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THE IMPORTANCE OF THE BIOTECHNOLOGY INDUSTRY AND VENTURE CAPITAL SUPPORT IN INNOVATION

HEARING

BEFORE THE

SUBCOMMITTEE ON RURAL ENTERPRISES, AGRICULTURE & TECHNOLOGY

OF THE

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THE IMPORTANCE OF THE BIOTECHNOLOGY INDUSTRY AND VENTURE CAPITAL SUPPORT IN INNOVATION

WEDNESDAY, JULY 27, 2005

HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON RURAL ENTERPRISES, AGRICULTURE AND TECHNOLOGY
COMMITTEE ON SMALL BUSINESS
Washington, DC

The Subcommittee met, pursuant to call, at 2:05 p.m. in Room 311, Cannon House Office Building, Hon. Sam Graves [Chairman of the Subcommittee] presiding.

Present: Representatives Graves, Barrow, Bartlett, Velazquez

Chairman GRAVES. Good afternoon everybody, and welcome to this hearing of the Subcommittee on Rural Enterprises, Agriculture and Technology on the Small Business Committee. I apologize for being a little bit late. We have got a string of votes that could happen at any time now so I thought we would go ahead and get started and get some of the opening statements out of the way. Then we will take our votes, and we will come back as soon as those are over.

Today, we are going to be discussing the importance of the biotechnology industry and venture capital support in innovation, and I appreciate everybody's support and participation, anyway, in today's hearing. We are going to have a good hearing. I think it is going to reflect both sides of this issue, and we are trying to find out as much as possibly about venture capital when it comes to the biotechnology field.

The Small Business Innovation Research program [SBIR] was created by Congress in 1982 to increase the participation of small technology firms that participate in federal research and development activities. Federal agencies with R&D budgets of over $100 million or more are required to allocate 2.5 percent of all federal research and development grants to small business applicants.

I take a particular interest in this issue since my undergraduate studies yielded me a degree in agronomy, particularly plant physiology. I understand the importance of and potential in biotechnology and the research these small companies do. In fact, the State of Missouri is slowly attracting more of these biotechnology firms from all across the country into our state. This means jobs for rural America and value-added products for farmers.

Without question, the United States remains the global leader in the field of biotechnology. Part of this success can be attributed to the federal government's role in promoting critical research and development. This program allows for cutting-edge research that may not, in its earliest stages, attract funding from other sources.

Venture capital funding is critical to the small biotech companies. They provide the initial seed money to help get some of these innovative ideas off the ground and running. Without this investment, given the nature of the biotech industry, it would be very difficult to finance this process. These small businesses are providing the country with the ideas and innovation that have become the identity of the United States.

The biotechnology industry is unique in that it takes hundreds of millions of dollars to bring a product to market from its conception. Biotechnology companies must rely on venture investment as well as grants for sufficient funding.

SBA regulations require that, to be eligible, a small company must be at least 51 percent owned by one or more individuals. The SBA recently clarified the definition of an "individual" to include only actual human beings and not other forms of investment. This clarification now excludes many of the small biotech companies that participated in the SBIR program in the 20 years prior to this SBA clarification.

Again, this hearing is going to examine this clarification and legislation that has been introduced, the Save America's Biotechnology Innovation Research Act. This legislation seeks to address the eligibility issue and restore the success of the SBIR program experienced prior to the 2002 SBA "clarification." The rule change resulted in the disqualification of many of the small biotech firms engaged in that research.

It is now my pleasure to turn the mike over to Ranking Member Barrow for his opening statement.

[Chairman Graves opening statement may be found in the appendix.]

Mr. BARROW. Thank you, Mr. Chairman. Mr. Chairman, some of the nation's fastest-growing and most successful small businesses are responsible for introducing many of America's high-tech products, and the economic benefits of these small firms is undeniable. They employ almost 40 percent of the country's high-tech workers. In Georgia, over half a million working men and women currently are employed in the high-tech industry.

The technology boon of the 1990's fueled the rise of these high-tech firms, an industry that has changed the face of the American economy. From biotechnology to information sciences, these industries have created good-paying jobs, and they have provided considerable benefits to Americans of all walks of life. We all recognize the significance of these firms, and I believe that Congress has to work together to keep technological innovation at the top of our agenda.

For over 20 years, one of the keys to sustaining our nation's technology advantage has been the SBA's Small Business Innovation Research program, providing between one to $2 billion a year in grants to start-ups and emerging firms. This program has invested over $14 million in Georgia companies. The SBIR program plays a

critical role in technology development by providing small companies with the valuable seed funding they need to get their ventures off the ground. This has helped thousands of small businesses across the entire high-tech spectrum to grow, taking their product from an idea to an established technology.

While the SBIR program provides an important source of seed capital, it alone cannot meet the financial needs of these emerging businesses. Research and development in the technology industry is incredibly expensive, often reaching millions upon millions of dollars. In order to fund new research and meet the goals of technology development and scientific advances, these businesses must have a healthy amount of venture capital. Without this vital source of financing, all of the great ideas that the SBIR program fosters will never have the opportunity to move from the drawing board to the board room.

Today's hearing will give us an opportunity to look at the important role that venture capital plays in the SBIR program. It will also allow us to review a current SBA rule that is limiting this critical source of financing for America's small technology companies, a rule that needs to be revisited.

In 2003, the SBA set an arbitrary cap on the type of investments that small businesses can receive, limiting the nation's emerging high-tech businesses' access to SBIR program. This rule runs contrary to the goal of the SBIR program, which is to assist in the development of technology that will have a place in the global marketplace.

I am sure we can all agree that it is not the intention of the SBA to block small firms in the SBIR program form succeeding. Clearly, there is a need to ensure that legitimate small businesses have access to SBIR awards, but putting a rule in place that appears to protect small businesses on the surface but ends up only hurting them in the process is not good policy. There are no few industries that need the infusion of venture capital funding more than small business technology sector. If left unchanged, this current rule will have a chilling effect on the future of the venture capital and high-tech industries.

Today's hearing will give us the opportunity to learn more about the nuances of the SBIR program. Those testifying this afternoon will present a firsthand account of how important the SBIR program is to small businesses, and their testimony will show that without proper public/private partnerships, we will be denying American small businesses the tools they need to grow in today's economy.

I have invited a fellow Georgian to come testify here today. His name is Tony Cruz, and he works for AviGenics, Inc., in Athens, Georgia. AviGenics is a biotechnology company that is developing therapeutic proteins for oncology infections and autoimmune diseases.

Mr. Cruz, thank you for being here today, and I look forward to hearing your testimony.

Thank you, Mr. Chairman.

Chairman GRAVES. Mr. Bartlett?

Mr. BARTLETT. I am very pleased to be here today to welcome an old friend, Jere Glover. It is good to see you again after many years.

In a former life, I was a small business person. I ran a company for 12 years and met a payroll every Wednesday morning, so I know the discipline that small business goes through. I am very pleased to be here in Congress today helping to look after the needs of small business, clearly the backbone of the economy in our country. Thank you, gentlemen, for being here.

Chairman GRAVES. We are going to break now. We have probably about five, six, seven minutes left on this vote, and then there are three, five-minute votes. We will break and then come back here immediately, pick up immediately after those votes are over. Then we should be clear for the rest of the afternoon to have a good hearing. But we will recess for just a few minutes, and we will be back.

[Whereupon, at 2:14 p.m., a recess was taken.]

Chairman GRAVES. We will bring the hearing back to order. I apologize again for the interruption with votes. Neither I nor Mr. Barrow make the schedule, unfortunately, so we have to abide by it when votes do come up, and hopefully we are going to have plenty of time this afternoon now to work through our hearings.

I want to point out that all of the statements made by Members and the witnesses will be placed in the record in their entirety, just so everybody knows, and we will start out with Mr. Douglas Doerfler, President and CEO of MaxCyte, Inc., and also you are here to represent the Biotechnology Industry Organization from Gaithersburg, Maryland.

I appreciate you being here. I know you have come not quite as far as some others, but I appreciate it very much. I know you all are very busy, and I am glad that you did take the time to testify. This is a very important subject. I appreciate you being here. I look forward to hearing your testimony.

STATEMENT OF DOUGLAS A. DOERFLER, MAXCYTE, INC.

Mr. DOERFLER. Thank you, Chairman Graves and Ranking Member Barrow. Thank you for the opportunity to testify today on the SBIR grant program.

As you mentioned, I am Doug Doerfler. I am the president and CEO of MaxCyte. We are a biotechnology therapeutics company located in Gaithersburg, Maryland. I have led professionally the development of a number of successful biotechnology companies and products over the last 25 years.

We founded MaxCyte in 1999. We have 20 employees and are developing novel therapeutics to treat serious diseases. We have one product in Phase I clinical human testing for the treatment of patients with leukemia and additional products in pre—clinical testing for the treatment of lymphoma, breast cancer, and ovarian cancer. These programs are in combination with a number of major universities, including Baylor College of Medicine, the University of Pennsylvania, and Harvard University. MaxCyte was a recipient of a Phase I SBIR grant in 2003, but we are no longer eligible to participate based solely on our source of investment capital.

Today, I am testifying on behalf of the Biotechnology Industry Organization, an organization representing over 1,100 biotech companies, universities, research institutions, and state biotechnology associations, in all 50 states. I want to thank the Subcommittee for holding this hearing on the SBIR grant program and applaud the introduction of H.R. 2943, the Save America's Biotechnology Innovative Research Act, by Chairman Graves.

I ask your permission to submit for the record a letter in support of Chairman Graves' legislation signed by 281 biotech CEOs from 37 states.

B.I.O. represents many established companies in the industry. Over 85 percent of BIO members are small emerging companies with fewer than 500 employees and half with less than 50 employees. Not surprisingly, the SBIR program has played a critical role in providing necessary financing for many of my fellow small biotechnology companies.

Unfortunately, a recent interpretation by the SBA regarding eligibility requirements for the SBIR program has prevented the majority of BIO members from participating in the program. Specifically, beginning in 2003, the SBA Office of Hearings and Appeals ruled that companies that were venture capital backed in excess of 50 percent were no longer eligible for SBIR grants. Prior to this ruling, during the 21 years the SBIR program has been in existence, the majority of venture capital-backed biotechnology companies fully participated in this program.

H.R. 2943 would rectify this problem and allow venture-backed, small biotech companies to once again pursue their innovative and cutting-edge research under the SBIR program.

By way of background, I would like the Committee to understand the unique aspects of the biotechnology industry. The average development cycle for a successful biotechnology product is 15 years, and only one of five make it from the start of Phase I human testing until it is approved. Therefore, before most products can become commercially available, years of research and often hundreds of millions of dollars are required to complete testing, gain product approval, and build the necessary manufacturing infrastructure. While there are many different funding strategies, the typical form of investment in promising, early stage biotechnology companies is venture capital.

In our industry, even the relatively small amount of money a company will raise in its first round,—this is called a "Series A"—between five and $8 million, generally results in new investors, usually a collection, a syndicate, if you will, of venture capital funds, owning more than 50 percent of the company.

Therefore, both SBIR and VC funding is necessary to support the lengthy and costly clinical development process. Limiting government support for biotech R&D risks delaying the discovery and development of promising new therapies for cancer, diabetes, Parkinson's Disease, and, significantly, many diseases where there is less commercial focus, like tuberculosis or diseases that would qualify for orphan drug designation.

In fact, according to a recent letter from Dr. Zerhouni, director of NIH, to the SBA, which I would also like to submit for the record, the SBA's current eligibility rule excluding majority venture

capital-backed biotech companies, and let me quote this, "undermines NIH's ability to award SBIR funds to those applicants whom we believe are most likely to improve human health, which is the mission of the NIH." That is a direct quote from his letter.

While almost all BIO members will need to raise venture financing to advance their products toward the marketplace, many small biotechnology companies have come to rely upon the SBIR program to fund cutting-edge research in areas where venture capital and other sources of financing are difficult to obtain.

For example, while a company is working on a lead research program, it often comes across a new application or new project opportunities that will need to be tested before attempting to raise additional funds. These new opportunities are precisely the type of research projects that should be eligible for SBIR grants. MaxCyte, my company's, project fell into this category.

During our fund-raising process in 2003, we submitted a proposal to NIH to do basic research on our technology and expand its capabilities so that one day it may be used for biodefense or for pandemic influenza vaccine development. Venture funds were not interested in this particular project, as it was too early and risky. We received $95,000 in funding for our Phase I and subsequently, in 2004, closed a $10.7 million venture round. We were able to satisfy the rigorous milestones of our project, including breakthrough science to prove general concept, but we are now not eligible to participate in any further funding for this project by the SBIR program. Due to this ineligibility, this project has been suspended. This is extremely frustrating for us since we believe that this project will have potentially a major impact on biodefense and in preventing potentially the pandemic flu crisis.

The legislative history makes it abundantly clear that Congress intended for the SBIR program to assist small businesses in commercializing their creations and products and to stimulate small, U.S.-owned firms to produce innovative technologies. Congress viewed the SBIR program as providing the necessary "proof of concept" to encourage venture capital investment in promising small businesses seeking to bring products from the lab bench to the marketplace. Moreover, Congress even created an SBIR Phase II preference for companies that attracted venture capital investment by providing special consideration in the funding review of Phase II proposals.

B.I.O. believes that this enormous promise of biotech R&D merits exploration and investment on a variety of fronts and by spectrum of creative, dynamic, and dedicated entities. Biotechnology is a fertile field, from which patients can reap huge benefits, if it is supported by both public and private investment. The rewards of biotech are limitless unless we choose to limit those who can participate in this effort. I urge the Subcommittee to favorably report H.R. 2943. I thank you, and I am pleased to take any questions you may have.

Chairman GRAVES. Thank you very much, Mr. Doerfler.

Next, we are going to hear from Daniel Broderick, who is the managing director of Mason Wells. You are representing the National Venture Capital Association from Milwaukee, Wisconsin. I appreciate you being here. I might point out to you that we gen-

erally do give minutes for statements, but I do not adhere to that very closely, so if you go over, it is no big deal. I am not going to crack any whips or anything. So I look forward to hearing your testimony, and thank you for coming today.

STATEMENT OF DANIEL J. BRODERICK, MASON WELLS

Mr. BRODERICK. It is my pleasure to be here. Again, my name is Dan Broderick. I am a founding managing director of Mason Wells Biomedical Fund, located in Milwaukee, Wisconsin. Mason Wells is a small, venture capital fund focused on seed and early stage investing in the life sciences in companies located in mid-America.

Today, I respectfully submit testimony on behalf of the National Venture Capital Association and those venture-backed companies that are developing innovative technologies that improve the quality of our lives and raise our standard of living. For the last 20 years, the dual financing sources of the SBIR program and the venture capital community have allowed many of these promising companies to conduct ground-breaking, scientific research while simultaneously building viable businesses that will bring these innovative products to the marketplace.

Venture capital is the investment of equity to support the creation and development of new, growth-oriented businesses. In terms of global competitiveness, the entrepreneurial segment of the economy is the true differentiator in America. U.S. companies originally funded with venture capital, like Genentech and Amgen, now represent 11 percent of our annual GDP and employ over 10 million Americans.

There appears to be a misunderstanding that venture capital firms are large corporations that control the small start-up company by having a majority control over the company's board. It is important to understand the organizational structure of a venture capital firm, its limited partners, and the relationship between the VC firm and the portfolio company.

