	$1,200,000

2.0 RECOMMENDATIONS FOR VENTURE CAPITAL AND NIH TECHNOLOGY

Vigorous arguments were made at the subject Roundtable about the need for venture capital financing to commercialize NIH funded technology. Several specific recommendations follow:

1. Establish a program dedicated to commercialization of NIH funded technology with characteristics similar to the NIST Advanced Technology Program (ATP). All organizational entities would be eligible.

2. Retain the eligibility requirements for SBIR competition as they are promulgated in the SBA SBIR Policy Directive. Enabling SBIR Program eligibility for businesses owned/controlled by large VC businesses is tantamount to allowing a gorilla in a very small tent reserved for small businesses.

3. ***DO NOT*** allow the provisions in HR 3567 to be enacted into law.

3.0 THE VALLEY OF DEATH

The "valley of death" is a reality that entrepreneurs and small businesses face sooner or later. The valley of death may apply to the overall business or individual innovations as pointed out by Senator Kerry at the subject Roundtable.

In the final analysis, this issue must be handled by the entrepreneurs and small businesspersons with the assistance of mentors, partners, networking and other supporting infrastructure.

SBIR agencies cannot "solve" the valley of death problem for the entrepreneur/small business. They can only provide assistance through networking opportunities, providing access to qualified mentors, etc.

The DOD Commercialization Pilot Program (CPP) has received much acclaim for the assistance it has provided in helping small businesses commercialize their technology. While the program surely has merit, it should be pointed out that every dollar of SBIR resources that goes into the CPP activity, funds for Phase 1 and Phase 2 awards are reduced.

Generally, I believe SBA and the SBIR agencies are doing an adequate job of assisting small businesses through the "valley of death" and that they should continue with their present activities.

Small businesses largely have control over successfully navigating the "valley of death." This is in sharp contrast to the issue of establishing who is eligible to compete for these precious resources. I urge Congress and the SBIR agencies to focus on limiting eligibility for SBIR competition to legitimate small businesses (as currently defined by SBA), and precluding access to the small SBIR tent by the large venture capital gorillas!!!

4.0 DATA RIGHTS

I encourage Congress, the SBA and the SBIR agencies to continue safeguarding small businesses' entitlement to data rights as promulgated in statutory and regulatory language.

As with the "valley of death" issue, it is my view that this issue is secondary compared to the critical issue of limiting eligibility for SBIR competition to legitimate small businesses as presently prescribed the SBA SBIR Policy Directive.

This means precluding SBIR competition eligibility for businesses owned/controlled by large VC firms.

END OF FILE

Response to BIO by the New England Innovation Alliance

- Purposes of the SBIR/STTR program

-Characteristics of small businesses

-BIO example: Physical Sciences Inc

-BIO NIH SBIR "statistics"

-Trends in NIH funding

-Trends in Venture Capital funding

-Who should be eligible for SBIR ?

NEIA

Purposes of SBIR Act of 1982

- Stimulate technological innovation
- Use small business to meet federal research and development needs
- Encourage participation by minorities and disadvantaged persons
- Increase private sector commercialization of innovations derived from federal R&D

Typical SBIR Company

No FDA approved product on the market

Employee-owned company

Fewer than 10 employees

Less than $1,500,000 in annual revenue

Profitable; “sweat equity”, bank financed

5 years away from having product revenue

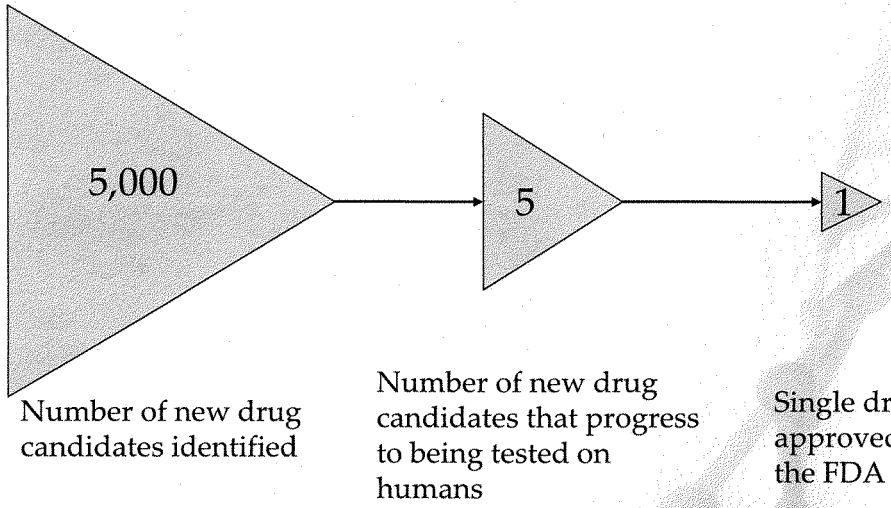
SBIR-funded; ***zero venture capital financing***

2-4 research and development projects.

NEIA

2

Risk of Failure



Bio
BIOTECHNOLOGY INDUSTRY ORGANIZATION

BIO pipeline statistics

- How is this relevant to SBIR?
- Should SBIR fund 5,000 Phase Is ?
- This clearly demonstrates why SBIR is ***inappropriate*** for drug development
- Is there another point to this chart?

NEIA

Examples of Frequent Award Winners

Radiation Monitoring Devices, Inc. (RMD)

- 363 SBIR/STTR grants
  - Prior to 2003: 309 SBIR/STTR grants
  - Post 2003: 54 SBIR/STTR grants
- Totaling $93,278,936
  - Prior to 2003: $70,889,162
  - Post 2003: $22,389,774

Physical Sciences, Inc.

- 552 SBIR/STTR grants
  - Prior to 2003: 467 SBIR/STTR grants
  - Post 2003: 85 SBIR/STTR grants
- Totaling $123,849,791.70
  - Prior to 2003: $96,785,639
  - Post 2003: $27,064,152

Cybernet Systems Corporation

- 181 SBIR grants
  - Prior to 2003: 157 SBIR/STTR grants
  - Post 2003: 24 SBIR/STTR grants
- Totaling $41,565,490
  - Prior to 2003: $37,986,375
  - Post 2003: $3,578,815

Bio
BIOTECHNOLOGY INDUSTRY ORGANIZATION

NIH SBIR/STTR funding to
Physical Sciences Inc

- BIO "example" ***misleading and incorrect***

- ***Cumulative NIH SBIR Funding to PSI is $11 M over life of the program***

- PSI has received ***most*** of its SBIR funding from the ***Department of Defense***, with increasing focus on military medicine

PSI
PHYSICAL SCIENCES INC.

