SMALL BUSINESS INNOVATION RESEARCH: WHAT IS THE OPTIMAL ROLE OF VENTURE CAPITAL?

HEARING

BEFORE THE

SUBCOMMITTEE ON ENVIRONMENT, TECHNOLOGY, AND STANDARDS

COMMITTEE ON SCIENCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

JUNE 28, 2005

Serial No. 109–20

Printed for the use of the Committee on Science

Available via the World Wide Web: http://www.house.gov/science

U.S. GOVERNMENT PRINTING OFFICE

21–948PS WASHINGTON : 2005

For sale by the Superintendent of Documents, U.S. Government Printing Office
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SMALL BUSINESS INNOVATION RESEARCH: WHAT IS THE OPTIMAL ROLE OF VENTURE CAPITAL?

TUESDAY, JUNE 28, 2005

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENVIRONMENT, TECHNOLOGY, AND STANDARDS,
COMMITTEE ON SCIENCE,
Washington, DC.

The Subcommittee met, pursuant to call, at 3:00 p.m., in Room 2318 of the Rayburn House Office Building, Hon. Vernon J. Ehlers (Chairman of the Subcommittee) presiding.

COMMITTEE ON SCIENCE
SUBCOMMITTEE ON ENVIRONMENT, TECHNOLOGY AND STANDARDS
U.S. HOUSE OF REPRESENTATIVES

Small Business Innovation Research: What Is the Optimal Role of Venture Capital?

Tuesday, June 28, 2005

3:00 PM – 5:00 PM
2318 Rayburn House Office Building (WEBCAST)

Witness List

Panel I

Representative Sam Graves (R-MO)
Member, U.S. House of Representatives

Panel II

Ms. Ann Eskesen
President
Innovation Development Institute

Dr. Ron Cohen
President and CEO
Acorda Therapeutics, Inc.

Mr. Jonathan Cohen
President and CEO
20/20 Gene Systems, Inc.

Dr. Carol Nacy
Chief Executive Officer
Sequella, Inc.

Dr. Frederic Abramson
President and CEO
AlphaGenics, Inc.

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HEARING CHARTER

SUBCOMMITTEE ON ENVIRONMENT, TECHNOLOGY, AND STANDARDS

COMMITTEE ON SCIENCE

U.S. HOUSE OF REPRESENTATIVES

Small Business Innovation Research: What Is the Optimal Role of Venture Capital?

TUESDAY, JUNE 28, 2005
3:00 P.M.—5:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

PURPOSE:

On Tuesday, June 28, at 3:00 p.m. the House Science Committee's Subcommittee on Environment, Technology, and Standards will hold a hearing to review the Small Business Innovation Research (SBIR) program, focusing on issues associated with awarding SBIR grants to small businesses owned, or partly owned, by venture capital firms.

WITNESSES:

Panel I:

Representative Sam Graves (R–MO), sponsor of H.R. 2943, the *Save Biotechnology Innovative Research Act of 2005,* introduced on June 16, 2005. The bill would allow more expansive venture capital participation in small businesses eligible for SBIR awards.

Panel II:

Ms. Ann Eskesen, President, Innovation Technology Institute, Swampscott, MA. The Innovation Technology Institute is a clearinghouse for information on SBIR technology and outcomes and supports collaboration between technology companies. Ms. Eskesen believes that venture capital is critical to technology development, but that SBIR rules should not be significantly changed to favor venture capital firms.

Dr. Ron Cohen, CEO of Acorda Technologies, Hawthorne, NY. Acorda Technologies is a small biotechnology company that develops treatments for neurological disorders. Dr. Cohen believes that venture capital investment in SBIR companies should not be restricted.

Mr. Jonathan Cohen, President and CEO, 20/20 Gene Systems, Rockville, MD. 20/20 Gene Systems is a small biotechnology company that develops diagnostic methods and test kits with applications in drug development and testing, homeland security, and disease diagnosis. Mr. Cohen believes that venture capital investment in SBIR companies should be limited.

Dr. Carol Nacy, CEO, Sequella Inc., Rockville, MD. Sequella develops diagnostics, therapeutics, and vaccines for tuberculosis. Dr. Nacy believes that venture capital investment in SBIR companies should not be restricted.

Dr. Frederic Abramson, President and CEO of AlphaGenics, Inc. of Rockville, MD. AlphaGenics is a small biotechnology company that focuses on the interactions between nutrition, metabolism, human development, and gene expression. Dr. Abramson believes that venture capital investment in SBIR companies should be limited.

OVERARCHING QUESTIONS:

Should companies that are majority-owned by venture capital firms be allowed to compete for SBIR awards? If such a change were made, what impact would it be likely to have on the SBIR program?

RECENT DEVELOPMENTS:

A spirited debate is underway in the research and venture capital communities on whether it is appropriate for SBIR awards to be given to small companies that are majority-owned by venture capital (VC) companies.

On December 3, 2004, the Small Business Administration (SBA) issued a final rule saying that to be eligible for an SBIR award, an entity must be a for-profit business at least 51 percent owned and controlled by one or more U.S. individuals, or 51 percent owned and controlled by another small business owned and controlled by Americans. Typically, VC firms are not controlled by individuals, but rather by entities such as private and public pension funds, financial and insurance investors, and endowments and foundations.

Also on December 3, 2004, to get more guidance on the issue, SBA published an Advance Notice of Proposed Rulemaking (ANPR), seeking additional public comment on the VC issue. In particular, SBA is seeking comment on what the impact of maintaining or changing the current rules would have on the eligibility and composition of the SBIR applicant pool, which firms would benefit or suffer from a change, and whether the broader participation of VC firms would lead to multiple award winners at the expense of innovation and diversity.

SBA has followed up the ANPR with a series of public meetings around the United States to obtain further public comment on the role of VCs in SBIR. These meetings will continue through June 30, 2005. Meanwhile, identical bills[1] have been introduced in the House and the Senate to change the eligibility rules for SBIR. The legislation would allow a firm to participate in SBIR even if a consortium of VC firms controlled a majority stake as long as no single VC firm held more than a 49 percent stake in the company. The legislation is supported by the Biotechnology Industry Organization (BIO) and the National Venture Capital Association (NVCA).

Proponents of changing the current rule argue that VC firms are a major source of financing in certain industries, such as biotechnology, and that VC support can help a firm continue research and commercialize products. Opponents contend that VC firms are often run by large corporations. Therefore, opponents argue, small businesses that are controlled by VC firms should not be seen as independent small businesses in need of special research funding, but rather as arms of large corporations that do not merit SBIR support.

BACKGROUND:

The SBIR Program

SBIR was established in 1982 by the *Small Business Innovation Development Act* [P.L. 97–219] to increase the participation of small, high technology firms in federal research and development (R&D) activities. SBIR has been reauthorized twice since its original enactment, and the current program authorization is scheduled to sunset in 2008. The Science Committee and the Small Business Committee share jurisdiction over the program in the House.

Under SBIR, departments and agencies with R&D budgets of $100 million or more are required to set aside 2.5 percent of their R&D budgets to sponsor research at small companies through the SBIR program. Currently, 11 departments and agencies sponsor SBIR programs: the Departments of Defense (DOD), Commerce, Education, Health and Human Services, Housing and Urban Development, Homeland Security, Transportation, Energy, and the Environmental Protection Agency, the National Aeronautics and Space Administration, and the National Science Foundation.

Each agency runs its own SBIR program, emphasizing research areas of interest to the particular agency. But SBA establishes broad policy guidelines for the SBIR program. SBA monitors program implementation and reports to Congress on the conduct of the separate departmental and agency activities.

Small businesses are eligible for SBIR awards if they are independently owned and operated for-profit companies, not dominant in the field of research proposed, and employ fewer than 500 people.

From its inception in 1983 to 2003, the most recent year for which reliable is available, over $15.2 billion in SBIR awards have been made for more than 76,000 research projects. In fiscal year 2003, SBIR made 6,224 awards, totaling $1.66 billion.

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[1] S. 1263, *Save America's Biotechnology Innovative Research Act of 2005,* introduced by Senator Bond, and H.R. 2943, *Save Biotechnology Innovative Research Act of 2005,* introduced by Representative Graves.

The Venture Capital Issue

The current dispute over VC funding began on January 10, 2001, when the SBA Office of Hearings and Appeals issued a ruling against the majority ownership of SBIR companies by VC firms. This ruling was based on the appeal of CBR Laboratories, Inc., of Boston, Massachusetts, to the rejection of its application for SBIR funding by the National Institutes of Health. CBR Laboratories' grant application had been rejected because a VC firm held a controlling interest (i.e., more than 51 percent stake) in CBR Laboratories. The ruling made by the Administrative Law Judge stated that VC firms were not "individuals," i.e., "natural persons," and therefore SBIR agencies could not give SBIR grants to companies in which VC firms had a controlling interest. The biotechnology and VC industries were dismayed by this ruling, seeing it as a new interpretation of the VC-small business relationship by SBA, which had treated VC firms as individuals up to this decision.

Advocates for Expanded VC Participation in SBIR-eligible Companies

The biotechnology industry is the strongest advocate for unrestricted VC affiliation with SBIR-funded companies. Advocates argue that the SBA rule at best creates a meaningless barrier to private-sector investment that inhibits growth of budding companies, and at worst blocks the translation of new discoveries into life-saving products for numerous fatal diseases. They point out that biotechnology R&D is capital-intensive and the involvement of VC money is critical to bring drugs through the development phase to market. BIO and NVCA have taken the official position that eligibility for SBIR awards should be expanded to include small companies that are majority owned by a consortium of VC firms.