Private venture capital funds are organized as limited partnerships and are managed by general partners. The general partners, like myself, are the individuals staffing the venture capital firm. They are responsible for and control all aspects of the fund's operations, including making the investment decisions. The venture capital funds are small organizations. In fact, the average number of general partners in any one firm in the United States is only 10. The investors in these limited partnerships are usually pension plans, foundations, trusts, and accredited investors, and they are called limited partners because they are limited from liability because they exert no control in the day-to-day operations of the VC fund, they do not participate in setting the strategic direction of the fund, and they take no role in making the investment decisions.

The limited partners' investment in a venture capital fund is not a revenue stream for the fund; rather, the money that LPs invest in a venture fund are to make investments in portfolio companies and as loans to fund the day-to-day operation of the fund. These investment dollars and loans must be repaid by the venture capitalist before the firm can then profit.

Based on my experience, the great number of companies that I see have established a board of three to seven members prior to any venture capital involvement. Members of these boards comprise founders, management, investors, and industry experts. Once a venture capital firm is involved, most boards slightly increase in size, with members representing the same groups of people. Each vote on the board is equal, and it is the fiduciary duty of each individual board member to act in good faith and in a manner to be in the best interest of the corporation. The groups involved generally do not vote as a bloc; rather, each member votes their own conscience.

I would also like to briefly address the relationship between corporate venture capital and traditional venture capital firms, as outlined above. Typically, corporate venture capitalists play a different role than a traditional venture firm. They generally only co-invest alongside a traditional firm and usually do not take a board seat. They also generally own less than 20 percent of the portfolio company because of corporate-reporting rules. Furthermore, corporations manage only 4 percent of all venture capital under management.

So why do venture capital firms care about SBIR grants? For the last two years, portfolio companies have continually alerted the NBCA to situations in which an SBIR grant has been denied because they have venture investors. Many of these firms were caught by surprise because this program has been working well for 20 years.

It is paramount not to confuse the role of venture capital funding with the role of basic R&D funding. Both are critical to bringing innovation to the marketplace; however, basic research funding is targeted at discovery and invention. It is this type of activity that the SBIR program has historically supported. Venture capital dollars, even those labeled early stage, are used to build a strong and viable business so that promising discoveries can be brought to market.

Some would argue that if a company receives venture capital, that it has hit the lottery and does not need government funding. Nothing could be further from the truth. In the life sciences sectors, the cost and time associated with bringing a discovery to market is colossal. Multiple rounds of financing at millions of dollars per round are required.

The cost of bringing a new drug to market is about $800 million. Young biotechnology companies cannot divert precious venture capital funds earmarked for business growth to embark on new research projects, although these projects may hold the next groundbreaking treatment for Alzheimer's, cancer, or other diseases.

Another belief is that venture investment only impacts select regions of the country. To the contrary, venture capital is a national phenomenon. While Massachusetts and California are the leading regions for venture capital investment, VC dollars have been flowing to all 50 states over the last 20 years and have directly benefitted regional economies across the country. Ironically, however, the SBIR program eligibility rule hurts the low-tech regions it is trying to support.

Mid-America is one example where investing in early stage technology companies is difficult because of the smaller percentage of venture capital investment. From my experience as the founder of the Mid-America Health Care Investors Network, I know the inability of small businesses to compete for and receive SBIR funds is of particular concern to venture-backed companies in mid-America. The ruling that disqualified VC finance companies from competing for SBIR grants removed an essential source of financing, causing R&D at many technology companies located in mid-America to slow or stop altogether.

A way to ensure the ongoing success of the SBIR program is to reopen it to the broadest and most qualified base of small businesses possible. This requires allowing venture finance companies to compete once again.

Since SBIR's inception some 25 years ago, venture capital and SBIR funding have been proven to work together to research, commercialize, and distribute innovative products on an accelerated basis. Recently, Congressman Graves introduced legislation that clarifies SBIR eligibility requirements for venture-backed, start-up companies. NVCA applauds this effort and encourages quick action on this legislation, and we look forward to working with the Committee to address this spiraling problem, and I thank you all for the opportunity to express my views.

[Mr. Broderick's testimony may be found in the appendix.]

Chairman GRAVES. Thank you, Mr. Broderick.

Next, we are going to hear from Barry Michael, who is President of B.A. Michael Consulting and here with the Small Business Technology Council from Clifton, Virginia. I appreciate you being here. Thank you very much.

STATEMENT OF BARRY MICHAEL, B.A. MICHAEL CONSULTING

Mr. MICHAEL. Good afternoon. My name is Barry Michael, and I head a consulting company whose primary focus is life science start-up companies in the Mid-Atlantic region of the U.S.

My business career began in 1972, after serving as a Naval Supply Corps officer during Vietnam. I have been part of the health care industry for the last 23 years. Many of these years, I worked for two major Fortune 100 health care companies. However, since 1993, I have worked primarily with start-up companies, with my focus including finance, strategy, tactics, and marketing. I have an engineering degree from Brown University and an M.B.A. from Wharton.

I am here today to support the small start-up company. I believe that it would be bad policy to expand the current criteria for SBIRs to include large, venture capital, majority-controlled start-ups.

I have worked closely with four different organizations that have had SBIRs awarded by the NIH. I believe that it is important to note their collective stories. SBIRs were critical as they formulated start-up strategies, developed products, and matured as businesses. For the purposes of perspective, I have also played a key role in a majority-controlled, venture-backed, biotech start-up. Therefore, I am at least somewhat aware of the fundamental differences, both financial and strategic, of these two types of start-up organizations.

Venture capitalists usually think in terms of investing several millions of dollars. They represent very sophisticated investors who demand that the VCs hit their specific financial targets and have specific timelines for success. Early, small, science start-ups almost never meet these conditions and thus almost never qualify for VC funding in their early stages when it is most critical financially and strategically. Their risks are too great, their timelines too long, and their management teams are still too unproven. But this unproven group is still taking the personal risk, and they represent one of the crucial ways that important life science breakthroughs can start.

When a person or a group of persons starts to develop their life science idea or invention, they are faced with daunting technology, market, and finance challenges. They will rely on their creativity and technical training to develop their idea, but usually they have to learn product development, business, and finance until their idea is proven.

Most of these life science companies are so unproven or so clearly risky that established companies shy away from supporting them until the data show some glimmer of hope. SBIRs support the generation of that data. The NIH also provides valuable feedback to SBIR applicants, and if the proposal does not make it the first time, it may make the grade when resubmitted. Getting an SBIR Phase I contract award represents important validation. Getting a follow-on Phase II, like one of the companies that I have worked with, makes it possible to undertake follow-up studies, and theirs was a medical device clinical study.

Many small start-ups plan to become competent enough to eventually be eligible to be financed by venture capitalists, both large and small. In the meantime, however, these start-ups have to rely on savings, spouse's income, friends and family, second mortgages on their homes, angels, and, most importantly, SBIRs to provide critically needed seed capital. SBIRs provide a significant percentage of this early financing effort. Small start-up companies typically generate several hundred thousands of dollars in funding. Funding for large, VC-controlled companies, when it is available, would be on the order of several million dollars.

Currently, the 2.5 percent of the NIH budget allotted to SBIRs creates a zero-sum game. Adding more types of eligible organizations that could threaten the current environment that very properly benefits the early, small, life science start-up company is something I would not recommend. These life science, young, start-up organizations represent the ongoing start of our country's innovation process. Said another way, in three of the four start-up companies I have personally worked with, there would not have been a company and a development effort if it had not been for SBIRs. None of these organizations were even remotely mature enough to qualify for VC investment, but their creativity and entrepreneurial spirit needed a chance.

Changing the current criteria to allow SBIR participation by large, venture capital-majority-controlled start-ups would be a major detriment to the life science start-up community. Bringing in new players with deep pockets will divert the current pool of money

away from small start-up companies. These early stage companies will be faced with even greater challenges.

Yesterday, the Small Business Technology Coalition released a survey of companies that received SBIR awards from the NIH. This survey is attached to Mr. Glover's statement for the record. Please note that nine out of 10 of these companies oppose giving large VCs greater access to the SBIR program funds. We are told that these companies are among the likely beneficiaries if large VCs are allowed to play a greater role. Yet these supposed beneficiary companies clearly oppose greater large VC involvement in the program.

While preparing this talk, I had an interesting comment from an expert in the public financial markets. He said, "I do not understand the issue. Venture-backed-capital companies already have their money." In fact, as noted in my attachment, they have $53 billion currently available to invest, and they cannot figure out how to invest it. Thank you.

Chairman GRAVES. Thank you, Mr. Michael.

Now we are going to hear from Jere Glover, who is the Executive Director of the Small Business Technology Council. Jere, thanks for being here today. I appreciate it.

STATEMENT OF JERE W. GLOVER, SMALL BUSINESS TECHNOLOGY COUNCIL, BRAND LAW GROUP

Mr. GLOVER. Thanks for inviting me, Mr. Chairman, Ranking Member. Jere Glover, executive director of the Small Business Technology Coalition. I have over 27 years of experience in small business innovation. I served as chief counsel for advocacy under President Clinton.

Let me start by saying that prior to enactment of the SBIR program, small business was virtually excluded from the federal R&D funding. This is true despite clear evidence that small businesses were more successful and more efficient at innovating than large firms.

This program is a magnificent success, widely praised, yields thousands of patents and billions of dollars in technology since 1992. It has had nine favorable GAO studies. SBIR companies are successful in commercializing their technologies to the extent of 40 percent, much better than even venture capitalists have been. It has worked so well that in its 20-plus years of existence, there have been very few and minor changes made to this legislation. It is not broken, and this fix is not needed.

The emphasis of the SBIR program is on early stage innovations and technologies, an area of little interest to the venture capital community. Less than 2 percent of venture capital investments last year went to early stage and seed investments.

There are four facts that are lost in this debate. First, Phase III specifically is designed to encourage and facilitate VC partnerships and investment in SBIR companies. Two, small venture capital companies can today own a majority interest in an SBIR company and that company remain eligible. Three, large venture capital companies can own 49 percent of an SBIR company without it creating a problem. And, finally, SBA is currently involved in the regulatory process on this very specific issue.

Where SBA has drawn the line is on allowing venture capital to own and control a majority interest in a small business SBIR company. This is based on Congress's core definition of a small business established more than half a century ago. A small business is one that is independently owned and controlled, 15 U.S.C. ◆ 632. There are numerous laws and regulations that are driven by that phrase and that provision. It is a very important underpinning of the Small Business Act. To my knowledge, this is the first time in the history of the SBA that Congress has been asked to redefine "small business" to include large businesses and companies that are owned and operated by them.

When this issue first came up, I surveyed the SBTC Board of Directors. They were unanimously and vehemently opposed to allowing venture capitalists to own and control SBIR companies. I later surveyed SBTC's membership, as well as SBIR participants, in a number of national SBIR meetings, always with the same results: Small businesses oppose the change in the definition to allow venture capital-owned and controlled companies to compete in the SBIR program.

Recently, we surveyed the NIH awardees. We referred them to BIO, the industry association, Web site where their position paper was located as well as referred them to ours. We then asked them the questions. Ninety percent opposed. This was true even when we asked the question about whether it was owned by institutions and pension funds.

In SBA's rule-making proceeding, there were a number of very interesting questions asked. Let me just mention those. Will the change in allowing venture capital-owned and controlled companies in the SBIR program shift the program emphasis to lower-risk technologies that are closer to the marketplace? Will it increase concentration in states like California and Massachusetts? Forty-six percent of venture capital money goes to California. Will it change the profile of successful and unsuccessful SBIR companies, and will it lead to calls for other changes to allow universities and large businesses in the SBIR program? I think the answer to all of those is yes.

These questions are very important, and I think they must be answered before Congress goes forward with such a radical change to a very successful program.

I wonder why SBA was not asked to present its views at this hearing. They certainly have the expertise, and with thousands of comments and dozens of field hearings, I think SBA should be heard.

The SBIR program is extremely competitive. For every company that receives an SBIR award, there are five to seven companies that have put in proposals that are not funded. This is especially true at NIH, where last year they received a thousand more proposals than the year before. There were 5,000 companies last year that submitted proposals to NIH that were not funded. Many ranked top, outstanding in science and technology, but there simply were not sufficient funds at the NIH to make the awards. Make no mistake: For every VC-owned company that receives an award, there will be a small business with outstanding technology that will go unfunded.

I fear that if the Small Business Innovation program is opened to venture capital-controlled companies, universities and large firms will try to make the same arguments, thereby defeating the underlying purpose of the SBIR Act, which is to make sure that small business has access to federal R&D funding.

The bill will result in increased geographic concentration of the SBIR program. As I mentioned, 46 percent of venture funds go to California. Ten states get 85 percent of venture funds. Having to compete with ventured-owned companies places small businesses and other states at a competitive disadvantage.

We are not unsympathetic to the concerns raised by BIO and the National Venture Capital Association. We have supported programs, such as the ATP program and the MEP program, that are not targeted for small businesses. At the Science Committee, it was suggested that there needs to be a program for a large VC and even large businesses to use the remaining 97 and a half percent of federal R&D to help them commercialize new drugs and new technologies. We are open to such a proposal. Our objection is to having funds for large businesses and VC-owned firms come out of the very limited funds that are available exclusively for small business. Thank you for allowing me to testify.

[Mr. Glover's testimony may be found in the appendix.]

Chairman GRAVES. Thank you, Mr. Glover.

I will turn it over to Mr. Barrow to introduce Mr. Cruz.

Mr. BARROW. Thank you, Mr. Chairman. With me today is a fellow Georgian to testify in today's proceedings. His name is Tony Cruz. As indicated before, he works for AviGenics, a company in Athens, Georgia. AviGenics is a biotechnology company that is developing therapeutic proteins for the treatment of oncology infections and autoimmune diseases. Mr. Cruz, thank you for being with us. I look forward to hearing your testimony.

STATEMENT OF ANTHONY P. CRUZ, AVIGENICS, INC.

Mr. CRUZ. Thank you. Chairman Graves, Ranking Member Velazquez, Ranking Member Barrow, and Committee members, Good afternoon. My name is Tony Cruz. I am the senior vice president of finance and administration at AviGenics. Before my involvement with the biotech industry, I served at active duty for five years as a captain in the U.S. Air Force, and I am thrilled to be a part of this democratic process.

On behalf of AviGenics and the biotech industry, I wish to thank members of this Committee for this opportunity to present my comments on the recently imposed obstacles which prohibit small biotechnology companies like AviGenics from participating in the SBIR program.

AviGenics is an up-and-coming biotechnology company located in Athens, a small town about 90 minutes from Atlanta. Our main offices and labs are located on the University of Georgia campus, and we are well integrated with the university's efforts to attract technology companies and to generate high-skilled, high-paying jobs for that area. AviGenics employs about 50 very highly skilled scientists, technicians, and specialized farm workers. Currently, Athens is better known for the university's football program rather than its expanding base of high-technology companies. We hope

that one day Athens, Georgia, will be recognized as much for its biotech excellence as the Georgia Bulldogs are for their football prowess.

This is an urgent issue. The SBIR and access to the SBIR funding can determine the future of this and other companies within the Athens area, including whether or not we survive in the near term.

