

**SBIR AND STTR REAUTHORIZATION: ENSURING
A STRONG FUTURE FOR SMALL BUSINESS IN
FEDERAL RESEARCH AND DEVELOPMENT**

ROUNDTABLE

BEFORE THE

**COMMITTEE ON SMALL BUSINESS AND
ENTREPRENEURSHIP
UNITED STATES SENATE**

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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JUNE 4, 2009
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THURSDAY, JUNE 4, 2009

UNITED STATES SENATE,
COMMITTEE ON SMALL BUSINESS
AND ENTREPRENEURSHIP,
Washington, DC.

The Committee met, pursuant to notice, at 9:39 a.m., in Room 428–A, Russell Senate Office Building, Hon. Mary L. Landrieu (chairman of the committee) presiding.

Present: Senators Landrieu and Shaheen.

OPENING STATEMENT OF THE HONORABLE MARY L. LANDRIEU, CHAIRMAN, AND A UNITED STATES SENATOR FROM LOUISIANA

Chairman LANDRIEU. Let me begin by calling this roundtable to order and thank all of you all for coming this morning. I am really very grateful that you have given your time to join us for this roundtable. I am hoping that Senator Snowe, who like me has many other hearings today—unfortunately, we are usually double-scheduled—but hopefully, she will be able to stop by sometime during the roundtable, and we are expecting some of our other members to come in, as well.

I am going to be spending some time with you all this morning and then turn it over to my staff that will be conducting the bulk of the roundtable. But these roundtables are very, very important opportunities as Congress attempts, particularly this committee, to reshape and reauthorize two very important programs in the SBA administration, which I am sure you are all familiar with and have strong opinions and are expert in and we are looking forward to hearing your views today.

As I said, the purpose of this roundtable is to discuss the reauthorization of the Small Business Innovation Research, SBIR, program and the Small Business Technology Transfer, STTR, programs, two of the most important and tech-focused programs in the SBA. We have several reauthorizations for SBA programs on the horizon, but these two continue to be our committee's top priority. In the coming weeks, we will also be discussing the reauthorization of the SBA's entrepreneurial development programs.

As you all know, these two programs—one was authorized in 1982 and the STTR program in 1992—among other things, it helps

to meet the government's research and development needs through small business. The last comprehensive reauthorization of the SBIR program occurred in 2000. The program was reauthorized for eight years. It was scheduled to sunset September 30, 2008. This program has received two temporary extensions. We must do a, in my view, a final reauthorization, hopefully for another eight-year extension, and that is my goal. I have made it a priority of this committee to get the comprehensive reauthorization bill to the President's desk before July 31.

So let me just briefly explain for those of you who have participated in roundtables before. When you would like to speak, just stand your card up like that and you will be recognized. Kevin Wheeler, who is the Director of this effort, Don Cravins, my Staff Director, and Thad Inge will be leading this discussion. They will be reporting back to me, as I said, and to Senator Snowe, and together, we will try to take the best of your ideas and submit them with our reauthorization.

We have a good foundation for this year's bill based on the committee work of the last two Congresses, but if anyone has an idea about changing a direction or adding, this would be your day to make specific comments about how you think our base reauthorization effort should be changed.

Unfortunately, sometimes with these programs particularly, we have had some difficulty actually keeping people focused on the facts and on specifics and not just spectacular statements about their points of view, so the staff has been instructed by me to keep everybody very focused on facts and statistics as we seek to reauthorize these two very important programs.

We have many policy goals and interests to balance. Obviously, we want these programs to stay focused as a bridge, help, and support for true small business, Main Street business, hometown businesses in America. That is what the SBA is focused on, entrepreneurship, growing small businesses to large business. It is not a hand-holder for larger businesses that have other options because of their size and ability to reach.

We want to encourage the exploration of high-risk, high-reward, cutting-edge research. That is what these programs are designed to do. We want a fair playing field so that Main Street and hometown businesses can compete for this very small percentage of the overall Federal R&D budget. We want commercialization, but not at the expense of turning programs into an acquisition program. We realize there are different ways to get to these goals. States with low SBIR activity and high SBIR activity, differences among small business, research universities, agencies, differences within States with little venture capital and those with more, but this committee wants to balance those interests.

As all of you know, these two programs have been enormously successful over the years since their inception. Both programs have played an unprecedented goal in stimulating technological innovation and allowing small business to meet Federal research and development needs and providing seed capital for small business to develop ideas until they are able to attract outside investment.

The SBIR program has awarded more than \$24 billion to 100,000 projects since it started. Recipients have produced more than

85,000 patents, generated millions of well-paying jobs across all 50 States. Both programs have garnered high praise from well-respected sources, and governments around the world are increasingly adopting SBIR-type programs to encourage innovation in their own countries.

Small businesses continue to receive only about four percent of research and development dollars, despite the fact that they employ nearly 40 percent of American scientists and engineers and produced 14 times more patents than large businesses and universities and produced patents that are of higher quality and are more than twice as likely to be cited. The SBIR and STTR programs are two of the very few Federal programs that tap into the scientific and technical communities found in America's small business. These programs foster government-industry partnerships by making competitive awards to firms with the best scientific proposals, regardless of size, and apply them to the research needs of our agencies, by helping to move technologies from the lab, from our universities to the marketplaces, or from the lab to insertion in government programs or systems.

I am just going to mention two success programs that we wanted to highlight. One of the technologies pioneered by an SBIR-funded small business is a machine that uses lasers and computer cameras to sort and inspect bullets at a much finer level than the human eye can manage. The technology created the invisible condensation trail of the B-2 bomber, a therapeutic drug to create chronic inflammatory disease, and a nerve gas protection system. We think that was a very good investment for the money that we spent.

With regard to the bullet-sorting technology developed by Cybernet Systems, a small woman-owned business located in Ann Arbor, Michigan, and currently in use in Iraq and Afghanistan, the SBIR technology is estimated to have saved taxpayers more than \$300 million. These are real cost savings and tangible technological improvement.

I am very familiar with one of our own Louisiana companies that has had great success in recent years, Network Foundation Technologies, known as NiFTy. I visited the company in Ruston, Louisiana, a relatively rural part of our State, but is home to one of our great universities, Louisiana Tech University, and right down the road, another well-known university, Grambling State University. NiFTy has worked closely with our guest, Kathy Wyatt from Louisiana Tech. Kathy, welcome. They used an SBIR grant from the National Science Foundation to develop technology that permits live streaming video over the Internet without the use of large amounts of bandwidth. They have been particularly successful in bringing sporting events live over the Internet.

NiFTy has grown to more than 40 employees, many drawn from the ranks of our own scientists there at Louisiana Tech. These are high-paying new jobs, high-paying jobs in Louisiana. Kathy will testify today that when they started this process, they were told that they could not build this business in Louisiana. It just didn't have the gravitas or the atmosphere or the possibilities because it was in a State that was not known for technology. But I beg to differ, as the Senator from Louisiana. We have some very exciting high-tech corridors being developed outside of the well-known Sil-

icon Valley and Triangle of North Carolina and places here in Northern Virginia.

There are pockets of extraordinary and exciting technologies and entrepreneurs from east to west, from north to south, in small places that people can hardly find on the maps, and it is the intention of this Chairman to make sure that these programs reach those small communities, particularly in rural areas outside of the well-known areas, to bring the great brains and talent of American citizens wherever they might choose to live for any number of reasons to give benefit to the taxpayer and to build the jobs in the next century.

So again, I encourage you all to make very constructive discussion. I know many of you flew in from parts of the country and the weather isn't terrific, so I thank you for your efforts.

I would especially like to, of course, recognize Kathy Wyatt, who I mentioned earlier. Kathy serves as Director of Louisiana Tech Technology Business Development Center, has long been active in small business. I thank Kathy for being here.

Dr. Kevin Kelly from Meso Technologies in Baton Rouge was also going to be invited, but unfortunately because of the weather had to be rerouted.

So I am pleased to have both of these great spokespersons from my own State and I look forward to being introduced to the rest of you all and look forward to your testimony today. Thank you very much.

We have been joined by one of my great leaders on this committee and a fierce advocate for small business, a woman who has done a lot of it in her career as Governor before she got here as a Senator, so Senator Shaheen, we are very grateful for you attending this morning, and please.

OPENING STATEMENT OF THE HONORABLE JEANNE SHAHEEN, A UNITED STATES SENATOR FROM NEW HAMPSHIRE

Senator SHAHEEN. Thank you, Madam Chair, and thank you for your leadership of this committee before putting together this innovative discussion this morning to talk about reauthorizing SBIR.

I also want to thank all of the panelists for coming today. As Senator Landrieu said, we especially appreciate your challenges getting here given the weather. For those of you who made it yesterday and got to be here through that awful rainstorm, we especially appreciate that effort.

I am sorry that, unfortunately, I am not going to be able to stay for the entire discussion this morning. We have a mark-up in the Energy Committee, another very important issue for all of us, so I will miss much of your discussion but will have the transcript that we can all review, and, of course, the staff will report the discussion this morning to all of us.

As a Senator from New Hampshire, I take particular pride in the SBIR program. As you will hear from Jim Barry, who is from New Hampshire, it was New Hampshire Senator Warren Rudman who in 1982 sponsored the Small Business Innovation Development Act, which established the SBIR program. I think Jim will tell you that Create, which he represents, was very instrumental in helping to develop the original Act. Many New Hampshire small businesses

have successfully competed for SBIR funding over these past 27 years, including Creare. Thank you, Jim, for coming to share your experiences with the committee.

All across New Hampshire, from Applied Geo Solutions in Durham to Mikros Manufacturing in Claremont, small businesses that otherwise would not be able to compete for Federal research and development funding have won competitive SBIR grants that advance technology and science and create good jobs. Over 794 Phase One awards and over 385 Phase Two awards have been won by New Hampshire small businesses. And as Chairman Landrieu has noted already, small businesses employ about one-third of America's scientists and engineers and produce more patents than large businesses and universities, and yet small business receives only about four percent of Federal research and development dollars.

I believe that our future economic prosperity depends on whether this country continues to be a leader in science and innovation, and that means, in my opinion, that we need to reauthorize and strengthen SBIR. So I am going to take what little time I have this morning to sit back and listen as you all begin this discussion about how we can reauthorize this legislation and hopefully create something that is going to be better for the future. Thank you.

Chairman LANDRIEU. Thank you, Senator Shaheen.

I am going to now turn over the program to Kevin Wheeler, our Director. She is going to lead us in an open discussion, as you all have been briefed, with some specific questions. And again, when you want to speak, just stand your name card up and we will call on you and try to have as much interaction as possible. Again, we want you to be, of course, very forthcoming. That is what the purpose of this roundtable is. But please try to keep your answers to the point and present as many facts or supportive documentation as you can.

Of course, the record of our committee will stay open for one week, so anything that you can't get in today but you feel like you want to back up a point, of course, we would love to receive your material.

So I am going to turn it over to Ms. Wheeler.

Ms. WHEELER. Good morning. Thank you. Before we get started, did you want to just go around the table and say your name and tell us your company or who you are representing so that the Senators have a sense of who you are? Do you want to start, Jim?

Mr. BARRY. Jim Barry, Creare, Incorporated in Hanover, New Hampshire.

Chairman LANDRIEU. If you all could pull the microphones a little bit closer. You have to really get them close to you, and, of course, because this is being recorded, it is important. Some of you are going to have to share them, but just pull them as close as possible. So Jim, could you restate that?

Mr. BARRY. Jim Barry, Creare, Incorporated, Hanover, New Hampshire.

Mr. CRANDELL. Keith Crandell, ARCH Venture Partners, which is a seed and early stage venture capital company in Chicago.

Ms. EYESTER. Laura Eyester. I am with SBA's Office of General Counsel.

Mr. IYER. I am Subash Iyer with the SBA, Office of the Administrator.

Mr. GLOVER. Jere Glover, Small Business Technology Council. Good to see you.

Dr. MCGARRITY. I am Gary McGarrity from VIRxSYS in Gaithersburg, Maryland, and I am also representing the Biotechnology Industry Organization.

Mr. MEHRA. I am Kunal Mehra with Scientific Systems in Woburn, Massachusetts. We are a small minority-owned business, very active in both the NASA and Department of Defense SBIR programs.

Ms. OLIVER. I am Linda Oliver. I am the Acting Director of Small Business Programs for the Department of Defense.

Dr. FEDORKOVA. Good morning. I am Lenka Fedorkova, representing the NIH SBIR program.

Chairman LANDRIEU. I have to stop you all. I can see people in the back of the room cannot hear you at all, so I am going to ask you again, when you speak, you have to speak like this, okay, close to the microphone so that people can hear you. These microphones are sensitive only if you are close. Try it again.

Dr. FEDORKOVA. This is Lenka Fedorkova representing the NIH SBIR/STTR program. Good morning.

Chairman LANDRIEU. Was that better in the back? Okay. Somebody back there be in charge, up or down.

Dr. WESSNER. My name is Charles Wessner. I am with the National Academy's Program on Innovation.

Chairman LANDRIEU. Thank you, Charles.

Ms. WILLIAMS. I am Cheryl Williams. I am with the Government Accountability Office.

Ms. WYATT. Kathy Wyatt with Louisiana Tech University.

Chairman LANDRIEU. Okay. Kevin.

Ms. WHEELER. Thank you. And then, also, I would just like to recognize Erik Necciai, who works for Senator Snowe, and he will represent their side.

So the first topic of discussion is length of reauthorization. As some of you may know, the last two reauthorizations for the SBIR program were eight years. The last reauthorization period for the STTR program was also eight years. In the 109th Congress, this committee voted to make the programs permanent. Then in the last Congress, we voted to reauthorize them for 14 years as a balance between the eight and the permanent.

Right now, we are operating under—the SBIR program, at least, is operating under a temporary extension and they have been six and eight months. We would like to establish on the record today from the small businesses, the agencies, how do the shorter or longer periods affect you so that it would guide us in going for the longer or shorter periods.

I would like to start with the businesses, if we could go around the table, and tell us, are shorter or longer periods better for your business?

Mr. BARRY. A longer period is preferred for us. It allows us to plan better, have some consistency as we go forward.

Ms. WHEELER. And are you worried at all about these temporary extensions?

Mr. BARRY. They are a little unsettling because one never knows whether the program is going to halt unexpectedly or be put on hiatus for a while, which would be very disruptive for the small companies that are involved.

Ms. WHEELER. Okay. Mr. Crandell.

Mr. CRANDELL. We are supportive of longer periods. I think the time line that the National Venture Capital Association also is supportive of is five years, and that way to allow the Phase One, Phase Two, Phase Three process to complete a full cycle and then be able to collect data and sort of understand the implications of actions and policies that have been taken.

Ms. WHEELER. So NVCA is in favor of a shorter period?

Mr. CRANDELL. Of five years, which is certainly longer than what we have—

Ms. WHEELER. But shorter than all the precedents of eight years?

Mr. CRANDELL. Five is shorter than eight, yes.

Ms. WHEELER. We will just go ahead and go through the agencies. Do you want to represent SBA, Subash?

Mr. IYER. Sure.

Senator SHAHEEN. Can I just ask a question, Kevin? Would you be opposed to an eight-year? It wasn't clear to me from what you were saying. Eight or ten years? Is there a reason why you think five is better?

Mr. CRANDELL. Well, I mean, the last couple of years, there has been—I have only been on the NVCA or involved in it for about three years as a board member. I have been involved in the SBIR issue for that entire period of time. It seems like there are some questions that are open to getting data to resolve. The National Academy has done a great job of starting, but they didn't have all the data available to be able to track some of the critical parameters. It seems like you would want to choose a period of time where you could get a full cycle of people applying, of awards being made, of programs being completed, and then results being developed so that you could then look at that result and know whether you had indeed achieved the ends that you were interested in.

Senator SHAHEEN. I understand that, and certainly what I have heard from businesses, and Jim can attest to this, is that a longer period is important so that people can plan. But what I am trying to figure out is are you saying that you think eight or ten years is too long and that five years is a preferred time period, or—

Mr. CRANDELL. Well, it to some degree depends on what is actually in the bills. From the venture capital-backed company standpoint, there are still issues about whether they can participate and how. Obviously, if they are excluded and it is an infinite authorization, that is something that disadvantages what we think are important participants who are prospective participants, who would like to participate but would be precluded.

Senator SHAHEEN. Thank you.

Ms. WHEELER. Just to clarify for the record, the committee was aware of concerns of regular reviews of the program, allowing you to go back in, and we did not see them as inconsistent with long periods of permanency or 14 years.

And for that reason, the foundation of the bill has the National Academies or National Research Council go back and at regular intervals, every four years, to update the comprehensive studies that they had done so we didn't lose that base of research. And then also your concern that firms would be excluded and therefore you would want to not have a longer window, one, VC firms are not excluded even today, and two, the foundation for the bill had a compromise to allow firms that are majority-owned and controlled by multiple VCs. So they wouldn't have been excluded in either scenario, not today and not even if last year's bill had passed, to address your concern.

Mr. CRANDELL. I appreciate that, and I appreciate you pointing out all those points. I think from our perspective, a majority of important firms that are venture capital-backed actually would have been excluded under what we have now, or at least their participation capped. Second, many firms have been excluded since 2003, and even though there are these review mechanisms that you have identified, and I am certainly a fan of review, in point of fact, it hasn't—the program was materially changed in 2003 from our perspective and the review process, even though there is, I think, significant relevant arguments to go back to the system that existed prior to 2003, it, in point of fact, hasn't. So I don't share the same level of confidence that you do in the program review.

Ms. WHEELER. Well, we will go into the VC issues further.

For SBA, what is the administration's position on, say, a 14-year authorization?