NIH Funding trend at Physical Sciences Inc.

- Pre - FY 2003: SBIRSTTR: $ 1,476,664

- Post - FY 2002:

FY 03	$ 1,766,038
FY 04	$ 1,985,813
FY 05	**$ 2,434,680**
FY 06	**$ 2,110,214**
FY 07	**$ 1,337,168**

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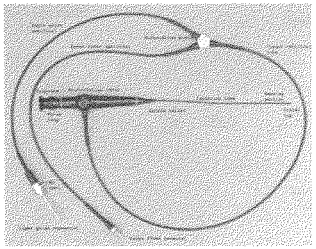
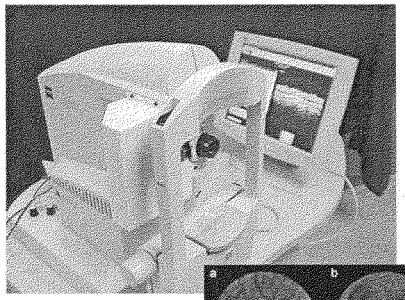
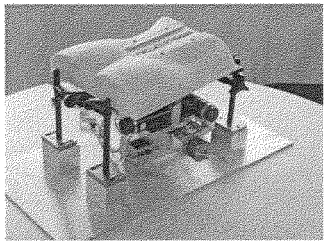
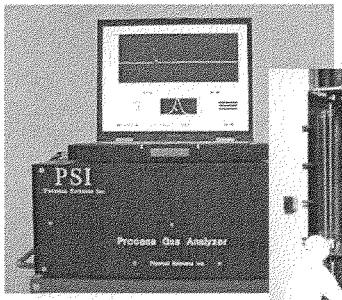
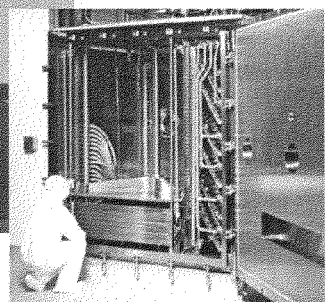
NIH SBIR Achievements at PSI

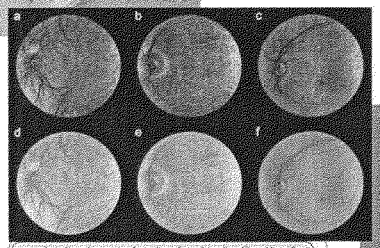


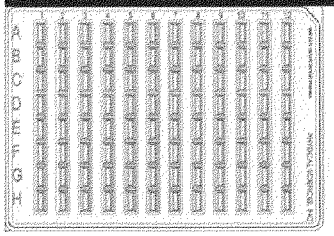


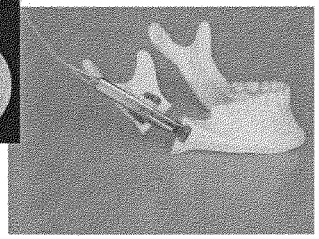












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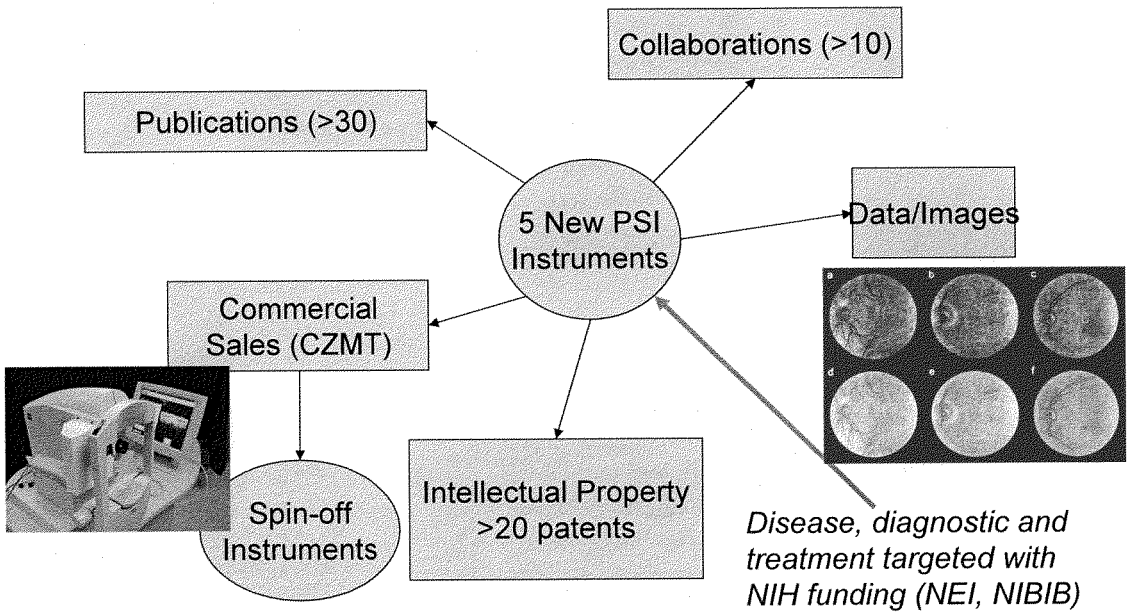
Diagnosis/ treatment of diseases of the eye



- ***Advanced instrumentation and tools for research in the lab and the clinic. Not one dollar of venture capital used; zero VC interest !***

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PHYSICAL SCIENCES INC

Diagnosis/ treatment of diseases of the eye

- *Revolutionary Ophthalmic Instrumentation*
  - *TSLO: Tracking, Scanning Laser Ophthalmoscope*
  - *TOCT: Tracking Optical Coherence Tomography*
  - *LSLO: Line Scanning Laser Ophthalmoscope*
  - *AOSLO: Adaptive Optics Scanning Laser Ophthal.*
- *Applications*
  - *Advanced diagnostics for Diabetic Retinopathy, Macular Degen.*
  - *Degenerative eye diseases in children and aged; Glaucoma*
  - *Basic research in cellular basis of disease in eye*
  - *New applications to neurosciences research*