AviGenics is not a subsidiary, nor is it a spinoff of a large pharmaceutical company. We are an independently owned and operated technology company dedicated to developing therapies for infectious diseases and cancer. The company's core technology is targeted specifically at producing protein-based therapies which are safer, more effective, and more affordable than those currently available on the market.

AviGenics's approach is somewhat different from the majority of the biotechnology industry in that we utilize modern research tools as well as traditional agricultural expertise. Specifically, our technology combines state-of-the-art molecular biology with Georgia's well-established poultry expertise to produce modern medicines at low cost in using chicken eggs as the core of our technology.

The value-creation cycle as experienced by the company over the last few years is very similar to those experienced by other biotechnology start-ups. Financial support from a combination of federal grants, including the SBIR program, and venture capital funding has been critical for the survival and growth of AviGenics up to date.

In the foreseeable future, SBIR funding will continue to be critical for technology development and preclinical testing of our products. SBIR funding and other federal grants make it possible for the company to establish a proof of concept for its base technology, and venture funding allows development of these specific products through very expensive clinical trials and the regulatory approval process.

Only by demonstrating proof of concept of our technology were we able to attract VC investment and thus then were able to hire new employees, pursue activities required for development of a lead product, and complete human clinical trials. Future expansion of AviGenics relies heavily on SBIR and other federal monies being available to develop proof of concept for the next set of technologies and future product candidates. This next set of technology validation will hopefully lead to more VC funding, which, in turn, will further hiring and completion of other clinical studies.

Early in the company's history, attempts were made to secure financial backing from industry to develop and validate the core technology. A cross-section of large pharmaceutical companies and established biotechnology companies were approached with an unproven concept of making low-cost and improved drugs through an unconventional technology, i.e., production of therapeutic proteins in chicken eggs.

The message from industry to AviGenics at that time was loud and clear: Come back when you can show us your technology works. The industry declined to fund the basic research, even when the promise of making drugs cheaper, better, faster, and safer was there. Funding from government research and a few angel inves-

tors was then necessary to reach the initial proof of concept for our technology. Then and only then was the company able to attract significant funding from VC firms, eventually leading us to where we are now, a 50-person company about to enter Phase II clinical trials.

In 2004, AviGenics completed a U.S. FDA-approved, Phase I human clinical trial for its lead compound to treat an insidious infectious disease. The data from the initial study suggests that our drug performs just as well or better and is safer than what is currently on the market. Furthermore, this drug will cost less than half of what it costs for a similar therapy today. Of course, more extensive human clinical trials are required for market authorization, but AviGenics's technology offers a significant promise to millions of patients who do not benefit from or cannot afford the currently available therapies.

Advancing our innovative technology to the point where we were able to initiate clinical evaluation was a path fully loaded with technical risk. This initial technology development took over four years as several different technical approaches had to be utilized without the SBIR grants or other federal funding.

It is important to note that even with the completion of a Phase I study for our lead compound, federal funding continues to be necessary for the company as we must continue to develop future products for other disease areas. Specifically, federal research grants are needed for technology-improvement projects, such as developing more effective and efficient ways to apply genetic engineering techniques.

According to the recently imposed eligibility standards, a business must be at least 51 percent owned and controlled by individuals who are citizens of the U.S., and the company may not have more than 500 employees, including affiliates. The SBA's current interpretation of "individuals" excludes venture capital funds. As a result, AviGenics is ineligible for future SBIR funding.

I believe AviGenics is a case study of what the SBIR program can do. Like I said, we currently employ close to 50 full-time employees, most of whom are highly educated and skilled. With SBIR and federal grants early in its history, our company was able to secure VC funding and thus initiate human clinical trials. We look forward to the day that our technology and hard work will result in affordable, effective therapies for those stricken with hepatitis, AIDS, cancer, or other ailments.

AviGenics strongly supports BIO's recommendation that the SBA adopt the rule that addresses the actual ownership structure of small biotech countries that are owned and controlled by venture capital companies. Since 1982, when the SBIR program was created, up until 2003, majority VC-owned, biotech companies were allowed to compete for SBIR grants. Specifically, we count on you to support this bill. Thank you.

[Mr. Cruz's testimony may be found in the appendix.]

Chairman GRAVES. Thank you, Mr. Cruz.

I am now going to recognize Ms. Velazquez, who is the Ranking Member of the full Committee. It is a pleasure to have you here. Thank you for coming for a statement.

Ms. VELAZQUEZ. Thank you, Mr. Chairman, and I would like to make an opening statement so that the record reflects my concerns about the SBIR program and the importance of venture capital and the role it plays in our economy. So I want to thank you for allowing me to make my opening remark.

We rely heavily on this nation's technology sector to advance us forward and to create the next generation of innovations that will carry us into the next century. Over the past two decades, small businesses have become the dominant employer of high-tech innovators, producing 55 percent of all new technological developments. Clearly, if this nation is going to continue striving forward in the fields of science, engineering, and computers, then we must be investing in these businesses. This is where the SBIR program comes in.

This program plays a critical role in enabling entrepreneurs with bright, innovative ideas in the technology field to receive the valuable seed funding they need to start and grow their businesses. The SBIR program is vital in empowering high-tech, small firms to obtain their end goal: to profit from its commercialization. However, the SBIR program needs some assistance when it comes to providing high-tech, small firms with the capital they need. That is why venture capital plays a vital role in turning innovative dreams into reality.

There is no doubt that the applied research in the high-tech industry is an expensive one. An example of this is in biotechnology and drug research where it is estimated to take $800 million and at least a decade for product development, testing, and movement to the market. Clearly, this is something that the SBIR program cannot finance alone. We need to ensure that there is a balance in getting venture capital to these aspiring technology firms. It is simply not a valuable option to limit the ability of small businesses to access one of their most significant resources: venture capital.

These businesses represent the next wave of innovations, and placing an arbitrary cap of 49 percent, as SBA proposed, on the investment they can receive will only hinder their ability to grow and develop. SBA's proposal simply takes opportunity away from high-tech, small firms wanting to make their way in the global marketplace.

There are many ways to ensure that this program truly maintains its focus on this nation's entrepreneurs without limiting their ability to access venture capital. These protections have already proven successful in other SBA programs. There is no reason why we cannot offer similar protections to the SBIR program. The issue here is that the need for venture capital within the technology sector is greater than ever.

Our nation simply cannot afford to have a policy that withholds venture capital investment from high-tech, small firms. The SBIR program clearly plays a vital role in empowering this nation's small business technology sector. However, without an adequate public/private partnership, its capabilities will be severely hindered. That is why it is important that any change to this program is guaranteed to maximize technological developments. A proposal that would only hold small firms back and rob them of available venture capital investment is simply not a good policy.

Without the resources offered through the SBIR program and adequate venture capital investment, small businesses will never have what they need to spur high-tech innovation and development in order to move this nation forward for generations to come. Thank you, Mr. Chairman.

Chairman GRAVES. Thank you, Ms. Velazquez. I appreciate it very much.

We are going to start with questions, and my questions, I guess, anyone could answer. I would be interested in hearing what all sides have to say about it, but one of the concerns with opening this back up is when a venture capitalist becomes a majority owner of a business, do they assume day-to-day control of the business, or—I might even rephrase that question—can they assume day-to-day control of your business? We will just start.

Mr. DOERFLER. We just completed our first venture capital financing round, so I am pretty intimately familiar with this one.

First of all, there was no single venture capitalist that owned more than 15 percent of our company at any given time. We put a syndicate together, and I am not aware of any company in our industry, the biotech industry, that is owner controlled by a single entity. The VCs came in as a syndicate. We were very careful, I think as was just mentioned, that we created a board of directors that was majority controlled by non-VCs to ensure that the control of the company was not in any group's hands. Management controls day-to-day operations, the board controls the company itself, and the shareholders obviously can appoint the board members.

Now, there is a shareholder agreement that most companies have—I believe virtually all companies have—that prevents any single VC from controlling the organization. The other members of the VC syndicate would not allow that to happen. So there is an inherent check and balance in our system to ensure that not one party will control the operations, certainly not control the day-to-day operations, of an organization.

Mr. BRODERICK. I would like to respond as well. It certainly is not what the venture capitalist even wants to do, is to control the day-to-day operations of a corporation. What we try to do is we try to find talented management to take care of that responsibility. They have the skill sets to do that. They have the experience generally to run the day-to-day operations of the company. Were we to have to step in to run the company day to day, it would be a bad situation. It would be probably a distress situation, and we would probably even then hire experts to come in and take over the orderly dissolution of that corporation.

As for controlling the company from the board of directors, it is our fiduciary responsibility as a member of the board of directors to act in the best interests of all of the shareholders involved for the purpose of increasing shareholder value. In all of the board memberships that I am aware of, each member has an independent vote. There are no side agreements: You vote my way. There are no club rules: I will vote for this if you will vote for that. Each member has a fiduciary responsibility to vote his own conscience on each issue as an individual.

Chairman GRAVES. Mr. Michael?

Mr. MICHAEL. I think that there are times when a VC-controlled or nearly controlled company is going to be frustrated about management's desire to take on new projects, and so although that is not possibly your definition of "day-to-day control," most energetic, creative scientists will often want to start new projects, and they will often be excluded from doing those projects unless they can get access to an SBIR grant. So that is a form of day-to-day control, and I think that happens fairly often.

Chairman GRAVES. Mr. Glover?

Mr. GLOVER. Most legal, underlying documents do provide the ability for the venture capitalist to take control if certain events do not happen or if certain things do not happen. To the extent the venture capitalist owns over 50 percent, collectively they have the option at any time to elect a new board, control that board, and make the decisions.

The SBA's size-determination rules for this and all other small businesses have always looked at the potential to exercise that control, whether it has actually been exercised or not. Legally, they will have the right to exercise that control, and SBA, to protect small businesses from that eventuality and to make sure that companies are legitimately small businesses, do look at the control issue, and they do look at the underlying documents, and, in most cases, those documents do provide sufficient opportunities for the majority holders to exercise those controls.

Chairman GRAVES. Mr. Cruz?

Mr. CRUZ. Just a short addition. In our case, at AviGenics, we are majority VC controlled; however, there are over 10 different funds that own that majority, and it is very, very difficult for any one fund to actually exert control over the company. As was said before, there are underlying legal documents that provide the distribution of decision-making throughout all of the funds, as well as the management team and other common shareholders.

Chairman GRAVES. Mr. Barrow? Ms. Velazquez?

Ms. VELAZQUEZ. Thank you, Mr. Chairman. Thank you, Mr. Barrow.

Mr. Broderick, I have a question, in particular, about how we can balance the need to allow increased venture investment versus protecting small businesses. If we had a structure in place that would allow venture capital companies to have an interest of up to 50 percent or more, if necessary, but made it clear that the day-to-day operations of the company rested with the small business owner and provided the investor the ability to step in and assume operations only if the company was in trouble, do you think this is something you could support?

Mr. BRODERICK. Thank you for the question. I believe that that is generally how the companies are operated today. There is a board of directors that is responsible for the control of the company, if you will, and we would be happy to work with you on evaluating that possibility, and, I think, look forward to doing that.

Ms. VELAZQUEZ. Thank you.

Mr. Doerfler, if we limit the amount of venture capital small biotechs can receive, where will they turn for financing?

Mr. DOERFLER. The question is, if we limit the amount of money we can bring in from venture capital. Well, the venture capital in-

dustry is perfectly suited to support the kind of work that we are doing because it is very high risk.

Ms. VELAZQUEZ. I am referring specifically, if we put a cap like SBA wants to do.

Mr. DOERFLER. Well, we will not be able to participate in SBIR. We, frankly, will not be able to do that, and investors will not come into the company unless they can invest as much as they want to and as much as the company needs to make it happen. If that cap continues, we will not participate in the program. It is that simple. It just is not worth our time to try to get around that.

Ms. VELAZQUEZ. So will this cause small businesses to choose between the SBIR or venture capital?

Mr. DOERFLER. Well, it will definitely be venture capital, not SBIR. We have no alternative. We would have to go with venture capital because, in my particular instance, our funding is 98 percent VC funding, and a very small amount is SBIR funding, and that is what we are doing for additional projects.

Ms. VELAZQUEZ. So what will that mean in terms of the biotech industry regarding development?

Mr. DOERFLER. I think that the biotech industry will walk away completely from the SBIR program. We are not able to participate.

I think there is another consequence to this. If companies like ours, like mine, for instance, who have demonstrated the ability to develop technology, do not participate in the SBIR, that SBIR program will lose its competitiveness. It will not be worth what it was before. There is a competitive spirit there. It raises the level of play, and if you have got a number of players that cannot participate, it lowers the relevance of that program and the overall portfolio of companies and entities that can help NIH.

So I think it is going to have a major effect. It will not have an effect on the industry as much as it is going to have an effect on the program and eventually NIH.

Ms. VELAZQUEZ. Would you like to comment, Mr. Broderick?

Mr. BRODERICK. Just one thing. Where would the biotechnology company go for money if they do not go to the venture capitalist? And I do not know. I do not think there is a choice. They would not be funded. They would go out of business, or they would continue to just get grant after grant after grant and never commercialize anything.

Ms. VELAZQUEZ. Thank you, Mr. Chairman.

Chairman GRAVES. Mr. Bartlett?

Mr. BARTLETT. Thank you very much. For the record, let me ask, if I am a small business company, and I get an SBIR, and if, in the process of the work on that, I come up with an innovation which is patentable, who owns the patent?

Mr. GLOVER. You would, sir. The SBIR company retains patent rights under the Small Business Innovation Act.

Mr. BARTLETT. Okay. Thank you. If I am a small company, and I attract venture capital to a project, is that committed to the project or to my company? Can I separate the project from the company, or is it given to the company?

Mr. BRODERICK. It is based on what is given to the company in general to have the company carry out the business plan, which includes a product development plan that the company has come up

with, vetted, and otherwise had it reviewed by experts, and the venture capitalist will put the money inside the company to support that business plan—

Mr. BARTLETT. I understand that under the present rules, if I am that small business company, and I have an idea that attracts venture capital money, that if more than half of my resources are venture capital money, then I cannot now apply for an SBIR for another idea I have. That is correct?

Mr. DOERFLER. That is correct. That is my understanding.

Mr. BARTLETT. By the way, I would like to ask Mr. Doerfler, do you own and control over 50 percent? I think you answered that. You own and control about 2 percent of it.

Mr. DOERFLER. Do I personally?

Mr. BARTLETT. Yes.

Mr. DOERFLER. Less than 1 percent.

Mr. BARTLETT. Less than 1 percent. Okay. I just wanted to get that on the record.

Mr. Glover, you indicated that there is not now anywhere near enough money to support the good proposals that come in to NIH for SBIR funding. Is that correct?

Mr. GLOVER. That is correct, sir.

Mr. BARTLETT. Okay. So we have two things here which appear to be in tension. One is small companies that have one good idea or maybe two or three, and they acquire venture capital funding, which now disqualifies them for SBIR, but, you know, this engine of creativity is not going to be limited to one or two.

I, in a former life, ended up with 20 patents, for instance. If I was pursuing one of those with venture capital money, then I could get no more SBIR money for one of those other ideas that I had. So that is on the one hand. We now have an idea that is going to add something of value to our economy. It is going to employ people. They cannot get any SBIR money, and the venture capital people, in spite of their name, are not really venturous, and they are not going to put any money out for this, and so now my idea goes begging because I cannot get any money.