Mr. IYER. Well, the SBA believes firmly that this reauthorization needs to be a long-term reauthorization and there are two reasons for that. The first is that at a program and agency level, it is important for program managers for planning purposes as well as broader considerations of how they develop their program and outreach, have a definitive long-term time frame for the program. In terms of the small business side, perhaps more importantly, small businesses need to also know that this program is there to exist for a long time.

As for the specific length of reauthorization, there is no firm position on that and I think that there needs to be a dialogue like the one that we are having right now to get all of the views on the matter before we can definitively suggest a length. But we do believe firmly in a long-term reauthorization.

Ms. WHEELER. Thank you.

Jere, your members from the Small Business Technology Coalition?

Mr. GLOVER. The stopping and starting uncertainty creates real problems in terms of recruiting and retaining the best scientists in the world to work for these companies. A long-term reauthorization, certainly the 14 years, the longer the better, and I think our folks really do think that the short-term doesn't serve any real purposes.

There is flexibility within the Small Business Administration. Hopefully, they are going to take a strong position and have a strong Office of Innovation, as the bill provides some strength. To the extent it needs to be tuned and tweaked, there are provisions within the policy directives that allow SBA to do that. So a short-

term reauthorization doesn't make sense, even for those who would like to change it from time to time.

Ms. WHEELER. Thank you.

Dr. McGarrity for BIO.

Dr. MCGARRITY. As a member of a small emerging biotechnology company, I think we could live with a 14-year reauthorization plan as long as, as previous speakers and you have mentioned, there is constancy there, because I think the big problem and the big hurdle is the changing rules going on. I would also emphasize what Mr. Crandell said in response to the eligibility requirements, and I think my approval or support for a 14-year reauthorization plan would be contingent on the proper eligibility requirements. I think you are partway there, but it is not fully where I think the biotechnology industry would like to see the playing field.

Ms. WHEELER. Thank you.

Kunal.

Mr. MEHRA. Yes. I strongly favor a lengthy reauthorization and for three very practical reasons. The first is I think we have seen in the past that whenever you get within four to six months of sunset, the process really pauses within the agencies. The agencies have to stop making decisions around awards. Contracts get stopped. As a consequence, it causes an incredible amount of stress and planning challenges for small businesses. We don't know whether we should recruit. We don't know whether we can actually rely on this revenue coming in. And I think as everybody would agree, planning is critical for all businesses, particularly for small businesses. So that is the first reason.

The second reason is when the bill finally does get reauthorized, there is an incredible backlog of awards of contracts, again, that the agencies have to grapple with, and that creates a lot of stress both for the agencies and for the small business concerns. So when you add up the impact, both on the stop of decision making and then the backlog of contracts, it is almost a year that you lose as a consequence of these short reauthorization cycles.

What do I do for a year? I have got the staff. I know that the award is potentially coming in and I could put some probability against it, but now I have to find other projects to put them onto. It impacts my ability to make hiring decisions. So from a planning perspective, it is very, very disruptive.

The third reason is, in terms of customers, we are, as a company, extremely focused on transitioning our programs to acquisition programs. So we will go out two to three years in advance and start engaging with customers and develop a transition plan. I mean, we are really doing what I think the SBIR program was intended to do. When we lay out that transition plan for them, we talk about various funding sources from Phase Two SBIRs, Phase Two enhancements, but I think as everybody knows, acquisition program managers are extremely risk averse and they look at that funding cycle and say, well, if SBIR is coming up for reauthorization, we can't rely on that funding. That introduces an incredible amount of risk. That therefore makes it even more difficult, compounding the problem for a small business to overcome that risk-averse culture and be successful with the transition of a technology.

Ms. WHEELER. Thank you. Very good.

Mr. NECCIAI. Kevin, if you don't mind, I wanted to see if we could touch on something you mentioned. I think a key issue is job creation, and before the Department of Defense has an opportunity to discuss that, if there is ever an issue where discussing job creation as it relates to SBIR, I would like you to emphasize that, if you could. You mentioned forecasting through reauthorization, how that may have an effect on, my decision to hire more people, or I had to lay off people because I wasn't able to obtain new contracts or new grants and such things. Were there any specific examples that your company had in having to reduce staff or where you couldn't hire?

Mr. MEHRA. Yes. I am glad you asked for clarification. My company, we are very fortunate. We have been on a growth trajectory. We actually grew about 40 percent in the last year. However, there have certainly been times where we have looked at our business forecast and we have said, okay, if reauthorization happens, we have space to hire another five or six people. In the worst case, if reauthorization doesn't happen, we are overstaffed by five people. And therefore, we say, all right, we are going to have to take a risk-adjusted view of this and probably not hire for at least six or seven months until there is clarity on whether these awards are going to come in.

That is a very disruptive process. It means that if the awards come in, we end up having to request no cost extensions, because we are understaffed. We have less investment capital to put into growth, going after new business. So it has this very deleterious effect that kind of tends to roll over for a long time and I think is not in the program's interest, it is not in our customers' interest, and it is certainly not in our own business interest or in the State's in terms of a hiring—

Mr. NECCIAI. What type of time frame would provide your company and companies like yours with the security of knowing that the program will be there and that there isn't this job fluctuation? Say you don't have to make those decisions every two years, every three years, every five years?

Mr. MEHRA. Well, I would say ten years would be great. Eight years would be a minimum. Ten years would be great. Upwards of 12, 14 years would be wonderful. But equally as important, I think, is to make sure that when reauthorization does come up, that that actually happens a year in advance of the sunset of the bill, and I know that that is a very difficult thing to have happen, but no matter how long the reauthorization is, at some point, the bill will sunset, and if we could clarify that, get the reauthorization done within a year of that sunset as opposed to waiting until the last minute, again, from a planning perspective, it makes it much easier and I think this is in the interest of overall economic growth.

Ms. WHEELER. Ms. Oliver.

Ms. OLIVER. That was such a nice, clear explanation that I have little to add except to say that from the Department of Defense standpoint, what we have to do in anticipation of possibly shutting down a program is labor intensive and wasteful, so we don't see—and we don't really see any benefit from it. We just see a lot of wasted resources.

Mr. NECCIAI. Ms. Oliver, as you know, the SBIR Program was supposed to terminate at last September, at the end of the last fiscal year last year. We reauthorized it until March. We reauthorized it again until July. Could you please estimate what type of costs is this incurring to your agency or similar agencies on having to do that type of fluctuation?

Ms. OLIVER. We have to—if I had to, I probably could translate it to dollars, but the sorts of wastefulness are we have to go out to vast numbers of people to explain to them what may happen. The communication process—in some ways, it is like jamming up the airwaves. It would be better if we didn't have to go through that drill at all because we need to be able to use their attention for things more useful than in a sort of a drill about we may not go on, and if we are not going to go on, here is what we are going to do. So even the communication part of not being sure whether something will be reauthorized is burdensome to—wasteful to an organization.

Mr. NECCIAI. So the Department of Defense would be more comfortable having a longer reauthorization?

Ms. OLIVER. Yes. Yes, we surely would.

Ms. WHEELER. Thank you.

Lenka.

Dr. FEDORKOVA. From the NIH perspective, I think key points were touched on. The timeliness of the authorization is definitely something that would also allow us not to have to spend sufficient time and effort to allay nervousness and anxiety in the community who is asking us how not reauthorized programs would affect the funding flow, even if we have the appropriations and the agency de facto is functioning normally. We feel, in general, too short of a reauthorization would be difficult for planning purposes, as was already alluded to. Too long of a reauthorization might pose other challenges where we would have fewer opportunities to do necessary checking in as to how the programs are doing and opportunity to perhaps adjust things as necessary.

So I think, in general, the eight-year interval has worked well. Again, as I think Mr. Mehra has mentioned, the key is when the authorization happens so that those involved don't have to spend that time managing the risks involved. So that would be our perspective on that.

Ms. WHEELER. Thank you.

Dr. Wessner.

Dr. WESSNER. Well, thank you. Our research on the SBIR program but also on other innovation programs, both in this country and around the world, would strongly argue that the advantages of this program are its scale, its stability, the continuity that allows for ongoing planning. So we would very strongly favor a long reauthorization.

I would like to stress the point that I think was touched on by both my colleagues from the agencies. If you want to have this small business and this program integrated into the procurement process, you do not want even three years out to be wondering whether or not this program is going to be reauthorized. I can think of nothing more disruptive to the credibility of the program than these tiny extensions that we have had in this period.

So without picking a particular time, the longest times that you have mentioned here would be fully justified with a very important condition, and that is that evaluation is ongoing, both internally and externally. If the evaluation is there, then I think you have the opportunity to revisit. I don't think a program that is extended over a long period of time, say 15 years, need not be looked at periodically, and I think it can be.

And I would like, with respect, to take very strong issue with my colleague, Mr. Crandell. The idea of holding the program hostage because we are not happy with one particular provision, I think understates the contributions that small companies are making to national defense and to energy. We need this program. We need their involvement. We are not unsympathetic to the point of view that Mr. Crandell might represent, but we very strongly think that it is putting—that it is having the tip of the tail wag the dog and we would like that not to happen. So with evaluation, we would argue for the longest possible extension.

I would also just like to venture, it is not here that—

Ms. WHEELER. Chuck, could you just pull your microphone a little bit closer?

Dr. WESSNER. I beg your pardon.

Ms. WHEELER. You are such a good speaker. I would hate for people in the back not to hear you.

Dr. WESSNER. You are very kind. You are very kind, and if I weren't so dumb, I couldn't use the mike and it would be better.

[Laughter.]

Dr. WESSNER. Anyhow, I will stop there. Scale, stability, continuity, integration, as long as possible, with evaluation. And I think we also need to look at a broader question about the need for obligation. The fundamental premise of the program is that we have to oblige the agencies to use the primary source of innovation in the economy, and that is small business. There is something fundamentally wrong about that. Thank you.

Ms. WHEELER. Thank you.

Cheryl, would you like to add? Does GAO have—

Ms. WILLIAMS. GAO's work has generally found the program to be very successful, but we have no position on the length of time for reauthorization.

Ms. WHEELER. Thank you.

Kathy, is there any perspective for the businesses that you help?

Ms. WYATT. Well, basically, I agree with the fact that it is very helpful to planning for small businesses. I can recognize where it would be very important for the agencies to have continuity. But what I would also like to point out is that in the small businesses that I deal with, I think there is a lot of wasted energy every time reauthorization emerges as a question because these businesses stop doing their research and focusing on the things that they are doing to bring innovation to the marketplace and they begin focusing on communicating the value and importance of the program to those who have the power or authority to keep it in operation. So I think there is a tremendous amount of wasted energy there.

And then I just think that it is extremely important for the Federal Government to do this in a manner that demonstrates their

continuing commitment to innovation and small business throughout the country.

Ms. WHEELER. And I think that is why we did—the committee voted for permanency in 2006, to address that issue, to take that away. But the compromise is now at 14 years.

Is there anything that anyone else would like to add before we move on to the next topic?

[No response.]

Ms. WHEELER. The next topic that we have on the agenda is the discussion of increasing the size of awards, and if you want to touch upon it, increases in the allocations of 2.5 and 0.3 percent. As you may know, the committee voted in the last two Congresses to raise the Phase One awards from \$100,000 to \$150,000, and the Phase Two awards from \$750,000 to \$1 million. There was also a 50 percent cap put on increases above those guidelines, which for Phase One would be about \$225,000 and Phase Two would be \$1.5 million, to address complaints, particularly from rural States, about jumbo awards.

So I would just like to—would anyone like to weigh in on those award sizes? Are they sufficient, et cetera?

Linda.

Ms. OLIVER. It makes sense to raise the award—the sort of recommended award value is really what it is—because there hasn't been any adjustment for a long time. The Department of Defense really does not favor caps, however. I think there are all sorts of mechanisms that help remind agencies that they need to be conscious of not using too much money in one place, but there are differences. There are times when you do need to go over the cap, or the suggested amount as it is right now, and SBA has consistently been reasonable about that.

Now, if there were, under the present system, if one of the agencies was acting a little crazy, I think SBA would step in and say, knock that off. But the system with no cap I think has worked well. I don't know of any actual excesses. I can make out the scenario in which there could be one, but I don't know of any actual excesses.

Ms. WHEELER. Two questions. Would the ability to go 50 percent above the guidelines be a problem for DOD, because GAO's report found that you were not—DOD did not have a particular problem with the guidelines. There were other agencies that had problems with this, but DOD complied with reporting, with justifications, and this is kind of getting at some of those other problems. So would \$225,000 and \$1.5 million not be enough, particularly since you also have the CPP, which goes up to \$5 million? I mean, to get at those other companies who you said at times need more money?

Ms. OLIVER. The—let me see. It is hard to understand why we should put a—we should have less flexibility when there isn't really a need for less flexibility. If there had been excesses, that would make sense.

In answer to your question, I don't think it is very likely that the Department of Defense will suddenly need to go—maybe ever need to go above the suggested guidelines. It is that one case that I worry about. It is that one case or two cases where if we had the flexibility, it would make a big difference. So it is the flexibility I

am in favor of, I guess is the way to explain what I am trying to say.

Ms. WHEELER. And what if there were the ability to apply to SBA for the exception when you needed to go above the 50 percent cap of \$225,000 or \$1.5 million? Would that address your concerns? Because we don't really see this problem at DOD. We didn't see this as being a problem. There were other agencies that had this problem, and to answer your question, what the small businesses came to us and said was, and the balance we were trying to get at is, if you make a Phase One award for \$2 million, you have eaten 20 Phase Ones. And so in some States where you have one or two awards, there is a possibility that those awards could go away.

And so for about eight years, we have been hearing concerns from Wyoming and, you know, Louisiana and other smaller States that have low participation that there is only so much money. And so we were trying to strike a balance. Yes, the agencies get flexibility, but there would be a limit for the abuses that had been identified. So would that exception get to what you are concerned about?

Ms. OLIVER. Not completely, probably. But, of course, it is surely a step in the right direction. I think the only thing—it seems to me that the weight between having SBA be able to step in when SBA needs to or having to go to SBA to ask if we can is—it seems like an unnecessary set of paperwork systems that would need to be set up, certainly from the Department of Defense standpoint, with no particular benefit. I mean, if we have a question—

Ms. WHEELER. If agencies are reporting, as DOD is, it was not a problem. Our problem was that some agencies were not reporting as required when they exceeded the guidelines and that is why the oversight wasn't there.

Ms. OLIVER. I see. I understand. I did not understand what you were saying.

Ms. WHEELER. That is why we had to work backwards to address that problem, to force the compliance with the reporting. But we will take that—

Mr. NECCIAI. I guess, Linda, what I am hearing from you is flexibility is very, very important—

Ms. OLIVER. Yes.

Mr. NECCIAI [continuing]. And I think that was something that was echoed in the National Academy of Sciences report. Though this may not have occurred in the past, you are saying there is one chance that it may, and having the ability to do that for a unique situation provides you with greater flexibility. Kevin was highlighting—and I appreciate Lenka bringing it up, that might be a direction that we would like to go with you as far as it seems like NIH was the agency that had, on occasion, gone over the limit. What would a cap for your agency do?

Dr. FEDORKOVA. Thank you. Yes. Our agency also feels like the DOD, and I think many others, that the flexibility is very much needed to ensure that we have the right kinds of incentives to encourage companies with high-risk, high-reward projects, depending on what field of biomedical research they are proposing these projects in, that they can submit realistic projects and budgets.

We do feel that some of our gap funding programs which we have instituted might be affected by some of the caps, but that, I think, would depend specifically on how things are phrased. I think the idea there is—and I know that you have a great appreciation for the diversity of the agencies and their missions within the program—as we are moving into some of the new fields, like nanotechnology and the well-understood costs that come with clinical trials. So I am referring to some of our programs like the continuing renewal programs, which are for our Phase Two applicants to do specific additional clinical work and prototype development which really incrementally rises in cost might be affected by the caps.

We do appreciate the recognition that the award levels need to be adjusted, as they haven't been for a long time, and in cases where projects do come to us with a higher proposal, they are automatically, so to speak, I guess, if you will, flagged and brought to the attention of the program officers at the Institutes. In those cases, those budgets have to be defended and justified. They have to really match what the company is proposing to do in their business plan. And at the same time, of course, we have companies who receive less than what the guidelines are now. So it really is judged on individual cases and that is, I think, especially why flexibility has been helpful.

Mr. NECCIAI. How often do you think that occurs?

Dr. FEDORKOVA. Which case?

Mr. NECCIAI. In which they are flagged and they go over?

Dr. FEDORKOVA. I don't have the numbers in terms of the frequency. I am sure that varies greatly from year to year depending on emerging technologies and new research areas. You know, we do sometimes see clusters of applications coming in in the hot topic areas, so that is hard to say. But I would be happy to look into that and provide anything for the record.

Mr. NECCIAI. Do you think it is unreasonable, to hear what Kevin was saying, in order to not reduce the amount of awards that would be issued if there are those type of "jumbo" type of awards, to have a review process through SBA or a review process through NIH?

Dr. FEDORKOVA. Well, and I think that that does happen to some extent already, really. If there are any extraneous circumstances, we do go to the SBA and that is where the process, I think, is already in place to address those kinds of scenarios already. So again, I think it would have to be carefully considered, what additional checkpoints we need to reduce flexibility or where the need arises to reduce flexibility.

Ms. WHEELER. Before we go on to Dr. Wessner, Cheryl, your GAO study looked at DOD and NIH for awards that exceed the guidelines.

Ms. WILLIAMS. Yes.

Ms. WHEELER. And so I don't know if I am on the right page 33. Do you want to tell us how often NIH exceeds the guidelines?