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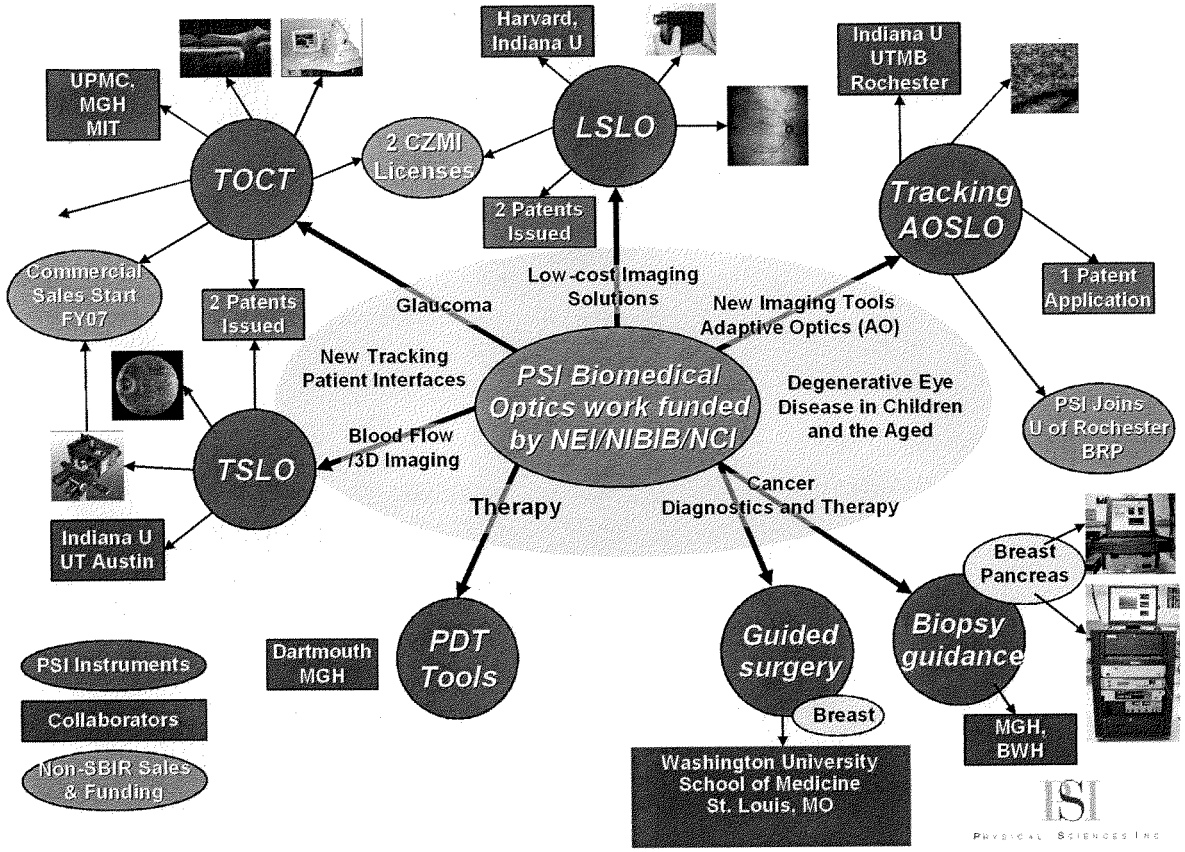
PSI Biomedical Optics work funded by NEI/NIBIB/NCI
Glaucoma
Low-cost Imaging Solutions
New Imaging Tools Adaptive Optics (AO)
Degenerative Eye Disease in Children and the Aged
Cancer Diagnostics and Therapy
Therapy
Blood Flow /3D Imaging
New Tracking Patient Interfaces
TOCT
UPMC, MGH MIT
2 CZMI Licenses
Commercial Sales Start FY07
2 Patents Issued
TSLO
Indiana U UT Austin
LSLO
Harvard, Indiana U
2 Patents Issued
Tracking AOSLO
Indiana U UTMB Rochester
1 Patent Application
PSI Joins U of Rochester BRP
PDT Tools
Dartmouth MGH
Guided surgery
Breast
Washington University School of Medicine St. Louis, MO
Biopsy guidance
Breast Pancreas
MGH, BWH
PSI Instruments
Collaborators
Non-SBIR Sales & Funding
PSI
Physical Sciences Inc

Other NIH-funded Research at PSI

- *Photodynamic treatment of cancer*
- *Guided breast and pancreas biopsy*
- *Optically guided breast surgery*
- *Facial surgery for children*
- *Laryngeal endoscopy*
- *Zebra fish tools for drug discovery*
- *Optical sensors for drug manufacturing*
- *Breath monitoring for metabolic screening*
- *Traumatic injury detection and treatment*
- *Early detection of ovarian cancer*
- *DNA assays with fluorescent aptamers*

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PSI collaborates with leading medical institutions in the US

- Beth Israel Deaconess Medical Center
- Boston University
- Brigham and Women's Hospital
- **Children's Mercy Hospital, Kansas City, MO**
- Dana Farber Cancer Institute
- Dartmouth College
- Indiana University
- Massachusetts General Hospital
- Rice University
- University of California, Berkeley
- University of Connecticut
- University of Texas
- University of Wisconsin
- **Washington University, St. Louis, MO**