Advocates for Limited VC in SBIR

However, the biotechnology industry is not entirely united in its opposition to SBA's policy. Some biotechnology experts and company representatives argue that, if SBA regulations allowed more VC-backed companies to apply for SBIR grants, they would crowd out completely independent small research companies run or owned by individuals. They also point out that SBIR-eligible companies are currently able to attract VC backing without giving away a majority stake, and therefore it is not necessary to expand the role of VC.

Beyond the biotechnology industry, some companies and small business advocates point out that many large companies, such as Intel, have set up VC funds as a means of investing in, and ultimately buying promising new companies that develop breakthrough technologies. They argue that if the Federal Government funded small businesses backed by such VC funds, the SBIR program could end up subsidizing the acquisition of small businesses by big businesses. This position is held by the Small Business Technology Coalition (SBTC), for example.

History and Background of Small Business Innovation Research (SBIR) program

The argument for the SBIR program as a whole was that while universities and large firms could compete successfully for federal research and development contracts and grants, small companies were at a disadvantage in spite of their great potential to contribute to the Nation's science base. SBIR was designed to redress this disadvantage.

In 2001, the most recent reauthorization of SBIR, the *Small Business Reauthorization Act* [P.L. 106–554] required a study by the National Academy of Sciences review of the largest SBIR programs to find out, for example, if SBIR research was leading to new products in the marketplace. The Act also required SBA to establish databases of SBIR activity to help track and assess the performance of the SBIR program, and encouraged SBIR agencies to do a better job of partnering with states.

The SBIR program is structured in three phases. Phase I awards (up to $100,000) fund research projects designed to evaluate the feasibility, and the scientific and technical merit of an idea. Phase II awards (up to $750,000) provide additional funding for Phase I projects that have demonstrated potential for successful development. Phase III is a not formally funded by the Federal Government, although some agencies have begun experimenting with Phase III awards. Phase III is where private-sector investment and support is supposed to step in and bring an innovation to market. However, Phase III funds may include follow-up contracts with federal agencies for the production of Phase II innovations. This is particularly true in the case of the Department of Defense.

SBIR Legislation in the 109th Congress

On June 16, 2005, Senator Bond and Representative Graves introduced identical bills, S. 1263 and H.R. 2943, the *Save Biotechnology Innovative Research Act of 2005*.

This legislation would expand eligibility for SBIR awards to include small businesses that are majority owned by a consortium of VC firms as long as no one VC firm held a majority stake. The legislation further would require that, for a small company to remain eligible, the participating VC firm cannot be owned by a large company. The legislation would allow start-up companies (defined as companies with sales of less than $3 million, and no positive cash flow from operations) to be eligible for SBIR no matter how large a stake a VC firm controlled in them. The legislation has been endorsed by BIO and the NVCA.

Issues Raised in GAO Reports on SBIR

The Government Accountability Office (GAO) has issued a number of reports over the years that assess various aspects of SBIR. The following are the more significant issues that GAO has highlighted:

- **Commercialization Rates**

In 1991, GAO gave SBIR a generally favorable review, stating that SBIR "clearly is doing what Congress asked it to do in achieving commercial sales and developmental funding from the private sector." GAO reported that an SBA study found that approximately one in four SBIR projects resulted in the sale of new commercial products or processes. GAO issued another report in 1992 in which it addressed Phase III activity, saying that although not enough time had elapsed since the beginning of the program for SBIR projects to fully mature, it appeared that SBIR projects were obtaining Phase III funding (an indicator of commercialization potential), with commercial activity totaling $1.1 billion in sales since the beginning of the program.

- **Multiple Award Winners**

In 1999, GAO testified before the House Science Subcommittee on Technology, summarizing the findings of its report on SBIR. In this testimony, GAO reported that the 25 most frequent winners of SBIR grants, representing less that one percent of the companies in the program, received about 11 percent of the program's awards, totaling $900 million over 14 years. GAO did note that one-third of winning applicants during a five-year period from 1993–1997 were first-time applicants, an average of 750 a year, which indicated that the program was not stagnating. What GAO focused most on, however, was the lack of consistent methods to define and track commercialization and thus evaluate the SBIR program's success, and the recognition of the fact that commercialization a) meant different things to different agencies and b) was not always consistent with the mission of the agency in question.

In its 1992 report, GAO noted that companies that received multiple Phase II grants appeared to have lower Phase III-related sales and private-sector funding than did those companies with lower numbers of Phase II awards. In addition individual companies have occasionally complained that there are companies that only do research but are not significantly involved in commercializing research results, and are thus dependent on SBIR Phase II grants to remain operational. These firms have been given the moniker "SBIR mills." SBIR mills do not appear to be a widespread phenomenon, but because of the lack of a uniform reporting, tracking, and analytical process for SBIR, it is impossible for program managers or anyone else to assess their true extent.

- **Geographical Diversity**

SBIR grants are heavily concentrated (about 40 percent of the total funding) in the states of California, Massachusetts, Virginia, Maryland, and New York, and this distribution has not changed significantly over time. Some critics have said that these concentrations are unfair and that SBIR managers should do a better job of distributing their awards geographically, and recruiting promising companies in under-served areas. Others argue that the distribution of SBIR simply reflects where clusters of research intensive companies are located. For example, Maryland receives significant amounts of SBIR funding because of the biotechnology companies clustered around the National Institutes of Health. SBA has an outreach office to publicize the SBIR program in under-served areas.

QUESTION FOR THE WITNESSES:

All of the witnesses were asked the following question:

In your testimony, please summarize your views on the Small Business Innovation and Research (SBIR) program, and answer the following question:

1. How should venture capital ownership of small companies be treated in the consideration of SBIR applications?

Chairman EHLERS. Good afternoon, and welcome to today's hearing, entitled "Small Business Innovation Research: What Is the Optimal Role of Venture Capital?"

I thank my colleague, Congressman Baird, for suggesting that the Subcommittee examine this important and timely issue.

The Small Business Innovation Research Program, known as SBIR, was created by Congress in 1982 to increase the participation of small technology firms in federal research and development activities.

Federal departments and agencies with R&D budgets of $100 million or more are required to set aside 2.5 percent of their R&D funding to sponsor research of small companies through the SBIR program. These departments include the Department of Defense, the National Institutes of Health, the National Science Foundation, as well as smaller agencies, such as the National Institute of Standards and Technology. From 1983 through 2003, more than $15 billion has been awarded to small companies for about 76,000 projects. In 2003 alone, more than $1.6 billion was awarded to small companies for 6,200 projects. These figures are surprising to most, including Members of Congress who do not closely follow the program.

The program has been reauthorized twice since its inception, and the current authorization is set to expire in 2008. While there are many aspects of the program that warrant further review, as Congress prepares to reauthorize SBIR, the specific issue we wish to discuss today is the role of venture capital in the small businesses that receive SBIR grants. For the past several years, this issue has been a hot topic for debate. The Small Business Administration, which sets the underlying rules of the program, has issued rulings that some interpret to limit the participation in SBIR of small businesses that are largely owned by venture capital firms. For small businesses in some industries, such as biotechnology, which generally have significant venture capital involvement, these rulings have caused great concern. Other small companies believe there should be limits on outside ownership for those companies wanting to participate in the SBIR program.

This is a complicated issue, and one which deserves to be aired. I am looking forward to hearing from our witnesses. I am pleased to welcome our Ranking Member, and I apologize for starting without you, Mr. Ranking Member, but I was assured by your colleague here that it would be all right, and your timing was impeccable, so I am now pleased to recognize you for an opening statement.

[The prepared statement of Chairman Ehlers follows:]

PREPARED STATEMENT OF CHAIRMAN VERNON J. EHLERS

Good afternoon and welcome to today's hearing, entitled "Small Business Innovation Research: What Is the Optimal Role of Venture Capital?"

I thank my colleague, Congressman Baird, for suggesting that the Subcommittee examine this important and timely issue.

The Small Business Innovation Research program (SBIR) was created by Congress in 1982 to increase the participation of small technology firms in Federal research and development activities. Federal departments and agencies with R&D budgets of 100 million dollars or more are required to set aside 2.5 percent of their R&D funding to sponsor research at small companies through the SBIR program—these include the Department of Defense, the National Institutes of Health, the Na-

tional Science Foundation, as well as smaller agencies such as the National Institute of Standards and Technology.

From 1983 through 2003, more than $15 billion has been awarded to small companies for about 76,000 projects. In 2003 alone, more than $1.6 billion was awarded to small companies for 6,200 projects. These figures are surprising to most, including Members of Congress who do not closely follow the program. The program has been reauthorized twice since its inception and the current authorization is set to expire in 2008.

While there are many aspects of the program that warrant further review as Congress prepares to reauthorize SBIR, the specific issue we wish to discuss today is the role of venture capital in the small businesses that receive SBIR grants. For the past several years, this issue as been a hot topic for debate. The Small Business Administration, which sets the underlying rules of the program, has issued rulings that some interpret to limit the participation in SBIR of small businesses that are largely owned by venture capital firms.

For small businesses in some industries, such as biotechnology, which generally have significant venture capital involvement, these rulings have caused great concern. Other small companies believe there should be limits on outside ownership for those companies wanting to participate in the SBIR program.

This is a complicated issue, and one which deserves to be aired. I am looking forward to hearing from our witnesses.

Mr. WU. Thank you very much, Mr. Chairman. Optimal use of time is very, very important, and I want to join you in welcoming folks to this afternoon's hearing.

The SBIR program is the largest federal program to support the development of new technologies. For the last fiscal year in which we have accurate numbers, in 2003, a total of almost $1.7 billion, and this compares to $44.5 million in awards made in the first year of its operation, way back in 1982, and my understanding is that this fiscal year, we are going to be close to the $2 billion mark.