On the other hand, we have legitimate small businesses where the owner controls more than 51 percent of it, and there is not even enough money to go around to fund the good SBIR projects there. Is that correct?

Mr. GLOVER. That is correct.

Mr. BARTLETT. Okay. Well, it seems to me that the solution to this problem is not to further dilute the effectiveness of that money by now spreading it over a broader field. It seems to me we need another program or an additional pot of money to fund those entrepreneurs who happen to have been successful enough to attract venture capital money and now have an additional idea that they want funded. You know, it just does not seem to me to be productive to go to the same well which already does not have anywhere near enough money in it to fund those for whom the program is currently specified. Is that correct?

Mr. GLOVER. That is correct, sir.

Mr. BARTLETT. Okay. Help me understand why it makes any sense to try and dilute the effectiveness of that money by spreading it over a larger field.

Mr. GLOVER. It does not, but I think, as I said, I sympathize with the Biotech and Venture Capital Association. There needs to be a program to take these companies, but it should not come out of the small business pot. We fought too hard to establish that small business preference.

Mr. BARTLETT. They may still be small businesses, if I might, but they should not come out of this pot—

Mr. GLOVER. That is correct.

Mr. BARTLETT. —because this is the pot that is designated for small businesses, just start-up, more than 51 percent owned by the person. I agree that there needs to be another pot of money and another program somewhere for these others, but I cannot see the value of diluting unless we are going to pour a whole bunch more money into this, and then you could not be sure it is going to the right place because we have two very different entities here vying for the money, do we not?

Mr. GLOVER. We do, indeed.

Mr. BARTLETT. Okay. One is an itty-bitty start-up company, and these other companies that could be not-so-itty-bitty start-up companies. Thank you very much.

Mr. DOERFLER. Dr. Bartlett, may I?

Mr. BARTLETT. Yes, sir.

Mr. DOERFLER. My company, before we received venture capital, was 17 employees. We are now 20 employees. So I think, by any measure, we are still a small company. I do not think it really made a difference how we got our financing, and the program worked fine for 21 years.

This change that happened a few years ago changed the eligibility and forced companies like mine, who had a good idea, who actually invented something, based on SBIR, put in a patent application. We are very hopeful we are going to be able to get that patent, we are ready to go for a Phase II, and we think it is going to be important, but we cannot participate now because we have a different form of funding. And we are still, in my mind, at least my wife's mind, a very itty-bitty company.

Mr. BARTLETT. I am very sympathetic to your dilemma, and there ought to be a program there for you, and there ought to be money there for you, but if this present program does not have enough money for the people who are now in the program, I am having some trouble understanding how we make the situation better by making the field larger so that there is going to be now even a smaller percentage of worthy projects that get funded.

I think that what our role ought to be, our goal ought to be, is trying to find more money in another program so that your second and third and fourth ideas can get the same kind of SBIR funding that your first one got.

Thank you very much, Mr. Chairman.

Chairman GRAVES. Mr. Barrow?

Mr. BARROW. Thank you, Mr. Chairman. I want to pick up on Dr. Bartlett's comments by coming at it from a different route because, on the one hand, you have got a new definition that makes the field of eligible participants smaller than it has been over the last 20 years than commonly understood to be. So now, all of a sudden, we have got a new order of things in which a more expansive defi-

nition had a larger field of eligible participants based on their internal organization structure vying for a piece of the same pie.

I certainly agree with Dr. Bartlett that to the extent we can provide more resources, we should do so, but unless and until we are prepared to do that, the question then becomes, how large should the field of eligible participants be? And the concern that I have got is that for 20 years we have had an accepted definition of "eligible participants" that has evolved and been applied consistently over the last 20 years while something else has been going on at the same time. Something else that has been going on at the same time has been the explosion of very capital-intensive ventures that can be very effectively started up by very small businesses that can grow into very big enterprises.

I have in mind a growth profile in which an infusion of $100,000 might be adequate for Phase I, an additional infusion of $750,000 might be adequate for Phase II, and then the venture capital folks can get involved at Phase III. But here we have, over the last 20 years, an explosion in the biotechnology sector, for example, in which it is possible for folks to do great things in small companies, but at Phase II you need a whole lot more than $750,000 to get from Phase I to Phase III.

So now what we have got, it seems to me, is a new definition which does not expand the resource pool at all, does not provide more money, but it does dramatically and all of a sudden alter the definition of "eligible participants" so as to shrink the pool of eligible people.

Now, in terms of picking winners and losers, I have not got much to say about that. It is just that it seems to me, clearly, the burden of proof is on folks who are supporting this change in definition to say that it is good public policy to shrink the eligible pool of participants so as to exclude this very valuable sector of our economy that has grown up in the last 20 years. The text for my message comes from the Book of Exodus. There rose up in Egypt a king that knew not Joseph.

Things change, and we have had two patterns going on simultaneously: this growth in the sector of our economy where we are going to have explosive growth in very small enterprises that do not fit the growth profile of the criteria, the amount of money you can get under this new definition. I sort of feel like we want to make sure that we continue to make it possible for folks under the old definition to compete for the same resources.

Let me follow up on that. Mr. Glover, one of the explanations that you offered basically in defense of this new definition which excludes people who have been participating up until 2003 for Phase II money along with venture capital firms in their structure is that there is a place for venture capital firms in Phase III. Well, how do you answer the needs of start-up firms that need a whole lot more than the $750,000 maximum you can get in Phase II in order to make the jump, make the move, from Phase I to Phase III? It is not enough to say that venture capital firms can come in at Phase III if you cannot get there from here. So help me understand why this definition serves that sector of our economy that we want to grow along with others that fit the more traditional growth profile.

Mr. GLOVER. Let me first clarify the definition issue because I think it is important. The Small Business Act and the rules and regulations at SBA have used the word "individual" to mean, in fact, an individual forever, and it is specifically defined in things like the women's business program, the minority business program, the 8[a] program, and other programs.

In 2000, for the first time, that issue came before an administrative judge at the Small Business Administration to say what is an individual. It was debated, it was discussed, and the decision came down in that case that said "individual" means individual; it does not mean a corporation or a trust or anything else. So several people challenged that decision in subsequent years. Some looked at specifically, "Well, gee, I am a venture capitalist, and it should not apply to me," and the decision came down, yes, it does. It means what we said it did in 2000.

So it is not like there was a rule that the SBA changed. There was an understanding. Now, certainly, some companies violated what the SBA ruling was in 2000 and 2003, but I am sure they were innocent and unknowing violations. But clearly, it is not like SBA suddenly changed something. It was the first time they were asked to interpret something.

Mr. BARROW. Do not get me wrong on that. My point is that until that clarification came down, there were firms that fit that were competing along with those that meet the new definition who do not meet the new definition as it exists now. They were competing, and they were participating in the SBIR program, and they are no longer eligible to do so because of this clarification. I am not at all being critical or attacking the means that we got from here to there.

My point is, up until that point, we had the different folks who qualified under either definition, either the earlier understanding or the new clarification, participating side by side and competing for SBIR participation. Now only one can, and my point is, how do you answer the needs of those folks who have now been rendered ineligible as a result of the new clarification?

Mr. GLOVER. Well, the same way we rendered the needs of these same companies in whole bunch of areas outside of the biotech area. By and large, SBIR companies have not had access to venture capital, with the exception of some biotech areas. Half of the program goes to defense contracting. You have not heard any small businesses come in and complain about this rule from the defense sector. We do not hear noises outside of anything than really the biotech area.

The challenge to find funding for your technology is the biggest challenge any small business has. There is no question that that has been there. It is well documented, and we have had some programs in the government that tried to work at that. The advanced technology program, the manufacturing exchange programs, to varying degrees, have worked at that. There is some help there. Obviously, getting good funding for your ideas has always be the biggest challenge in America, and that is what they have to work hard at, whether they are a venture-backed fund or not. Some biotech companies actually have skipped the venture capitals altogether and gone public and done quite well.

Mr. BARROW. Well, I hear what you are saying, and I want to work with you to try and make sure that there is enough help to go around. The concern I got is that we now have folks who are no longer eligible to participate who were in a sector of the economy that clearly is an American success story that they want to nurture and grow. I do not want to penalize other folks who can compete for opportunities to participate in this program alongside of folks like that.

But it looks to me like the new clarification is what is doing the penalizing, and to the extent we can work it out in such a way that we address the legitimate concerns that big businesses not be masquerading as small businesses and the like, and we deal with the problems of effective management and control being in the hands of the people who are really the creative inspiration for these enterprises. I think that meets my concerns without penalizing this sector of the economy.

That makes me want to turn, if I may, Mr. Chairman, to Mr. Cruz and ask him, but I know that Mr. Michael wants to say something.

Mr. MICHAEL. May I make a comment, please?

Mr. BARROW. Sure. Go ahead.

Mr. MICHAEL. One thing that is probably helpful for the Committee to understand is that although we very often talk about the $800 million needed to develop a drug, the NIH SBIR programs also support diagnostic products, they support medical devices, both inside and outside of the body, and many businesses can get started on much less than the 20, $30 million that might be needed to jump start, and it needs to be part of our focus.

Mr. BARROW. No question about it.

Mr. Chairman, if I am not trespassing on the Committee's time, I hear you on that.

Mr. Cruz, you touched briefly, and others have as well, on the subject of internal management and control, and I think you just passed on it. Can you help us understand a little bit better what sorts of things are actually at work in order to make sure that large venture capital firms are really not able to control the management of companies such as yours?

Mr. CRUZ. There is, as was said, the legal documentation that determines sort of the voting of each of the classes of shareholders, and for anything large enough that would impact the direction of the company, there are votes necessary across the different classes of shareholders. So there are, as the company progresses, different shareholders, different venture capital that invest throughout the life of the company. So inherent in that is the check and balance of different shareholders or different funds having control or a portion of the control for changing the direction of the country. So that is one level.

Another level, the board of directors is usually defined in the bylaws of the company, and that usually takes into account, again, the different classes of ownership,—preferred shareholders, common shareholders, and management—and that is usually negotiated between the VCs and the management team and the previous angel shareholders to make sure that there is not one single

party, one person, controlling, you know, the direction of the company.

Mr. BARROW. Thank you.

Chairman GRAVES. Mr. Bartlett?

Mr. BARTLETT. Thank you very much. I just wanted to clarify for the record. We really never changed the rules, did we? Didn't we just interpret the rules?

Mr. GLOVER. That is my review of the case law. That is correct. There is no change in the rule.

Mr. BARTLETT. It is still the same rule; it is just that before, the definition of "individual" was not clearly understood, and now that it has been defined, that precludes firms that have more than 51 percent venture capital funding from participating in this program. That is, in fact, where we are, isn't it?

Mr. GLOVER. Yes, sir, with the exception that it can be a small venture capital firm and still be eligible at even over 51 percent.

Mr. BARTLETT. Okay. For the record, I would just like to note again that there is now not enough SBIR money for the good SBIR proposals, as the participants are now determined by the interpretation of what an "individual" is. If NIH had more money, they could give it to more good proposals. Is that correct?

Mr. GLOVER. Yes, sir.

Mr. BARTLETT. Okay. And it is primarily NIH money we are talking about.

Mr. GLOVER. Yes, sir.

Mr. BARTLETT. Okay. If you are looking at these two different groups of companies,—one is the really small guy who started out, has no meaningful venture capital funding, and the other firm that has had a successful project, successful to the extent that they have now got venture capital funding—there are two of them now, and each one of them has a new proposal they are coming in with, this is not quite a level playing field because the firm that has already had enough success to get venture capital funding, they now have a group of investors who have confidence in them. They have already indicated that they have an idea good enough that they can fund.

Now, if they cannot convince those people that this next idea is also good enough to fund, I do not think we have quite the level playing field with the new firm that has no prior history and no venture capital funding. And again, I am very sympathetic to that firm that has more than one good idea. What the heck are they going to do with the second and the third and the fourth good idea? They ought to be able to get funding for that.

But I think, Mr. Glover, you are kind of where I am. They may need funding but not from this pot because this well is not even deep enough to fund the good proposals that come in. Is that correct?

Mr. GLOVER. That is correct.

Mr. BARTLETT. Okay. So I think that what the Committee ought to be about is finding additional funds, perhaps under an additional program, so that you do not have these two not quite on the same playing field, so that you do not have these two groups of companies competing with each other. But I agree completely that if we are not able to fund small companies that have more than

51 percent of venture capital money and a second, a third, and a fourth good idea, that we are limiting the opportunities for entrepreneurship and creativity in this country. But I also agree that if we simply open up this program to that, that there is not enough money to go around now. So why would we want to spread this money thinner over a broader field?

I think that we have a really great argument here for a specific program and additional funding, and this is the kind of thing that the Americans and the Congress can support because you can show a very good return for the taxpayer's dollar in these programs. Thank you, Mr. Chairman.

Ms. VELAZQUEZ. Mr. Chairman, I just would like to work with you and the Committee and the people here, and maybe what we could do, expanding on what you were just talking about, the pot. What we could do is expand the amount of money, instead of going from 2.5 to 5 percent, that 2.5 is the ceiling. It is the base. It is the floor. It is not the ceiling. So why can't we expand the program and then have more people participating?

Mr. BARTLETT. My preference would be 2.5 for this program and 2.5 for another program because they are not quite the same population of companies. They are just not quite the same. You would reach the same goal you want to reach, but now you do not have these little guys competing with the company that is already bigger, with venture capital and maybe more consultants and so forth that puts them on a different playing field.

Chairman GRAVES. Mr. Doerfler?

Mr. DOERFLER. I am not sure how long this would take, but I think there is a tremendous amount of urgency around this issue. I mentioned a letter that we put into the record by Dr. Zerhouni, who said that right now it "undermines NIH's ability to award SBIR funds to those applicants whom we believe are most likely to improve human health...." I think that there is a concern—at least, I have a concern—that the level of the applicants today—the applications are not what they were a year ago or two years ago or three years ago, and it is affecting public health, and that is something we have got to address immediately.

I also believe that there will be more data coming in from analyses at NIH and NCI that we can put more empirical information around this issue so it is not something that is subject to opinion, but it is actually subject to someone who actually is looking at these applications to see if the level of the quality of the application is actually going up, staying the same, or going down. That is, I believe, a critical element of what we need to do with this program.

Chairman GRAVES. Real quick, Mr. Glover.

Mr. GLOVER. I have not seen this particular letter, but I can tell you, on 20 years' experience with the NIH on SBIR programs, they have been against it from the very beginning. They fought it. They have announced surveys and data which looked at universities and rated them on a five scale and rated small businesses on a four scale and announced we were lower. Only after we found out, did they have to apologize and say they were wrong.

They have never been strongly supportive of small business at the National Institutes of Health, and I would look with interest at whatever they did based on this long-term history, not what the

current people are doing. They may be doing a fine job, but I do know this long history, and it has been a very embarrassing situation, and they have not done their homework.

Chairman GRAVES. Yes, real quick.

Mr. MICHAEL. One very quick comment. Public policy should not be based on just what is happening today, I think. Today, there are many, many people who cannot get venture capital funding. The flow of money, certainly in the Mid-Atlantic, is not supporting a lot of companies, so you are left without an option. It is very impressive to meet people who have those venture capital alliances, but that is not the norm certainly in the Mid-Atlantic right now. So SBIR has become increasingly important.