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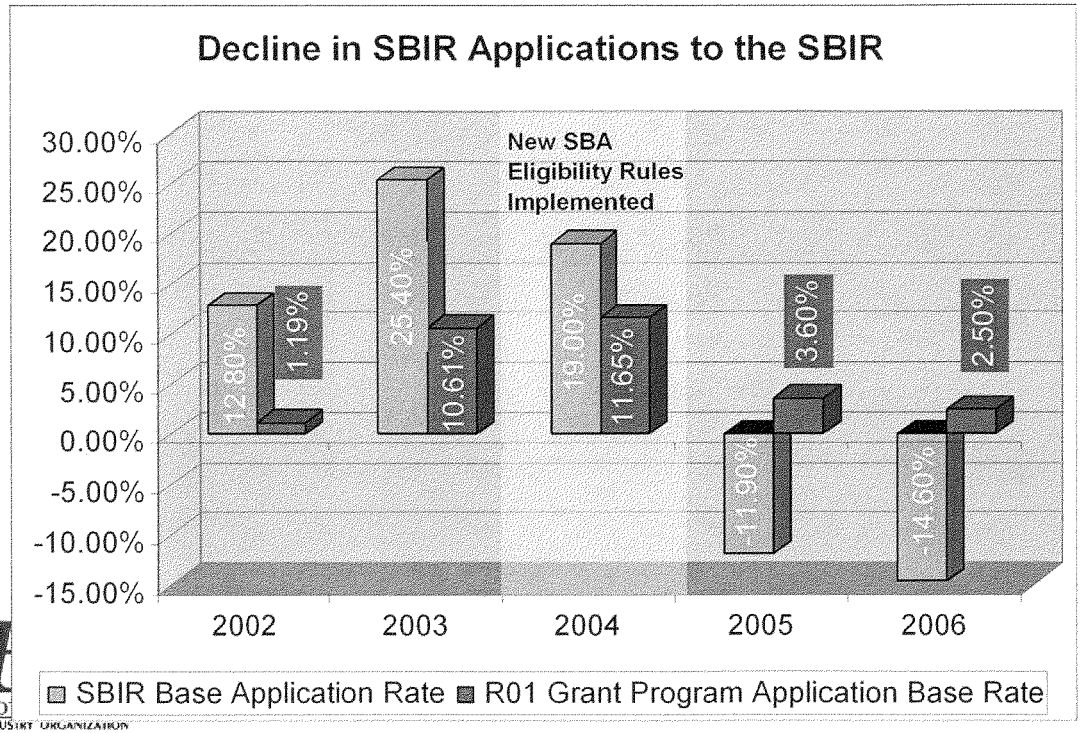
NIH SBIR Statistics



BIO
INDUSTRY ORGANIZATION

What "problem" is BIO addressing?

- NIH 2008 budget is ***down 12%*** *in real terms since 2004, and average SBIR award size is up, leading to fewer awards, not fewer applications.*

- "Although the number of RPG's increased from 25,000 in the early '90s to more than 35,000 (see Figure 2), ***the number of grant applications has increased so fast*** that the success rate is now well below the success rates of the NIH doubling period 1998-2003 when they exceeded 30 percent. Several NIH institutes would see success rates well below the 20 percent" ....**AAAS Report XXXII**

- *"In the first quarter of this year, seed investors put $1.1B into such businesses, a* ***quarterly record for the medical-device industry****, and a 60% increase over the same period in 2006, according to the* ***National Venture Capital Association****, a trade group".....NY Times, June 11, 2007*

NEIA

*The facts behind the **BIO** "statistics"*

- The number of new companies receiving NIH SBIR awards has declined as the overall proposal success rate has declined and the size of awards has increased (***mainly to VC-backed firms, according to the GAO)***

- The "top 100" firms continue to be successful because SBIR is a very successful, ***peer-reviewed, merit-based*** program. The decline in awards is ***not due to 2003 rule***

- Dr. Zerhouni's statement that the current eligibility rule "undermines" the original intent of SBIR could be equally applied to ***permit large businesses and universities to compete for SBIR***, which can access the "other" 97.5% of the NIH budget

NEIA

*Here is what the GAO found in April, 2006**

- At NIH, number of SBIR awards to firms with venture capital increased 61%
- At NIH, SBIR award dollars to firms with venture capital increased from 14% to 22%
- At NIH, since enforcement, ***SBIR applications increased*** from 3,601 to 6,122

* GAO report on NIH and DoD SBIR, 2002-2004

(from year before through year after rule change)

NEIA

Recent trends in "angel" and venture capital financing in the US

- *" US business angels ....injected $11.9 B into 24,000 ventures in the first half of this year".....UNH Center for Venture Research*

- *" In the same period,* ***venture capital firms invested $14.5 B in 1,822 companies, ...National Venture Capital Association.....the trend in VC is to later stage deals***

- *"...angels typically invest $100K to $1M, compared with the $2M to $10M for venture firms".....angels are the "go-to financiers for start-ups"...Boston Globe, 10-29-07*

- *Third quarter, 2007: 35% of VC to Silicon Valley,14% to NE,* ***less than 1% to South Central region !***

*Here's the **Real** Issue*

- SBIR/STTR was designed to foster innovation in the public interest, and to commercialize wherever possible. It is funding 8,000 companies without ***any*** venture capital

- SBIR/STTR was meant to provide ***unfettered seed capital*** for high risk/high payoff innovation that the VCs would ***never*** touch....***NOT*** to subsidize VC firms and thereby deny SBIR funds to others !

- SBIR/STTR was ***NOT*** meant to provide funding to companies with $200M of venture capital ! Does this company, with "49 % equity", actually exist ?

NEIA

BIO Supports:

- Allowing small, domestic companies that are majority venture capital backed to compete for SBIR grants.
- Limiting eligible venture capital investment to exclude: **(NEIA query: is this in the House Bill?)**
    - Corporate venture capital companies
    - Foreign venture capital companies
    - Majority ownership by a single venture capital company

Bio
BIOTECHNOLOGY INDUSTRY ORGANIZATION

NEIA Supports:

- Allowing small, domestic companies that are venture capital backed to compete for SBIR grants…***as allowed since 1982***

- Allowing a single venture capital company to be a majority owner…. ***if the VC company is itself a small business, as allowed since 2003***

- ***Excluding*** venture capital investment from :
  - *Corporate venture capital companies*
  - *Foreign venture capital companies*
  - *University or endowment-based venture firms*

NEIA

Administrator Preston's response to Senator Kit Bond's questions regarding SBIR program eligibility rules at March 9, 2007 Hearing

In the Questions for the Record from the March 9, 2007 hearing of the Senate Committee on Appropriations Subcommittee on Financial Services and General Government, you asked two questions about the SBIR program. The first question concerned data given to you by NIH that showed a decline in NIH SBIR applications for 2005 and 2006 compared to a general slow-down in NIH RO1 applications. The chart you refer to appears to show annual percentage changes in the number of applications, or proposals, to the two programs. You asked if the 2005 and 2006 drops in NIH SBIR proposals might be the result of "new SBIR rules" and a "new restriction on venture capital financing."

There are two points I would like to make in reply: First, the question itself reflects a possible misunderstanding of SBIR eligibility requirements and the history of recent changes to these rules. I will provide some background information in this response, however, I would strongly encourage you to schedule a briefing for your office by my staff on this complex issue as soon as possible. Second, the program application numbers fluctuate considerably in response to many factors and it is not possible to draw the conclusion you suggest from this data. (I will address this point further below).