Last year, at home in Oregon, we had a roundtable focusing on SBIR and the Advanced Technology Program, and I can attest that in Oregon, there is very, very strong interest in both SBIR and ATP, and a group of vibrant high-tech startup companies in part depend upon the competitive availability of these programs. And I have become increasingly aware of the difficulties that some of these organizations have in bringing their research ideas to proof-of-concept.

Today, we are going to focus on one SBIR issue, and that is the appropriate role of venture capital, or VC firms, who may invest in small high-tech businesses, and we have a panel of witnesses later on who will be presenting their views on this issue. I would like to recognize the leadership and work of my colleague from Southwest Washington, Congressman Brian Baird, for bringing this issue to this committee's attention through his work about 12 months ago, as I recall.

And before I close, I would like to say that I hope the committee will conduct a thorough review of the SBIR program before it sunsets in 2008. The core goals of the program have not changed much since its inception in 1982. The business environment and the support infrastructure, the financial support infrastructure, of our business community, especially the high-tech community, has changed substantially in the last two decades plus, and it is this committee's responsibility to ensure that the SBIR and other early public finance programs supports the high-tech small business sector while promoting U.S. economic competitiveness. And I look forward to the insight of Mr. Graves and our other witnesses today.

Thank you very much, Mr. Chairman. I yield back the balance of my time. Would my colleague from Washington like to make a statement?

[The prepared statement Mr. Wu follows:]

PREPARED STATEMENT OF REPRESENTATIVE DAVID WU

I want to join Chairman Ehlers in welcoming everyone to this afternoon's hearing.

The Small Business Innovation Research (SBIR) Program is the largest federal program to support the development of new technologies. SBIR awards in 2003 total almost $1.7 billion—this compares to the $44.5 million in awards made in the first year of it's operation. It is doubtful that anyone would have been able to forecast the size and scope of this program back in 1982.

Last year I sponsored a roundtable in my district focusing on programs such as the SBIR and the Advanced Technology Program (ATP). In Oregon we have a group of vibrant high-tech start-up companies. I wanted to make them aware of opportunities for support. I am also aware of the difficulties they have in bringing research ideas to proof-of-concept, the so-called "valley of death" and the need to create a bridge across this gap.

Today we are going to learn about one current SBIR issue, that is, the appropriate role of venture capital firms who invest in small high-tech. businesses. We have a balanced panel of witnesses who will present their views on this issue. I would like to add that we shouldn't discount either the role of venture capital or the SBIR program in supporting the development of new technologies in the U.S. As Congress begins to focus on this issue, today's hearing will provide us some guidance. I also want to thank my colleague and neighbor, Rep. Baird for bringing this issue to the Committee's attention.

Before I close, I would like to say that I hope the Committee will conduct a thorough review of the SBIR program before it sunsets in 2008. The fundamental goals of the program have not changed much since its inception 1982. However, few could argue that the economic and business climate have changed considerably since then. It is this committee's responsibility to ensure that the program supports the high-tech small business sector while promoting U.S. economic competitiveness. I hope our witnesses will have some insight on this issue as well.

Chairman EHLERS. I am pleased to recognize Mr. Baird for an opening statement.

Mr. BAIRD. I thank my distinguished Ranking Member and good friend from across the Columbia River. Thanks for your leadership on this, Representative Wu, and with our mutual high-tech companies, this is obviously important.

Chairman Ehlers, thank you, again, for once again, you have looked ahead to a problem, and we appreciate the leadership on that, and the time on this issue. I want to commend Mr. Graves for his work on this and his legislation. We have been working at this bill for some time, with this issue, and I am proud to be a cosponsor of your bill.

In essence, we believe in the SBIR program. We would like, in some ways, to expand it. Possibly—personally, I think it might be expanded in terms of who is eligible for it. At the same time, there are some concerns that have been raised about whether or not the money invested in SBIR always leads to products that can be of use. And so, I hope today that we can explore both of those issues, how we might make SBIR funds more available to effective and successful companies, and how we might observe areas in which SBIR moneys might not be used as effectively as they may be, and I look forward to today's hearing, and thank, again, the Ranking Member and the Chairman.

[The prepared statement of Mr. Baird follows:]

PREPARED STATEMENT OF REPRESENTATIVE BRIAN BAIRD

I would first like to thank Chairman Boehlert and the distinguished Chairman and Ranking Member of this subcommittee for working with me to schedule a discussion on the topic of the Small Business Innovation Research program. I would like to thank the panelists for their attendance today and valuable insight, and thank Mr. Graves for his leadership on this issue. I am an original co-sponsor of his bill, the *Save Biotechnology Innovative Research Act of 2005,* and I look forward to continuing to work with him.

Venture capital (VC) investment has become increasingly important and, in some cases, a necessity for many small businesses interested in producing new technologies and products. However, it is my hope that we can also spend time today exploring some broader aspects of the program in an effort to improve this vital program so that we can begin to understand the extent to which this program truly meets the intent of the original legislation—to encourage small business to explore their technological potential and provides the incentive to profit from its commercialization.

The recent restrictions the Small Business Administration (SBA) placed on venture capital-backed companies participating in the SBIR program was brought to my attention by constituents of mine, a small, privately-held company called *nLight.* They manufacturer high-power semiconductor diode lasers and are supported, in part, by *four* venture capital firms. They have been impacted by the SBA's rule to restrict VC-backed small businesses from competing for SBIR grants, and are no longer able to participate in this competitive process.

The SBIR program is an approximately $2 billion technology development program aimed at small business. This makes it the single largest technology development program supported by the Federal Government. It is my view that the SBA's new rule creates a barrier to private-sector investment and inhibits the growth of start-up companies as well as commercialization. It has become incompatible with the original intent of the law.

I look forward to the discussion today and hearing both sides of the issue. It is my hope that in exploring the role that venture capital plays in the SBIR program we may also touch upon ways in which we can improve it to meet the original intent of Congress.

Chairman EHLERS. If there is no objection, all additional opening statements submitted by the Subcommittee Members will be added to the record. Without objection, so ordered.

[The prepared statement of Mr. Honda follows:]

PREPARED STATEMENT OF REPRESENTATIVE MICHAEL M. HONDA

Chairman Ehlers and Ranking Member Wu, thank you for holding this hearing today and for allowing me to participate.

This issue is very important to me, because so many of the companies in my district either are small start-ups or have grown up from the start-up stage to what they are today. The ones that made the transition successfully relied on a combination of factors, including hard work, good ideas, perhaps fortunate timing, and funding.

The sources of that funding can be many, such as angel investors, venture capital, and government grants and contracts from the local, federal, or State level. Sometimes more than one of those sources are needed, especially at the early stages. In many cases, venture capital investors are unable to accept the level of risk inherent in investing in an early stage company. Another source of funding, such as government funding through the Small Business Innovation Research (SBIR) Program, can help to reduce the level of risk these investors feel.

Unfortunately, the way the law is currently being interpreted, companies that have received venture capital funding are no longer eligible to compete for and receive SBIR awards. I think this is a flawed interpretation of the law, and have cosponsored legislation to restore the SBIR eligibility of start-up venture backed firms.

I look forward to hearing the thoughts of the witnesses on this matter, and on other changes that might be made to the SBIR program to help it achieve its goal of bringing the results of basic research to technological and commercial maturity.

Panel I

Chairman EHLERS. At this time, I would like to introduce our first witness, Congressman Sam Graves from Missouri.

Mr. GRAVES. Thank you, Mr. Chairman.

Chairman EHLERS. Mr. Graves is a valued Member of the Congress, and I serve with him on the Transportation Infrastructure Committee, where he contributes a great deal. I especially admire him, because he is doing what I used to do, and don't have either the time or money for now, and that is flying airplanes. He is also a firearms expert. If you combine those two, maybe that is why he is so good at shooting down silly ideas that float around here once in a while.

We are pleased to welcome you. Mr. Graves has introduced legislation regarding the involvement of venture capital in the SBIR program, and obviously knows a great deal about this issue, as does Mr. Baird. Congressman Graves.

STATEMENT OF HON. SAM GRAVES, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mr. GRAVES. Mr. Chairman, thank you, Ranking Member, Congressman Baird. I appreciate the opportunity to testify today before your subcommittee on the vital need to protect small businesses backed by venture capital.

As Chairman of the House Small Business Subcommittee on Rural Enterprise, Agriculture, and Technology, I know the importance of venture capital to small businesses, particularly small biotech companies, and I appreciate you holding this hearing, and bringing this issue even further into the light.

Venture capital funding is critical to small biotech companies. They provide the needed 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, I think it would be very difficult to finance this process. These small businesses are providing the country with the ideas and the innovation that has become the identity of the United States. Without these thoughts and ideas, the United States, I believe, will fall behind the rest of the world in innovations and breakthroughs. Unfortunately, these small companies and venture capitalists are being blocked out of the promising investment, investment that is needed in rural communities all across the United States.

The Small Business Innovation and Research program, or SBIR, as you all referred to, this program is obviously a federal program administered by the SBA. The program allocates a specific percentage of all federal research and development grant moneys to small business applicants. This program allows for cutting edge research that may not, in its earliest stages, attract funding from other sources.

Eligibility requirements to SBIR are murky at best. According to the SBA, to be eligible for a grant, a small company must be at least 51 percent owned by one or more individuals. For a while, this requirement gave the small businesses backed by venture capital access to this critical seed money. However, the SBA recently ruled that "individuals" would exclude investment by venture cap-

ital. This rule change resulted in the disqualification of many small biotech firms engaged in promising research towards tomorrow's cures.