Chairman GRAVES. I want to thank all of the witnesses for being here today. We do have another series of votes. But this is obviously a very important issue. I appreciate hearing both sides. We have exposed some very good ideas. You know, America's technology and innovation is world renowned, and we certainly want to do everything we can to promote that and push it forward and provide as much resources as we possibly can from all sectors. But I do appreciate all of the witnesses being here. This was a great hearing. Thank you very much.

[Whereupon, at 4:20 p.m., the Subcommittee was adjourned.]

SAM GRAVES, MISSOURI
CHAIRMAN

JOHN BARROW, GEORGIA
RANKING MINORITY MEMBER

Congress of the United States
House of Representatives
109th Congress
Committee on Small Business
Subcommittee on Rural Enterprises, Agriculture and Technology
2361 Rayburn House Office Building
Washington, DC 20515–6319

The Importance of the Biotechnology Industry and
Venture Capital Support in Innovation
Subcommittee on Rural Enterprises, Agriculture and Technology
Chairman Sam Graves
July 27, 2005
2:00 pm
311 Cannon

Good Afternoon and welcome to this hearing of the Subcommittee on Rural Enterprises, Agriculture and Technology. We will be discussing "The Importance of the Biotechnology Industry and
Venture Capital Support in Innovation." I appreciate everyone's participation in today's hearing.

The Small Business Innovation Research program (SBIR) was created by Congress in 1982 to increase the participation of small technology firms that participate in Federal research and development activities. Federal agencies with R&D budgets of over $100 million or more are required to allocate 2.5 percent of all federal research and development grants small business applicants.

I take a particular interest in this issue since my undergraduate studies yielded me a degree in agronomy. I understand the importance of and potential in biotechnology and the research these small companies do. In fact, the state of Missouri is slowly attracting more of these biotechnology firms from the other side of my state and across the country, and this means jobs for rural America and value-added products for farmers.

Without question, the United States remains the global leader in the field of biotechnology. Part of this success can be attributed to the Federal government's role in promoting critical research and development. This program allows for cutting-edge research that may not, in its earliest stages, attract funding from other sources.

Venture capital funding is critical to the small biotech companies. They provide the initial "seed" money to help get some of these innovative ideas off the ground and running. Without this investment, given the nature of the biotech industry, it would be very difficult to finance this process. These small businesses are providing this country with the ideas and innovation that has become the identity of the United States.

The biotechnology industry is unique in that it takes hundreds of millions of dollars to bring a product to market from its conception. Biotechnology companies must rely on venture investment as well as grants for sufficient funding.

SBA regulations require that, to be eligible, a small company must be at least 51 percent owned by one or more individuals. The SBA recently clarified the definition of "individuals" to include only actual human beings, and not other forms of investment. This clarification now excludes many of the small biotech companies that participated in the SBIR program in the 20 years prior to this "SBA clarification."

This hearing will examine this clarification and legislation that I have introduced, H.R. 2943, the *Save America's Biotechnology Innovation Research Act* (SABIR). This legislation seeks to address this eligibility issue, and restore the success the SBIR program experienced prior to the 2002 SBA "clarification." This rule change resulted in the disqualification of many small biotechnology firms engaged in promising research towards tomorrow's cures.

I now turn to my colleague and Ranking Member, Representative Barrow.

The Importance of the Biotechnology Industry and Venture Capital Support in Innovation

Subcommittee on Rural Enterprises, Agriculture and Technology

July 27, 2005

Daniel J. Broderick, Managing Director, Mason Wells

On Behalf of

The National Venture Capital Association

My name is Dan Broderick. I am a founding Managing Director of Mason Wells Biomedical Fund located in Milwaukee, WI. Mason Wells is a small Venture Capital fund focused on seed and early stage investing in the life sciences industry in Mid America. Prior to joining Mason Wells, I spent 18 years at the Mayo Clinic, in Rochester, MN, where I led their medical technology commercialization efforts. I also serve on the Board of the National Venture Capital Association (NVCA). NVCA is a trade organization representing approximately 470 venture capital firms in the United States. Additionally, I am the Founder and President of a non-profit association called the Mid America Healthcare Investors Network which I will explain later in my testimony.

I respectfully submit testimony today on behalf of the NVCA, and those venture-backed companies that are developing innovative technologies that

improve the quality of our lives and raise our standard of living. For the last 20 years, the dual financing sources of the SBIR program and the venture capital community have allowed many of these promising companies to conduct groundbreaking scientific research while simultaneously building viable businesses that will bring these innovative products to the marketplace. However, changes in the interpretation of SBIR grant eligibility have prevented many small companies that receive venture financing from also receiving SBIR grants, effectively cutting off a critical research lifeline. This dynamic has negatively impacted young companies across the country, particularly in the life sciences sector, but in other high tech industries as well.

What is Venture Capital?

Venture capital is the investment of equity to support the creation and development of new, growth-oriented businesses. Venture backed companies are critical to the U.S. economy in terms of creating jobs, generating revenue and fostering innovation. In terms of global competitiveness, the entrepreneurial segment of the economy is the true differentiator for America. U.S. companies originally funded with venture capital now represent 11 percent of annual GDP and employ over ten million Americans. Companies that were originally funded with venture capital dollars include FedEx, Genentech, Intel, Cisco, Amgen, Apple, Starbucks, Amazon, e-Bay and Google.

Understanding the Venture Capital Structure

There appears to be a misunderstanding that venture capital firms are large corporations that control the small start up company by having a majority control over the company's board. It is important to understand the organizational structure of the venture capital firm, its limited partners (LP's) and the relationship between the VC firm and the portfolio company.

Private venture capital funds are organized as limited partnerships and are managed by general partners. The general partners are the individuals staffing the VC firm. They are responsible for, and control all aspects of the fund's operations including making the investment decisions. Venture capital funds are small organizations. In fact, the average number of general partners in a firm is only ten. The investors in these limited partnerships are usually pension plans, foundations, trusts and accredited investors. They are called limited partners because they are exempt from liability because they exert no control in the day-today operations of the VC fund, they do not participate in setting the strategic direction of the fund, and they take no role in making the funds investment decisions. This holds true even if one LP is the majority investor in the fund.

The LP investment is not a revenue stream for the VC fund. Rather, the money the LP's invest in a VC fund are to make investments in portfolio companies and as loans to fund the day-to-day operation of the VC fund. The only way that a VC fund makes a profit is by successfully investing in a

company over a five to ten year period, which is later sold for amounts greater than the amount of money invested. Even then, the VC must first repay the LP's entire principle amount including the loan used to support the VC fund operations. Only then do the LP's and the VC fund share profits in a predetermined ratio, usually 80 to 20. Conversely, in most cases management will profit upon a sale of the company from the first dollar. It is important to remember that the dollars associated with a VC firm are investment dollars **not** revenue dollars.

Typically, it is the start up company that seeks out VC funding. Company management and founders who decide to raise venture capital are looking for more than money. They are looking to the VC to add expertise, experience and a network of contacts to the company in order to help shepherd it through the commercialization and growth process. This is often accomplished through the workings of the companies' board of directors.

Based on my experience, the great majority of companies have established a board of three to seven members prior to any VC involvement. Members of these boards usually comprise founders, management, investors (shareholders) and industry experts. Once a venture capital firm is involved, most boards slightly increase in size by two to four members, with the members representing the same group of people. Each vote on the board is equal. For example, the management (i.e. CEO) vote is equal to the investors (i.e. VC) members vote. It is the fiduciary duty of each individual member to act in good faith, and in a manner to be in the best interest of the

corporation. The groups involved generally do not vote as a block, rather each member votes their own conscience.

I would also like to briefly address the relationship between corporate venture capital and traditional VC firms as outlined above. Typically, corporate VCs play a different role than a traditional VC firm. They generally only co-invest with traditional VC firms and usually do not take a board seat. They also generally only own less than 20% of the portfolio company because of corporate reporting rules. Furthermore, corporations only manage 4% of all venture capital under management.

Why do venture capital firms care about SBIR grants?

For the last two years, portfolio firms have continually alerted us to situations in which an SBIR grant has been denied because they have venture investors. As a result, several of these companies have shelved research projects, laid off scientific teams, or scaled back operations. Many of these firms were caught by surprise because this program has been working well for over 20 years.

For example, Kereos is a small St. Louis biopharmaceutical company that is collaborating with an academic lab at Washington University School of Medicine to bring an exciting but early stage technology to patients with cancer or cardiovascular disease. Kereos did not apply for SBIR funding because it intended to accept venture capital funds that would result in over

51% ownership by U.S. venture capital firms which, under current rulings, makes them ineligible for SBIR funding. As a result, they are not able to pursue a number of exciting research opportunities for product extensions that would advance medicine and innovation but which lie outside the venture capitalists' focused initiatives.

It is paramount not to confuse the role of venture capital funding with the role of basic R&D funding. Both are critical to bringing innovation to the marketplace. However, basic research funding is targeted at discovery and invention. It is this type of activity that the SBIR program has historically supported in the past. Venture capital dollars are applied later in the life cycle and used to build a strong and viable businesses so that promising discoveries can be brought to market.

Some would argue that if a company receives venture capital, it has "hit the lottery" and does not need government funding. Nothing could be further from the truth. In the life sciences sector, the cost and time associated with bringing a discovery to market is colossal. Multiple rounds of financings at millions of dollars per round is required. In 2004 alone, the venture capital industry invested more than $5.7 billion in the sector with the average investment in each biotech company at $9.8 million.[1] Yet these venture capital investments are aimed at commercializing products and are not sufficient to meet a company's ongoing research needs. With the average

[1] PricewaterhouseCoopers/Thompson Venture Economics/National Venture Capital Association Money Tree Survey (NVCA Yearbook 2004)

cost of bringing a new drug to market at $800 million[2], young biotechnology companies cannot divert precious venture capital funds earmarked for business growth to embark upon new research projects. Although these projects may hold the next ground breaking treatment for Alzheimer's, cancer or heart disease, under the current eligibility interpretation, the SBIR program cannot fund these projects if the venture capital firm owns 51 percent of the company. This stalls or permanently shelves additional research, and the SBA has missed a tremendous opportunity to support a promising innovation.

Venture Capital National Impact

Another belief is that venture investment only impacts select regions of the country. To the contrary, venture capital is a national phenomenon. (See Exhibit A.) While California and Massachusetts are the leading regions for venture capital investment, VC dollars have been flowing into all 50 states over the last twenty years and have directly benefited regional economies across the country. More than $10 billion has been infused into states such as Texas, Pennsylvania, Colorado, New Jersey and Washington, respectively. Other states such as Florida, Connecticut, Illinois, Maryland and Minnesota have received venture investment of more than $5 billion each. As a result, these states have experienced economic growth in terms of jobs and revenues. A combination of venture capital and SBIR grant distributions in any region would have an incredibly positive impact, as

[2] Journal of Health Economics, vol 22, p 151

groundbreaking research could be conducted simultaneously with new products being brought to market.

Ironically, the current SBIR eligibility rule hurts the very "low tech regions" it is trying to support. In regions such as these, where venture capital lacks presence, numerous venture firms must frequently join together to fund a promising start up, as a single local firm does not have the resources to meet the company's need. As each firm takes an equity stake in the company, the total venture ownership stake quickly rises above the 51 percent threshold as defined by the SBIR eligibility. Consequently, companies in regions with a smaller VC presence are unjustly penalized by the current SBIR eligibility rule. Since there is no way to tell in advance which small companies will grow to tomorrow's large public success stories or important regional employers, nurturing companies in all segments of the country is important.

Mid America is one important example where investing in early-stage technology companies is difficult because of the smaller percentage of venture capital investment. In 2002, I founded the Mid America Healthcare Investors Network to help investors in Mid America to more efficiently work together to invest in companies located in this large geographic area. This region consists of 14 states in the central part of the country. The inability of small businesses, owned 51 percent or more by VC firms, to compete for and receive SBIR funds is of particular concern to venture backed companies located in Mid America. The ruling that disqualified VC financed companies from competing for SBIR grants removed an essential

source of financing to support R&D efforts. Since the ruling, the pace of R&D at many technology companies located in Mid America has slowed, or stopped altogether, which delays commercialization of technology and the resultant products that benefit to the public.

Technological Innovation: SBIR and VC working together

The 2000 Small Business Reauthorization Act sought to expand and improve the SBIR program, stimulate technological innovation, use small businesses to meet Federal research and development needs and strengthen the technological competitiveness of small businesses in the United States. By excluding venture-backed companies from eligibility, the SBIR program is bypassing many of America's most promising and innovative small businesses. After all, these are the companies whose technologies, business plans, financial strategies and management teams have all been vetted by highly skilled professionals with extensive backgrounds in science and business, who earn their living identifying the best and brightest opportunities.

The venture capitalist searches for companies that are poised for success, companies that will be viable for years to come, companies that intend to put a product on the market that will improve lives. Funding these types of companies is also in the best interest of the SBIR program as it prevents government dollars from ending up in grant mills, funding technologies that

will never see the light of day. Funding venture backed companies brings the science to life.

A way to ensure the ongoing success of the SBIR program is to re-open it to the broadest and most qualified base of small businesses as possible. This requires allowing venture-financed companies to compete again. The venture capital industry has been a major player in augmenting the SBIR program since its inception 25 years ago. Venture capital and SBIR funding have been proven to work together to research, commercialize, and distribute innovative products on an accelerated basis. The relationship between the two is symbiotic, with the beneficiary being Americans who are the recipients of life saving innovations, time saving technologies and standard of living enhancements.

Conclusion

Recently, Congressmen Graves, R-MO introduced H.R. 2943. This legislation clarifies SBIR eligibility requirements for venture backed start up companies. H.R. 2943 would amend the Small Business Act by adding a definition allowing any business concern that is at least 51 percent owned and controlled by one or more individuals and/or venture capital companies, provided that no affiliated venture capital company shall own or control more than 49 percent of the business concern, nor be controlled by a company which is not a small business to participate in the program. The NVCA applauds this effort and encourages quick action on this legislation.

We look forward to working with the committee to address this spiraling problem.

Thank you for the opportunity to express my views on these vital issues.

Mr. Chairman and Members of the Subcommittee, thank you for allowing me to appear here today.

I am Jere Glover, Executive Director of the Small Business Technology Council. SBTC is the nation's largest organization of small, technology-based businesses in diverse fields. Over 200 SBTC members have received contract awards under the Small Business Innovation Research (SBIR) Program.

I also have been deeply involved in small business policy for 27 years, including 7 years as the Chief Counsel for Advocacy at the Small Business Administration.

I believe that what is at stake here today is nothing less than the direction of the SBIR Program and the future of small business innovation. H.R. 2943 and a related rulemaking by SBA would bring about a fundamental shift in a successful, widely-praised federal program that has yielded more than 45,000 technology patents and hundreds of billions of dollars in technology innovations since 1982.

Since the Program's inception, its focus has been on funding early-stage innovations and developing them. Its underlying statute has limited it to companies with fewer than 500 employees.

There has always been a place for venture capital companies in the SBIR Program. The commercialization phase of SBIR, "Phase III," was explicitly designed to facilitate venture capital (VC) partnerships with SBIR companies.