Regarding your reference to new SBIR rules and restrictions, I would like to clarify that SBA has made no change in SBIR program eligibility requirements that would further restrict VC participation in the program. (As you know, institutional investors such as VCCs or large corporations have, for the life of the program, been allowed to own up to 49 percent of a small business SBIR awardee so long as they do not have the power to control the awardee). In fact, the one change SBA made to SBIR eligibility requirements in recent years relaxed the eligibility requirements in order to allow subsidiaries of eligible small businesses to be eligible for the program awards. 13 C.F.R. § 121.702. Although this rule was not directly addressing the issue of VC involvement, it had the effect of allowing some small VCCs to own and control SBIR awardees. (See the Background section below for additional detail on the rule changes).

In your question, you refer to the 2003 Cognetix, Inc. decision. It should be clarified that this decision, by SBA's Office of Hearings and Appeals (OHA), was neither a new eligibility rule, nor a new restriction on venture capital financing within the SBIR program. The OHA decision denied the appeal by Cognetix, Inc. in which Cognetix argued that the term "individual" in the program's 51 percent ownership requirement should be interpreted to include non-corporate institutional investors such as VCCs. However, the 51 percent requirement is there precisely to distinguish between individual owners and owners that are institutional entities for the purpose of ensuring that SBIR funds go only to small independent U.S. firms. The interpretation put forth by Cognetix in their appeal would effectively nullify, or in the words of the Administrative Judge "eviscerate," this long-standing 51 percent ownership requirement.

The 51 percent ownership requirement has been an important element of the SBIR program. It has helped us keep the program targeted to the U.S. small businesses for which it was created. The SBA OHA decision in the Cognetix case merely maintained the ownership requirement of the program.

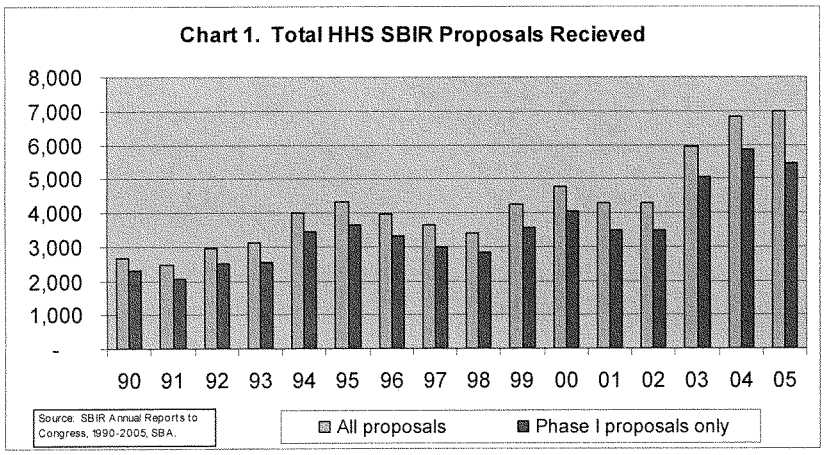
Some have claimed that the long-standing eligibility requirements, in particular, the 51 percent rule, were not known or not enforced prior to the Cognetix case. If this was the case, then the publicity of the Cognetix case could have had the effect of deterring some ineligible firms from applying. This is, I believe, what you are suggesting the NIH chart indicates. However, in the extensive public comment period following the ANPRM on the issue, and in the public hearings on size issues where this was discussed, we received no evidence to support this claim. (Public comments to the ANPRM can be viewed online at http://www.sba.gov/size/anprm_sbir_comments-01.html, also see Summary of Comments below).

The other point I wanted to make regarding your first question, is that it is not possible to draw the conclusion you suggest simply from observing the data on the NIH chart. Yearly changes in applications are a volatile series of numbers and are affected by many factors, both outside and inside the program. Aside from changes in economic conditions influencing business start-ups or innovative activity, SBIR program outreach efforts and initiatives designed to assist firms in preparing their SBIR applications are certain to have had a significant impact on the number of applications. Changes in the levels of funding for the FAST and ROP programs, and the state-level activities they instigated, as well as changes in NIH SBIR outreach activities are all likely to have influenced the application rates.

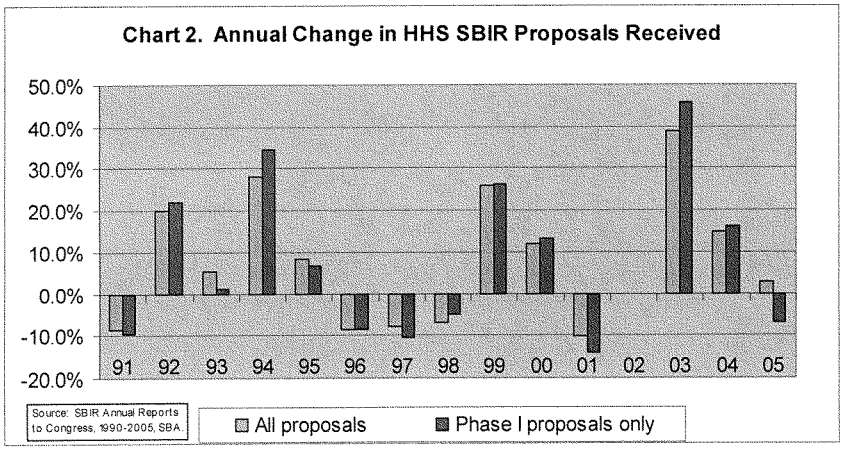
It is worth mention here that the recentU.S. Government Accountability Office (GAO) report, "Small Business Innovation Research: Information on Awards Made by NIH and DOD in Fiscal Years 2001 through 2004," GAO-06-565 at 27 (April 2006)found increasing VC involvement in SBIR awardees. This finding certainly does not support the idea that the Cognetix case had a significant deterrent effect.

If there are some ineligible firms that would have applied, but who decided not to apply as a result of the information they obtained from the Cognetix case, it might be possible to isolate the effect of these particular non-applicants on changes in annual application numbers through new survey data and statistical modeling. However, this analysis has certainly not been done.

A principal reason not to hang one's hat too quickly on one explanation of annual change numbers such as those in your NIH chart is that these figures are quite volatile. Yearly percentage changes will be statistically more volatile for SBIR applicants than for RO1 program applicants due to the smaller size of the program. Also, if you look at a greater time spam, the data shows significant variance. The official data SBA received annually from NIH and reports to Congress, show a general rising trend in overall SBIR proposals received, albeit with a somewhat cyclical rise and fall within this trend (Chart 1 below). 2005 is the latest year for which this data is available--SBIR agencies, including NIH, have not yet filed their official 2006 numbers with the SBA. While the number of Phase 1 applications fell in 2005, the number of all applications (including those for Phase II) rose slightly.