As you know, and as was pointed out, I recently introduced H.R. 2943, the *Save America's Biotechnology Innovation Research Act of 2005.* Specifically, this bill will allow small, venture capital-backed companies to be eligible for the SBIR program, as long as no single venture capital fund has a majority interest in the company, and the fund is not owned by a large firm.

This legislation is larger than that, however. Not only does H.R. 2943 restore small business access to this essential program, but it also further encourages venture capitalists to provide critical investment in the future of this country. It is the research that these companies are doing that leads to technological innovations, keeping the U.S. at the forefront of discovery.

Mr. Chairman, it is imperative that venture capital-backed small businesses are not blocked out of the SBIR program. Small biotech companies are unique in that it costs millions of dollars just to begin research. These companies rely greatly on both venture capital and the SBIR program. It is this combination of funding that will lead to advancements in fighting things like cancer, diabetes, and other research in many other fields.

Mr. Chairman, again I want to thank you for allowing me the opportunity to discuss this issue before your committee, and I commend your efforts, and I would like to offer my continued participation in any future action that your committee take, or your Members may take in helping small business. I think it is crucial. I think it is important in these particular areas, and again, I do appreciate the opportunity to testify.

[The prepared statement of Mr. Graves follows:]

PREPARED STATEMENT OF CONGRESSMAN SAM GRAVES

Thank you, Mr. Chairman, for allowing me to testify before this Subcommittee on the vital need to protect small businesses backed by venture capital. As Chairman of the House Small Business Subcommittee on Rural Enterprise, Agriculture, and Technology I know the importance of venture capital to small businesses, particularly small biotech companies. I appreciate you holding this hearing.

Venture capital funding is critical to the small biotech companies. They provide the needed "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. Without these thoughts and ideas, the United States will fall behind the rest of the world in innovations and breakthroughs. Unfortunately, these small companies and venture capitalist are being locked out of promising investment; investment that is needed in rural communities across the country.

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Mr. Chairman, I thank you for allowing me this opportunity to discuss this issue before your committee and I commend your efforts. I would like to offer my continuing participation in any future actions you may take to help small businesses.

Chairman EHLERS. I thank you very much for your testimony, Congressman, and we will certainly be pursuing this issue in the months ahead. So as you know, it is customary that we do not allow questions of fellow Congresspersons, because we all have time to question you afterwards, and so we will, with that, excuse you.

Mr. GRAVES. Thank you very much. And please, anything I can do to help, I would love to.

Chairman EHLERS. Thank you. We appreciate that.

Panel II:

Chairman EHLERS. Next, I would like to introduce our next set of witnesses. If they would take their places at the witness table, please.

Our first witness is Ms. Ann Eskesen, who is President of the Innovation Development Institute, located in Swampscott, Massachusetts. Interesting name. Dr. Ron Cohen is President and CEO of Acorda Therapeutics, Incorporated, located in Hawthorne, New York. Mr. Jonathan Cohen is President and CEO of 20/20 Gene Systems, Incorporated, located in Rockville, Maryland. Dr. Carol Nacy is Chief Executive Officer of Sequella, Incorporated, located in Rockville, Maryland. And finally, Dr. Frederic Abramson is President and CEO of AlphaGenics, Incorporated, located in Rockville, Maryland.

We have a good representation here from Rockville. I hope at some point we hear from the rest of the country, too. The witnesses should know, and should have been told, spoken testimony is limited to five minutes each, after which the Members of the Committee will then have five minutes each to ask questions of you.

We will start with Ms. Eskesen. Would you please turn on your microphone? Just push the button. Push it again, or pull it toward you. Push it again. It is still not on.

STATEMENT OF MS. ANN ESKESEN, PRESIDENT, INNOVATION DEVELOPMENT INSTITUTE, SWAMPSCOTT, MASSACHUSETTS

Ms. ESKESEN. This has been a highly divisive issue, that has been ongoing for well over two years now, and one of the most startling things is that it has proceeded without anybody bothering to actually look at the extent and form of venture capital involvement in the SBIR program.

I have been invited to provide that information. My name is Ann Eskesen. I was part of that small group who were involved in the original development and passage of SBIR, and I have been there for just about every fight that there has been since. I don't have any answers today, and I might comment that most of what I am going to say is going to upset everybody on both sides of this issue, but in order to be able to do what I do, I have been systematically keeping the SBIR record. I can tell you exactly how much money has been awarded to whom, for what, by when, and what has happened to it. I can also tell you a great deal about the companies who were involved, and in my written testimony, there is considerable detail of the type of information we compile on the companies that have been SBIR involved.

The reason I was invited here today, I am sure, is that I also keep exquisitely detailed information on VC activity within the SBIR program. As of today, there have been precisely 1,083 firms who have been in receipt of SBIR funding, and also have been venture capital funded. But before I get into the detail of what that all means when you look at the information, I want to underscore and to stress the point that was made in the introductory remarks of what SBIR is. It is not a small business program. I don't think it was ever intended to be a small business program. It is fundamentally a program that is designed to support the development of new technologies. Those new technologies are fundamental to the health and well-being of an industrialized economy.

What has happened as a result of the SBIR participation over this time, and I should tell you, as of last Friday, we have in this company, in this situation, invested a hair under $19 billion. But one of the consequences of this activity has been to create, within SBIR, the largest single concentration of technical talent anywhere in the United States. We exceed by a factor of 300 percent all of the engineers and scientists who are employed by all of the academic institutions in the United States added together. We are issuing patents at the rate of one every three hours, which is comparable to that which is being achieved by some of the major corporations in the United States. We now have 47,000 issued patents in the United States in the SBIR community.

In order to be able to realize the value that is created in that enormous range of technical assets, a different set of resources are required to those of, specifically, SBIR. And for those firms which present the profile of being centered towards large markets, with an opportunity for a liquidity event in a reasonable time framework, that other resource is venture capital. As of this point, over the life of the program, just over seven percent of all SBIR awardees have been VC funded. That is nine percent, if you look at companies more recently funded. And if you extract out those companies who are doing what we would consider to be leading edge work, you are probably looking at between 18 and 20 percent of all SBIR involved companies are VC funded.

What is very interesting is that this is not a recent phenomenon. In fact, if you look into my written testimony, we have documented by year and by agency the number of awards made to VC funded firms over the entire life of the program since 1983. Averaging out over all the agencies, that factors to between 18 and 20 percent of

all awards ever made in the SBIR program have been made to companies who are VC funded.

Significantly, perhaps, given the emphasis of today's effort, the largest concentration of that activity is in the National Institutes of Health, where after a slow start in '83 and '84, we have settled into a situation where between 20 and 25 percent of all dollars awarded by the National Institutes of Health are awarded to companies who either are or will become VC funded.

VC is extremely valuable to an SBIR company. It has the effect of allowing the company to bring the technology that they have under development much further along in the development cycle before they need to apply for SBIR dollars, and in my testimony, I have given you indication of when companies are, in fact, getting their SBIR dollars.

What I want to concentrate on in the few minutes I have, is to look at why the VC community been so interested in being involved in the SBIR program? All of the reasons offered by those, most of those opposing the current effort to try and extend VC involvement in SBIR fund, turn out to be actually inaccurate. The number of the proportionate size of the award pool for the venture capital community is absolutely consistent with the number of companies that are involved.

More recently, the assumption has been that after the collapse of the markets in 2001, that VC funded companies have been flocking to the SBIR program in order to be able to get funding from that source. Well, it turns out, in fact, that the extent of VC involved companies in SBIR has actually gone down. We are now looking at a situation where a significantly smaller percentage of the companies that are SBIR involved are VC funded.

If you add up all of the money that has been invested by the venture capital community in the SBIR firms, it factors out to about $20 billion. If you add up in total all of the SBIR dollars that have been received by those funded companies, it comes out to $2.5 billion. That negative ratio of ten venture capital dollars for one SBIR dollar is probably a surprise—it certainly was to us—to—but it certainly is a surprise to most people. And it poses the very obvious question, why are the venture capital community trying to hang on and expand the extent and form of their SBIR involvement, when all they have to do is to just drop a bit more money, 10 percent more, into the companies who are venture capital SBIR funded. And if you understand why the VC firms are so interested in SBIR, I think the entire discussion that we have been having for the last two years shifts radically in focus.

And what I have done in my testimony is walked you through, on page 10, what we have, how we have tried to make a determination of that interest of the VC community. There have been, since 2001, 607 firms who have been both VC funded and SBIR funded. The investment by the VC community in that population is $1,566,768,635.50. Obviously, I am joking about the $0.50. But the SBIR investment in those companies, I am sorry, I have got these numbers the wrong way around. The $15 billion is what the VC companies have invested, and $1.5 billion has come from the SBIR program. If you look at what has been happening to those companies, the answer for why VCs are so interested becomes very obvi-

ous. Of those 607 firms, 208, 28 have achieved some form of liquidity event, 211 have gone public, 41 have been acquired, and a couple have gone belly-up, and so on. If you calculate the value of those companies, i.e., what the market has said the value of those companies is, it comes out to somewhere between $45 and $50 billion. For an investment by the VC community of $4.5 billion, and an investment by SBIR of $790,639,970.

What I think, if you think about it, this statistic demonstrates is what is the most important thing about SBIR, and that is it is a wealth/value creator. For the VC community, it enables them to identify and to validate the overall competency of a potential investment. It allows them to mitigate and to reduce the technology risk on the project, and on a whole lot of other things, too, and potentially, it increases significantly the value of the investment that they have made. What it comes down to is that——

Chairman EHLERS. Could I ask you to wrap it up?