Ms. WILLIAMS. I don't have the specific numbers in front of me as you do, but we did find that awards exceeding the guidelines were more frequent at NIH and they accounted for a larger proportion of the SBIR dollars than was the case at DOD.

Ms. WHEELER. If I am looking at this top thing, it says in 2004, they exceeded it 19 percent of the time—

Ms. WILLIAMS. That sounds right.

Ms. WHEELER. And then at DOD, if I look at this, it was two and one percent, basically. So there was a difference.

Ms. WILLIAMS. Yes.

Ms. WHEELER. Okay. Thank you.

Dr. Wessner.

Dr. WESSNER. Well, thank you. I think there are several issues here that are worth looking at. Just on your last point, my understanding is that NIH exceeds the awards almost all the time, and that is because they have adjusted the awards for inflation. Their average awards, I think, are 150K in the Phase One, and that is good. It should be. So we would strongly endorse, as we do on the record, in raising the ceiling. We recommend \$150,000 and the \$1 million caps.

I think if I could suggest, Ms. Wheeler, an alternative, I think the awards—the legislation should call for the awards to be readjusted with inflation. The SBA has the power to do this and has been derelict in not readjusting the awards. So the problem is not to blame the agencies for adjusting to the realities of the marketplace but to insist that the SBA do this and we not do this on an eight-year or a ten-year cycle. I mean, that makes no sense at all if you want to fund current research.

So first, we strongly endorse raising the ceiling and we strongly endorse having this as a regular nearly automatic process, at least a regular report accounting for inflation, and it might be even more important, because in medical science, inflation has far outstripped the inflation across the country.

The second point that we would like to stress is the flexibility. One of the key findings of the National Academy study was that the virtue—and I would like to respectfully point out that the two largest agencies in the program are asking that that flexibility be retained. We are on record as arguing that if the scientists at NIH feel that there is an award that would help address cervical cancer, that they should be allowed to put the money in that that they need to do so. The current process calls for SBA approval of those larger awards. They have to get permission, and that should be given more meaning with perhaps a more robust SBA looking at it.

The Academy report also called for these large awards. We did not condemn the awards. We welcome them. But they should be defined and defended and evaluated. What are you trying to do? Why do you need to make more money available? And have some metrics for what you are seeking to achieve. So letting them do what they think they need to do is the hallmark of—and this gets back also to integrating the program in the acquisition process or taking advantage of scientific opportunity.

With respect to the disadvantaged regions—forgive me, but these are separate issues—the GAO report in 1999, which I have always found is both accurate and funny, is that the best ways to achieve success in a basketball game is to shoot and the best way of getting accepted in the SBIR program is to apply, and that the regions that

are not applying don't get many awards. There is some logic there, I would respectfully say.

Ms. WHEELER. Which we—we address that correlation that GAO found.

Ms. WILLIAMS. And lastly, to close, if we are looking for more money in areas that are not having a high success rate, then I think the outreach programs, the possibility of State levels and perhaps matching Federal funds to facilitate applications makes more sense than trying to freeze the top of the quantity of any particular award.

Ms. WHEELER. Okay. And just so everyone is clear, that right now, SBA has the authority to adjust the awards for inflation every five years. The foundation for our bill moves that from five years to three years, which is what the committee voted for last year. So I think—would that address what you are talking about, to keep up with the pace and the cost and the size of awards? You were saying, let them regularly update it, and we have now made it more often.

Dr. WESSNER. Well, that is a very positive step. The key thing, I think, is to get some data on the costs of research, and that is available. That doesn't require a major study. And then evaluate that on a regular basis.

I think this type of flexibility and regular updating is particularly important if you accept our first intervention, which is that the program should be extended for a long period of time. So if you are going to extend, then you have got to build in lots of flexibility and regular updating.

Ms. WHEELER. Okay. Cheryl, did you want to add to that?

Ms. WILLIAMS. No. I just—we did hear from the agencies that there needed to be some increases to keep pace with inflation. But also, as you pointed out, for the awards in excess of the guidelines, at NIH, they consume 70 percent of the SBIR dollars compared to 23 percent for Department of Defense. Those do need to be evaluated individually.

Ms. WHEELER. And where were they concentrated? Weren't they concentrated in certain States?

Ms. WILLIAMS. We found that ten States accounted for the bulk of the awards made by both agencies, although there were slightly different States for each of the agencies. We found that the ten States accounted for about 75 percent of NIH awards that went to firms that had received venture capital investment and about 70 percent of the DOD awards that went to firms that had received venture capital. And California and Massachusetts together accounted for about a third of all of the applications, as well as all of the awards.

Ms. WHEELER. Okay. Thank you.

Kathy, did you want to make a comment on the size of the awards?

Ms. WYATT. The main thing I was going to ask about is that when we are talking about the size of the award, I do think it is very valuable to be making this adjustment that is—or an indication of the need to increase award amounts because of inflation, but then the total set-aside to me is something that is very important in this question, also, because I know from our perspective, we

would like to see that the number of opportunities remain large and that many people have the opportunity to submit applications and compete in this highly competitive program.

So from a small rural State's perspective that is developing this sort of opportunity, we would like to see the amount of award increased, but we would like to see a corresponding increase in the set-asides so that the number of opportunities is not diminished when the size of those awards go up.

Ms. WHEELER. Thank you. I am glad you mentioned that. For those who want to be reminded, the committee voted last year to increase the allocation for SBIR from 2.5 percent to five percent incrementally over ten years and to double STTR from 0.3 to 0.6 incrementally over years. And at DOD and Department of Energy, those were dedicated to only furthering tech transition, not for Phase One and Phase Two, and the exception was that NIH would not get any increase. So we appreciate your saying that that is important to your State.

Dr. McGarrity, did you want to make a statement?

Dr. MCGARRITY. Yes. I spent a significant part of my career in academic research. In fact, I had to generate my salary and my laboratory's operation through NIH grants. I also participated in a number of committees at NIH, including study sections which actually evaluate grant applications that are coming in, both from academic scientists and SBIRs, and first, I would say, that is an outstanding system of peer review. In fact, it may be unmatched, or I would challenge anyone to match it around the world.

So these people who are reviewing the grants, these are, for the most part, academic scientists from across the country. They are top-tier scientists. And NIH, I would assume, has literally hundreds of these scientists doing the peer review. I think they do an outstanding job, and if you look at their qualifications, these are scientists who conduct research as a major part of their livelihood. They know the cost of doing research. They know what it costs to buy a machine or employ a young Ph.D. or M.D.

So when I look at the possibilities of saying, well, should we put that authorization in the hands of NIH or do it from a much higher level, I would say I think NIH does an outstanding job of administering competitive grants and competitive grant reviews, and I would think that it is much better to empower an agency like NIH to look at these on a case-by-case basis by scientists who do everyday research and say, all right, this is justified that we are going over two percent, five percent, ten percent. And I would feel much more comfortable, and I think the system is better served by having an empowerment of the agency rather than saying, we are going to dictate this to you from Capitol Hill or the Small Business authorization. Let the people who do this on a full-time basis empower them to do their job and I think the public will be rewarded and I think the SBIR dollars will be wisely spent.

Ms. WHEELER. Thank you.

Kunal, did you want to add to that?

Mr. MEHRA. Yes. I just want to—first of all, I strongly agree with both Ms. Oliver and Dr. Wessner. I think that the award size should be increased to the proposed 150K and \$1 million limit for Phase Twos. Just to provide some data, in the last five years alone,

my company has seen about a 30 percent increase in salaries, pretty much across the board, for existing employees when you look at the cost of hiring a fresh Ph.D. out of MIT or some of the other universities where we recruit heavily. I have actually had one or two very passionate employees come and offer to take salary cuts so that they could finish the work underneath the size of a small Phase One. So I hope we could avoid that.

But the second point that I really do want to touch upon is I believe that it is integral to increase the size of the set-aside——

Ms. WHEELER. Which we call the allocation. We think set-aside is a dirty word in the small business community.

[Laughter.]

Mr. MEHRA. I agree. Increase——

Ms. WHEELER. We think that is a cultural issue at the agencies who refer to this as a tax, a set-aside. So we say allocation. These are competed things. They are not handouts.

Mr. MEHRA. I will put soap in my mouth for using a dirty word. I do apologize.

[Laughter.]

I strongly support increasing the allocation of the program, both as a taxpayer and as a small business owner, and let me describe why. I mean, right now, the program is tremendous at fostering innovation, and there are many successes of transitions of technology out of the SBIR program into the acquisition cycle. But it is fundamentally undercapitalized. When you look at the pharmaceutical industry, which I think is probably the most successful in terms of fostering innovation all the way from true experimentation through to product development, when you look at the way they manage their pipeline, there is a continuous steady increase in funding as products reach more maturity.

I can speak to the Department of Defense, where I have the most experience. It is very well recognized that there exists this valley of death. So as a taxpayer, I look at it and say we are investing an incredible amount of money in the SBIR program. We are fostering a lot of innovation. But then we are failing to put the investment after the Phase Two to actually really develop the technology, turn it into a prototype that can then transition over to the acquisition system.

The commercialization pilot programs that have been enacted, I think are probably one of the best pieces of legislation to happen to the SBIR program in the last ten years. My company is participating in both the Air Force and the Navy programs and I think that they have both been tremendous in terms of helping us increase our chances for success to actually turn our research business into a viable business selling product to the government and truly creating value for the taxpayer and for the military.

Ms. WHEELER. Wonderful. Thank you for that.

Any other comments before we move on to the next? Erik, did you have any? Oh, I am sorry. Go ahead, Jim.

Mr. BARRY. I just wanted to share that we are also very supportive of increasing the recommended award amounts to the levels that have been mentioned, 150 and one million, and the allocation adjustment, as well. I think the program is very, very important and deserves more funding, and our experience with the CPP pro-

gram has also been very valuable in helping us to transition several different technologies towards commercialization.

Ms. WHEELER. Wonderful. Thank you for that feedback.

I am sorry, Subash? Oh, okay. We are running over time. Subash, do you want to make one more comment? No, no, go ahead and then we will go to Jere. Go ahead.

Mr. IYER. Great. I think there are three issues in this that we wanted to just quickly weigh in on. The first is around the size of the allocation. In the National Academy study, it was very clear, and they made it clear, that the SBIR program could handle more funding and still do it effectively. Whether that is through an increase in overall Federal R&D budgets or through other means, we believe that it is an important program that has had a long history of success that should have increased funding associated with it.

The second point is around the actual award size, and that is something that the SBA is actually actively looking into, as well, to figure out what the best option is on the award size.

The third issue was the issue around the caps, and I think that here, there are two principles that we need to make sure that we are balancing. One is the flexibility afforded to the program agencies. This has been a hallmark of the SBIR program and it is something that we would like to see continued in reauthorization.

The second principle is that any SBIR program or agency needs to have adequate oversight, and that is something that the SBA is committed to and the administration is committed to. So I just wanted to weigh in on those three areas.

Ms. WHEELER. Thank you. Just FYI on that oversight, part of the reason we put that in the bill is because they weren't reporting to the SBA, which is why we found a data insufficiency on these awards. There was nothing to say what the increases had gone for. They weren't reporting them. And so we agree with you. But it was to help SBA that that provision was in there.

Mr. IYER. We believe in oversight, and I think it is a priority for the new Administrator as well as the SBA across the board, so that is something that we are looking into, as well.

Ms. WHEELER. Thank you.

Jere.

Mr. GLOVER. Yes. Large awards, and NIH has made some in the \$8 million range, a million a year for seven or eight years, those do crowd out significantly other technologies. There has not been an evaluation as to whether these large awards actually result in more commercialization, more success, better science. That clearly needs to be monitored. There needs to be a gated process for larger awards in excess of the amount so that somebody outside the immediate chain reviews that. I think SBA has done a good job of that when asked to do so. My understanding is they have never turned one down. But the process of preparing the application, looking at it and justifying it, is a very important process.

Crowding out is a real concern. This program was always designed to fund the earliest stage research. It has been remarkably successful. Allowing agencies discretion to change that to where a few companies get a lot of money and lots of States don't get any money is a real problem. I like SBA's involvement and I think SBTC is in support of that.

Ms. WHEELER. Thank you.

Okay, now we will move on to the next topic, which is maintaining the flexibility, which has been mentioned many times, of the program and preserving the basic program structure. This was a recommendation of the National Academies, National Research Council. There have been requests to change the basic structure and bypass Phase One.

NRC, I think, has recommended against this, and so I would like to first ask the NRC why they concluded that Congress should not allow agencies to bypass Phase One. And if you want to have a little time to think about it, since you have moved on to studies—

Dr. WESSNER. Oh, no. Trust me, I have had to think about it—

Ms. WHEELER [continuing]. We can ask the next question and come back. Okay.

Ms. WILLIAMS. The study has occupied us, as you know, for a number of years. The great virtue of this program, as the celebrated venture capitalist Burt McMurtry, who helped fund a start-up called Microsoft—some of you may know the company—argues that the great virtue of the program is it is letting 100 flowers bloom. So we think that the Phase One gate where you offer the prospect of proof of principle, as Jere Glover was just arguing, to a large number of companies is a great virtue.

The fact that it is also highly competitive, however, that this is not an automatic process and that 15 to 20 percent of the companies are those that succeed in Phase One is equally important.

We also felt—the committee felt that the fact that there was flexibility for NIH, that if you want to make a larger Phase One award, you can do so—one of the arguments for dropping Phase One is, well, if you know how to do this, you should be able to just proceed quickly. Well, if they have that flexibility, then they can make a larger Phase One and push that research process on fast. We very much associate ourselves with this requirement that this be justified and defended to the SBA. And we also in our report pushed, again to repeat, NIH should be able to document what they are trying to achieve and what appropriate metrics should be there.

So we see no—we have a 25-year history now of a program with remarkable success based on a double-gated innovation awards system and we see no reason to drop that, particularly if there is flexibility when they want to move quickly to pull something across, something forward faster. There is no compelling reason to make—you know, there is an irony. Some of the things that we have heard talked about, which involve one-time, very large awards to single companies, we support that type of program. We used to call it the ATP program and we think it is an excellent program. It is just not the SBIR program.

Ms. WHEELER. Would anybody else like to weigh in on bypassing the Phase One? Kunal.

Mr. MEHRA. Yes. I just want to say I also think that bypassing Phase One is not a good idea. I think the hallmark of the program is competition. That is what gives it so much credibility. That, I think, is also crucial to providing the sole source authority for Phase Three and beyond, because it has already been competed

twice. So I see going straight to a Phase Two as being detrimental to the integrity of the program.

However, I do think we should make attempts to accelerate the process of going from Phase One to Phase Two, and I think in order to enable that, the agencies need more administrative support from the program, and I would certainly favor that as a—if it is linked to increasing the size of the allocation funding for the program. I think that is also critical.

Ms. WHEELER. Thank you.

Mr. NECCIAI. So in theory, by skipping Phase One, government would be funding potentially poorer science because it hasn't had that extra hurdle of peer review?

Mr. MEHRA. That is exactly right. That is exactly right. That is exactly the way I view it.

Mr. NECCIAI. Thank you.

Ms. WHEELER. Lenka.

Dr. FEDORKOVA. Yes, just wanted to comment on the fact that there are certainly circumstances where we have heard from companies who are first time applying to the SBIR, at either agency, but in our case, companies that feel they have generated certain preliminary data, which is not necessarily required for Phase One applicants. But let us assume they do have that kind of data. Right now, under the mechanism, they can't jump into Phase Two.

While that is not happening and we don't have the ability to do that, I think our agency has in a creative way responded by creating the Fast Track program, which is a one-time application for a company that can demonstrate. Their data will be judged and scored. So if they are going to submit any data, it has to hold water. If they do that, they can then just apply an application and proceed through Phase One and directly into Phase Two once they meet certain milestones, and that has proved to be valuable for those who need to move in an expedited time line.

The fact that they don't have to reapply for Phase Two—again, there is no guarantee they will be able to move there. But if they meet the milestones and can, they don't have to wait or waste six to nine months applying, waiting for review, and hearing back from the agency. So saving six to nine months can sometimes mean a difference between sustaining a project or keeping staff on board or not.

So that has been one way that we have dealt with that. But I think certainly—I am not familiar with all the discussion surrounding skipping Phase One, but I think we are not in support of that and that will certainly be in a minority of cases, and in those cases, we suggest to companies, maybe you should think about the fast track.

Ms. WHEELER. But again, it is not automatic that they get a Phase Two.

Dr. FEDORKOVA. No.

Ms. WHEELER. It is just that they have the potential.

Dr. FEDORKOVA. The only elimination is of the second application to a Phase Two, which otherwise happened for someone just applying for Phase Two. It is just a one-time application for the entire program. The Phase One and Phase Two are subject to the same

criteria, same requirements, same award levels, and everything else applies. It is just a shortened review period.

Mr. NECCIAI. Is there just one review, or is it still two?

Dr. FEDORKOVA. No. There is one review. There is one review. A final report at the completion of Phase One has to be compiled and specific milestones have to be met. So again, it is reviewed by the council which has on its review board members from the small business community or from the for-profit sector, and then they get a go or no go decision.

Ms. WHEELER. Thank you.

Do you want to go ahead, Jim?

Mr. BARRY. I don't want to repeat what everyone else has said, but Creare is certainly in favor of maintaining the Phase One competition going forward. I think the program as constituted works very well.

Ms. WHEELER. Thank you. Anyone else?

[No response.]

Ms. WHEELER. So the next—there is a subset of that topic and that is the idea of preferences. In last year's bill, there was a section that encouraged applications for nanotechnology-related projects, and in the NRC's comprehensive report—Dr. Wessner, I hope I have this right—it directed agencies to give high priority to firms that do energy efficiency and renewal energy. And so there has been a lot of concern whether there should be preferences at all, and so my first question would be, are preferences consistent with the NRC's recommendations to preserve the flexibility of the programs for agencies instead of dictating priorities? Chuck, do you want to weigh in on that?