The annual percent change in these numbers are graphed in Chart 2. Chart 2 shows a longer time period than that selected in the NIH chart you presented. This reveals a number of significant ups and downs over time. While we have not conducted an analysis of the factors influencing these changes, this chart shows that drops in applications are not uncommon and occurred fairly regularly over time, even prior to the OHA decision on the Cognetix, Inc. case.



In your second question, you urged me to "look at ways to ensure that the most innovative small firms–including those that raise private funds, such as venture capital–are able to participate in the program." I appreciate your concern—that small firms with great potential for innovation yet requiring the stimulus of public funding such as SBIR awards be eligible to apply and compete in this program. As the lead agency for the SBIR program, we take the targeting of the SBIR program, through its eligibility requirements, very seriously. [NOTE: what about restating that VCs already can participate under the current regulations? Otherwise, it seems like they can't.]

Adjustments in the eligibility requirements of innovation programs such as the SBIR must be made very carefully, with an eye to balancing both technological risk and market risk. To be effective, SBIR funds must go to innovative small business projects with good market (commercialization) potential. However, to be effective, it is equally important that the funds not go to projects that would be funded through other sources in the absence of the SBIR award. Public programs that fund low-risk, already well-funded, projects are rightfully subject to the charge of "cherry-picking," "crowding-out," or "corporate welfare." To keep the program effective, we must continue to be mindful that it is intended, designed, and administered to *stimulate* innovation not simply to *reward* firms that are innovating.

In addition to these considerations of risk balance, we must also ensure that the program truly benefits U.S. small business.

As the lead agency for the SBIR program, the SBA monitors the program, assesses the need for changes or adjustments to the program, and has an established process for identifying and implementing such changes. We continually welcome new ideas on ways to improve the program and would be very interested in meeting with you and your staff to discuss the issue of eligibility requirements for the SBIR program.

BACKGROUND

The issue of altering SBIR eligibility to allow greater control by VCCs was brought to SBA's attention through public comments responding to SBA's Notice of Proposed Rulemaking published in the *Federal Register* on June 4, 2003 (68 FR 33412). With this notice, SBA proposed to modify Sec. 121.702 of its Small Business Size Regulations (13 CFR 121) to allow a small business that is owned and controlled by another eligible small business concern to be eligible for funding agreements under the SBIR Program.

Specifically, the SBA proposed to modify the ownership clause in the eligibility requirements so that the SBIR awardee must meet one of two criteria: (1) It must be a for-profit business concern that is at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States (as the pre-existing regulations required); or (2) it must be a for-profit business concern that is 100% owned and controlled by another for-profit business concern that is itself at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. The purpose of this Proposed Rule was to add a specific flexibility in the requirements to allow SBIR awardees the option of conducting their innovative SBIR work through a wholly owned and controlled subsidiary.[1]

The Proposed Rule was open to public comment from June 4, 2003 to July 7, 2003. Most of the comments were in favor of the proposed change. Some comments argued that the rule need not require 100 percent ownership and control—that less than 100% ownership and control by another concern should be allowed. In addition, a number of the comments addressed an issue related to VCCs that was not a subject of the Proposed Rule. Some of these stated that a concern should be allowed to participate in the SBIR Program even if one or more VCCs have majority ownership or control of the concern. In addition, most of these commenters believed that if one or more VCCs owned or controlled a concern, the VCC should not be deemed affiliated with the concern. The justification offered was that VCC investment is crucial to startups in the biotech industry and that SBIR funds are needed to reduce the private risk of these investments.

[1] For this reason, we refer to the resulting rule change as the "subsidiary rule."

Another element of the SBIR eligibility requirements is the size standard requiring that an eligible small business concern, with its affiliates, have no more than 500 employees. Under current regulations (13 CFR 121.103, *What is affiliation*?), when a business entity has control of a firm in which it invests, it is considered affiliated with that firm. This holds for any business entity including VCCs and other investment vehicles. The Proposed Rule did not propose to change this 500 employee size standard for the SBIR Program or the meaning of affiliation.

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

This rule did not change the size standard requiring that an SBIR awardee, together with its affiliates, have no more than 500 employees. The Final Rule became effective January 3, 2005 and is the current rule.

Because SBA had received a significant number of comments on the Proposed Rule concerning ownership of SBIR Program participants by VCCs, SBA decided to advise the public at large of the concerns and seek additional information on this issue through the December 3, 2004 ANPRM. The ANPRM comment period was from December 3, 2004 to April 3, 2005. Public hearings were held in throughout the country between June 2, 2005 and June 29, 2005.

SUMMARY OF PUBLIC COMMENTS ON ANPRM

Comments received in response to the ANPRM divide broadly into those that argue in favor of allowing a greater degree of VC ownership and control in the SBIR program, and those that argue against any such change in the program's eligibility requirements. The comments in favor of a change include general arguments that VC ownership and control should be allowed without restriction; arguments that business affiliations of VCCs should be excluded from applicant size determinations; and arguments that, in addition to an affiliation exemption, the ownership restriction, or "51 percent rule," should be changed by redefining the term "individual" to encompass business entities such as VCCs in addition to natural persons. The comments we received against changing program eligibility argued that the program's current requirements enable an appropriate level of participation by VCCs and that allowing greater VC ownership and control would be detrimental to the program and contrary to its statutory purposes.

Specific arguments in favor

- Biotech industry has special innovation financing needs and SBIR awards are needed in addition to majority VC funding. The cost of testing products ranges from $300 million to $900 million.
- Businesses majority-owned by VCCs generally consist of combinations or syndicates of VCCs with no one VCC having a large or majority ownership stake.
- Businesses majority-owned by VCCs are generally controlled by its board, which includes the principles of the business.
- Companies majority-owned by VCCs have limited access to financing for early-stage, proof-of-concept research.
- Businesses majority-owned by VCCs often have 5 to 50 employees and therefore qualify as small entities.
- VC majority ownership has been common practice in SBIR in the past and SBA recently changed the interpretation of the eligibility requirements. (No evidence presented.)
- VC majority ownership indicates commercial success and small firms should not be "penalized" for such success.