Venture capital firms of any size may own minority stakes in SBIR companies. Small venture capital firms – those with fewer than 500 employees, including affiliates and subsidiaries – may own *majority* stakes in SBIR companies, as long as the VC is, in turn, owned by individuals.

Where SBA draws the line - because both common sense and the statute tell it to - is in allowing large VC's to control SBIR companies. That amounts to calling a large business a small business. It also flies in the face of Congress' core definition of a small business, established over half a century ago: **A small business is one that is independently**

owned and operated. The citation is 15 USC 632. Dozens of laws and regulations are based on this simple legal phrase.

Now large venture capital (VC) firms, and some in the biotech industry, want this changed. They want access to SBIR contract awards irrespective of the true size of the company.

Contrary to the repeated claims of those proposing this change, there never was a time when SBA allowed big VC's to control SBIR companies. There were times when SBA *did not know* it was occurring, and times when SBA *learned of it happening after the fact* and took appropriate action. But to state that SBA used to allow it and no longer does is untrue.

To my knowledge this is the first time in the history of the Small Business Administration that Congress has been asked to redefine small business to include large businesses and companies that are owned or operated by them.

A Change Opposed By Its Supposed Beneficiaries?

When this assault on the SBIR Program began two years ago, I wondered what the reaction would be in the SBIR community. After all, the VC's offered the promise of an expanded access to investment capital.

I got my first taste of the reaction when, in 2003, we matter-of-factly put the issue before the SBTC Board, 19 of whose 21 members were current or former SBIR awardees. The vote was both unanimous and vehement -- against the proposal. A subsequent poll of our full membership was nearly as strong and equally vociferous.

But what about the companies most likely to benefit?

The proposal to let big VC's obtain majority interests in SBIR companies has been heavily promoted as a boon to biotechnology companies that obtain SBIR contract awards from the National Institutes of Health (NIH).

We wondered how these companies felt about the proposal.

At the House Science Committee hearing on the issue in April, two small biotech companies testified against the proposal. Today a financial consultant to small biotech companies is testifying against it.

Are these companies and consultants representative?

Recently, we contacted all the companies that had won SBIR awards from NIH in the past two years. We asked them to read two position papers that are very similar in their

focus. One was in favor of the proposed change. It was drafted by the Biotechnology Industry Organization (BIO). The other opposed the change – same length, focusing on the same points, and not directly taking issue with the BIO paper. SBTC drafted it.

Then we asked the respondents to vote on whether they wanted to allow large VC's into the SBIR program. I must say the response surprised even us. Mind you, this is a pool of *potential beneficiary companies*. Yet **90% opposed the change**.

Even when we asked a slightly different question – whether to let VC's into the SBIR Program if the VC's were owned by companies and institutions rather than individuals -- the answer came through equally clear: **89% opposed**. (Attachment A)

Now, why would companies that have something to gain from this proposal oppose it?

SBA's Questions

For a glimpse at the answer, we can turn to the set of questions that SBA has been asking of people who offer written and oral comments on the proposal:

Would allowing large VC's to control SBIR companies:

- Shift the program toward lower-risk technologies that are closer to the market?
- Increase the geographic concentration of the program (in states like California and Massachusetts, where VC's are most active)?
- Change the profile of successful and unsuccessful SBIR companies?
- Lead to calls for a further change in the SBIR rules – like allowing large institutions such as universities to own SBIR companies?
- Shift the profile of the SBIR program more toward multiple and repeat award winners?

Our answer to each of these questions was "yes." That's also been the reaction of a great many small company commenters on the issue.

What many, if not most, of the commenters seem to grasp is this:

Venture capital companies operate according to relatively settled business models. They look for rapid, high-double-or-triple-digit percentage paybacks. This approach fits technologies that are lower-risk, have large numbers of potential customers, and are nearing commercialization. It rarely fits technologies in the early conceptual and design

phases (equivalent to Phases I and II of the SBIR Program) or technologies with fewer potential customers and larger downstream risks.

In many situations, however, the technological gaps that federal agencies are trying to fill through the SBIR Program are inherently "narrow" and "risky". The only "customer" may be the federal government itself. Consider defense technology innovations, the largest component of the SBIR Program by dollar value. Venture investments have been rare in these technologies because they are "exotic" and likely to have a single buyer (the Department of Defense). Similarly, major pharmaceutical companies have tended to invest in "blockbuster" biotechnologies aimed at large markets rather than diagnostics, research tools, unusual illnesses or "orphan diseases".

Venture Capital Company Priorities – Or Agency Mission Priorities?

The SBIR program is extremely competitive. For every award that is made under the program there are seven companies and technologies that are not funded. This is particularly true for the NIH, where there were 1,000 more applications for the SBIR program in 2004 than there were in 2003. Over 80% of the small businesses who apply for a SBIR award do not win.

If large VC's and the dollars they represent begin flowing into the SBIR Program, the program will inevitably be transformed. By definition, large VC's will have greater resources to devote to winning SBIR contract awards than will smaller technology companies, even smaller companies backed by small VC's. SBIR applicants that are backed by companies with millions – or billions – of dollars in revenue, and hundreds – or thousands – of employees, can logically be expected to produce far larger quantities of far more polished applications than truly small companies. Moreover, larger companies can invest far more time and effort in developing relationships with the contracting agencies, officials and program managers. In time, this could very well shift agency SBIR solicitations further and further toward the preferences and capabilities of the larger companies.

And VC's do have preferences about the research focuses of their technology investments. Broadly speaking, they reflect Wall Street's preferences at any given time.

Large VC's in the SBIR program will drive companies and technologies in the direction of these preferences. SBIR companies that fit the preferred VC profiles are likely to be the winners in this transformation; those that don't, the losers. The more prominent the VC presence and cash flow becomes, the more pronounced this shift is likely to become.

And VC's themselves are only the beginning. Once such large venture capital owned and controlled companies have broken through the legal framework that has kept them out of the SBIR Program, there would be no equitable argument for keeping universities, corporations, and other large research institutions from participating in the program.

Yet the legislative history of the SBIR Program clearly shows that it was developed precisely for the purpose of allocating a share of federal R&D contracts to small businesses, *so that* universities and large corporations would not monopolize these contracts.

Stepping a bit further back, if SBA waives its affiliation rules in this situation – for the first time in the fifty-plus year history of the agency and the Small Business Act – it would open up every other small business program in the nation to challenge.

If large companies can force their way into the SBIR Program, why should they be kept out of the SBA's other federal procurement programs, its 7(a) lending program, its Small Business Investment Company program, its surety bond guarantees? Why should SBA's Office of Advocacy continue to distinguish between large and small companies in its efforts to reduce the federal regulatory burden?

The implications of this proposed rule thus transcend the SBIR Program itself, federal R&D contracting, or even overall purchasing practices by the federal government.

Geographic Concentration

Allowing large VC's to control SBIR companies also would be likely to further concentrate SBIR awards in states like California and Massachusetts, where the VC's make 58% of their investments. Ten states account for 85% of VC investments, while fourteen states did not receive a *single* venture capital investment last year. Likewise, none of the 100 largest VC's were located in thirty-one states. Only two percent of venture capital goes to seed and early stage investment-the type SBIR companies need most. (See attachments B and C.) Yet technology-based companies are found throughout the nation. Congress has repeatedly emphasized that it wants the SBIR Program to harvest useful technologies from all areas of the country.

A Solution for the Problem

The SBIR Program consists ***entirely*** of a 2½% allocation of federal R&D contracting dollars by ten large agencies. Large companies, including VC's, have multiple means of access to the remaining 97½%, but something more specific also may be possible.

In the recent House Science Committee hearing, several witnesses – including some of those favoring the large VC's – seemed to come together around the idea of developing a new program from "a blank sheet of paper" that would meet the needs of large VC's, using a tiny fraction of the remaining 97½% of NIH's funds. This is surely a notion worth exploring. There would be no need to distort a small business program by letting big companies into it. Nor would there be friction between program goals that emphasize early-stage R&D needed by the federal government and the VC's normal focus on later-stage R&D work in technology areas favored by investors.

SBTC would be willing to help craft such a proposal. And from what we know of recent changes at NIH, the agency might welcome it.

The SBIR program has worked well for over 20 years. There have been very few changes to this successful program. Changing the Small Business Act to allow large businesses to compete as though they are small businesses is a bad idea.

The Small Business Technology Council strongly opposes S. 1263 and H.R. 2943.

We urge the bills' backers to rethink their approach. We are prepared to work with them on this.

Thank you for allowing me to testify.

SBTC
Small Business Technology Council

PRESS RELEASE

Survey Shows Small Tech Companies Oppose Proposed Changes in Federal R&D Contract Awards

July 26, 2005

FOR IMMEDIATE RELEASE

Contacts:
Jim Morrison, 202-785-4300, or Rob Yunich, 202-293-8830

Washington, D.C. - A precedent-shattering proposal to give large venture capital firms greater access to the federal government's top research and development program (R&D) for small companies is opposed by 90 percent of the most affected R&D companies.

That is the key finding in a survey released today by the Small Business Technology Council, the nation's largest organization of small technology-based companies in diverse fields.

At stake is the overall direction of the Small Business Innovation Research (SBIR) program, a widely-praised federal program that has yielded more than 45,000 technology patents and hundreds of billions of dollars in technology innovations since 1982. Large venture capital (VC) firms that are ineligible to control companies in the SBIR program are seeking changes in the program's rules to allow such control.

The proposal has been heavily promoted as a way to aid biotechnology companies receiving SBIR awards from the National Institutes of Health (NIH).

SBTC surveyed a group of likely beneficiaries -- all SBIR contract awardees from NIH during the past two years. The changes sought by the large venture capital companies would give these awardees wider access to venture capital, if they and the VCs agreed.

Survey respondents were presented with a position paper prepared by the Biotechnology Industry Organization (BIO) in support of the proposed changes, and an SBTC position paper of equal length, covering the same points, opposing the changes.

When then asked whether they "favor allowing large venture capital firms to control companies in the SBIR program," **90 percent of the NIH awardees respondents said they were opposed.**

When asked a related question, whether they favored "allowing VCs that are owned other companies, universities, pension funds and other institutions to control companies in the SBIR program," **89 percent of these potential beneficiary companies said they were opposed.**

BACKGROUND INFORMATION

The SBIR program: SBIR was created by Congress in 1982 to help meet the federal government's own R&D needs. The program allots 2.5 percent of the R&D budgets of 10 federal agencies to a competitive program of contracts awards to small businesses. Companies must meet the definition of a small business contained in the SBIR statute (fewer than 500 employees) to qualify for these contracts. The SBIR program has been repeatedly praised for its effectiveness by such third-party evaluators as the Government Accountability Office, the National Academy of Science, and the National Academy of Engineering.

Current status of venture capital firms in the SBIR program: SBA permits venture capital firms of all sizes to hold minority interests in SBIR companies.

Small venture capital firms -- defined as those with fewer than 500 employees, including all affiliates and subsidiaries -- may hold a *majority* interest in SBIR companies, as long as the VC is itself owned by individuals and not by other companies or institutions.

Large venture capital companies - those not meeting these standards - may hold a minority interest, but not a majority interest, in SBIR companies. That is what large VCs seek to change.

At issue: Can a "small" business that is controlled by a large business access a federal R&D program for small business? For this to occur, SBA would have to waive its "affiliation rules" for the first time in the 52-year history of the agency. That is exactly what proponents of the change have sought. Without waiting for SBA to act on that request, they are now asking Congress to legislatively void the "affiliation rules" for large venture capital firms (*S. 1263*, *H.R. 2943*). Doing so would contradict the legal principle underlying dozens of small business laws and hundreds of regulations -- that a small business is one that is "independently owned and operated" (15 USC 632a).

Other questions: Why should large venture capital companies be given access to a 2.5 percent allocation for small business when they already have access to much of the remaining 97.5 percent as well as more than $53 billion in their own uninvested capital? *

How would the whole SBIR program change if large companies have access to it? Is it meaningful to call it a "small business" program at that point?

How would the research direction of the program change? Would it shift away from the early-stage research that the program has always emphasized and toward late-stage technologies that venture capital firms have always preferred? How would such a change impact upon the nation's innovations?

ABOUT SBTC

SBTC is the nation's largest organization of small technology-based companies in diverse fields. More than 200 SBTC members have received competitive R&D contract awards from the SBIR program. SBTC also serves as the technology council of the National Small Business Association, the nation's oldest nonprofit advocacy organization for small business, which today represents more than 150,000 small companies. Visit our Web site, SBTC.org.

ABOUT THE SURVEY

The SBTC survey was sent to a list of 535 SBIR award winners at NIH during the past two years. The survey instrument stated neutrally that there was a controversy regarding the role of venture capital companies in the SBIR program. It invited respondents to view the arguments in favor of large venture capital company access to SBIR, via a link to a position paper on the Biotechnology Industry Organization Web site, and arguments opposed, via a link to a parallel position paper on the SBTC website. Respondents then were asked to vote on the two questions stated above. Seventy companies, representing about 13 percent of the sample, responded to the survey.

Source: VC Funds Overlang Survey, Dow Jones Venture One, March 24, 2005

B

NEW growth

AFTER A LONG WINTER, VC FUNDING IS BEGINNING TO BLOOM AGAIN.

After three years of relative drought, the "MoneyTree" is growing again. A total of 608 startup and early stage companies got their first round of venture capital in 2004, according to a special analysis of the "MoneyTree Survey" prepared for *Entrepreneur* by PricewaterhouseCoopers, Thomson Venture Economics and the National Venture Capital Association. Together, those early stage companies received $2.68 billion in funding. Both figures are up notably from 2003—the first increases in three years. On average, startup companies received $2.1 million each, while early stage companies averaged $5 million each.

More encouraging is that the factors underlying this growth are organic. Since investing peaked in 2000, VC firms have naturally spent a large portion of their time working with companies in which they had already invested. Now, as many of those companies have matured, VCs can turn more attention toward the next crop of seedlings. The VCs on this year's list are doing just that: The median number of first-time investments in startup and early stage companies is four, compared to a median of three last year. This year, VCs had to complete at least three qualifying deals just to make it onto the list. Last year, two was enough.

Still, cultivating venture capital is no easy task. Entrepreneurs must combine an idea's potential with equal measures of prudence and perseverance.

—Tracy Lefteroff, global managing partner, venture capital practice, PricewaterhouseCoopers

ONLINE EXCLUSIVE Curious about 2004 VC investments in expansion and later-stage companies? Go to www.entrepreneur.com/vc100 to find out more. There, you'll also find the most recent "MoneyTree Survey" numbers, noting VC investments for the first quarter of 2005.