Dr. WESSNER. Yes, thank you. No, they are not. The risk that we describe in the report that is just coming out on the venture issue is the—and I think this is a serious risk to the program—is the Balkanization. You can—if you set up a program that—we encourage work with women and minorities, but if you start to set up a quota system, either implicit or direct, for minorities, for veterans, for disadvantaged regions, you can count the ways you can divide the program up and cripple it. It is successful because it is a highly competitive program based on scientific and technological and commercial merit and we need to maintain that open, competitive system.

I would just add, we do need to facilitate applications to the program. We do need to encourage States who are not active in the program to become more active. But this would be the wrong way to go.

Ms. WHEELER. In preferences. And so do the agencies—I know sometimes the agencies are opposed to these preferences. So for the agencies here, are there ways for you to focus on something that is a priority for the nation without having to do it legislatively? I mean, would you—

Dr. FEDORKOVA. The short answer is yes.

Ms. WHEELER. Would you come to us and say that you could not give a preference or a priority to a topic such as energy efficiency or renewable energy or nanotechnology or orphan diseases because it would be preferential? Is there a way for you to focus on that?

Dr. FEDORKOVA. No, and I guess it may be a choice of words. We speak in terms of research priority areas, and I think that those involved on review boards and those who are really involved with the research community and know what the emerging trends are and emerging areas are are very much aware, and we do have the flexibility in issuing requests for applications. We have many different kinds of mechanisms. So there are specific ways where we can issue more tailored, topically focused requests for applications to the research community, although the traditional way of funding at NIH is such that the community responds and submits ideas to us. So they are not looking for a match, which is different to some of the other agency missions. I think the core difference is that we are not a procurement-focused agency but are research-based, and so the way of science being so nimble and unpredictable.

But yes, we have mechanisms where if we feel we need to invest in a particular area, we can prioritize that, and depending on the institute, or broadly speaking across the NIH, if it is an interdisciplinary research area, multiple institutes can support a particular funding program. So I think at the moment energy, nanotechnology, those areas, we already do fund and everyone is really very excited about those areas. It is kind of the hot topic of the day, of the year. And we do correspond when we respond to the research community.

Chairman LANDRIEU. Okay. Thank you. Jere.

Mr. GLOVER. I think it is difficult for the Congress to predict what is going to be needed down the road. This is a multi-year process. Hot select topics, like energy efficiency now, that is great, nanotechnology. I think it is certainly nice to give guidance and suggestions.

What I remember doing when I was at SBA is we brought the Office of Science and Technology Policy in to meet with the Tibbetts Award winners and the program managers and tell us what they saw ten years out, 15 years out, and I remember them bringing up nanotechnology, which is something nobody knew anything about and nobody talked about, and now it is a huge topic. But they basically said, these are some areas we think are good. The agencies then took them back and worked on them. I don't think that picking those ideas today will be the right ones in four or five, eight years.

But the flexibility of—I think SBA should provide that role of bringing in the best scientists and then sharing that with the agencies and looking out, because if the program ever looks—and does what science and technology is today, they are missing the bet. The hot issue is going to be something that we don't think about in five years. So we need that flexibility to go down the road, but we certainly—locking the program into an area that may become less important in four or five years is the wrong thing for Congress to do.

Ms. WHEELER. So even if it were not in perpetuity and it were, say, three years or five years as a preference or a high priority or encouraging applications, SBTC would take the position that it is better not to legislate special topics?

Mr. GLOVER. I think that is correct.

Ms. WHEELER. Okay. Chuck, did you want to weigh in on that?

Dr. WESSNER. If I may, in two ways. One is we perhaps could get together on a sidebar conversation, but to the best of my knowledge and belief, in a very substantial number of volumes, we did not—we talked about the way the program can do these things. We did not recommend—unless I am mistaken, and I may be—that it be a specific—

Ms. WHEELER. I am probably wrong, so—

Dr. WESSNER. Well, no, not wrong. There are many things there and I just would like to—

Ms. WHEELER. I have this page 95, but we will talk about it afterward.

Dr. WESSNER. On which report?

Ms. WHEELER. Good point.

Dr. WESSNER. But more broadly, and that is why I took the mike and I appreciate the opportunity to reintervene, very quickly, in order to do things like in renewable energy, which we do think are important—I fully associate myself, by the way, with the flexibility and ability of agencies to identify these things.

Funding more research involving the National Laboratories and with the program, we have ARPA-E, which involves a substantial sum. If we want to do more work on renewable, then let us make sure that where we are putting new research funds, that this program is included.

It is also possible to think about—at least I hope it is possible to think about agencies increasing the funding of the program on a voluntary basis when you are trying to bring things forward quickly. I think the case of NIAID at the National Institutes after the 2001 attacks where they had a very open-ended question on bioterrorism and very positive response, very large numbers of responses from companies, is illustrative of how it can quickly adapt to a pressing national need without legislating.

Ms. WHEELER. Thank you.

Let us take a quick break. Let us take a five-minute break and then let us come back and we will just finish the rest of the agenda. Does that sound good?

[Recess.]

Ms. WHEELER. Hi. Could we get everyone to sit down and we will continue with the roundtable. Thank you.

Mr. INGE. I have been asked by some people in the back to remind everyone to speak into the microphones.

Ms. WHEELER. Okay. So our next topic is outreach and technical and commercialization assistance. Part of the discussion today is the GAO report that was referenced earlier in the late 1980s or early 1990s that looked at geographic distribution of SBIR projects around the country and found that there was a correlation between awards to applications. In States where there were more applications, they had higher awards. And so to increase participation in low-activity States, Senator Bond in 1990 created the Federal and State Technology Program to give matching grants to States to raise awareness of the programs and increase those that apply and improve the quality of their applications to win awards.

Part of the foundation for this year's bill will be to reauthorize the Fast and Rural Outreach programs and to increase the authorization amounts that go to those programs, and I wanted to ask if

participants could speak to these programs and how they help their States or their businesses better compete. Kathy, did you want to go ahead and speak to this?

Ms. WYATT. Yes, I will be glad to do that. First of all, I would like to say that I really appreciate the fact that this legislation is recognizing the difficulties that those small and emerging firms in more rural and isolated or underserved areas have in trying to compete in this program. For people who come from metropolitan areas and very resource-rich environments, they may not realize how limited the types of management expertise and even access to capital, or things that you take for granted like having a patent attorney within your community that you can work with in order to advance these types of technology discoveries and businesses that we are working with.

So it is very critically important that we have this program to help people overcome those types of obstacles and I can give some examples of the ways that we have used these programs effectively in doing training events and even bringing in outside resources to help our businesses develop their capacity. And just by virtue of having this event, sometimes the networking that takes place and the communication and connections that are made can be very helpful.

For instance, we hosted a forum to provide—help increase awareness and provide information about the SBIR and STTR programs and one of our researchers actually met up with a business interest that was there to learn more about the program and found that they shared a common interest and a license agreement actually occurred as a result of that particular event taking place.

When you look at the fact that we have used these programs to the best of our ability, although we have had limited funding through this program to offer events around the entire State, we have seen tremendous growth. Within a five-year period, we have gone from having no SBIR participation to currently having 19— or having received 19 awards in the last five years and eight different entities participating in the program. And of those achievements, we do have one company that is a viable start-up that you spoke about, which is NiFTy Television that has grown in the last few years to employ 40 individuals, and not only do they employ a good number of people, they are employing them in higher wage-earning jobs than what we would typically see in our community and we are seeing them also grow in the number of customers that they have and strengthen as a business.

We also are seeing that we are not only increasing the number of awards, but these kinds of initiatives partnered with some of the State programs that are coming forward, and just the very solid research capabilities that are available at our university, are helping us to attract companies from outside locations, not so much that they are coming and relocating in our community, but they are looking at and actually opening satellite offices in a small community that has a population of only 20,000 people, and without this kind of incentive or the opportunity to attract them to this area, they would never have even considered us as an option for a business location.

So I just cannot—I mean, I could go on forever about the things that I consider to be valuable about this program and I consider it to be a very important component of the SBIR–STTR program and an extremely important component of this currently proposed legislation.

Ms. WHEELER. Part of what the legislation does is reduce the matching requirement for States that are rural and States that are in the lowest 18 or 19—of the 18 or 19 lowest-participation States. Has the matching requirement ever been a problem? Should there be a matching requirement? I just don't know what Louisiana—if they have had a hard time making their match.

Ms. WYATT. It would be very—I think it would be extremely difficult for us to make a one-to-one match. I think it is very helpful that there is a reduced matching requirement. I do think that the State is committed to innovation and that they are willing to put forward some money to try and help advance these types of programs, but it would be very hard for us to be able to provide that one-to-one match. So the reduced opportunity of a 35 to 50 percent match is extremely important for us to be able to take full advantage of this program.

Ms. WHEELER. Great. Thank you.

Jere, did you want to weigh in on that?

Mr. GLOVER. I think one of the most disturbing trends is the number of new firms applying for SBIR first the time is going down, and that happens concurrently with the lost of Fast and Rural Outreach funds and the diminished importance and role of the national conferences that have been held. In the old days, meaning two or three years ago, the Department of Defense and NSF funded the national conferences. They have gotten out of that program.

But Rural Outreach, and I think you may need to waive any match the first year to get them back in place very quickly because there is a funding cycle in the States. Often, the legislatures don't often meet a year or two. If you require matching, you may not have people coming in quickly, and those programs seem to do so well and be so good in the States that you may need to do something very quickly for one year or two years until you get into the State funding cycle.

But I would encourage that some administrative expenses be allocated. I think the National Academy study recommended that the percentage be increased by 0.3 percent or something like that. So if it is 2.5, make it 2.53. If it is 3.5, make it 3.53. That is the best way to do that. But some of that money clearly should go to not only administer the program within the agencies, but also for outreach, and the agencies should be required to use some of that money to help get the message out and get new companies and keep new companies applying.

Ms. WHEELER. And I think you are referencing what Kunal did earlier and saying that right now, agencies are not allowed to use any portion of their allocation for administering the program, such as you said, outreach, training, et cetera. That is not true outreach. And so they should be able to use a portion of it, but only if it is tied to an increase in the—

Mr. GLOVER. No, I think it is so important that I would prefer it be tied to an increase. But if it can't be, this program is successful because it covers all 50 States and we have winners everywhere. But without the reach and without Fast and Rural Outreach and our partners in the various States, we are not going to continue that good success. It was a good idea when it was put in. Maybe you can come up with a better way to do it, but I would clearly at any cost make sure that we do Fast and Rural Outreach and we do provide some additional funds for that, obviously monitoring it and making sure that the agencies don't just simply replace work they are doing already and do new things is important.

But I would encourage the committee to go forward and I think our membership certainly supports that. We didn't at first, but after we thought about it and talked to the agency people, we are comfortable that that should happen. But we also think it needs to be focused to getting new companies into the program.

Ms. WHEELER. So if there was not an increase in the allocation but the agencies were allowed to use three percent of their funds, at DOD, your annual SBIR budget is about \$600 million, is that right?

Mr. GLOVER. No—

Ms. WHEELER. I am sorry.

Ms. OLIVER. One-point-six.

Ms. WHEELER. One-point-six. Sorry.

Ms. OLIVER. That is correct, 1.6.

Ms. WHEELER. Okay. So you would advocate using three percent of those dollars, even without an increase?

Mr. GLOVER. I think somewhere between one and three percent. If it is an increase, then I think the three percent number works. If it is no increase, then maybe something less than that. But it is too important to have the agency programs administered properly and for there to be outreach. We really do have to change that, and the committee authorizing it but it not being appropriated funds for Rural Outreach and the Fast programs would be a mistake. We can't not get new companies all over the whole country educated about the program and participating in the program. The beauty of it is 25, 30 percent of companies applying for these awards every year are brand new to the program and we have got to keep generating the next generation of new technology companies.

Ms. WHEELER. Well, the Fast appropriation would be separate than taking it—it wouldn't come out of the allocation. I guess the concern would be taking so much money away from awards without an increase in the allocation.

Mr. GLOVER. I think we did support that in the CPP program, and as long as it is used wisely and it is monitored by SBA and the Congress, I think we have to be able to realize this program has grown from—grown significantly, fourfold over the last ten or 15 years. SBA has virtually no personnel assigned to this task. While the program has quadrupled, the personnel have gone down by two-thirds. There needs to be more administration. The same thing goes for the agencies. I think you are going to have to administer the program and have enough people in it and add enough people to make it work well.

Ms. WHEELER. Okay. Thank you.

I am sorry, go ahead.

Mr. NECCIAI. I just wanted just to clarify real quickly, and just a yes or no answer from DOD and NIH. I am presuming that administrative fees for you would be favorable, correct?

Ms. OLIVER. Yes.

Dr. FEDORKOVA. Yes.

Mr. NECCIAI. Okay. I think—and Jere was mentioning—what we are trying to clarify is out of the 2.5 percent, if it came out of the 2.5 percent without increasing that, is there anyone here that would be in favor of keeping it, as Jere had mentioned, keeping it within the 2.5 percent, which has the potential to decrease the opportunities or the awards that are going out otherwise? In other words, you are taking a chunk out of the 2.5 percent versus increasing it, which is something that we were advocating in the past. If you increase 2.5 percent to a higher percentage and then take it out of that percent, because you are increasing the pie, which, as we were talking about before, increasing the pie total, there would be less of an effect. Is there anyone here that would be in favor of that?

Ms. OLIVER. The Department of Defense would be.

Mr. NECCIAI. Okay.

Ms. OLIVER. Let me make sure I am clear about this. The Department of Defense believes that the program could be so much improved if we had—if we weren't an afterthought for most of the work that is done in connection with the SBIR program. If when we had reviews, when we find scientists and persuade them to look at the submissions, if it weren't an "other duty as assigned," if we were able to be moved up in their priority, which that is just what money does, we think the program could be—the quality of the program could be improved so much with—outreach is a good example.

You know, the Department of Defense quit doing those outreach programs, not because we didn't think they were a good idea, but we have to have the program run or there is no point at all in doing outreach. So yes, the Department of Defense would be in favor of using up to three percent of the current allocation—if the allocation doesn't change at all, we would still be in favor. We think it, for the long run, would benefit the program.

Ms. WHEELER. Why would DOD oppose increasing the allocation by an equivalent amount to give you the funds that you are saying would be so helpful?

Ms. OLIVER. Now you understand that—

Ms. WHEELER. You can't say it.

Ms. OLIVER. What I think—well, no. What I—the Department of Defense has to work out its positions and come to one answer instead of this piece of the Department of Defense thinks this and the other one thinks something else. We are surely not there. In fact, it has not been a question asked. In this administration, that question has not been asked. That hasn't gone through any of that clearance process. The last time that question went through the clearance process, although it was a prior administration, Department of Defense as a whole did not favor increasing the allocation.

Basically, the—I mean, one way to look at it, at least, is the program managers felt that what they were intending to do with those program funds moved their projects forward more fully than using—than adding that money to the existing SBIR program. And this goes right back to the difficult communication problem.

Ms. WHEELER. Well, I guess that I will just send this out there, and I know it has been said many times, but we will put it on the record again. The problem is, as was mentioned at the roundtable in 2007—Mike Skolanti [ph.] brought this up—we have all these ideas to increase the grant sizes, to possibly let other businesses in, but we are not increasing the allocation. The agencies want administrative funds. And so at some point, there has to be a compromise to say, how are we doing all of this without undermining the whole mission of this program, which is to promote innovation? And so it seems it would be a very small task for the administration to increase the allocation by an amount to give the agencies what they think would be so powerful to get these innovations.

So I know you can't comment and I appreciate that you said as much as you did, but I guess that would be the message, and for Subash, too, who I know is involved in these, and Lenka.

Okay, Kunal, you go ahead, and then we will turn to Lenka.

Mr. MEHRA. Well, actually, I think you very eloquently stated the point that I was going to make, which is just I think all these points are extremely valid and it just underscores the importance of increasing the size of the allocation. I support increasing the award sizes. I support using part of the budget for administrative fees. I support CBP. I support the commercialization assistance programs. But when you add all these things up, the net effect, just when you do the math, is you are going to decrease the volume of awards by 40 or 50 percent at a time where the country is in the worst recession since the 1920s.

It is a well-documented fact—I am sure Dr. Wessner could speak to this more eloquently than I can—that small business is always the growth of innovation that helps the country recover from these types of crises. It would just seem counterintuitive to me to not increase the allocation, and I just think we are at a turning point here. We have the opportunity with a small increase in the size of the allocation to have a disproportionate effect on the value of the program and the effectiveness of the program because we understand so well where the weak points are.

Ms. WHEELER. Thank you.

Lenka, did you want to follow on?

Dr. FEDORKOVA. Yes. I just wanted to—back to the question of the Fast. We also feel it is a very valuable program where you would have the States come to the SBA and be able to support, you know, whether it is an application where it can cost \$5,000, \$10,000 for a company, they may not have those kinds of administrative funds available. So I think that is a very good effort, to try to revive that program. We would definitely like to see that happen again and I think it has affected some start-ups that haven't been able to receive that kind of support.

On the size of the allocations, I would similarly, like DOD, say that that has to be carefully revisited. I know you are already familiar with some of the reasons from the previous administration

from the NIH's perspective related to the agency's flat budget as part of the concerns about some of the proposals to increase. We do, however, feel that some of the National Academy's recommendation to, I think, 0.3 percent allocation from the allocation would be of great help.