Ms. ESKESEN. Sorry, sir. What I am trying to get to in the body of my testimony is that we need to understand why the venture community are interested, and we find that it is because of the achieved valuation. What I think what that leads me finally into is a couple of general comments about the fact that the VC community itself has changed radically, and the circumstances in which they operate have similarly changed radically, and most definitely, that has occurred in the biotech community.

So, my final comments have to do with, if you look at companies like Biogen and Genzyme, who were, in their early days, SBIR involved, they were startup, early stage companies, who were VC funded shortly after their startup condition. They were also income/revenue generating quite early. They were selling the picks and the shovels and the tools, fee for service, to the pharmaceutical industry. It was comparatively easy, given a revenue stream, for them to be perceived as good investments, and they were brought to public offering.

Post that period, we now have a circumstance where the biotech firms have become drug discovery companies, and none of their revenues are now in place. They are, in fact, in most cases, dependent upon being able to make some sort of liquidity event occur after clinical trials have occurred. What happens, effectively, is this company is now valued. It took you a lot more money, and a lot longer time to get you there. And so what I find myself saying is that I think that the VC community have been enormous beneficiaries of the SBIR program, and I have laid out in a lot more detail in my testimony why that is. Venture capital is extremely important, but just as important is the SBIR program to the VC community, and I think there are a number of questions that have to be posed to the VC community as to why we should justify opening the doors to a continuing access to SBIR funding, when the major beneficiaries of that continuing access are, in fact, the VC community themselves.

[The prepared statement of Ms. Eskesen follows:]

PREPARED STATEMENT OF ANN ESKESEN

First let me say that I appreciate the opportunity to offer my perspectives on this complex but important issue of venture capital ownership in firms participant in the federal SBIR program. The often rancorous 'discussion'—now almost two years in

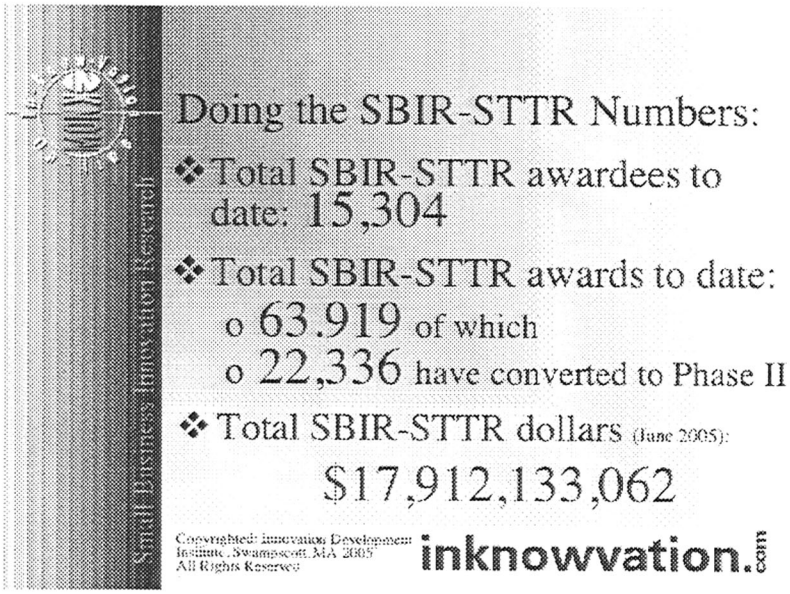
duration—surrounding this issue has been distracting and highly divisive across the SBIR community and outside, almost to the point of being destructive. Certainly it is the case that the effort and resources expended could have been far more productively utilized on issues of greater consequence to the future of SBIR.

Of major concern to me has been that this entire effort seems to have proceeded with remarkably little reference to any systematically compiled, topic-relevant information about the *actual* form and extent of VC-funded companies activity in SBIR. Small sample surveys of firms which have been encouraged to believe that they will be adversely affected; forums in which participants speak but do not listen; and anecdotal accountings in the media by carefully selected firms of anticipated adverse impact on them of a decision one way or the other has generated a great deal of heat. . .but has done almost nothing to persuade either side of the validity of the other's position. The result is almost total impasse with efforts now to force resolution legislatively in a manner that will probably will *not* only not solve the underlying problem, but could well have ramifications with potential seriously to damage the integrity of SBIR program longer-term.

I do not claim in any way here to have "The Answer." However, I am probably better placed than most to provide useful and relevant large volume, analytical data—I am sure that being the reason I was invited here today. Before proceeding, I should note that in the process of setting out my observations and conclusions I will almost certainly upset many of the parties on *both* sides of this issue. Those who are firm in the rightness of their cause will likely remain unconvinced, if they are listening at all. However, the far larger number who understand the compelling need to find appropriate resolution to this divisive issue and to get back to business will hopefully be open to some shifting in the focus of discussion that my analysis may suggest.

Good afternoon: My name is Ann Eskesen. I am the founding President of the Innovation Development Institute, Swampscott, MA. I was among that small group—others are here today—involved in development and passage of the enabling legislation for this important small-business program in 1980–82. To a greater or lesser extent, I have been involved in the three reauthorizations since, and in most of the SBIR–STTR crises, controversies and confrontations through the years. At the time of initial development, the concept of SBIR was highly controversial and, for some, to an extent has remained so. Following passage of the enabling legislation it was my decision, therefore, to stay involved to monitor program implementation.[1]

[1] I should say that it was never my intent that SBIR advocacy would become my primary professional activity these many years—advocates generally don't get paid and we have been no exception.



To function in that capacity, from the very earliest days I have systematically **kept the SBIR record.**

This process began simply by tracking in a single data base the detail of **every SBIR award—**by funding agency, recipient small firm, Principal Investigator, relevant dates, project title, Technical Abstract, dollar amount(s), Phase II conversion, etc. Through the years that **awards monitoring process** has continued and our SBIR–STTR data is complete and accurate to announced awards of recent weeks.

FYI: as of Friday, June 24, 2005, a total of 63,919 Phase I awards had been made of which, to date, 22,366 have converted to Phase II. Involving a population of 15,304 firms over the life of the program, this factors to a total dollar distribution as – again of last week - of

$17,912,133,062.

These numbers will certainly be higher this week

Over the last several years we have extended our efforts also carefully to track various aspects of the firms which have been/are SBIR-involved. These data now include:

- **Basic business information—**current name(s), location and contact information;[2] founding date, current employment, revenue stream, etc.; and a Business Identifier and Profile.
- Various **business activity data** to include:
  - **Issued patents** (domestic and international) along with, usefully, a **full patent citation index.** Almost **47,000 U.S. patents** have to date issued to SBIR involved firms.

[2] Simply to maintain the currency of names and addresses is a very demanding task in itself since this is a highly mobile group which seemed to have a great propensity for changing their name(s) as well as their location.

- All **Merger and Acquisition** activity—so far **619 transactions.**
- **Public offerings,** daily **stock price** and other relevant **trading information** on those **550 firms** and aspects of their **various SEC filings.**
- Various **Collaborative activities—**in and out licensing, subcontracting, joint ventures, etc.

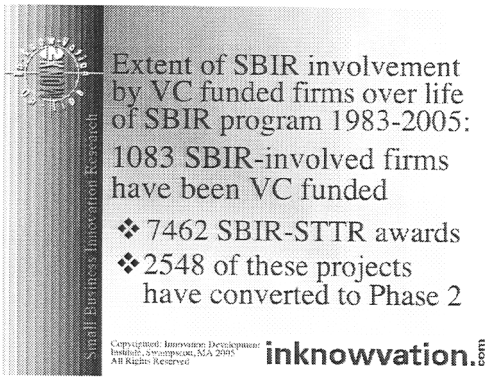
To allow us better to identify and track their technical competencies, other areas of data compilation which have more recently been added and are in various stages of development include:

- Several sophisticated business and technical **classification systems;**
- Compilation of a Full **Capability Statements—**with a primary emphasis on the 4800–5000 firms doing what we would consider **leading-edge** work;
- **Biographies** on all Principal Investigators and company principals;
- **Professional papers** and **referencing articles;**
- Along with a systematic listing of all **Recognition Awards.**

Using a sophisticated relational database system, all these elements are indexed and fully integrated. Elegant, proprietary tools have been developed enabling some extremely interesting and often quite complex analyses across the entirety of the SBIR program[3] or within any selected subset.

Perhaps most useful and important to today's topic, we also compile on a systematic basis:

- the extent and form of **Venture Capital[4] activity** involving SBIR firms to include a detailed tracking of outcomes—commonly referred to as liquidity events.



It is useful to note that our data in this category for more recent years (2001–present) is compiled such that, to some extent, we are able to set the SBIR VC experience in the context of all venture capital activity in United States. It is primarily from this part of our databases that I have drawn for the analysis undertaken for discussion here.

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[3] It is worth noting that in many important respects SBIR reflects—is a mirror for—important changes in the larger economic environment: in effect, a living lab that could function as a powerful and exciting analytical tool in its own right. To argue for SBIR as a causative agent is probably not appropriate. Certainly, however, the evidence is strong that effective SBIR participation is positioning a important percentage of SBIR-involved firms to take business advantage of new opportunities that those changes are creating with major positive impact on the economy overall.

[4] It is important to note what our VC data does and does NOT contain. We know how much, from whom, on what date and what stage—seed, Series, round, etc. It is not a matter of public record and we do NOT know on any systematic basis the prepaid for that investment—the percentage ownership.

Before proceeding to my analysis proper, let me first speak briefly to where SBIR came from: what, in my judgment, was both the basis for advocacy for SBIR and the Congressional intent.

Why did Congress establish SBIR?