Top 100 Venture Capital Firms for Entrepreneurs

VC	Location of VC	Number of early stage deals in 2004*	Website
Maryland Technology Development Corporation	[illegible], MD	15	www.marylandtedco.org
Draper Fisher Jurvetson	[illegible], CA	12	www.dfj.com
Ignition Partners	[illegible], VA	12	www.ignitionpartners.com
Austin Ventures	[illegible]	11	www.austinventures.com
Mobius Venture Capital	[illegible], CA	9	www.mobiusvc.com
Versant Ventures	[illegible], CA	9	www.versantventures.com
ARCH Venture Partners	[illegible]	8	www.archventure.com
Enterprise Partners Venture Capital	[illegible]	8	www.epvc.com
MPM Capital	[illegible]	8	www.mpmcapital.com
Tech Coast Angels	[illegible], CA	8	www.techcoastangels.com
Venrock Associates	[illegible]	8	www.venrock.com
Angels Forum & the Halo Fund	[illegible], CA	7	www.angelsforum.com
Band of Angels	Menlo Park, CA	7	www.bandangels.com
Intel Capital	Santa Clara, CA	7	www.intel.com/capital
Mayfield Fund	[illegible], CA	7	www.mayfield.com
Noro Moseley Partners	[illegible]	7	www.noro-moseley.com
Rho Ventures	[illegible]	7	www.rhomanagement.com
Village Ventures	[illegible], MA	7	www.villageventures.com
Altira Group	[illegible]	6	www.altiragroup.com
Benchmark Capital	[illegible], CA	6	www.benchmark.com
Domain Associates	[illegible]	6	www.domainvc.com
General Catalyst Partners	[illegible], MA	6	www.generalcatalyst.com
Highland Capital Partners	[illegible], MA	6	www.hcp.com
New Enterprise Associates	[illegible]	6	www.nea.com
Novak Biddle Venture Partners	[illegible], VA	6	www.novakbiddle.com
Redpoint Ventures	[illegible], CA	6	www.redpoint.com
Sequoia Capital	[illegible], CA	6	www.sequoiacap.com
Sevin Rosen Funds	[illegible]	6	www.srfunds.com
U.S. Venture Partners	[illegible], CA	6	www.usvp.com
Alloy Ventures	[illegible], CA	5	www.alloyventures.com
Appian Ventures	[illegible]	5	www.appianvc.com
Bay Partners	[illegible], CA	5	www.baypartners.com
Flagship Ventures	Cambridge, MA	5	www.flagshipventures.com
Frazier Healthcare and Technology Ventures	[illegible]	5	www.frazierco.com
Hummer Winblad Venture Partners	[illegible]	5	www.humwin.com
InterWest Partners	Menlo Park, CA	5	www.interwest.com
North Bridge Venture Partners	Waltham, MA	5	www.nbvp.com
Oxford Bioscience Partners	Boston	5	www.oxbio.com
Polaris Venture Partners	Waltham, MA	5	www.polarisventures.com

*First-sequence financing in startup/seed or early stage companies

Top 100 Venture Capital Firms for Entrepreneurs

VC	Location of VC	Number of early-stage deals in 2004*	Website
Three Arch Partners	[illegible]	[illegible]	www.threearchpartners.com
Accel Partners	[illegible]	[illegible]	www.accel.com
Allegis Capital	[illegible]	[illegible]	www.allegiscapital.com
Alta Partners	[illegible]	[illegible]	www.altapartners.com
ArrowPath Venture Capital	[illegible]	[illegible]	www.arrowpathvc.com
August Capital Management	[illegible]	[illegible]	www.augustcap.com
Aurora Funds	[illegible]	[illegible]	www.aurorafunds.com
Bessemer Venture Partners	[illegible]	[illegible]	www.bessemervp.com
Canaan Partners	[illegible]	[illegible]	www.canaan.com
Draper Atlantic Venture Fund	[illegible]	[illegible]	www.draperatlantic.com
Greylock	[illegible]	[illegible]	www.greylock.com
Innovation Works	[illegible]	[illegible]	www.innovationworks.org
Intersouth Partners	[illegible]	[illegible]	www.intersouth.com
Lightspeed Venture Partners	[illegible]	[illegible]	www.lightspeedvp.com
Maryland Dept. of Business & Economic Development	[illegible]	[illegible]	www.choosemaryland.org
Menlo Ventures	[illegible]	[illegible]	www.menloventures.com
Mohr Davidow Ventures	[illegible]	[illegible]	www.mdv.com
Morgenthaler Ventures	[illegible]	[illegible]	www.morgenthaler.com
New Jersey Technology Council	[illegible]	[illegible]	www.njtcvc.com
OVP Venture Partners	[illegible]	[illegible]	www.ovp.com
Palomar Ventures	[illegible]	[illegible]	www.palomarventures.com
Partech International	[illegible]	[illegible]	www.partechvc.com
Red River Ventures	[illegible]	[illegible]	www.redriverventures.com
Storm Ventures	[illegible]	[illegible]	www.stormventures.com
Sutter Hill Ventures	[illegible]	[illegible]	www.shv.com
Techno Venture Management	[illegible]	[illegible]	www.tvmvc.com
The Venture Capital Fund of New England	[illegible]	[illegible]	www.vcfne.com
Walden International	[illegible]	[illegible]	www.waldenintl.com
Advanced Technology Ventures	[illegible]	[illegible]	www.atvcapital.com
Alexandria Real Estate Equities	[illegible]	[illegible]	www.labspace.com
Atlas Venture	[illegible]	[illegible]	www.atlasventure.com
Battery Ventures	[illegible]	[illegible]	www.battery.com
Buerk Dale Victor	[illegible]	[illegible]	www.bdvllc.com
Burrill & Company	[illegible]	[illegible]	www.burrillandco.com
C&B Capital	[illegible]	[illegible]	www.croft-bender.com
Care Capital	[illegible]	[illegible]	www.carecapital.com
Charles River Ventures	[illegible]	[illegible]	www.crv.com
CMEA Ventures	[illegible]	[illegible]	www.cmeaventures.com
Council Ventures	Nashville, TN	3	www.councilventures.com

*First-sequence financing in startup/seed or early stage companies

Top 100 Venture Capital Firms for Entrepreneurs

VC	Location of firm	Number of early stage deals in 2004*	Website
Crosslink Capital	[illegible]	3	www.crosslinkcapital.com
De Novo Ventures	[illegible]	3	www.denovovc.com
Doll Capital Management	[illegible]	3	www.dcmvc.com
Draper Fisher Jurvetson Gotham Venture Partners	[illegible]	3	www.dfjgotham.com
Globespan Capital Partners	[illegible]	3	www.globespancapital.com
Granite Ventures	[illegible]	3	www.granitevc.com
Grayhawk Venture Partners	[illegible]	3	www.gvp.us
HLM Venture Partners	[illegible]	3	www.hlmventurepartners.com
JK&B Capital	[illegible]	3	www.jkbcapital.com
Kleiner Perkins Caufield & Byers	[illegible]	3	www.kpcb.com
Longworth Venture Partners	[illegible]	3	www.longworth.com
Mid-Atlantic Venture Funds	[illegible]	3	www.mavf.com
New England Partners	[illegible]	3	www.nepartners.com
Norwest Venture Partners	[illegible]	3	www.nvp.com
Oak Investment Partners	[illegible]	3	www.oakvc.com
Pennsylvania Early Stage Partners	[illegible]	3	www.paearlystage.com
Pequot Capital Management	[illegible]	3	www.pequotcap.com
Prism Venture Partners	[illegible]	3	www.prismventure.com
Prospect Venture Partners	[illegible]	3	www.prospectventures.com
Sanders Morris Harris	[illegible]	3	www.smhhou.com
Sprout Group	[illegible]	3	www.sproutgroup.com
Stonehenge Capital Company	[illegible]	3	www.stonehengecapital.com
Thomas, McNerney & Partners	[illegible]	3	www.tm-partners.com
Trident Capital	[illegible]	3	www.tridentcapital.com
Valley Ventures	[illegible]	3	www.valleyventures.com
Venture Strategy Partners	[illegible]	3	www.venturestrategy.com
Virginia's Center for Innovative Technology	[illegible]	3	www.cit.org/gap
Voyager Capital	[illegible]	3	www.voyagercapital.com
vSpring Capital	[illegible]	3	www.vspring.com
WI Harper Group	[illegible]	3	www.wiharper.com
Woodside Fund	Redwood City, CA	3	www.woodsidefund.com

*First-sequence financing in startup/seed or early stage companies

CRUNCHING THE NUMBERS: Wondering how we came up with this list of the top venture capital firms for entrepreneurs? Rankings are based on the number of first-time fundings to companies in the startup and early stages of development made by VC firms and similar entities in calendar year 2004, as measured by the "MoneyTree Survey" from PricewaterhouseCoopers, Thomson Venture Economics and the National Venture Capital Association (at www.pwcmoneytree.com).

Companies in the startup stage of development may have been in business for only a few months. Companies in the early stage of development have generally been in operation less than 24 months. These fundings represent the first time a company received financing from a professional VC firm in exchange for equity. More mature companies—those in the expansion or late stages of development—are not included in the analysis even though they may have gotten venture capital for the first time in 2004. ■

05/03/2005

By:
George Lipper
National Association of Seed and Venture Funds
Chicago, IL
http://www.nasvf.org/web/allpress.nsf/pages/10907

Categories:
· VC Industry

Preview:
A state-by-state look, courtesy of the Money Tree, at first quarter venture investing and an analysis of the trend line in venture capital risk avoidance. Ten states get 85% of the venture funds. Seed stage companies attract less than 2%

Article:
There is precious little evidence in the first quarter 'Money Tree' statistics to suggest that startup and early stage companies are attracting a larger share of the total capital being invested by those companies reporting their data to the PricewaterhouseCoopers/National Venture Capital Association/Thompsom Economics information system. Last week's NetNews reported the bable of bragging rights carried in local papers. Today we'll examine some of the devil in the detail of the statistics.

First of all, let's take a look at the state-by state distributions. Not much new here. California captured nearly half the dollars (46.3%) and Massachusetts scored a distant second with 12.3% with about $569 million. Total venture capital distributions over the past ten years show these two coastal centers usually claim more than half the money. Other states reaping more than $100 million include, in order, Texas (7.5%), New York (3.7%) Colorado (3.5%), Pennsylvania (2.9%), New Jersey (2.7%) and Washington (2.3%). Florida and North Carolina just missed the hundred-million level. As the stories last week noted, several states made the elite list because of a single huge investment. These ten states snared more than 85% of the money.

State by State 1st Q '05 Money Tree Distributions

STATE	All Investments		Initial Investments*	
	Deals	Amount	Deals	Amount
AK	0	$0	0	$0
AL	1	$4,250,100	0	$0
AR	1	$12,500,000	1	$12,500,000
AZ	7	$25,850,000	2	$6,550,000
CA	265	$2,142,009,100	56	$264,939,000
CO	17	$163,795,000	3	$9,010,000
CT	6	$24,062,000	0	$0
DC	1	$0	0	$0
DE	2	$2,500,000	1	$2,500,000
FL	11	$99,272,700	1	$4,800,000
GA	14	$42,282,200	4	$10,850,000
HI	2	$555,000	0	$0
IA	0	$0	0	$0
ID	1	$5,999,900	0	$0
IL	16	$69,704,900	4	$4,650,000
IN	1	$1,500,000	1	$1,500,000
KS	0	$0	0	$0
KY	1	$15,000,100	0	$0
LA	0	$0	0	$0
MA	77	$569,106,100	18	$81,067,000
MD	15	$51,239,100	8	$10,600,100
ME	0	$0	0	$0
MI	0	$0	0	$0
MN	14	$54,896,000	1	$126,000
MO	3	$9,030,000	1	$7,000,000
MS	0	$0	0	$0
MT	0	$0	0	$0
NC	13	$96,010,100	3	$14,360,000
ND	0	$0	0	$0
NE	0	$0	0	$0
NH	5	$24,000,000	2	$17,000,000
NJ	20	$127,634,200	3	$8,500,000
NM	2	$5,158,000	1	$1,135,000
NV	0	$0	0	$0
NY	24	$171,718,900	3	$3,400,000
OH	11	$51,974,800	3	$1,200,000
OK	0	$0	0	$0
OR	9	$48,238,000	1	$6,400,000
PA	25	$135,544,500	8	$8,108,000
PR	1	$1,700,000	1	$1,000,000
RI	2	$16,744,800	1	$250,000
SC	1	$250,000	0	$0
SD	0	$0	2	$5,000,000
TN	10	$18,918,000	11	$108,738,000
TX	41	$345,779,300	4	$15,118,000
UT	10	$89,578,900	3	$9,675,000
VA	16	$87,900,100	0	$0
VT	1	$825,000	4	$13,749,000
WA	26	$110,045,300	0	$0
WI	0	$0	0	$0
WV	0	$0	0	$0
WY	1	$1,500,500	1	$1,700,000

State by State 1st Q '05 Money Tree Distributions

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	Deals	Amount	Deals	Amount
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MD	15	$51,239,100	8	$10,600,100
ME	0	$0	0	$0
MI	0	$0	0	$0
MN	14	$54,896,000	1	$126,000
MO	3	$9,030,000	1	$7,000,000
MS	0	$0	0	$0
MT	0	$0	0	$0
NC	13	$96,010,100	3	$14,360,000
ND	0	$0	0	$0
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OR	9	$48,238,000	1	$6,400,000
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VA	16	$87,900,100	0	$0
VT	1	$825,000	4	$13,749,000
WA	26	$110,045,300	0	$0
WI	0	$0	0	$0

At the other end of the spectrum 14 states failed to capture a single deal, including, not only the regulars at that table, but a couple of surprises in Michiagn and Wisconsin. Alaska, Iowa, Kansas, Louisiana, Maine, Mississippi, Montana, North Dakota, Nebraska, Nevada, Oklahoma and South Dakota also had zeros aside their nameplates.

States that registed a single investment include Alabama, Arkansas, Idaho, Indiana, Kentucky, South Carolina, Vermont and Wyoming.

In fairness, it should be noted that while the 'Money Tree' data collection system is robust, it does not capture the details of every venture investment because it is a voluntary reporting system. It does obtain about 70% cooperation, certainly enough for useful relative comparisons.

But perhaps more important that the geography of venture capital is the trend line. We've noted in these quarterly examinations that the venture capital distributions have increasing been moving to safer, later stage deals over the past several years. The VC community enjoys professing its role as the source of seed and startup companies that eventually grow to become the gazelles of tomorrow, but the statistics tell a different tale.

We've been tracking the trend line for seed deals closely, because that's the space in which we work. We've watched it diminish over the past decade from about 20% of distributed funds to about 2%. So this month, we decided to look from another angle. Same results:

Amount Invested

Stage of Development	2005 Qtr 1		2004 Qtr 1		2003 Qtr 1		
Startup/Seed	$ 74,925,000	1.6%	$ 67,067,100	1.3%	$ 86,152,000	2.0%	$ 42
Early Stage	$ 752,301,000	16.3%	$ 877,375,100	17.5%	$ 682,425,400	16.1%	$1,13
Expansion	$ 1,969,417,200	42.6%	$ 2,447,251,100	48.7%	$ 2,529,536,400	59.7%	$1,72
Later Stage	$ 1,830,876,900	39.6%	$ 1,635,430,400	32.5%	$ 936,470,000	22.1%	$ 74
Undisclosed/Other	$ -		$ -		$ -		$ 1
Totals	$ 4,627,520,100		$ 5,027,123,700		$ 4,234,583,800		$4,04

Number of Deals

Stage of Development	2005 Qtr 1		2004 Qtr 1		2003 Qtr 1		199
Startup/Seed	32	4.7%	36	5.4%	49	7.3%	
Early Stage	200	29.7%	198	29.8%	180	26.7%	
Expansion	267	39.6%	290	43.6%	338	50.2%	
Later Stage	175	26.0%	141	21.2%	106	15.8%	
Undisclosed/Other	-		-		-		
Totals	674		665		673		

The chart above examines 'stage of development' statistics in the first quarter of each of the past three years...then looks back to a pre-bubble first quarter of roughly the same overall size. Note if you will that more than 18% of the deals and 10% of the money in the first quarter of 1998 was directed to the startup/seed strata. Today, it's so small a slice of the pie that it discourages, not only the fly-over states, but the entrepreneurs in search of financial partners. Expansion and later stage deals now account for more than 80% of venture capital funds.