We are very committed as an agency to doing outreach, really, since I joined the office. Just a few months ago, I have myself been on the road really every few weeks and we have—at least 50 percent of those have been to minority, women-owned business types of conferences in New Jersey, or we will have some local events. We will try to partner also with States' Business Development Departments, see how we can reach out to the local communities, make sure we can do some local things where travel costs are not entailed. That seems to be a big barrier for companies to come out to some of our events.

I wanted to also mention that we are going to be holding in Omaha, Nebraska, at the end of this month the NIH Annual SBIR–STTR Conference, so we are going out to the middle land and we will try to reach out to the area small businesses.

But also to the point of not having certainty from year to year about what kinds of funds we have available from our agency to do the outreach, whether it is generating materials to support the outreach and communicate necessary information to the community, it has been really uncertain from year to year and I think we need to address that accordingly. So the Academy's recommendation, I think, is welcomed.

Ms. WHEELER. Okay. Thank you.

Dr. WESSNER. Did you want to comment?

Dr. WESSNER. Yes. I would like to associate myself with Mr. Glover's remarks about the importance of the outreach activities. We did not, I would like to stress, in this particular capacity with respect to the Fast program, we did not examine that, but our view is—our unofficial view is that it is a positive program that needs—I am just concerned, though, that we not go back to the size that it was. Federal programs of \$2 million strike me as inherently—

Ms. WHEELER. I think we take it up to five.

Dr. WESSNER. Could I hear ten?

[Laughter.]

Ms. WHEELER. I am sure you could get support for that.

Dr. WESSNER. We have—

Ms. WHEELER. It may be ten, actually. It may be ten.

Dr. WESSNER. Remember "Charlie Wilson's War"?

[Laughter.]

Dr. WESSNER. But there is an important point there. The critical mass in these programs matters, and if we are actually going to do outreach, we don't want it to be an appearance of outreach but actually something that can fund an ongoing effort and draw on the ingenuity of our nation's entrepreneurs in these disadvantaged States.

A second point which is equally important, and this is within the program, I would almost plead with you, we really need to find some way—you find the way of getting management funds. At \$300 million, it may not have mattered, or 1.2, but at 2.5 going towards three billion, not providing funds—if you can, working with the

Armed Services Committee, convince them to instruct the departments to make available funding on the level of the Navy—I mean, it is almost mind boggling. We have an example of best practice, but without quoting any particular service, when we say that the Navy does it well, the reaction seems to be, what is your point? It works well if you provide these additional funds and the effective management that is characterized in that program. So how can we emulate that? And I would count on your ingenuity to find some way of doing that.

We came up with the 0.3 simply because we didn't think it should come from the program or would come from the program, and we have been waiting 25 years for the agencies to step forward and be helpful, so that was the compromise we came with. But the best way would be for the agencies to make the money available to run an important program effectively. Thank you.

Ms. WHEELER. Thank you. Any other comments on that one? No? [No response.]

Ms. WHEELER. Okay. Now we will turn to the next topic, which is the venture capital issue. As some of you may know, in last year's bill, there was a compromise to allow up to 18 percent of the SBIR dollars to go to firms that are majority owned and controlled by multiple venture capital firms, and at the other agencies, eight percent of the SBIR dollars could go to these entities. To give us some data to go on to come up with compromise, we relied on the GAO. They had a study that looked at the two years before a clarification and the two years after, and I know that some people don't use the word "clarification." Some use the word "change."

So what we will do is we will turn to GAO to lay out what we see—the facts of the ownership eligibility and then to talk about what the mission was of their study and their conclusions. I know you couldn't really make recommendations, but you had findings. And then we will do that for the National Research Council, too. Do you want to go ahead, Cheryl?

Ms. WILLIAMS. Certainly. We were asked by this committee to look at the extent to which SBIR awards at DOD and NIH were going to firms that had received venture capital funding, and more to the extent of what changes, if any, had occurred before and after the 2002 clarification by the Small Business Administration. We talked to agency officials and we reviewed documentation from the agencies—NIH, DOD, and SBA—regarding the eligibility criterion of ownership.

In our view, we believe that it was not a change but it was a clarification. Part of the documentation that we reviewed was also decisions from the SBA's Office of Hearings and Appeals. Typically, when SBA has made a change, it is subjected to the rulemaking process in which there is public comment and notification. So we believe that it was a clarification, not a change.

In terms of what we found, we found that since 2002 when SBA made the clarification, that a larger number of awards went to firms that had received venture capital funding, that the awards were larger at NIH, and that in the aggregate, firms that had received venture capital funding received a larger share of the SBIR dollars at both agencies.

We found that over the time period—and we selected for our study the time period that was evenly divided by that clarification because we felt that awards made in fiscal years 2003 and 2004 could reflect changes from awards made in fiscal year 2001 and 2002 that could be related to the clarification and to the agency's efforts to inform potential applicants about that clarification.

And we found that since—over the four years that we looked at, that an increasing share of the SBIR dollars at each agency was devoted to firms that had received venture capital funding. More specifically, at NIH, in fiscal year 2001 and 2002, firms that had received venture capital funding accounted for 14 percent of the SBIR dollars. That increased to 20 percent in fiscal year 2003 and 22 percent in fiscal year 2004.

We found the same trend at the Department of Defense, but to a lesser extent. There were five awards to firms that had received venture capital, accounting for five percent of the funds that DOD awarded in fiscal year 2001 and increased to seven percent for fiscal years 2002, 2003, and 2004.

Ms. WHEELER. And we had asked GAO to also look at the geography of these, the distribution. Were they concentrated in certain places?

Ms. WILLIAMS. Yes, they were concentrated and ten States accounted for the bulk of the awards made to firms with venture capital funding. Specifically, California and Massachusetts were responsible for overall about a third of both the funds and the—the applications and the awards. Most all of the other States accounted for a very small percent. I think approximately maybe only four States for NIH awards had more than five percent and maybe six States at DOD had more than five percent.

Ms. WHEELER. And why did GAO conclude that it was a change versus—I mean, why did they conclude it was a clarification versus a change?

Ms. WILLIAMS. Well, largely, this is what the agency officials told us. I mean, for example, at NIH, as the process unfolds and as NIH is making decisions regarding awarding, making awards, they attempt to verify the information that applicants provide to them, and as part of that process, they were focusing prior to 2002 on the number of employees as an ownership criterion, or as an eligibility criterion. After the SBA clarification, they focused more on ownership. So the agencies were telling us there hadn't been a change. We looked at the Office of Hearing and Appeals Records. Their conclusion was that there hasn't been a change. And the SBA officials told us there hadn't been a change.

About this same time, there was a change in eligibility criterion related to whether or not you could be owned by another company and that was subjected to the rulemaking process and they did receive comments on that before making a decision, and we felt that that would have been—had there been a change, they would have subjected that change to the similar process.

Ms. WHEELER. That was the subsidiary rule?

Ms. WILLIAMS. Subsidiary, precisely.

Ms. WHEELER. Okay.

Mr. NECCIAI. Ms. Williams, is it GAO's opinion that majority-owned venture capital firms were not permitted in prior to the ruling as well as obviously after the ruling?

Ms. WILLIAMS. Based on the SBA criterion, that is exactly our position, that they should not have been participating in the program before and they should not have been afterwards.

Mr. NECCIAI. Hence the term clarification, not change?

Ms. WILLIAMS. Precisely.

Ms. WHEELER. And again, that came from interviews also with the NIH officials—

Ms. WILLIAMS. NIH, DOD, and SBA.

Ms. WHEELER. Okay.

Mr. INGE. Is there a chance some firms were participating before 2002 or 2003?

Ms. WILLIAMS. Certainly.

Mr. INGE. And why would that be the case?

Ms. WILLIAMS. Either information did not appear to—was not made available to the agency officials. Perhaps firms misinterpreted the information about eligibility criteria. It could be for any reason. We didn't conduct any interviews with people. And at the time that we did our review, the agencies weren't collecting centralized data on applicants that they had found to be ineligible for any reason so that we didn't have any pool of people that we could have gone to for more clarification.

Mr. NECCIAI. Two questions. You mentioned the study and you mentioned the 14 percent and then the 20 percent. So that is obviously an increase. Is it correct, 14, 14, 20, 22?

Ms. WILLIAMS. Yes.

Mr. NECCIAI. So the investment did not change and, in fact, increased following 2003?

Ms. WILLIAMS. Based on the information we had.

Mr. NECCIAI. You had mentioned that National Institutes of Health had in its own evaluation requested if it is an individual or citizen. So you are saying that the Institutes themselves had been fully aware that it is a requirement that they were not allowed to have majority-owned venture capital?

Ms. WILLIAMS. That was our understanding based on the interviews we conducted.

Mr. NECCIAI. Thank you.

Ms. WHEELER. Chuck, did you want to turn to the NRC study to tell us what you were charged with reviewing and what your findings were?

Dr. WESSNER. Well, yes. We were asked to look at the impact of the change in the eligibility rules that occurred as a result of the ruling, and I think to take a step back here, a key issue of difference is that we did not find the same levels of participation that our friends at GAO seem to have found with venture-backed firms.

But there is a broader issue. Our study, as you all know, found that this is a highly effective program that has been performing well for 20 years, and during that 20-year period and during our study of that period, at no time was this issue raised as a problem. When we—the committee could not find ill effects on the program from the participation of venture-backed firms or majority venture-backed firms.

Our specific findings, and I am happy to go over those, but our— one of the key things that we found is that the impact of the SBIR—first, there wasn't a problem. We have with that inimitable American way managed to now identify a problem which we are now seeking to address.

I think it is important to keep in mind the limitations of the data in all these areas. Ownership is a very complex process. What constitutes control is not always self-evident. Our research showed that the impact of the SBA ruling was quite limited in the number of affected firms. Again, keep the data caveats in mind. But our estimate was that it is between four and—roughly between four and 12 percent. However, the committee and our own research suggested that the impact on program commercialization—can you hear me in the back?

The impact on commercialization is nonetheless significant. That is because some of the most promising firms now appear to be excluded from participation in the SBIR program. This was a point that Dr. Zerhouni identified early on. The evidence suggests that the impact of the ruling falls most heavily on the limited number of firms—limited number of firms—that have been selected both by the NIH for their promising technologies and commercial potential and by venture investors for their commercial potential.

I would simply stress that venture capitalists, although I am sure they are nice people, don't invest in companies because they think they can advance the science. They do that because they think they can make very substantial gains.

One of the things that we found is that non-venture-backed firms actually reached the market more frequently in the period we studied than do venture-backed firms. We don't think that that makes one more virtuous than the other. We think that is good for the program.

The firms that do reach the market that are venture-funded, however, are more likely to generate more significant sales. The figures are about 55 percent of the non-venture reach the market. About 38 percent of the majority venture-owned firms reach the market. But the smaller number of venture companies—think about this, it is actually logical—when they do reach the market, they have substantially larger sales.

So given that restricting access of SBIR funding to firms that benefit from venture investments, we believe would risk—not certainly—we believe it would risk, disproportionately affecting some of the most promising small, innovative firms. And to that extent, the SBA ruling has the potential—the potential, not the certainty—to diminish the positive impact of the nation's investments and research and development and particularly in the biomedical area.

Do you want me to go on to the recommendations?

Ms. WHEELER. If you would like to, sure.

Mr. NECCIAI. I think that is important.

Dr. WESSNER. All right. Well, the key—we suggested that the consideration should be given either to restoring the de facto status quo eligibility requirements, and by de facto status quo what we meant was what was going on for 20 years, where there were companies with majority-backed ventures that participated with no harm apparent.

Failing that, we recommend making some other adjustment that will permit the limited number of majority venture-funded firms with significant commercial potential to compete for SBIR funding.

We also add that SBA should maintain the commendable program flexibility that it has exercised in the past. We suggest—we assert that the SBA and the agencies should maintain the open competition that is based on scientific quality and commercial potential, and note that we do not talk about financial structure.

And we assert further that they should continue to rely on agency managers' judgment, experience, and understanding of mission needs to effectively administer the program. Our belief is that if there is a problem, that the agency managers will be the very first ones to detect that problem and be able to address it in an expeditious manner. We are fearful of legislative efforts to manage a program. Thank you.

Ms. WHEELER. Thank you.

Question: You said, Chuck, that there was a difference between NRC and GAO on the levels of VC participation, but I thought you were both around 14 or 15 percent overall, not majority owned but VC participation overall.

Dr. WESSNER. We are under that. I would have to take a closer look at the GAO report. But what I would like to stress here is the uncertainty on some of these numbers. These are self-reported. There are various forms of investment. Everybody who doesn't know about small companies and doesn't know about venture investments has greater clarity on this than the companies that actually participate in the venture communities. Venture funding is by no means a homogeneous entity. We had vigorous debates in our committee about what kind of control are you talking about. What do you mean by control? And, of course, debates on why does it matter?

So we think the numbers are—I think, if I may use the analogy rather than the specific numbers, we think what we are talking about here is a very small number, but it is a little bit like the top five percent of the West Point class. That is where the stars are most likely to fall. So we don't think the overall numbers are large, but we think the potential for commercialization from those companies are large.

Keep in mind, if we thought——

Ms. WHEELER. Based on money, not based on proportion, but just on dollars that they bring back in. I think that is what——

Dr. WESSNER. Yes, and the potential that both the NIH has made in its judgment and the venture capitalists have then validated. As I mentioned before, they are not in this to be nice. They are in this because they think there is a substantial market. Remember, they are shooting for very large returns and this often would involve things like important drugs or other medical devices that would potentially—and why do they have that return? It is because they have very significant social and medical benefits. That is why people will pay for them. That is the hope. So that is where we are on it.

But I have talked with our Chairman—well, not since yesterday—and one of the things that he mentioned was the really important thing about the venture issue is to reauthorize the pro-

gram. Please, just reauthorize the program. He asked me to say that.

Ms. WHEELER. We agree with that.

I want to go back to the point on venture capital firms validating. VC in a firm indicates that they are the most promising, but it doesn't mean that they are the most likely to commercialize the SBIR project—

Dr. WESSNER. Reach the market.

Ms. WHEELER [continuing]. Because as even your study found, of all the firms identified as being majority-owned and controlled, only six received their venture capital investment after their SBIR award. And so we tried to be very careful in creating a war between these two sides to say one side's research isn't as promising because they haven't attracted any venture capital. Oftentimes, they have attracted venture capital for another lead project, which I suppose Mr. Crandell could speak to more clearly.

Mr. NECCIAI. Actually, before we move to Mr. Crandell, I just wanted to ask one quick question. How long did it take to do the study?

Dr. WESSNER. Uh, it depends—I don't want to—it depends what you mean by do the study. Do you mean—

Mr. NECCIAI. Not the term of the study. How long did it take to do—

Dr. WESSNER. Well, we worked on it about—

Mr. NECCIAI [continuing]. It from the beginning—

Dr. WESSNER. Yes, but we worked on it—I am not quibbling to be facetious. We worked on it for about two years.

Mr. NECCIAI. Okay.

Dr. WESSNER. We had an extremely rigorous review process. Our study from our perspective was completed last September. We spent six months in review and we had a doubling of the number of reviewers assigned to it and there were great discussions. And I appreciate the question. So calendar, roughly about two years, but how many hours—

Mr. NECCIAI. What was the return—

Dr. WESSNER. Keep in mind, we were producing a substantial number of other reports during the same—

Mr. NECCIAI. Absolutely. What was the return rate on the questionnaires that you had out?

Ms. WHEELER. Response rate?

Dr. WESSNER. I would have to get back to you on that, Erik. I don't recall that number.

Mr. NECCIAI. Was it roughly 20 percent, if that was—

Dr. WESSNER. It was, yes, roughly—actually, I think it was 18 percent, 18 and change.

Mr. NECCIAI. And for GAO, how long did it take to—roughly—do your study?

Ms. WILLIAMS. Typically, our studies take between nine and 12 months. I don't remember for this one specifically.

Mr. NECCIAI. And what was the return rate for yours?

Ms. WILLIAMS. Well, in this case, we didn't do a survey, but generally speaking, we shoot for 75 percent response rate. But we will report results out, depending on the circumstances, with a response rate of more than 60 percent.

Mr. NECCIAL. Thank you.

Dr. WESSNER. Could I just add, Erik, that you can have higher standards if you don't do the surveys.

Mr. NECCIAL. Okay. Thank you.

Mr. CRANDELL. Thank you very much. I think the question was, what are the parameters that venture capital firms are typically looking to see in an effort in order to invest capital and how might that compare with opportunities that present perfectly good science but may not meet those criteria, and correct me if I am—I mean, I am repeating your question, Kevin, so—

Ms. WHEELER. Well, I just wanted to give you a chance to respond. When I said that the VC dollars that were already in the firm—were often already in the firm before they ever applied to the SBIR program, so there was not necessarily a correlation between VCs existing and their promise to commercialize, so—

Mr. CRANDELL. Okay. Well, I am probably best speaking from my own personal experience, which my partners and I started as graduate students at the University of Chicago in the mid-1980s following the Bayh-Dole Act. We were chartered with spinning out new companies from the University of Chicago and Argonne National Labs. There were no previous spin-outs or commercial activity at those institutions before we started our effort.

We raised a small venture capital fund at that time, which was about \$9 million. It took us about 15 months and we presented to about 100 institutional investors to raise that capital. And we set about starting companies and running them ourselves. We did 12 companies during that period of time and looked at probably several hundred different invention disclosures that were turned in by the University or by Argonne National Laboratory researchers.

Of those 12 companies, some of the ones that we chose was an elementary school math curriculum that is called Everyday Mathematics. Those of you that have children and help them with their homework will probably have suffered through some of that, but that is now the largest market share math curriculum in the U.S. with 18 percent market share and it has generated hundreds of millions of dollars in revenue and I think employs a lot of people—

Ms. WHEELER. And that was an SBIR project?