At the time of passage of the SBIR enabling legislation, this country was in the throes of recession. Unemployment rates were high, quality (read: high-paying) jobs were moving offshore, the cost and availability of capital were issues (particularly early-stage, high-risk) and many of our major industries were under competitive strain. It was broadly understood then, as it is now, that economic viability and growth regionally and nationally is anchored primarily in **effective technology development—**using what we know. There was compelling evidence from a range of studies that small firms were a prolific and cost-effective source of that technological innovation. Add in the fact that small firms had been recently shown to be the economy's **primary job creator** and the context for passage of the SBIR enabling legislation was set.

This intentionally stresses the fact that passage of SBIR was fundamentally grounded in the notion of the program as a **technological, business and economic development resource.** The proposed investment—as noted above now 20 years later approaching $19 billion—was not because these firms were small or deserving. It was because this population included some of the Nation's best and brightest minds—persons at the time, and who had over an extended time period previously, been largely excluded from access to federal R&D support. Providing them that access, it was argued, was key to improving their **potential for important economic impact.**

The evidence that SBIR has already delivered in major ways to that early promise is compelling. Though this *is* probably the place, this is not the time to present that evidence. However, one factor clearly bears mentioning. Beginning in the late eighties/early nineties, the structure of U.S. Labor Markets has undergone a major shift. Who the technically trained now work for in this country has changed radically.

Our compiled SBIR employment and biography data suggests that some **400,000 graduate engineers and scientists** now work for SBIR-involved firms. Using NSF's data on university employment as the comparative index, that means that the number of SBIR–STTR employed scientists and engineers today factors to almost three times as many as all those in U.S. academic institutions. In other words, the SBIR community now the **largest single concentration of technical talent** in the United States. By itself, this is a quite remarkable and hugely important return on the SBIR investment that has been made. This is a concentration of talent that—if we are as a nation to compete effectively in the global economy—it is vital that we not only retain and but also enhance.

As evidence of that concentration of technology development capacity, SBIR companies are now issuing patents at a rate comparable to the most prolific of the major corporations—one patent approximately every three to four hours—for a total now in excess of 47,000. That rate far exceeds that of academic institutions, and SBIR firms also are achieving a rate of patent citation—often used as an indicator of patent importance—that is substantial.

Realizing that value:

Critical to this current debate is to understand that *to realize the value of that created asset base requires more than SBIR funding.* This program is designed to support the high risk, early stage research and development of creative new ideas. The all-important transition of those ideas which show promise to some appropriate type of use-condition—completion, if you like, of the innovation process—requires a *different set of resources* and, it should be added, often also demands a *very different set of skills.*[5]

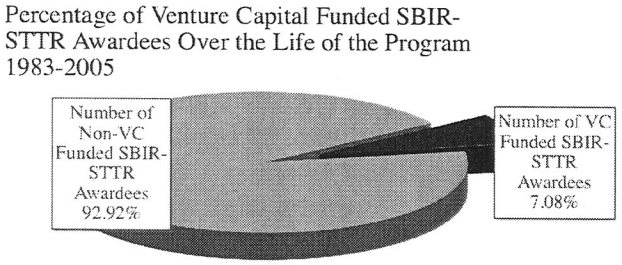
[5] Not central to this discussion but critical to the continued effective functioning of the SBIR program is how we deal with the fact that a major percentage of those firms doing what would seriously be considered leading-edge work—about 4800–5000 of them over the life of the program; about 2500–2800 currently—lack the requisite skills and access to the resources which are needed to bring their technologies to use-condition.

Facilitating that access is probably not the answer. The problem is more structural. SBIR awardees are component, not full-systems builders. The market—public and private—demand whole product. To require our guys to assemble all those other elements to meet the demands of the market is an unrealistic and inappropriate use of their capabilities. The real SBIR challenge, in my judgment, is not the current VC eligibility debate, but rather how effectively to draw down on the wealth of what has been created.

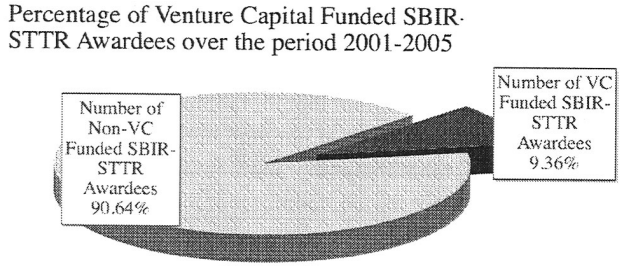
For that subset of SBIR–STTR Awardees addressing potentially large markets and offering the likelihood of some form of liquidity event (i.e., an IPO or acquisition), among those "other resources" is frequently **Venture Capital.**

1083 VC Funded SBIR–STTR Awardees: The number of SBIR firms to have been in receipt of venture funding has now reached 1083: That represents

- **7.08 percent** of *all* SBIR funded companies over the life of the program.



- Among those more recently SBIR-involved—2001–2005—that percentage[6] of firms that are VC funded has actually increased to **9.36 percent.**



Factoring only to firms doing leading-edge work—some 4800–5000 overall (about 2500–2800 currently)—that percentage is even higher: perhaps as much as 15–20 percent.

[6] As an important and useful indicator of the extent of VC previous and current interest in SBIR, it is worth noting that these *percentages are far larger* than in any random group of small technology-based firms. There is substantial evidence from the work of others as well as our own to suggest that SBIR participation significantly increases the likelihood that the small firm which presents the appropriate VC required profile (large market and the prospect of a liquidity event) will attract that often important support. Though I cannot document the fact with certainty at this point, that seems to be even more the case for those firms located in States which are less well VC endowed.

Over the life of the program, SBIR has proven a valuable and important resource both

- to many of the firms funded by the venture capital community
- and, critically, to many of the VCs who have made those investments.

Not a recent phenomenon:

Though I suspect not intentionally, discussion around the eligibility issue has largely proceeded as if VC SBIR involvement is a new trend: that fall-out from dot.coms, post-2001 market conditions having shut off liquidity events and reduced (and still reducing) achieved ROIs on their portfolios has caused these VC funds to look elsewhere to leverage on their available dollars. I would suggest this misperception has actually served to skew the discussion. In fact, VC involvement in SBIR is

- neither a recent condition,
- nor is it limited to any one agency.

As part of the analysis for this hearing, we backtracked the awards record of every SBIR VC funded awardee by year and agency. The Chart and Table below shows clearly that *VC funded firms have been an important percentage of SBIR activity from the onset of the program.* Beginning less than a year or so into program activity, the pattern of participation has been consistent. In the aggregate across the agencies, 10–12 percent of awards made have involved firms also been in receipt of venture capital at some stage in their business development.

Perhaps significantly in the context of recent events, by far the largest percentage all of SBIR dollars taken by VC-funded companies has been in the National Institutes of Health. By the late '80s, the number of awards made to firms in NIH which either already were, or subsequently became, VC supported entities had settled around the range of 20–25 percent of all their awards.

Though somewhat lower in totals, NSF has similarly consistently made a substantial percentage of awards to venture capital funded firms. In fact some important level of SBIR VC funding activity can be found in every one of the participating SBIR agencies, even the very smallest.

Percentage of SBIR-STTR Awards to VC Funded Firms
by Agency and Year 1983-2004

	DOD			NIH			NASA			DOE			NSF			Smaller to include DHS		
	Awards to VC Funded Firms	Total Awards	% SBIR dollars to VC funded firms	Awards to VC Funded Firms	Total Awards	% SBIR dollars to VC funded firms	Awards to VC Funded Firms	Total Awards	% SBIR dollars to VC funded firms	Awards to VC Funded Firms	Total Awards	% SBIR dollars to VC funded firms	Awards to VC Funded Firms	Total Awards	% SBIR dollars to VC funded firms	Awards to VC Funded Firms	Total Awards	% SBIR dollars to VC funded firms
1983	14	288	4.86%	15	144	10.42%	9	105	8.57%	6	106	5.66%	9	103	8.74%	1	52	1.92%
1984	29	372	7.80%	23	232	9.91%	9	125	7.20%	9	102	8.82%	8	107	7.48%	4	74	5.41%
1985	43	555	7.75%	80	433	18.48%	12	150	8.00%	12	109	11.01%	14	125	11.20%	3	103	2.91%
1986	70	1022	6.85%	75	425	17.65%	15	168	8.93%	9	101	8.91%	16	152	10.53%	4	117	3.42%
1987	113	1265	8.93%	58	365	15.89%	19	207	9.18%	12	113	10.62%	24	156	15.38%	5	125	4.00%
1988	111	1086	10.22%	55	338	16.27%	27	228	11.84%	10	134	7.46%	29	183	15.85%	4	113	3.54%
1989	122	1078	11.32%	83	445	18.65%	29	257	11.28%	17	157	10.83%	30	168	17.86%	4	116	3.45%
1990	125	1365	9.16%	96	459	20.92%	26	290	8.97%	12	169	7.10%	30	195	15.38%	8	134	5.97%
1991	138	1347	10.24%	109	516	21.12%	37	302	12.25%	16	172	9.30%	30	215	13.95%	3	150	2.00%
1992	126	1101	11.44%	108	578	18.69%	45	349	12.89%	13	198	6.57%	34	263	12.93%	11	174	6.32%
1993	142	1283	11.07%	112	644	17.39%	34	378	8.99%	17	168	10.12%	45	318	14.15%	9	183	4.92%
1994	164	1397	11.74%	142	660	21.52%	40	438	9.13%	29	269	10.78%	35	301	11.63%	9	197	4.57%
1995	158	1390	11.37%	170	725	23.45%	40	333	12.01%	25	221	11.31%	51	300	17.00%	12	249	4.82%
1996	136	1364	9.97%	150	651	23.04%	32	388	8.25%	23	192	11.98%	30	267	11.24%	8	175	4.57%
1997	173	1495	11.57%	194	868	22.35%	34	385	8.83%	30	216	13.89%	28	231	12.12%	15	251	5.98%
1998	153	1487	8.94%	163	829	19.66%	26	344	7.56%	18	217	8.29%	31	249	12.45%	20	206	9.71%
1999	152	1449	9.17%	199	952	20.90%	18	308	5.84%	25	222	11.26%	26	264	9.85%	21	227	9.25%
2000	108	1365	7.91%	267	1129	23.65%	18	300	6.00%	14	221	6.33%	12	131	9.16%	23	249	9.24%
2001	110	1619	6.79%	177	988	17.91%	24	328	7.32%	18	235	7.66%	26	220	11.82%	13	212	6.13%
2002	165	2274	7.26%	203	1029	19.73%	21	296	7.09%	18	247	7.29%	38	328	11.59%	12	245	4.90%
2003	174	2049	8.49%	265	1157	22.90%	26	354	7.34%	17	236	7.20%	52	414	12.56%	11	169	6.51%
2004	182	2569	7.08%	244	1286	18.97%	14	327	4.28%	13	309	4.21%	16	165	9.70%	28	230	12.17%
Totals	2668	29220	9.13%	2988	14853	20.12%	555	6360	8.73%	363	4114	8.82%	614	4855	12.65%	228	3751	6.08%