Specific arguments opposed

- Changes in eligibility requirements allowing greater control by VCCs, such as the exemption to affiliation, would allow large corporations to benefit directly from the SBIR program through VCCs. Small firms controlled by VCCs are no longer independently owned and operated.
- Purpose of SBIR is early-stage, high-risk, "pre-VC." VC investments are downstream, closer to market, lower-risk. They compliment each other and should not be merged as these eligibility changes would do.
- SBIR and VC approaches to innovation commercialization are incompatible.
- Large VCCs and syndicates have 97.5% of extramural federally-funded R&D, SBIR reserves only 2.5% for truly small independent businesses.
- Suggested change would subsidize venture capital investments.
- When VCCs take majority position, company does not need continued SBIR funding.
- Altering eligibility requirements to address the needs voiced by the biotech lobby would set a precedent for industry-specific special requests.
- Allowing businesses majority-owned by VCCs would likely shift the geographic distribution of SBIR awards from rural areas to R&D centers such as California, Massachusetts, and New York.
- Rule change would encourage federal agencies to bundle or create larger SBIR projects.
- Rule change would make it harder for smaller firms to participate in the SBIR program.
- VCCs currently have ample funds for investment purposes and do not need government subsidization.
- VCCs with majority ownership have the potential to control. This is a key concept in affiliation determination.

Questions from Senator Bond

Senate Committee on Appropriations
Subcommittee on Financial Services and General Government
Questions for the Record – Small Business Administration
March 9, 2007 Hearing

Questions from Senator Kit Bond

1) With respect to the SBIR program: As I mentioned earlier, I am concerned that we are shooting ourselves in the foot by limiting biotechnology companies' access to this program. We recently received this data chart from NIH. It shows that for the last 2 consecutive years, the number of applications to NIH's SBIR program has decreased. This is significant because the new SBIR rules were first applied to a specific company (Cognetix decision) in 2003, but the agencies (such as NIH) did not fully implement them until 2004. So it is fair to say that the 2005 and 2006 numbers represent the first 2 years that the new restriction on venture capital financing has been fully in effect. Look at the impact on applications at NIH.

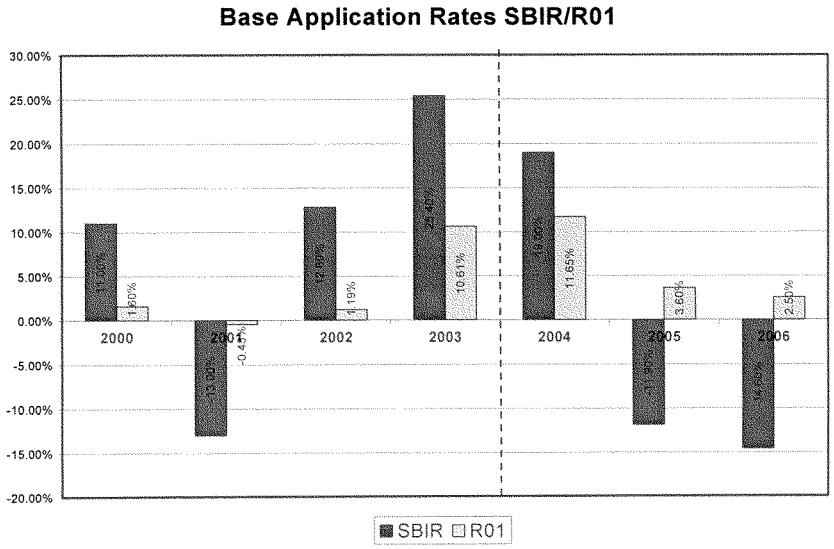
   The chart also includes figures for R01 applications. I am told that it is the largest NIH grant program to universities and academia. So while applications for NIH's SBIR program fell significantly in 2005 and 2006, applications for R01s continued to increase (albeit at a slower rate than previously). Would you agree this makes the case that the decrease in SBIR applications is specific to something going on with the NIH SBIR program and not a result of scientific trends or some other outside factor? Technology

   2) Mr. Preston, as you evaluate the SBIR program with an eye toward regulatory or legislative changes, I urge you to look at ways to ensure that the most innovative small firms – including those that raise private funds, such as venture capital – are able to participate in the program. The SBIR authorizing statute listed the raising of private funds by a company as a positive factor that agencies should take into account when awarding SBIR Phase II grants. Congress viewed raising private research funding as a good thing in 1982; that has not changed.

   As America's high-technology companies compete for funding in an increasingly global marketplace, the ability to attract and retain capital has become more important than ever. The SBA should not discriminate against good science by small entrepreneurial companies simply because they have been successful in raising venture capital.

   Are you willing to work with us to address this problem administratively, so that a legislative fix will not be necessary? Technology

Questions from Senator Bond, Page 2



October 18, 2007

The Honorable John Kerry
Chairman
Small Business and
Entrepreneurship Committee
428A Russell Senate Office Building
United States Senate
Washington, DC 20510

The Honorable Olympia Snowe
Ranking Member
Small Business and
Entrepreneurship Committee
428A Russell Senate Office Building
United States Senate
Washington, DC 20510

The Honorable Nydia Velazquez
Chairman
Small Business Committee
2361 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20515

The Honorable Steve Chabot
Ranking Member
Small Business Committee
B-363 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20515

The Honorable Bart Gordon
Chairman
Science and Technology Committee
2320 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20515

The Honorable Ralph Hall
Ranking Member
Science and Technology Committee
H2-389 Ford House Office Building
U.S. House of Representatives
Washington, DC 20515

Dear Chairmen Kerry, Velazquez, Gordon and Ranking Members Snowe, Hall, and Chabot:

As you consider the upcoming reauthorization of the Small Business Innovation Research (SBIR) program, we urge you to restore venture capital-backed companies' eligibility to compete for these grants. The SBIR program is a set-aside of federal research and development grant monies that are reserved for innovative, small business applicants. These funds provide critical "seed" money for early stage research and development being undertaken by small companies with fewer than 500 employees.

After twenty years of participating in the program, the Small Business Administration (SBA) ruled in 2003 that small companies that are majority venture capital-backed could

no longer apply for grants regardless of how few employees the companies have. Because of the unique capital needs of biotechnology companies, most are now ineligible to compete for grants. As a result of the reinterpretation, the SBIR applicant pool is shrinking at the National Institutes of Health (NIH), and work on life-saving and life-enhancing technology is being postponed. As NIH Director Elias Zerhouni, MD, stated in a letter to the SBA, "NIH must turn away many deserving applicants, and the goals of the SBIR program are being undermined".