Mr. CRANDELL. That was not an SBIR project, but it did have the attributes of a potentially larger market and we were able to invest our capital toward productization of some raw research and did the work.

The second project that we—or another one that is worth mentioning is the company that became Averon. This is the company that did the cold-adapted flu vaccine. It is the FluMist that kids spray in their noses so they don't get injectable vaccines. That was a 13-year project. It took ultimately hundreds of millions of dollars to commercialize. But again, the vision was that if the technology worked and we could get additional funding, and it came from a lot of different sources over that time, ultimately, there would be a payoff.

We also worked on what the Economist has called the very first nanotechnology company, which was spun out of Argonne in the

late 1980s, and worked on a host of others in the chemicals, materials, instrumentation space.

So in the intervening 22 years, our company has done about 122 of these companies. We are now focused nationally on the leading academic institutions and national labs. So in large part, our firm has grown over time. We now have about 15 professionals that do this work. We have offices in Seattle, in Austin, one on the West Coast, and our headquarters and administrative functions in Chicago. We have funded companies in the fly-over States because the science in many cases is extremely good, but it is much more difficult to gain financing in those locations and it is much more difficult to attract managers that have experience because you have got a bit of a chicken-and-egg issue there.

So part of our process, and I think most of the groups that do what we do, and there aren't a huge number of them—if there were more, we probably wouldn't be having this discussion, in a way, because there would be much more capital available to fill that gap—is we bear more technology risk—it is in a sense we have a concept that we hope would have large commercial potential, but we have to do the investigation to validate that there is a commercial opportunity and we also have to establish that the invention is consistent with the laws or physics or at least the best judgments that are available.

So part of our process of determining how to get there is to develop plans along those lines to get the answers to those questions, and this gets back to where the SBIR program fits in, and I apologize for the long intro there but the context is sometimes helpful. And that is we set a strategy to try and find a way to build the things that we think are commercially important and we then look to overlay those with the results and the interests of these major funding agencies and we scan the literature and the proposals to see if there are things that match. And often there are because the things, as Dr. Wessner pointed out, the things that create the most value are usually socially important, and they certainly are in the life sciences and the physical sciences.

So our process is to evaluate the commercial viability, and we need large markets. People will not give you capital to invest if you cannot generate a return because they can put their money in Treasury bills or whatever denominated security that is much safer.

Also, our process is imperfect. Even though we feel like we have armed ourselves with every possible advantage and we have people that have experience, which is extremely important to making the right business decisions, we still crater or fail in about a third of our efforts.

I think as we—one of the hallmarks—

Ms. WHEELER. I am sorry. Are any of your investments ineligible for SBIR right now?

Mr. CRANDELL. Yes, under what I will call the change, they are not eligible, and I think—

Ms. WHEELER. And they were before? Your companies were before?

Mr. CRANDELL. Well, we view ourselves as small businesses. As I said, we have 15 professionals on our support staff. Our compa-

nies typically have a dozen or two dozen people in them. They are small, focused, entrepreneurial groups that are at risk that are going after big challenges. And right now, there is a cooling both because of the notion of potential caps, because if you are not sure that you are going to—if you have the potential of being the one that gets cut, you have to make a second judgment beyond just the SBIR program as to whether or not you are going to be able to make it into the program, even if everything else lines up perfectly. So there is an issue there.

And then second, most technologies that are what I will call core technologies based on the physical and life sciences are extremely capital-intensive projects. You know, the notion of people developing a new drug in their garage is just not happening. I haven't seen it. Maybe it could be done.

But the point is that these funding sources basically interweave and are complimentary and I think the exclusion, the damage that is done in a situation where there is essentially an arbitrary cap that is set or discrimination against a certain group is that it limits the options of the entrepreneurs that are running the business because it makes it less attractive for them to take capital. It makes it less interesting for the venture capital people to participate in those start-ups and fund them because they know that their companies are not going to be able to garner additional capital which is necessary for them to succeed.

And then finally, from the standpoint of a venture capitalist who has operated for 22 years in a fly-over State, we are fighting every way we possibly can to get our companies the capital so they can have the planning horizon and be able to make the plans and execute on them to succeed, and that is—you know, I have a receipt for my five-year comment earlier and I would like to say that I support longer planning horizons for all the reasons that people had outlined. But it is basically the same issue that we suffer from here.

Ms. WHEELER. May I just ask a question? What was it before 2002 that made your firm think that your companies were eligible? With the terms majority-owned by individuals, 51 percent owned by individuals or U.S. citizens, by what standard would your companies have felt that they were eligible?

Mr. CRANDELL. Well, let me say that we started in 1986, and I think it was the SBIR program predates our involvement. I think that we viewed ourselves as small businesses and we applied for those, or our companies did, answering the questions that were asked of them, and there were other peer groups that had it. You know, all this differentiation about 51 percent ownership is not something that was discussed or control. I mean, I think we have heard earlier that this whole notion of control at the operating level of the company or at the board of directors is something that is not super clear-cut and I think there wasn't a lot of attention spent, frankly.

Ms. WHEELER. But the self-certification form from NIH has a box which they must check which says 51 percent by U.S. citizens, right?

Dr. FEDORKOVA. Correct.

Ms. WHEELER. So I am just so curious, because I know you all are just really upset about this and feel that before, you could self-certify that such firms were eligible. So I am curious just how a company looks at that and says, I am just going to take the example, there are three venture capital firms that together make up the majority of the ownership and control of this SBIR applicant. So when they checked it, what in it was making them—by what standard did they think that they could check that box?

Mr. CRANDELL. Well, maybe two important points there. One is I don't think there is a visceral reaction, and if I have in any way—

Ms. WHEELER. No, I mean that you are—

Mr. CRANDELL [continuing]. Conveyed that—I am passionate about it—

Ms. WHEELER. You feel—yes—I am sorry—

Mr. CRANDELL [continuing]. Because I live it every day.

Ms. WHEELER. I mean that you feel strongly about it.

Mr. CRANDELL. Right.

Ms. WHEELER. I didn't mean that as negative at all.

Mr. CRANDELL. Yes.

Ms. WHEELER. I am just trying to understand how somebody checks that box, and NIH's self-certification form has that.

Mr. CRANDELL. I think—first off, you would have to ask them, okay, and I am sure there are as many different answers for that question as there are people that are out there doing it.

I will say that in your description, I believe there is a misunderstanding of language that is possibly at the root of all this—

Ms. WHEELER. Okay.

Mr. CRANDELL [continuing]. And one is the notion that if you have a syndicate of venture capital funds—each of those, by the way, is an independent manager that has capital from different sources that is focused in different areas that may never co-invest with the other investors at all—so the notion that three—in your example, I think it was three venture capital groups exert control over it. In each round of financing, those venture capital funds may decide not to continue to invest. They may sell their position if they want to to some other group. It is not a tightly aligned group of anything, and I have served on enough venture capital-backed boards to know that if you get three or four people in a room from different venture capital funds, the only thing you know for certain is they are all going to have different perspectives on it.

So I guess if, in your example, there were three groups that had control, it was clear-cut control, and if they all were colluding in some fashion, then I imagine they would have a hard time checking the box. If, on the other hand, they are small businesses themselves, they operate independently, their capital structures are absolutely independent, then the whole notion that there is some double-secret handshake that makes these folks collude against or organize themselves, I just haven't—I haven't seen that. So I think that is probably the point where the cognitive dissonance sets in is that there is a preconceived notion perhaps that these—that venture capitalists organize themselves the way large corporations do and I don't—I haven't found that in my experience.

I also would say that we are better off as a country here if we get more money focused on commercializing the things that are going to have impact and make a difference, and—

Ms. WHEELER. But that would be an argument for not making a change because the NRC identified that the majority of the applicants who commercialize, 55 percent are non—don't have VC.

Mr. CRANDELL. Well, I mean, again, this is—

Ms. WHEELER. But you know what? Aside from that, there is a compromise that is out there of 18 and eight percent. Those would get your companies in.

Mr. CRANDELL. Well, I mean, again, I don't want to monopolize the time here, so you have got to use this type of symbol—

Ms. WHEELER. Well, we will let everybody comment on it. So 18 and eight percent, that addresses the issue that you are concerned about, that now some of your investment firms would not be eligible. Now, they would be.

Mr. CRANDELL. And Kevin, I—

Ms. WHEELER. Is that sufficient?

Mr. CRANDELL [continuing]. I appreciate that fact, and if you are in Washington and you are making a gesture or putting this type of thing together, it is splitting the baby. I am sure that happens here all the time. I only come once in a while so I am a little more sensitive to it.

So I think there are two things that to me I think are problematic there. One is, from a policy level, the country faces huge challenges in clean tech, in energy independence, in the biological area with things like pandemics, and if you are arbitrarily capping this, what you are basically doing is telling those groups you don't want their ideas, okay. So do we want to be the group that tells the agencies that they shouldn't get the very best ideas in, especially if one or two of those may make all the difference, and I think we are hearing from Dr. Wessner that these are some very high-powered ideas.

I am absolutely a fan of competition in these things. Let them be peer reviewed. I think that is a great process for our groups and for the agencies and I think they do a great job.

But from a policy standpoint, what you are essentially doing by putting a cap in, that you are saying, don't send in your ideas because we are going to add one more level of uncertainty, so that even if you do everything right and even if it takes the nine months, even if you file all the forms, you still may not get it because you are somehow the last one through the door, and that is—

Ms. WHEELER. Well, actually, right now, they can't participate at all. So actually, we would be saying the door is open for you to come. And furthermore, the 18 percent is far above what the GAO found was the participation for all firms with VC before the clarification. And, in fact, if it were enacted, based on the data we have from 2006—let me see, you would be getting proportionately and dollar-wise more than they were getting before SBA qualified. So before the clarification in 2001, GAO found that the firms with venture capital received 14 percent, or \$57 million, of all SBIR dollars at NIH. And in 2002, they received 14 percent, or \$72 million.

If we were to put in this 18 percent and they were to use it all—would they get to that? Some have argued that they wouldn't because these amounts are smaller than that. It would be an increase of 84 percent over the amount of funds firms with venture capital were sharing—sharing. Now, this would be all for this class of firms that you are advocating for, and a possible increase of 45 percent over what they were sharing in 2002.

And at DOD, it would be an increase of 47 percent over the funds they were sharing in 2002 and 65 percent of what they were sharing over 2001.

So they weren't arbitrary. We understand what you are saying. But we don't see that this is in any way limiting. Right now, these firms you are talking about don't have access. And based on the information we have here and these self-certification forms, they were never—I mean, they might have been in there, but they weren't supposed to. And so now they would actually really explicitly have access.

Mr. CRANDELL. Well, I mean, again, I have been working this project, I guess you could say, on the SBIR side because it affects the commercialization gap and the interplay between venture capital entrepreneurs and technologists and I view it as an important one. So I appreciate your assurances that things will be good, and in this room, it sounds reasonable.

But I think in point of fact, from a ground-level person, what it is going to do is add in uncertainty about whether or not they are going to be the last—whether their good ideas are going to be the last ones through the door, and that is going to chill the effect of people applying, number one.

And number two, from a policy standpoint, we need the best ideas coming in to the country and to the research agencies, and that is what they want, and it is a contest of ideas in meritocracy. The agencies choose the topics. They peer review them separately. And I don't think that it makes sense, both from the National Venture Capital Association, from me as a taxpaying person, too, to arbitrarily discriminate against a high-performance group of idea people when the country is in the throes of some serious challenges and forcing them to have to think through the idea that they are making it more uncertain.

So if you are saying the caps are generous, I have a receipt for that point. I would say there were no caps before 2002 or 2003. In hindsight, you are saying these folks perhaps shouldn't have been participating, or not all of them. Nobody is quite sure who would have been in, who wouldn't have been in. I think we are looking to take this back where it worked for 20-some years, where we know it worked, and just make that modification, and I don't—if the caps are—if the numbers are so good and we should feel so strong about them, I kind of wonder, why are people so interested in putting them in and doing this sort of set-aside-like discrimination. Again, from my narrow perspective, I don't get it. It is the top scientists with peer-reviewed ideas. It is what America is about, is competing for meritocracy on that and let them be where they are—

Ms. WHEELER. Because it is a small business program and we have to define small business. Right now, these firms are not considered a small business—

Mr. CRANDELL. Right now.

Ms. WHEELER [continuing]. And so—

Mr. INGE. Let us—do you want to open it up for comment, just because we have got to be out of here at one. The court reporter has another appointment. It would be good to get—I know Dr. McGarrity will probably want to say some stuff, and then some of the small businesses.

Ms. WHEELER. Kathy, did you want to make a comment?

Ms. WYATT. Yes. I would just make a brief comment. One thing I would like to say is that I particularly appreciate your comment that this is not intended to be something that pits VCs against small businesses, because I think the truth of the matter is that we are both playing a vitally important role in sustaining and improving our quality.

I just would like to throw in from the small business more than anything that I think a small business perspective is to want some assurances that those diamonds in the rough that are out there that this program will help us to identify by the way that it has been operating in the past continue to have access to this program in a way that will be effective for them and it will help us grow some of those potential rising stars of tomorrow that will be good candidates for venture funding.

And the other thing that I do think is important is to remember that it is a small business program, and I think that there is importance in having the definition of small business be consistent across programs that the Small Business Administration is actually in charge of overseeing and operating.

Ms. WHEELER. Thank you, Kathy.

Kunal.

Mr. MEHRA. Thanks. I guess I want to share a few observations, just taking a step back for a second, and then raise just what I think are a couple practical issues in terms of how you would even implement a policy like this.

So just by way of background, I think I have a little bit of a unique perspective on this because I spent quite a bit of time as a manager consultant advising venture capital firms. I was in on the management team of a VC-backed company that was acquired by IBM for four years and now I am part of a privately held company competing with firms that have VC capital. So I have sort of looked at it from three different sides.

So let us just take a step back for a second and make some general observations. When you look at the SBIR program, I think two major motivations and two major goals of the program have remained consistent for the last 25 years and I think are never really in dispute. The first is a recognition that small businesses, by and large, are the hotbeds of innovation in America and in the world and that the Federal Government historically has had a very hard time tapping that innovation for whatever reason. So one of the major objectives of SBIR was to provide a mechanism for the Federal Government to benefit from that innovative mindset and creativity in small businesses.

The second major recognition was that small businesses, particularly minority-owned small businesses or small businesses in rural areas like Louisiana or other States, are inherently disadvantaged. They lack the same access to capital that large businesses have. They lack the access to advisors and other forms of distribution to actually get into the Federal Government and be able to support such an incredible sales process.

And I think when you hold up companies that have significant venture capital investment, and whether it is majority-controlled or not, I don't see how they pass those two tests. How can a company that has raised \$10, \$15, \$20 million be considered disadvantaged? It just doesn't make any sense.

And I am not worried about the entrepreneur that has got a really successful technology that could raise \$10 million. I am worried about the entrepreneur in Louisiana or some other State that has no access to capital and has to compete with that person. Suddenly, this program that was very egalitarian where the best ideas won becomes much more competitive and starts to lock out those two people.

And on the first test, again, the focus of the program is on spurring innovation. There is a great place for venture capital in the SBIR program. That comes in what we call Phase Three, the commercialization process. And Mr. Crandell's comments, all of which I think were fantastic, one of the things he talked about was the first thing that they do when they come in is to evaluate the commercial potential of the technology that has been developed, not evaluate the merit of a crazy idea that a scientist has to create a revolutionary technology. That is what SBIR Phase One and Phase Two is for. So I think on those two tests, it fails.

And then let me now just talk about some really practical issues in terms of—even if there was an allocation for venture-backed companies or majority controlled venture-backed companies, I think there are some really practical questions you have to ask.

The first is, how are you going to determine if a company is majority-controlled or majority-owned by a venture capital firm? It is not as simple as just looking at who owns the shares of the company because in most instances that I have seen or that I have been involved in, when an outside investor comes in investing capital, they will take preferred equity shares or they will invest with debt instruments that are convertible to equity over time. So they might not look as if they own two-thirds or 75 percent of the equity of the company, but in effect, they control that amount, or they can have a disproportionate number of board seats.

So I think just answering that simple question to figure out what category they fit in and whether they fall under that eight percent cap or that 18 percent cap or not is incredibly difficult.

The second point I would raise is, again, right now to participate in SBIR, the firm has to be majority-controlled by an individual who is a U.S. citizen. How do you apply that test to a company when it has got a substantial number of private investors? Do you look at the citizenship of the sponsors in the venture capital firm? Do you then go back to the investors in the VC firm and look at their citizenship? I mean, I think that—and then does that create a double standard? If you are going to penalize an entrepreneur for

not being a U.S. citizen but you don't penalize a company that has got VC-backed investment from foreign investors and other folks, it seems to me like that is a double standard.

And I think that is even further compounded when you look at DOD, where there are some real national security concerns. I mean, in my company, the vast majority of projects that we work on are ITAR restricted. We can't have non-U.S. citizens even be in the same room when somebody is working on a project like that.

So again, how do you deal with that issue when you have got an institutional investor that may or may not have foreign ties? And I am not ruling one way or the other. I am just saying it is a very vague thing and I think it becomes extremely difficult to legislate for.

So those are two, I think, important considerations. The other observation I would make is I think there are also some fairly big differences between the NIH program and the DOD program. In DOD, the marketplace for the eventual technology is the Department of Defense itself. So a lot of the commercialization that needs to occur happens through the natural mechanisms in the DOD to acquire technology, and again, I think we have talked about—I certainly feel like that could be improved.