With the slimming pressures in the federal budget for R&D funds, SBIC's and SBA loans, increasingly worthy entrepreneurs are finding angels as their court of last resort. Fortunately, or perhaps via cause and effect, angel involvement shows significantly increased activity over the past few years, particularly at the sensitive, deprived startup stage.

The Washington Times ★ THURSDAY, JULY 21, 2005 / PAGE A17

Letters

Biotech R&D and small firms

Biotechnology Industry Organization (BIO) President James C. Greenwood, in his July 13 Op-Ed column, "Support small business: SBA bill aids biotech firms and marketplace," failed to point out the detrimental impact the legislation he champions would have on hundreds of small, emerging biotech companies across the United States.

The Small Business Innovation Research (SBIR) program was created in 1982 to strengthen the role of small firms in federally supported research and development undertakings. Under the SBIR program, a mere 2.5 percent of the outside funding provided by the National Institutes of Health and several other federal agencies is set aside for small companies. Lawmakers recognized that while small businesses lack the laboratory infrastructure and personnel roster of a major university or large pharmaceutical firm, they tend to be very innovative and accepting of risk and often advance novel products and technologies much faster and less expensively than large, established institutions. After more than two decades, the significant value of the SBIR program has been documented in numerous studies by government and nongovernmental organizations.

Unfortunately, BIO and lobbyists for the venture-capital industry want to usurp this program by passing a law that would entitle firms owned and controlled by large pension funds, insurance companies and other large institutional investors to compete with cash-strapped start-ups for the 2.5 percent set-aside. All other things being equal, NIH favors SBIR applicants that present polished applications with weighty preliminary data. This is costly to generate. Inserting companies whose backers have deep pockets and large staffs into this process would significantly change the outcomes. The kind of start-up companies the program was designed to help — the companies that have made the program so successful — would be placed at a major competitive disadvantage. If companies owned by major investment houses are permitted to siphon off a significant percentage of the modest available funds in the SBIR program, the 2.5 percent set-aside for small companies would shrink quickly to 1 percent or 0.5 percent.

This would shift funding away from research and development already under way at many small companies. In many cases — including biodefense, vaccine development, diagnostics, platform technologies, research tools, orphan disease therapies, agricultural biotechnology, and environmental biotech, to name but a few — this research and development is critical for public health and national security but out of favor with Wall Street and the type of companies that would become eligible for SBIR funds if House Bill 2943 becomes law.

Also, the proposed changes to SBIR eligibility would decrease support for high-impact, high-risk innovative research at which small, independently owned companies historically excel, in favor of lower-risk, closer-to-commercialization product development favored by most venture capitalists.

At the Maryland Technology Development Center (MTDC) in Rockville, a county-operated facility that houses one of the largest concentrations of biotech start-ups in the mid-Atlantic region, few, if any, companies are owned by venture capital firms. Instead, most have been funded through the SBIR program along with investment from individuals and small companies. The biotech entrepreneurs at the MTDC overwhelmingly oppose BIO's efforts to change the SBIR size standards.

Simply put, a company owned and controlled by one or more large venture capital firms is not a small business and should not be entitled to access the minuscule percentage of funds set aside for small businesses. These companies typically lack the culture and attributes of small, individually owned companies, including the ability to "turn on a dime," take substantial risks and address smaller and less predicable markets, including those unpopular on Wall Street. To permit this change would essentially take the S out of SBIR.

Proponents of changing long-standing definitions of small business are barking up the wrong tree by pressing for changes to the SBIR size standards. Instead, they should be focusing their efforts on the other 97.5 percent of federal R&D funding that is not set aside for small, individually owned companies. While historically most NIH funding has gone to support academic basic research, this has been changing over the past few years. An expanding number of programs are available to businesses of all sizes, at NIH and other agencies, for high-risk, high-impact R&D or the development of products with small or unpredictable markets such as orphan drugs or vaccines against bioterrorism agents. These programs have substantially more funding available than the SBIR program.

Congress should encourage this trend and consider new initiatives, open to companies of all sizes, that help bridge the growing "valley of death" between basic discoveries and delivery to patients of innovative drugs, devices and diagnostics. At the same time, the integrity of programs like SBIR that safeguard the viability and productivity of our nation's most innovative, small biotech entrepreneurs must be protected.

JONATHAN COHEN
President and CEO
20/20 GeneSystems Inc.
Rockville

JERE W. GLOVER
Executive Director
Small Business Technology Coalition

Jere Glover is the Executive Director of the Small Business Technology Coalition (SBTC), a group of small high tech companies most of whom are involved in the Small Business Innovation Research (SBIR) program. Jere is also an attorney with the firm of Brand and Frulla in Washington, DC representing small businesses.

Jere's experience with the SBIR is extensive, as he is one of the fathers of the program. As counsel to the House Small Business Committee, he directed an extensive set of hearings on small business and innovation that laid the ground work for the SBIR in 1978. He was also the lead-off witness before Congress when the law was first proposed, and throughout the laws existence, he has been one of its most active supporters. As Executive Director of the SBTC, he has led the organization's fight to prevent the bill from being weakened, to finalize the phase III SBA guidelines, and to prevent the SBIR from being eliminated in a number of government agencies.

Jere has a unique blend of private and public sector experience. A former CEO and attorney in private practice, Jere also spent many years in government service, most of it focused on minimizing the regulatory burden on business. For more than six years, he was the federal government's lead defender of small businesses in the regulatory process. In that capacity, he systematically analyzed hundreds of regulatory actions by federal agencies, identifying flaws and shortcomings in many of those actions and helping the affected businesses seek relief. Information developed by Jere's team led to rollbacks of dozens of regulations and formed the basis of a number of successful lawsuits. The work that Jere directed saved the private sector more than $20 billion in annual regulatory costs, and it cut a wide swath across many types of businesses – including mining, fishing, telecommunications, transportation, financial services and agriculture. He has testified before Congress over 30 times and appeared in over 100 agency proceedings, including rulemakings, adjudications, enforcement proceedings and others.

In the private sector, Jere previously was the CEO or principal of a biotech company, a medical technology company and a group of medical clinics. Since re-entering the private sector last year, he has become the managing director of another medical technology company and counsel to a variety of SBIR and technology companies.

Jere obtained his undergraduate and law degrees from the University of Memphis and an L.L.M. in Administrative Law and Economic Regulation from George Washington University.

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AviGenics, Inc.

Testimony of Anthony P. Cruz to the House Small Business Subcommittee on Rural Enterprises, Agriculture, and Technology

Wednesday, July 27, 2005

Anthony P. Cruz
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Key Points:

- SBIR Programs allow development of early-stage technologies which can lead to novel human drugs that address diseases of significance to U.S. public health. These technologies can lead to (1) lower cost of development for human drugs and/or (2) more effective and safer drugs not possible with current processes.
- SBIR funding combined with venture capital funding can lead to creation of new biotechnology clusters and high-skilled, high-pay jobs within geographic areas not traditionally associated with the pharmaceutical or biotechnology industries.
- High-risk, high-payoff technologies can fall "under the radar" of the mainstream pharmaceutical industry due to inherent risk profile or uniqueness of the technology. Without the appropriate funding, these technologies may lie dormant or undeveloped for years, perhaps missing its window of opportunity to make an impact to human healthcare.
- SBIR and Venture Capital (VC) monies have separate and important roles in small biotech. SBIR funding is used for basic research and early-stage technology development. If this initial research and development is successful, VC funding can be attracted to fund clinical trials and eventually, commercialization of human therapeutic products. Both sources of funding are essential to bridge basic research to the therapeutic products used by physicians to treat patients.
- AviGenics supports BIO's recommendation that the SBA adopt a rule that addresses the actual ownership structure of small biotechnology companies backed and controlled by venture capital companies. Specifically, change the size requirements to permit venture capital ownership of SBIR applicants to count toward the 51% U.S. ownership and control requirement.

Mr. Chairman and Committee,

Good Afternoon. My name is Anthony Cruz. I am the Senior Vice President of Finance and Administration of AviGenics. Before my involvement with the biotech industry, I served as a Captain at the U.S. Air Force in the area of weapon system acquisition and I understand the importance of federal funding to this country's well-being. On behalf of AviGenics and biotechnology industry, I would like to thank the members of the House Small Business Subcommittee on Rural Enterprises, Agriculture, and Technology for this opportunity to present my comments on the recently imposed obstacles which will prohibit small biotechnology companies from participating in the Small Business Innovation Research (SBIR) program.

AviGenics is an up and coming biotechnology company located in Athens, Georgia, a small town roughly 70 miles from Atlanta. Athens is better known for its powerhouse college football program than its technology companies.

AviGenics, Inc.

However, with future SBIR grant support to its VC-backed companies, Athens may one day become better known for its biotechnology excellence. AviGenics employs about fifty very highly skilled scientists, technicians and farm workers. The Company is located on the University of Georgia campus and we are well-integrated with the University in its efforts to attract technology companies and to generate more high-skilled, high-paying jobs.

AviGenics' mission is to develop affordable and improved medicines for infectious diseases and cancer. The Company's core technology is aimed at producing protein-based therapies which are safer, more effective and more affordable as compared with those currently available on the market. Our technology combines state-of-the-art molecular biology techniques with Georgia's well-established poultry breeding expertise to produce modern medicines at low cost.

AviGenics has recently completed a US-FDA approved Phase I human clinical trial for the lead product to treat an insidious infectious disease. The data from this initial study suggests that our drug performs just as well or better and is safer than what is currently in the market. Further, this drug will cost less than half of what it costs for the similar therapy today. Of course, more extensive human clinical trials are required for marketing authorization, but this technology offers a significant promise to millions of patients who do not benefit from or cannot afford the currently available therapies.

Reaching the appropriate technology development stage and initiating clinical evaluation was a difficult path filled with significant technical risks. Our progress until now has been made possible, in large part, through support from the US government in the form of research grants. The Company's technology accomplishments, achieved through federal support, made it possible to attract follow-on funding from VC groups. VC funding is absolutely critical for conducting the expensive clinical trials and obtaining the necessary regulatory approvals of a new therapeutic product. As you know, taking a therapeutic from concept to the market takes hundreds of millions of dollars.

AviGenics is not a subsidiary or spin-off of a large pharmaceutical company. We are an independently operated technology company dedicated to developing cost-efficient and improved therapies. Early in the Company's history, attempts were made to secure financial backing from industry to develop this technology. The message from the industry to AviGenics was loud and clear, "Come back when you can show that the technology works." The industry declined to fund the basic research around our unconventional technology even if it had the promise of making drugs cheaper, better, and safer. Funding from government research grants and a few angel investors was necessary to obtain "Proof of Concept" for our technology. Then and only then was the Company able attract significant funding from VC firms. The initial technology development took over four years as several different technical approaches had to be investigated. The Company probably would not have made the technical strides or even have survived without SBIR grants and other federal funding. Thanks to federal funding, we are now about to begin a Phase II clinical trial for our lead product.

Even after the Proof of Concept stage, the Company is still dependent on federal funding for its basic research. VC funding is available primarily for high cost activities such as animal testing, human clinical trials and regulatory filings for a specific therapy. Federal research grants are needed for technology improvement projects such as development of more effective and efficient ways to apply genetic engineering techniques.

According to the current eligibility standards, a business must be at least 51% owned and controlled by "individuals" who are citizens of the United States and the company may not have more than 500 employees, including its affiliates. The SBA's current interpretation of "individuals" excludes venture capital funds. As a result, AviGenics is ineligible for future SBIR funding.

I believe AviGenics is a case study for what the SBIR program can do. We currently employ close to 50 full-time employees, most of whom are highly educated and skilled. With SBIR and other federal grants early in its history, AviGenics has been able to secure VC funding and thus, initiate human clinical trials. We look forward to the day

AviGenics, Inc.

that our technology and hard work will result in affordable and effective therapies for those stricken with hepatitis, AIDS, cancer, or other ailments.

AviGenics strongly supports BIO's recommendation that the SBA adopt a rule that addresses the actual ownership structure of small biotechnology companies that are owned and controlled by venture capital companies. Specifically, change the size requirements to permit venture capital ownership of SBIR applicants to count toward the 51% U.S. ownership and control requirement. This would allow broader, quality participation in the SBIR program and small companies reach the point where their technologies and novel therapies can potentially save lives.

Thank you.

July 26, 2005

The Honorable Samuel Graves
1513 Longworth House Office Building
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Graves:

We, the undersigned biotechnology executives, thank you for introducing H.R. 2943, the "Save America's Biotechnology Innovative Research (SABIR) Act," legislation that would restore the eligibility for Small Business Innovation Research (SBIR) grants to venture capital-backed bioscience companies. We represent start-up biotech firms with fewer than 500 employees, with the majority employing fewer than 100 people.

These are small businesses, but they're doing big science. America's biotechnology companies are unraveling the molecular mysteries of such diseases as cancer, Alzheimer's, heart failure, obesity and diabetes. To date, they have brought more than 200 new therapies and vaccines to patients, and their scientists are exploring hundreds of additional ideas for saving lives.

These are just the kind of ideas the SBIR grant program was designed to advance. Unfortunately, recent changes in the SBA's interpretation of eligibility standards for the grants now disqualify most early-stage biotech companies. Specifically, SBA regulations require that, to be eligible for a grant, a small company must be at least 51 percent owned by one or more "individuals." The SBA's new interpretation of "individuals" excludes the firms that provide venture funding to conduct the painstaking and costly research necessary to bring biomedical products to market. The vast

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majority of biotech companies raise between $5 million and $15 million in their first round of venture financing, an amount that usually results in the venture capitalists owning more than 50 percent of the company. The investment group, however, usually consists of several firms, none of which owns more than 15 to 20 percent of the company.

The National Institutes of Health, the National Science Foundation, and nine other federal agencies administer the SBIR program. These agencies follow guidelines issued by the Small Business Administration (SBA) to determine eligibility and performance criteria necessary for companies to receive an SBIR grant. These grants have helped make the U.S. the world's leader in biotechnology by providing critical early-stage funding for innovative research. In 2003, more than $460 million in SBIR grants were issued to small companies in the states we represent. In addition, SBIR grants serve as a catalyst for future venture capital investment because potential investors are more likely to invest in a project that has received support through a grant peer-review process.

The SBA's new interpretation of the eligibility guidelines upends this successful program by preventing innovative biotech companies from receiving crucial start-up money. This policy will have a devastating effect on the future of the industry and the patients we serve.

Although recent SBA action to clarify the issue of affiliation sought to allow participation of some companies majority owned by other entities, it does not address the fundamental obstacle to participation of small biotech companies in the SBIR program. Given the critical role SBIR grants play in helping emerging biotech companies, it is imperative that Congress intervene.

Again, we thank you for sponsoring H.R. 2943, legislation that will restore the eligibility of venture capital-backed bioscience companies to receive SBIR grants.

Sincerely,

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