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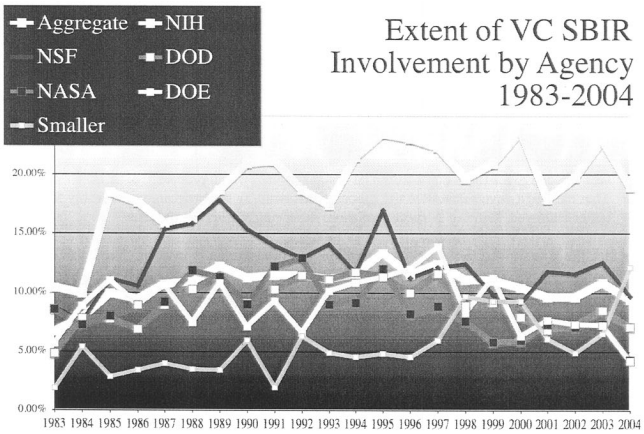


Value of SBIR to VC-eligible firms:

Effective use of SBIR may often permit a small firm to hold off on the time at which they need to raise external dollars and/or to reduce proportionately the amount they need initially to raise. Note that though use of SBIR award dollars to open the doors has dropped significantly in the period 2001–2005 (from 26.05 percent to 11.09 percent), the percentage of those taking their first award(s) in the next one-two year period has increased. Examination of a cross-section of the start-up records of these firms suggests that SBIR award dollars are being used to bring onto the professional staff[7] people whom they probably could not otherwise afford—part of that start-up making the transition towards being a viable business and a hugely important pre-VC, risk-reduction process.

[7] Development of the original SBIR regulations were specifically crafted to support this condition. At the time of applications, whom a potential PI works for is not an issue. The commitment must be that at the time of award, that PI must join the recipient small firms for more than five percent of their time.

When are VC-Funded Firms becoming SBIR involved?		
	Entire program	Currently involved
Open doors	26.05%	11.09%
Within One Year of founding	16.16%	18.18%
Within TWO years of founding	15.18%	17.27%
	57.39%	46.55%
Within THREE years	9.70%	12.91%
Established firms	32.91%	40.55%

Rarely, if ever, are VC firms in the picture at that time.

Particularly for Awardees in states which are reasonably well VC-endowed,[8] being effectively SBIR-involved seems to serve quite well to lower the high-risk profile that the small firm presents and, therefore, proportionately may actually reduce the price they have to 'pay' for that money, i.e., they must give up less of the firm.

Value of SBIR to the VC:

Analysis of our data suggests that the **type of SBIR value** that is of high-interest and importance to the VC Community is almost certainly *NOT* that which many who are opposed to any form of eligibility rule-change for majority VC-owned, SBIR-involved firms assume it to be. Most of that oppositional discussion seems to have organized around one or more of several basic points:

- That VCs want access to the funding dollars that SBIR provides as a useful supplement to/substitution for their own investment.
- That VC funded firms are effectively 'siphoning off' of these dollars when they already have so much more money available to them, this argument continues, is an inappropriate use of SBIR support.
- A widely-held view (probably not valid) is that the fact that VC supported firms are already well-funded gives them competitive advantage in the awards process.
- That the SBIR-involvement of VC funded firms is tilting the program unfavorably towards the better endowed, limiting the access of more deserving, earlier stage firms.

In fact, the data shows clearly these assumptions are fundamentally in error. See Table following.s

[8] For SBIR-involved firms in less well VC endowed states, this risk reducing, better price factor seems to be far less evident. The relative lack of options (competition) for the deals puts growth oriented firms in these states at an immediate disadvantage. Just as—perhaps even more important—is the serious shortage in those states of professional service providers with the requisite skills and direct experience to negotiate to an appropriate price.

Extent of SBIR Awards Activity and Funding Among VC and Non-VC Funded Firms

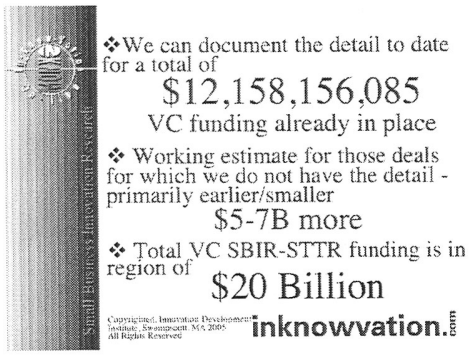
	Number of Firms	Total Awards	Average number of awards	Total SBIR Dollars Received (Phase I & Phase II) Note 1
1983-2000				
Non-VC Funded	13,773	52,774	*3.83*	$12,918,015,890
VC Funded	1,049	7,031	*6.70*	$1,876,845,827
2001-2005				
Non-VC Funded	5,877	17,794	*3.03*	$5,479,845,658
VC Funded (Notes 2 & 3)	607	2,176	*3.58*	$767,045,941

Note 1: Particularly in NIH, Phase II dollars are awarded in several increments over a number of years. In our databases we track that process by making a separate entry for each award segment and then aggregating that data in the company record. When we cull out certain years for analysis, as in this instance, this process may result in a some double-counting of the dollars on projects which straddle the split years. This time the overcount amount in question is about $200M.

Note 2: It is important to note that the data indicates that 573 of the 607 VC Funded SBIR firms currently active in the program pre-date the 2001-2005 period broken out here. Some having been involved for many years both before they received VC funding and after.

Note 3: A total of only additonal 34 VC-funded firms have become awardees during the recent period 2001-2005. This number is much smaller than would have been expected.

- The extent of SBIR dollars taken by VC-funded firms individually[9] is significantly *less* than I think most people are assuming. Collectively totaling 'only' about $2.6B over the life of the program this amount is substantial, but entirely proportional to the number of firms involved.
- A common assumption made by opponents to the pressure to achieve special treatment of VC funded firms is that the **numbers of awards and dollars taken by VC funded firms** having ramped up since the Stock Market downturns of 2001 onwards. In fact, the number of awards per VC funded firm has actually gone down.[10]



The SBIR awards rate to VC-funded firms is now only slightly higher than to non-VC funded. Over the earlier period of SBIR activity—1983–2000—the average awards totals achieved by VC funded firms was significantly higher to than to non-

[9] Separate, but connected to this VC issue, is that relating to the number of very large SBIR Phase I (and Phase II) awards which have been made, especially in the National Institutes of Health. Of the 12 Phase I awards made in a dollar amount of $750K or more (three at over $1M), not one involved a VC funded firm.

[10] The suggestion that proponents for size-eligibility rule change will almost certainly make here that this drop-off is because VC funded firms are no longer applying for SBIR award and/or are being rejected as ineligible actually does not fit the facts. This reduction in per-award participation actually pre-dates by at least a couple of years the current controversy.

VC funded: 6.70 percent versus 3.83 percent. It now stands at 3.58 percent per to 3.03 percent to the non-VC funded.

We know who got VC funding and can document the detail of how much VC has been invested in SBIR-involved firms to date to a total of slightly over $12B. Investment made in the years prior to 1998 are less complete in their detail in our databases but we estimate these factor to about another $5–7B. That suggests a total VC investment in SBIR involved firms to date of about $20B.

- By far the most telling point made by analysis of the VC SBIR track record, however, is that the amount of VC investment made in SBIR-involved firms far and away exceeds anything that they are receiving from SBIR awards as such—see chart below.

The collective VC SBIR Awardees investment currently stands at almost

$20 Billion

Total SBIR Award dollars received calculates to some

$2.5 Billion

close to a 10:1 *negative* ratio

For every ONE Dollar received by the VC funded firm in SBIR Awards, TEN investment dollars have been recorded.

This **negative-ratio finding of SBIR to Investment dollars** was a surprise to us initially and, I suspect, will be an entirely unexpected finding to just about everyone who has been part of this two-year controversy on either side or—as many Members of Congress and their staffs have been—who have been caught in the middle.

In fact, given this highly unexpected finding, the very obvious question which must addressed in he context of this overall discussion becomes:

Why has so much effort and resources been allocated to the task of trying to achieve a major size-eligibility rule change that is opposed by so many program advocates – myself included?