In the NIH, the situation is different. In the NIH, there is no—the marketplace for technology developed by the NIH is the commercial sector. And so I wonder if it makes more sense to think about VC participation more in the NIH sector than it does in the DOD sector.

And then finally, just to provide one thought process for how I think everybody can sort of have their cake and eat it, too, there are companies that recognize the importance of getting VC funding to commercialize their technologies. PSI, Physical Sciences, Inc., in Andover is a fantastic example. So what they do is they take that technology, they spin it out into a separate entity, and then they invite venture capitalists to invest in that entity. That entity is focused on commercializing the technology and therefore that is what the VC dollars are directed at. Meanwhile, PSI, the parent company, can continue to be majority controlled by individuals and can continue to compete for SBIR funding. And I think that that is a very fair compromise that exists within that kind of framework.

Mr. NECCIAI. Have you found in your experience that this is a successful process and one which many firms use in order to both get the advantage of VC and SBIR?

Mr. MEHRA. I think, one, it is a very successful model. And secondly, given all the points I just tried to raise, the practical points, I don't even know how the SBA would legislate, would be able to manage the process. We would have to have forensic accountants going in and assessing the capital structure and doing all these other things to figure out, is it majority-controlled? Is it not majority-controlled? Is there a national security risk or is there not?

This mechanism that I just described, I think if we were to publicize it and just make more people aware of it, is just a really simple practical solution to, I think, a very clear set of issues.

Ms. WHEELER. Thank you, Kunal.

Dr. McGarrity.

Dr. MCGARRITY. Thank you. What I would like to do is add my personal experience and tell you about two companies that I have been involved with, VIRxSYS, where I am presently, and another company called Intron, where I was CEO.

Intron started in 1996 when a very young innovative physician who had just completed his training at NIH was looking for a job and he invented some technology literally in his living room and actually using his children's crayon and construction paper to sketch out the scope of the invention. He was able to get some seed funding from the Cystic Fibrosis Foundation because they had an application for a possible treatment, and then later, Intron received a Phase One SBIR grant from the NIH. In fact, in a rarity, and as I said to you, I have been a reviewer for hundreds of applications, grant applications, at NIH, including SBIRs, the grant review committee actually doubled the budget of the requested budget and I have never heard of that happening before.

We completed that Phase One study. We applied for a Phase Two study. A separate group of experts, 18 to 20 of them, said this is one of the most innovative, thoughtful, and exciting applications they ever read, and we got fully funded.

On the basis of that, we went out and we acquired VC funding, small, modest amounts, and so our lead program was Cystic Fibrosis. The VCs, I mean, to what Keith has said, said, well, it is the same amount of work, it is the same amount of time, the same amount of money to develop a product for a major market like cardiovascular than it is for cystic fibrosis, so let us focus on cardiovascular disease and then we will continue to get grants to support the cystic fibrosis program.

We went out and we did that. We got another Phase Two from Cystic Fibrosis at the NIH which would have taken us into clinical trials. Now, that is when the change in rules occurred and NIH came to us and said, we question your eligibility requirements for this. Let us go through the paces.

Because of the VC funding, that grant was actually rescinded and we actually had to terminate people that were working on that program. Also, our collaborator at the Cystic Fibrosis Center at the University of Iowa had to stop funding two graduate students who were working on the project.

So that is fairly typical, and I think the experiences we have are representative of a large number of small and emerging biotech companies.

Eventually, Intron was acquired by VIRxSYS, my present company. VIRxSYS was founded in 1998, so we are 11 years old. We still have no revenues. We are in clinical trials for HIV/AIDS, and those trials are going well. We are also developing an HIV vaccine, and the technology at VIRxSYS came out of Johns Hopkins.

Now, VIRxSYS is unusual, if not unique, in that we have no major VC funding. We have literally several hundred private investors that put in their money and have supported us over the past ten years. So actually, I am sitting here representing VIRxSYS, a company who is eligible for SBIR grants. So you might say, well, if you are eligible for NIH grants, what is your position on this? It is in my best interest to say, keep those VC-funded companies

out of the mix. It is better for me. I have a better chance of competing for the limited amount of research dollars.

And, in fact, that is not my position. I don't think the purpose of the SBIR program is best served by excluding young, innovative technologies, and I think what Keith said is absolutely true. The purpose of the SBIR program is, as its title has said, it is looking for innovative research. And I sit here and say I have absolutely no hesitation in competing for research grants with every other biotechnology company in the country. If I go and I get my grant funded, that is good for me. If I fail to get a grant award, I have to go back and work harder and retool and get that.

We are going to put in an SBIR application this September for some work that developed out of our clinical trials with AIDS. It is some new findings we have got and it is basic science which we think would have commercial application. But it is a long-term process. And I can't justify going to my investors, who have been funding the company for 11 years, and say, also give me money to fund this new avenue of research. So as we are eligible, we will apply to NIH for an SBIR grant.

I also think if the rules go back to the way they were, and I support what the National Academy report said, that worked very, very well. And also, I refer to Table 5.2 in your program where it said, what are the major reasons why these various companies are not presently applying for SBIR funds, and among the reasons given, there was the likelihood of getting an award is too small. That was 13.6 percent of the respondents. There was another one that there are significant delays in the funding. If I put an application in for an SBIR grant right now at NIH, it is going to be nine months before I get word back. And then also the size of the award is too small. So those three groups represent 30 percent of the respondents. Thirty percent of the respondents said, I am not going to apply.

So you are not going to have a run on SBIR grants if you change this rule. I think you will get a small number of applications like you had before for early stage projects, for highly innovative projects, and also, as our experience showed, it is also an application that are in orphan diseases where the common marketplace doesn't address those needs. And I know just last year, I think there were 50 patient advocacy groups came and said, we are getting shut out of this kind of a market.

We have had—when I was at Intron, we had requests from several organizations and from several scientists for, for example, wanted us to work on a disease called spinal muscular atrophy, a terrible disease, very, very small number of patients, very small market, and we said we can't do it with the basic capital markets. At that time, we were not eligible for SBIR. So those people are being shut out of eligibility for many of these kinds of—yes?

Ms. WHEELER. Dr. McGarrity, I wanted to ask you a question. On your first company, what was it that made you all self-certify that you were 51 percent owned by U.S. citizens?

Dr. MCGARRITY. Well, I think it was the—first of all, we didn't have any legal department to say, go check this out. And also, I think it was the common experience in the community that it didn't make a difference whether you had venture capital or not.

Now, that doesn't excuse that, and in fact, that was rescinded at a very early stage. But also, at the same time—

Ms. WHEELER. But just logically.

Dr. MCGARRITY. Yes.

Ms. WHEELER. I am just trying to get why the companies are going about it, because they are so upset that they are now excluded and I am just curious, if they had this self-certification form—

Dr. MCGARRITY. As I said—

Ms. WHEELER. Explain to me what you say that you look at and you say, so I own—I don't know how much you owned, but I am just going to say you owned—did you own 52 percent of the company so you said, I checked that box?

Dr. MCGARRITY. Well, first of all, I think there is an SBIR program at NIH, and I no longer have the slides, but every year, they would have a communication and a show, a meeting, to say here is what the SBIR program at the NIH is all about. Now, I went through those slides and I kept them for a couple of years. But if I went back to the 2003 show and went through every slide there, there was no check-box on if you have VC funding, you are no longer eligible. It was the size—it was judged by the size and the percent American ownership, and they were the two big headlines that companies like myself would look at and say, all right, we are a U.S. organization. We have far fewer and we have—you know, here we are. We have 20 employees—

Ms. WHEELER. Plus affiliates, 500 including affiliates.

Dr. MCGARRITY. Well, that—yes, but in the organizations that we had, that was with the VC—

Ms. WHEELER. That is true. Okay. So you could check that box—

Dr. MCGARRITY. Yes.

Ms. WHEELER. Okay.

Dr. MCGARRITY. And so, as I say, I think it—and I am not necessarily excusing it, but I am saying that was the common experience in my neighborhood or my community of small and emerging biotech companies, and you saw the companies that were getting it. We didn't hear otherwise from NIH. So we applied in good faith, thinking it was the same old eligibility requirements that we had in the first couple of awards that we received.

Ms. WHEELER. I see. Okay.

And I just want to clarify for everybody the facts. Firms with venture capital are not excluded. They are not. They never have been and they aren't excluded now. It is the ones that are majority-owned and controlled by, as the Cognetics case points out, non-individuals, right? So they found pension funds, corporate entities, and venture capital funds. I think it is very important that we stick to the facts.

Under this compromise, your firm would be eligible to compete.

Dr. MCGARRITY. My firm is eligible right now.

Ms. WHEELER. I know, but the first one that you mentioned—

Dr. MCGARRITY. Yes. Yes.

Ms. WHEELER [continuing]. That you decided to focus on cardiovascular—

Dr. MCGARRITY. Yes.

Ms. WHEELER [continuing]. And then you wanted to pursue government grants for the cystic fibrosis. So you would now be eligible to compete.

Dr. MCGARRITY. Mm-hmm.

Ms. WHEELER. Are you in support of this compromise?

Dr. MCGARRITY. Well, I would—first, I am a scientist, so I have to start asking—and don't take it personally. I mean, we are—

Ms. WHEELER. We just want to get this program reauthorized. So we are trying to get to compromise, so—

Dr. MCGARRITY. Yes, but my question back to you, if you were saying that at NIH, you had 14 percent were going to firms with VC funding, and then you are saying, let us put 18 percent on the table, I would say, well, then that sounds to me very artificial. Why do you need 18 percent if we are coming in at 14 percent or all of the VC-backed firms would be eligible and the number is under that percentage?

Ms. WHEELER. Well, first of all, if you want it to be 14, I am sure there is a lot of support to match the number.

Dr. MCGARRITY. No, no, but I wasn't trying to be a smart aleck—

Ms. WHEELER. No, I know you weren't, but I am just saying, you understand that we based it on data that we had, and again, I want to be very careful with terminology. The 18 percent in the compromise is not only for firms with VC. It is for firms that are majority-owned and controlled by multiple VC firms. So they would now not be sharing this pot of money. They would be able to get up to that entirely for themselves. That is why they are doing better dollar-wise and percent-wise than what they were doing before.

So we went above 18 percent because there were people on the committee that felt very strongly that—above 14 percent because they felt very strongly that NIH was the one place where this was really needed and that it was focused on biomedical. So the compromise was that we would go up beyond the data that we had. So it wasn't arbitrary. It was based on data.

So if you have data that tells us that you need more than 18 percent and there is a justification for it, you know, we are going to mark up this bill very soon, so as Senator Landrieu said, today is the day to make the case that the compromise that this committee voted on is not sufficient.

Dr. MCGARRITY. Yes. Well, I would say, looking at the alternatives, where we are zero right now and you are saying 18 percent, 18 percent is obviously better than zero.

Ms. WHEELER. Right.

Dr. MCGARRITY. But I still think—I have trouble understanding the rationale of saying why we want to go to 18 percent, which theoretically would accommodate all of you people or all of the companies that have VC backing. When we were talking earlier about the length of reauthorization, we said we wanted to keep it simple. We wanted to keep it constant over time so it is predictable.

And so if that percentage were to increase—let us say it is highly successful and it is highly successful, but let us say the percentage of NIH in, if you are talking about a long-term authorization program, let us say in seven or eight years, you hit the ceiling of 18

percent. Then what do you do? Do you have to then start saying, well, I am sorry. We are going to have to have quotas here to say that some of these companies are going to get turned down because we are over the 18 percent—

Ms. WHEELER. If you have 501 employees, are you turned down? I think the point that Senator Kennedy's staff made on Health and Human Services was we have to draw the line. We have to define a small business. And unfortunately, there might be that firm that has 501 employees or that comes in at that 18 percent. Right now, we have no data that says that there is a need.

And just from a policy perspective, it is the totality. It is not just the fact that you are saying they can't compete. We have heard data here that of the awards that go to firms with VC, they account for, was it 70 percent of the awards in SBIR? So let us look at this in totality.

So we are saying that up to 18 percent of awards, SBIR dollars at NIH, can go for firms that are majority-owned and controlled by multiple VC firms. Then we look at the GAO study and we look at extra data we have that says that any firm—I mean, firms that have VC, but we are assuming they are not majority-owned because it was in 2004, after the clarification, it is very clear they can't apply anymore—we assume they aren't. That is 22 percent. So we add 22 percent to 18 percent and we are now moving the program of getting to—we are moving towards half of the program going to firms with venture capital.

Then we take the data that we have from the NRC study which says that a larger per share—the majority of commercialization comes from firms that don't have VC, 55 percent versus 38 percent. Then we add on top of it that where is the concentration of the awards that go to firms with VCs? They go to mostly California and Massachusetts and then somewhat in ten States, that they get the larger awards. So we have it geographically imbalanced and one of the goals of the program is to do economic development.

So we look at the totality of circumstances and we say, what is the balance we can get here for innovation of this country? And then on top of it, we look at this and we say, what are the types of research that VCs go after versus those that are non-VC, and it is our experience, and Keith can weigh in and you can weigh in, they are different. They look different. And we want this program to still go after those projects that are really high-risk. We want them to not turn this into an acquisition program.

And so we look at the totality and we say, we see the case that you are making. We see the case that you are making and here is the compromise. And you know what? We are going to base this compromise on actual data that we have. That seems pretty fair.

Dr. MCGARRITY. Right.

Ms. WHEELER. So what is not fair about 18 and eight percent and what data does BIO have to give us that there is a different compromise?

Dr. MCGARRITY. Well, I think—

Ms. WHEELER. And we are willing to listen to it, but today is the day to make the case.

Dr. MCGARRITY. Okay.

Ms. WHEELER. I mean, we want this program reauthorized. This has gone on for years. And so, please, if you have a better idea, let us know, because we struggled with nine months over this.

Mr. NECCIAI. And before you respond, I am sorry, we are coming down shortly here—

Ms. WHEELER. Yes. Sorry.

Mr. NECCIAI [continuing]. If you could make your response quickly, we want to get to a share of the people and we want to head to affiliation rule before we wrap up.

Dr. MCGARRITY. Okay. Well, I think one is that—I would say that biotech companies are different than some of the companies that you are talking to and about at the Department of Defense. When you are saying that the non-VC-backed companies are getting to market and generating revenues quicker, that is absolutely true, because I think in Department of Defense or if you are in IT, you are going to generate revenues very quickly. As I said, we have been around 11 years and we still do not have a penny of revenue. So that is a hallmark of biotechnology companies. I mean, to the response—

Ms. WHEELER. And the compromise recognizes that.

Dr. MCGARRITY. I appreciate that. I appreciate that. So what I said to you is saying that from looking at zero percent now and 18 percent, obviously, I picked the 18 percent, but I still question as to the wisdom and the rationale, why there has to be a limit, because you are saying, all right, you are eligible but you are only eligible up to a certain point and you are putting a ceiling and what I see as an artificial boundary around the kind of percentage that you have.

Ms. WHEELER. It goes back to partly—and I will finish this—what Kunal referenced. If you go back and you read all these thick legislative records on the creation of the program, it was to get seed capital to firms that had not yet attracted outside funding, private sector funding, and the government had recognized that small businesses were the biggest innovators. They did it faster, it was more cost effective, and they were saying, for the best use of our Federal R&D dollars, we should be trying to incorporate small businesses more to meet our research needs.

And therefore, because we want a level playing field, the majority of these dollars are going to huge corporations and universities, we are going to create this allocation to make sure that there is a level playing field and this is part of it. And so typically, one would say these firms have attracted the outside capital and they have graduated. At some point, you would say they have graduated. Eighty million dollars. We have had witnesses who have come here and participants who have \$80 million in VC, \$140 million in VC. Kunal mentioned levels of \$5 and \$10 million, smaller, but still they have proven. They have attracted the outside funding.

So this is a compromise. So I guess what I am saying, instead of just saying no or you don't—what is the compromise? Are you saying that it is 100 percent?

Dr. MCGARRITY. I would prefer to have VC-backed firms be equal partners and being able to apply. I mean, I heard Mr. Glover say

there is a crisis because the number of SBIR applications are going down. I have heard the former Director of NIH say the quality—

Ms. WHEELER. I think he said first-time applicants, because that is a measure that we look at for growing economic development.

Dr. MCGARRITY. Okay. Then my notes—

Ms. WHEELER. Sorry.

Dr. MCGARRITY [continuing]. My notes are wrong. But the number was going down. I heard from NIH that the quality is going down. And when I look at the overall objectives of this program, it is for innovation to provide job opportunities and generate revenues, and I think, well, if everyone can fit under the 18 percent cap, why have the 18 percent cap? I don't mean to be antagonistic and I am saying 18 percent is much better than zero percent, but I think let the system, and for biotech, let NIH—empower them to bring this forward with no artificial caps or just artificial boundaries.

Ms. WHEELER. Okay. Jere, do you want to—

Mr. INGE. Dr. Wessner, I think, had it up first.

Ms. WHEELER. Oh, sorry.

Mr. INGE. Do you want to go quickly, and then Jere?

Dr. WESSNER. Just very briefly, I think there are two key points. One is that the program, to the best of our knowledge and understanding, is not trying to help disadvantaged companies. The program is trying to draw on the ingenuity of the very best small companies wherever they may be located. And those States that have had trouble getting in the program are also States who have levels of education which are not as high as the successful States. They have underfunded universities. They often have unfriendly business environments. And they don't have the infrastructure that is required, putting the onus for a whole systematic set of failures on the outcomes of the SBIR program. They also don't apply to the program. So I really think that the shining quality of this program is that it is open to competition from all concerned.