Small biotechnology companies take basic scientific discoveries, many of which originate from universities, and conduct further research and development to turn discoveries into commercially available treatments and cures. This collaborative relationship is one of the ways universities and academic researchers serve the public by contributing to the development of new treatments and cures and supporting the local economy. Small biotechnology companies require significant venture capital investment, and unfortunately the SBA reinterpretation of the eligibility rules has hampered the continued research and development into biotechnology products, thereby delaying the delivery of future treatments to patients.

Many bioscience companies in the United States today were aided by the SBIR program because it provides critical early stage funding for research. For example, of 163 companies and affiliates involved in the development of the 252 FDA approved biologics, 32% of those companies and affiliates have received at least one SBIR/STTR award. Interest in competing for SBIR grants remains strong. In a recent survey or small biotech companies, 85% said that if the rules were changed to allow them to apply for these grants they would do so. These companies are researching and developing therapies for diabetes, Alzheimer's, lupus and leukemia, among others diseases.
As the world's leader in biotechnology, the United States and patients have greatly benefited from the SBIR program. The current eligibility guidelines are prohibiting many of the most innovative companies from competing for crucial early state research and development funding, which impacts the future of the research being pursued by universities and the patients that ultimately benefit from new treatments and cures.

For these reasons, we respectfully urge you to take restore SBIR eligibility for majority venture-backed companies in the upcoming reauthorization of the program.

AA CSA Foundation
AIDS Vaccine Advocacy Coalition
Alliance for Aging Research
Alzheimer's Drug Discovery Foundation
American Association for the Study of Liver Diseases
American Autoimmune Related Diseases Association
The ALS Association
Celiac Disease Center at Columbia University
Children's Cause for Cancer Advocacy
Children's Tumor Foundation
Christopher & Dana Reeve Foundation

Crohn's & Colitis Foundation of America
Coalition of Heritable Disorders of Connective Tissue
C3: Colorectal Cancer Coalition
Costello Syndrome Family Network
Cutaneous Lymphoma Foundation
Cystinosis Research Network (CRN)
Digestive Disease National Coalition
Epilepsy Therapy Project
FasterCures
Genetic Alliance
Genetic Alliance BioBank
Hepatitis Foundation International
The House That Tree Built Foundation
Huntington's Disease Society of America
Infectious Diseases Society of America
Juvenile Diabetes Research Foundation
Kidney Cancer Association
Leukemia & Lymphoma Society
Marti Nelson Cancer Foundation
Michael J. Fox Foundation for Parkinson's Research
Muscular Dystrophy Association
National Alliance on Mentally Illness
National Hemophilia Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders (NORD)
National Prostate Cancer Coalition (NPCC)
National Tay-Sachs & Allied Diseases Association, Inc. (NTSAD)
PXE International
Parent Project Muscular Dystrophy
Parkinson's Action Network
Pediatric Adolescent Gastroesophageal Reflux Association, Inc – PAGER
Research!America
RetireSafe
Scleroderma Foundation
Society for Neuroscience
Society for Women's Health Research
SMA Foundation
Suicide Awareness Voices of Education (SAVE)
Tourrette Syndrome Association
Trimethylaminuria Foundation
Vital Options International

U.S. Small Business Administration
Senate Small Business and Entrepreneurship Committee
Roundtable Discussion "Reauthorization of the Small Business Innovation Research Program: How to Address the Valley of Death, the Role of Venture Capital and Data Rights."

Chairman Kerry, Ranking Member Snowe and members of the Committee thank you for holding this roundtable to discuss among other things the important issue of the role of venture capital (VC) companies in the Small Business Innovation Research (SBIR) Program.

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

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

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

concern that is at least 51 percent owned and controlled by another for-profit business that is itself 51 percent owned and controlled by individuals who are citizens of, or permanent resident aliens in, the United States. The Final Rule became effective January 3, 2005.

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

The 51 percent requirement is there precisely to distinguish between individual owners and owners that are institutional entities to ensure that SBIR funds go only to small, independent U.S. firms. It is important to note that the OHA decision constituted neither a new eligibility rule, nor a new restriction on venture capital financing within the SBIR Program.

In December 2004, SBA decided to advise the public at large of the concerns raised by VCs and seek additional information on this issue through an Advance Notice of Proposed Rule Making (ANPRM). The ANPRM sought public comment on whether SBA should revise SBIR eligibility requirements to allow greater ownership and control by VC companies. Specifically, SBA asked for comments on whether SBA should provide an exclusion from affiliation with VC companies in determining small business eligibility. The SBA also held public hearings on this and other small business issues.

As a result of the ANPRM comment solicitation and public hearings was that SBA did not receive any compelling arguments for change to the long-standing rules concerning affiliation and ownership for the SBIR Program. We note that only 2.5 percent of extramural research dollars ($2 billion) are set aside for small businesses under SBIR. That leaves 97.5 percent - approximately $80 billion – available to companies with majority venture capital ownership.

SBA wants to ensure that the integrity of the program is maintained and that it remains a program for small businesses. Therefore, SBA does not believe the proposed legislation in H.R. 3567 is necessary or beneficial.

VC participation has been allowed and encouraged since the inception of the program. Currently, more than one venture capital company may invest any amount of money into small businesses, with the only restriction that they cannot in concert own more than 49 percent and/or have the ability control the SBIR awardee. In addition, if a VC is for profit and is owned at least 51 percent by one or more individuals who are U.S. citizens or permanent resident aliens, it may own more than 49 percent of the SBIR awardee so long

as the awardee and its affiliates (including the VC and its affiliates) have no more than 500 employees in total.

Exempting VC or other institutional investors from affiliation in size determination abolishes the transparency needed to determine program eligibility as well as the intent that the program benefit businesses that are small. Further, any changes to SBA's size standards will also affect SBA's lending and other government contracts programs.

SBA is particularly concerned with possible changes to its affiliation provision. Affiliation is a key concept in defining a small business. Along with a numeral measure of the size of business, the Small Business Act includes the criterion that a small business must also be "independently owned and operated." Without a consideration of affiliation, Federal assistance targeted for small businesses would be inappropriately provided to a business concern that is part of a large business. SBA is concerned that changes to the existing statutory language may lead to new interpretations of affiliation that could inadvertently allow arrangements with large businesses to be acceptable. Accordingly, SBA advises Congress to proceed with the utmost caution in this key concept of defining a small business.

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