I have a simple point here. I would hope that whatever compromise you reach, that you would require some monitoring of this by the agencies. As we state in our report, we found—you know, we don't have a dog in the fight. We found no evidence that these companies were being excluded. We found no damage to the program from their previous inclusion. We believe that the program managers could surely correct, if there is a tilt in the program where there are inappropriate companies—as they do, by the way, for some of the contract research companies who feel so strongly about not having them in who are relatively large, well-functioning, well-funded companies. They correct for them when they think that they are overwhelming the program with applications. That goes back to the flexibility. It goes back to the judgment of the people on the ground.

So I would hope you would have some monitoring in there—

Ms. WHEELER. We do put in—we have tried, and, of course, you can weigh in on that. We did put in the foundation has much more detailed data collection so if you went back in, if GAO went back in, that you would have an easier time of identifying these firms and giving us the characteristics that we need, not relying on prox-

ies, et cetera, so that we could revisit it and see whether the amounts are appropriate, whether it works or doesn't—

Dr. WESSNER. And let me refer you just to one. There is on page 28 of our report, box two, we honestly believe—we stated lower figures than GAO, but our best survey people argue that we are underestimating the impact of the program, the impact of the—that the numbers of venture-backed firms in biotech have risen very substantially and we are not able to capture that completely.

Ms. WHEELER. Well, you only went through 2002—

Dr. WESSNER. Right.

Ms. WHEELER [continuing]. And GAO went through 2004, and—

Dr. WESSNER. Well, there is, as biotech—

Ms. WHEELER [continuing]. I guess NIH wants you to look beyond that.

Dr. WESSNER [continuing]. Industry is maturing—yes, we would. Keep in mind, in addition to the monitoring, we do ask for a second snapshot. We don't know—I mean, ironically here, and I say this very constructively, we are talking about having all this hard data and we know how thin the data is and we would very much like to get a second snapshot of where we were in 2002, where we were in, say, 2008.

Ms. WHEELER. I understand, but this is where we are and this is the information we have.

Dr. WESSNER. Right.

Mr. NECCIAI. Chuck, I appreciate your comments on that and I think we agree and emphasize the importance for reporting and oversight and making sure that the numbers are right and, in fact, what the numbers are. And I know that you encouraged the reporting of minorities and women and such in past reports and that is something that we are pushing for in our current legislation.

Would you say that the 18 percent and eight percent provides a large enough—as Dr. McGarrity eloquently said, zero to 18 is certainly better than zero to zero, but would 18 percent provide a large enough umbrella or window for those participating before and after to continue to participate?

Dr. WESSNER. Well, based on two years of study and very careful examination of the data, I can tell you that we don't know.

[Laughter.]

So it is, therefore, important for you to keep in mind that perhaps—I am not arguing about the percentages, but 18 percent implies we know that this is—so do 20 percent or something and then have a reassessment. Have a reporting requirement, some—

Ms. WHEELER. That makes no sense. I mean, we based it on 14 percent, so that is the best data we have, we know. And yours says, what, 61 firms were excluded over ten years, or 4.9 percent, although I realize that is not share of dollars, that is 4.9 percent of companies. But we feel like there is the room there to take that into consideration.

Dr. WESSNER. Well, I read—I am not disputing the two percent with you. I am simply suggesting that 18 suggests that we are hitting a target on the head and I just am cautioning you, as I have been asked by the Academies, that the data is quite uncertain, that I think we need to rely on management, and that you should set

up something that can be reassessed as you go. I am addressing your concerns that we reassess this as we go forward and have them report.

And I would point out that both the advocates from BIO have, in our view, in the Academy's view, overstated the damage, and the opponents of participation of venture-backed firms, in our view, have overstated the problem altogether and that we have basically a good program.

Ms. WHEELER. Thank you.

Mr. NECCIAL. Do you want to go, Jere?

Mr. GLOVER. Yes. First, I believe Intron, the folks in cystic fibrosis left the company, went out and did the same research and got funded elsewhere and completed it, isn't that correct? They actually—

Dr. MCGARRITY. Absolutely not. Absolutely not.

Mr. GLOVER. They didn't leave the company? They didn't fund it?

Dr. MCGARRITY. No.

Mr. GLOVER. It never got done?

Dr. MCGARRITY. No, never got done.

Mr. GLOVER. Okay. You know, 25 percent of the key innovations in America come from this program. Thirty to 50 percent are commercialized. This program is working very well. If you are going to remove any restrictions, if you allow VCs in, don't restrict them. Change the name of the program. Make it the Venture Capital Innovation Research Program, because if over half of them who are going to participate are going to be VCs, change the name of the program.

A couple of things that are pretty clear to me. When I look at this, 80 percent of the firms in Dr. Wessner's study lost money. Of VC-funded, controlled firms, 80 percent lost money. Three-hundred million dollars, they lost. The nine that made money only made \$52 million. I am not sure the VC-controlled firms have such a sterling record they can brag about. And the fact that the majority of companies in the NIH program that were not VC-funded were able to get in the marketplace for commercial sales.

If somebody can find another R&D program in the world that does a better job of getting the commercial technology, getting to the marketplace than this program, say so right now because I don't think there is one anywhere and I have never heard of one. So it is a great program. Congress has a wonderful chance to screw it up, and they may well do it. But for 27 years, it has worked very, very well, and minor tweaks, that is acceptable. But somebody finds out in five years we have screwed up the best innovation program the United States ever had, we are going to be back crying and wondering what happened.

But if you are not going to restrict the amount of VC participation, change the name of the program. It is no longer a small business program.

Ms. WHEELER. And even though you have arguments against changing the eligibility rules, could your organization's members live with a compromise of 18 and eight?

Mr. GLOVER. We did when this bill was brought up before the Senate. We recognized that. We agreed with BIO and NVCA at the time. That was acceptable. We obviously recognize reality. But

clearly, there needs to be a number of things in this to make sure that there are controls and balances on that. We need to make sure that, monitoring it, we control it, we know what is there, we know it is U.S.-owned venture capital companies, not foreign venture capital companies. We need some clear safeguards and protection within that 18 percent. The Senate bill went towards that goal, but I think more protections and certainly more monitoring so we don't find out we have done something we didn't mean to do.

Ms. WHEELER. Thank you.

We are about to lose our court reporter. Jim, did you want to comment?

Mr. BARRY. I won't repeat many of the things. One of the things that was most troubling to us, particularly in not the legislation produced here but the House, was the combination of changing the eligibility, increasing the award sizes, and allowing companies to skip Phase One. And I think that combination is particularly terrifying to a lot of the companies that have been involved in the program. So I think that your bill certainly addresses that and we are supportive on that basis.

Ms. WHEELER. And for Creare, would it be acceptable for there to be a compromise of 18 and eight, or do you want zero, or is it acceptable?

Mr. BARRY. Well, I guess I would prefer zero, but the compromise, we supported that last fall and we continue to support that.

Ms. WHEELER. Okay. Lenka.

Dr. FEDORKOVA. Yes. I just want to say we really appreciate you trying to reach a compromise. It is a very difficult issue and I think we need to look forward into how to maintain the quality of the program.

I am not going to comment about what percentage is appropriate. I think that is always a very difficult situation to enter into that discussion. But I would just say that from an NIH SBIR survey which was OMB-approved, we know that about 65 percent of our Phase Two awardees will require FDA approval. Federal dollars are not able to go that far. The Federal requirements, the FDA requirements for clinical studies and milestones are extremely expensive, so I think the question should be who will support that kind of a gap funding?

We talk about the valley of death and there is only so far the government can support small businesses, and to help them get close or across the valley of death, our competing renewal programs are not going to be sufficient, either. I think there is a logical synergy that exists and has always existed between small businesses and other types of investors. The VC firms are also a very diverse group of investors, very small, very large to very high-risk averse. That is where the government steps in to support the start-up companies.

I don't believe that companies that have in the past participated and had VC funding claimed to be disadvantaged. I think we are talking about something very else. We are talking about the geographically disadvantaged groups, minority, women-owned, and those who don't have access to capital. As we all know, that is very much concentrated on the coasts, as the data supports that. You

obviously will have a lot of California and East Coast-based companies that successfully compete for very good reasons, that they have access to those resources.

So I think the number is an arbitrary number in terms of not allowing sufficient room for instances where companies feel they can come back into the program—

Ms. WHEELER. Based on what?

Dr. FEDORKOVA. Based on the need of what the biomedical enterprise requires in terms of costs and what the Federal dollars—

Ms. WHEELER. What data do you have that says that 18 percent would not be sufficient and why do you use the word “arbitrary” when we have said it is based on the GAO report data? And if you all didn’t think that data was so good, why did you pay \$300,000 or \$400,000 for a study that looked ten years back instead of going forward?

Dr. FEDORKOVA. I don’t have an answer to that, but I would say—

Ms. WHEELER. Right, so—

Dr. FEDORKOVA [continuing]. I also question—I haven’t seen the—

Ms. WHEELER. They used proxies. They identified—

Dr. FEDORKOVA. I wanted to actually ask a question of the GAO to clarify the 70 percent of awards from all NIH awardees being VC-backed.

Ms. WILLIAMS. I was just getting ready to correct that. The 70 percent was awards above the guidelines, and of the—70 percent of all awards, NIH awards above the guideline. I am sorry. Seventy percent of NIH’s dollars went to awards above the guidelines, which supports the notion that biomedical does take a lot of money, and NIH operated under a blanket waiver so they were not reporting to SBA, at least at the time of our report, each individual instance. And it was of those awards above the guidelines, 18 percent of those went to firms that had VC investment. I think both the NRC study and our study showed that the majority of awards went to firms that did not have VC investment.

Dr. FEDORKOVA. Thank you. I really was concerned that maybe the perception was going to be there that 70 percent of our companies had VC backing, which really did not sound correct.

Ms. WILLIAMS. Right. No. It was—

Dr. FEDORKOVA. We have so many Phase One companies that are nowhere near being ready for that kind of investment.

Ms. WHEELER. If NIH has data to show us that this amount is not sufficient, please give it to us. As we said, today is the day to make the case, okay?

Dr. FEDORKOVA. That is, unfortunately, challenging. OMB doesn’t allow us to survey and ask particular questions. That, in fact, may be helpful to maybe consider how companies, I mean, agencies could be empowered to ask some questions. That is the large unknown we are not able to, unfortunately, really get a handle on.

Mr. NECCIAI. Okay. Any data that anyone is able to provide, I think Kevin might have mentioned it or Chair Landrieu might have mentioned it before, but the record will be open for one week starting today until next Thursday, the 11th, COB.

Ms. WHEELER. Kunal.

Mr. MEHRA. Thanks. Just a very quick, two points or observations. One is all of the arguments that have been presented in the last hour about whether to allow VC participation in the program or not have all been based on examples from the biomedical space. So my question is, since that is where all the examples are coming from, since that is really where the interest is coming from to allow participation, why don't we be a little careful here, to Jere's point, not to risk killing something that is working so well and instead pilot this in the NIH and wait longer and then reassess whether it makes sense for the DOD, because I am really not hearing anybody from the DOD side, industry, the agencies themselves, or any lobbies stating that this is integral for DOD. So that is the first point I would like to make.

The second thing is, again, black or whites don't apply here. I think there are shades of gray. What makes a disadvantage? What doesn't make a disadvantage? But I think there needs to be a cap on how much venture capital investment is allowable or not. Clearly, a company that has raised \$100 million is not disadvantaged. Now, I know there is no data to support this, so is the number \$5 million, \$10 million, \$12.5 million, \$12.6 million? I don't know. I would suggest maybe seven or eight or ten as the max, as a cap. But I think that there has to be that kind of cap in the legislation.

And I also think that individual agencies should have discretion to disqualify certain companies if when they look at them they just don't think that they are a small business. It would be very difficult to do that right now.

Ms. WHEELER. Thank you. Thank you, Kunal, for those recommendations.

Keith, did you want to go quickly?

Mr. NECCIAL. I am sorry. Just to be fair, there is very, very small, but there is some existing—they might not be sitting at the table today, but we have had in the past representation for VC majority-owned firms at the Department of Defense and at other agencies. But you are right. They are very small.

Mr. CRANDELL. I guess I would say that, no question, the focus of this is sort of geared toward the NIH and the life science-related programs. I do believe, however, there is a major investment that the Federal Government is making in labs and universities for new technology that isn't physical science-based and it is called things like nanotechnology. It is called clean tech. It is called energy tech. So the notion that there aren't groups, and from the NVCA's standpoint, we believe those should be equal. In fact, we don't understand why they would be different unless there is some notion that somehow we are trying to stop innovation or not fund it as well in those particular areas. So I would like to just make that point.

And then just one little other one is just that, again, for the purposes of sitting in a room like this, it is much cleaner and easier to say, well, there is a Phase One, then there is a Phase Two, then there is a Phase Three, then there is venture capital, then there is private equity, then there is public markets. The world is much more complicated than that and I think actually we are all better for that, because if we had more experienced people that were doing investing at the early stages, there would be more choice and

advantage for the entrepreneurs that were starting companies in that space. So while it might seem attractive here to exclude people, in point of fact, I think we really want to be inclusive and try to bring capital to that gap. And the people that have that capital are venture capital people or wealthy private individuals in many cases.

So I don't want to burn much more of your time. Thank you.

Mr. NECCIAL. I know. We are really, really coming down to the last minute here and I really wanted to at least see if we can get, just for a moment, if SBA wouldn't mind, briefly describing the affiliation rule, as this is kind of a dove tail to the VC issue, and then perhaps open it very, very briefly to any comments.

Ms. EYESTER. Sure. In SBA's regulations in Part 121, we set forth the two eligibility criteria for businesses to receive an SBIR Phase One or Phase Two award, and there are size eligibility criteria. There are other criteria or requirements in our policy directive, but these are for size.

The first one everyone knows is the 51 percent owned and controlled requirement.

The second part is that they have to meet the 500-employee size standard. When SBA looks at size, okay, in 121 we have size standards for all of our programs, not just SBIR, we have either revenues or employee-based size standards. This one is employee-based. We always look at the business concern and its affiliates. So this is a concept that has been in SBA's regulations since, I believe, the first time we ever issued regulations on size.

Affiliation has been around for a very long time. There are some exceptions to affiliation. Most of them are done legislatively. There are some that are done by regulation. Our size regulations are done on notice and comment rulemaking, so everyone has had a chance to comment on this or see what SBA has proposed.

The basic—I guess the way I can sum up affiliation is we are looking at control. So we are looking at if a business concern is applying to the program, we are trying to see who controls that business concern, and it may be that they are 51 percent owned by another company or it may be that the stock is so widely held that you would have to look at the board or directors or the president to determine who controls the concern. But that is what we would look at, and then we would see who controls the concern, and if it is a person or a business, we would look to see who that person—what other businesses they control, and then we affiliate them for size purposes.

I am not sure if anyone has questions on it or—

Mr. NECCIAL. I guess one of the main concerns is that majority-owned venture capital firms have been excluded. Have there been, or in what instance would you say as far as number-wise—I don't know if you report this, but have come to you that don't know? I think there is a lot of confusion whether firms just don't know if they qualify or not.

Ms. EYESTER. Sure. We get—I mean, SBA gets calls every day. I know I get calls at least once a week from businesses trying to either—even when they are trying to set up, they are trying to figure out how would they be eligible for a certain program, not just SBIR, but all of our small business programs. We have our district

offices that get calls all the time and our size offices and we talk them through our affiliation regulations and the ownership and control requirements, and every business is different. There are different nuances.

But yes, if you are 51 percent owned and controlled by a business and that business owns several other businesses that they control, not just own, but they control them, again, we would call them affiliates and we would count all the employees from those other businesses if it is an employee-based size standard and count them towards the employees of that business applying for, for example, the SBIR program for Phase One and Phase Two awards, not Phase Three.

Ms. WHEELER. And would SBA be in favor of exempting the employees of portfolio companies of VCs that have majority ownership and control of an SBIR applicant?

Ms. EYESTER. I am going to—

Mr. IYER. That is an issue that we would be interested in hearing different people's perspectives on. I think it is a complicated issue. But at the moment, the SBA does not have a position on that particular rule, but we can get back to you.

Ms. WHEELER. And just for clarification, does SBA consider that it changed its eligibility standards in 2002 or does it consider it a clarification?

Ms. EYESTER. What I did was I looked back through the regulations, and our regulations—I will start with the OHA decisions. The OHA is an administrative tribunal and they are composed of the administrative judges and administrative law judges, and what they did in both of their decisions, the CBRL and the Cognetics, is they looked at their regulations and the wording in the regulations, and the regulations at the time specifically talked about 51 percent owned and controlled by individuals who are U.S. citizens or permanent resident aliens.

I went back to the first time we ever used it in the regulations, those exact terms, the individuals owned by U.S. citizens. It was 1989, and that was put into our 13 CFR 121, and according to the preamble in that regulation, we were mimicking what was in the policy directive which had been issued way back then. So I don't see that there was any change in the plain language of our regulation starting from at least 1989 until we issued the change to basically broaden the eligibility requirements of the program.

Ms. WHEELER. And was there a change in interpretation?

Ms. EYESTER. Again, I can tell you that the plain language of the regulation did not change and that is what OHA looked at.

Ms. WHEELER. Does NIH believe there was a change? Just yes or no. I mean, sorry, we are running out of time.

Dr. FEDORKOVA. No.

Ms. WHEELER. Does DOD believe there is a change?

Ms. OLIVER. I don't know.

Ms. WHEELER. Okay, fair enough. Okay.

Thank you. If anybody has changes to the base legislation, as we said, would you please get it to us. You have one week. And thank you very much, and particularly those who came through this very bad weather.

Mr. NECCIAI. Yes. Thank you.

[Whereupon, at 1:13 p.m., the committee was adjourned.]