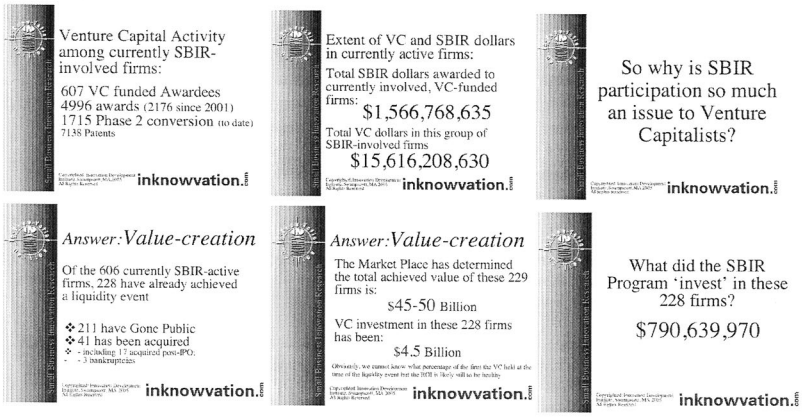
If the amount that VC funded firms are getting from their SBIR participation is proportionately so small, one might well ask—why haven't/don't the VCs simply put in a few extra dollars into the SBIR–STTR firms in their portfolio and just avoid all this current hassle?

The fact that they have not done that, in my judgment, is the true essence of this issue and should significantly *shift the focus of discussion.*

In effect, to find resolution to the current impasse demands that we understand *why* SBIR–STTR has been, and continues to be, valuable to the VC community.

A useful way here to find probable answer to this important question can be demonstrated by our walking through the set of Powerpoint slides provided below.

This set of slides examines in some detail those 607 VC funded firms which have been SBIR program involved since early in 2001; and the achieved liquidity event of 228 of those firms.



SBIR is about value/wealth creation:

In effect, what this analysis shows **is at the very core of why SBIR overall is such a powerful and important program** not only specifically for those who invest in SBIR-involved firms, but for the economy overall. *Effective SBIR participation is fundamentally about value-creation.*

A fundamental premise of the VC endeavor is that a quality investment with significant potential return is one in which an earlier injection of the right sort of cash will have a multiplier effect. In this instance, for many VC funds, SBIR is that 'right sort of cash'. With *no dilution in investor's ownership* in the firm, SBIR supports can serve well

- at least at some level to validate the overall competency of the potential investee
- certainly to mitigate/reduce the technology risk in the project and, with a whole lot of other things also
- then potentially to increase significantly the value of that entity.

An interesting side comment to this point which underscores important shifts in how technology value is being drawn down:

- Over the life of the program up to mid-May 2005, **619 SBIR awardees** have been involved in **M&A transactions**,
- Of these only 154 have involved VC funded firms.
- All the rest have been acquired by or merged with firms (other SBIR awardees as well as larger firms) primarily because the SBIR Awardee had created something of value to that other entity.

The average price paid in those deals is dropping from the monopoly money days of the late 1990's/early 2000 but is still over $400M. The medium price on SBIR M&A deals is at $60-70M.

To an important extent, this condition of **value creation is a characteristic of all those firms in SBIR which we judge to be doing leading edge work.** The option available to firms which present the appropriate VC profile (high growth and liquidity event)—*and that is largely missing for the more general SBIR Awardees*—is a way of being able to draw down on that created value—an IPO or MA& event.

The hugely important challenge that this achievement creates for the next generation of SBIR discussion, in my judgment is, how must the program be tweaked and/or supplemented to support the draw-down of a greater percentage of that value.

This is not, I would strongly suggest, a task that should be left, as it is now, almost entirely to the initiative of individual awardees. It is just too important.

To their credit (and their achieved benefit), many in the VC community I would argue, have early recognized this value-added condition of SBIR. By being so extensively involved in SBIR from the beginning, these VCs *have been doing their job*—to provide a quality return on funds raised from the own investors.

The challenge presented by the current debate is to consider the extent to which **we permit use of SBIR support to increase the potential for that financial return to those investors?**

It has taken me a long time—both here and in analysis of these data over these many months—to get to the point where I think we can demonstrate how to

- move away from the largely corrosive discussion of how to provide/prevent an across-the-board eligibility rule-change that would treat all VC-funded SBIR-involved firms as a single group—*clearly a completely unacceptable condition*
- and proceed instead to a discussion which considers the two critical issues which are at the heart of this issue:

❖ Valuation and
❖ Graduation

The essence of my contribution to this debate is that—in my judgment

- it is entirely inappropriate that we permit the present discussion to continue as if all VC-funded SBIR firms are at the same stage of development and should be treated such that the same rules apply to all. To open the door to the potential of ever-lasting SBIR participation regardless of the state and stage of the firm involved is not acceptable.
- Just as unacceptable, however, is the notion that we should in any way impede the full and effective SBIR participation by those VC funded firms which, by any other criteria, would more commonly be judged 'small business'.

These two findings are neither contradictory nor mutually exclusive.

To operationalize these findings, I would suggest, will require the institution of

1. Some mechanism which would enable a level of *segmentation of the VC-funded SBIR-involved firms.*
   a. The obviously ineligible are fairly evident—actually quite a small number.
   b. Just as evident are the firms which are clearly *not* (yet) in that ineligible pool.

   The challenge is to craft the rules to handle that two-three dozen firms which fall in the mid-range.
2. A set of rules appropriate to *define SBIR graduation.* This is a concept which has already been broached but more usually with reference to the so-called "proposal mills."[11]

Overall, it would be my assertion that this mechanism of differentiation probably should not be so much by age and size of the firm as by stage of development of the project. In effect, let us consider allowing use of SBIR to sweeten the deal—allowing qualified firms to undertake higher-risk, earlier-stage work which might well not otherwise get done. This is a classic role assumed through the years by the Federal Government. Later stage, pre-market development work is more appropriately funded by private sources.

Some final general observations:

- **Venture capital:**

There are few who would argue the critical importance of venture capital to the effective development of a technology, innovation-based economy. The fact that almost every other industrialized and industrializing economy seeks to emulate the U.S. VC model (and the SBIR program) speaks to that fact. However, U.S. venture capital today is quite distinctly different from the industry in its early days, and has changed in many important ways even since the mid to late '90s. Those changes[12] manifest in how, from whom—and how much—VC funds are raised; what type of investments are being made and at what stage of development; at what dollar levels; how return on investment is realized; and with what achieved ROI.

In effect, it is my considered opinion that it is critically important that that percentage of **SBIR involved firms who are addressing substantial markets and growth opportunities as their firm develops should not be excluded from SBIR participation.** This population currently represent something in excess of nine percent of all currently active, SBIR-involved firms; a significantly larger percentage of that population of companies which our analysis suggests are doing leading-edge work.

To disallow the participation of these firms at the appropriate point in their development could seriously weaken the overall viability and effectiveness of the SBIR

[11] Based my considerable SBIR experience through the years, I would suggest that this perennial accusation is pure myth and fiction, entirely without basis in fact and should be finally eliminated from any serious SBIR discussion.

[12] Though not directly the subject of today's hearing, it could be argued that modern VC has many of the characteristics of a maturing industry with all of the implications of that condition.

program as a business and economic development resource. Growth-oriented, small firms requires substantial access to capital far in excess of any that could be—and has been—provided by the SBIR program and, critically, is of a quite different type. The adverse consequences of putting any serious impediment in the way of their access to this type of capital could have major economic-impact repercussions

- **Current SBIR eligibility rules may need a tweak but wholesale redefinition of those rules in not necessary. It ain't broke; we don't need to fix it:**

As a longtime SBIR advocate, it has been my considered opinion throughout the life of the program that the rules pertaining to SBIR participation and eligibility *should not be changed to accommodate to the special needs of any sub-set of otherwise SBIR-qualified small firms.* This would include any special dispensation for geographic distribution, particular industry segment and, in this case, firms in receipt of external equity investment.

A basic premise from which SBIR has proceeded from the outset has been that the only criteria by which selection for award should be judged are the competency of the firm involved and the technical validity of the project submitted. This fundamental premise has maintained the integrity of the SBIR program over now twenty-two years.

It would be my judgment that to set aside size eligibility requirements, particularly when the reasons for that need are *entirely external to the SBIR program,* is a dangerous precedent to set. If a special dispensation for majority-owned VC funded firms is permitted, who will be the next group for whom exception must be made?

Present Condition of VC Funded SBIR-Involved Firms

	1983-2000	2001-2005
Still in Business and employing fewer than 500 people i.e. would ordinarily be considered **SBIR eligible**	198	547
Acquired/Merged/Divested	217	53
Bankrupt/Out of Business	12	4
Not small	49	3

BIOGRAPHY FOR ANN ESKESEN

President of Innovation Development Institute (idi) since 1983, Ann Eskesen is recognized as among the leading experts nationally on effective usage of the federal Small Business Innovation Research (SBIR) program and as a longtime, lead advocate for this important small business development resource and for those involved. A dynamic public speaker, she has an almost unparalleled SBIR knowledge integrated with a considerable expertise in the complex task of bringing technology from the lab to the marketplace. That experience is most currently being utilized in the development of an important new form of intellectual asset trading entity—Phase III Ventures (P3V)—targeted specifically to realizing the created value in SBIR-involved small firms. Involving several major corporations and others with extensive financial interest in SBIR awardees, the P3V effort is anchored in the most comprehensive, complete and in-depth databases developed by idi, documenting the technology competencies and intellectual assets of SBIR awardees—at this point over 15,000 firms.

Ms. Eskesen has close working relationships with the various players in the SBIR community ranging from relative new-comers to the long-time involved awardees. She works closely with the principals in a range of State SBIR–STTR Support organization to make more effective the form and extent of SBIR–STTR participation in their geographic regions. Her detailed understanding of how SBIR–STTR reflects what is going on in the larger economic environment bring many invitations to work

with senior players in major corporations, the federal agencies, etc. She is often featured as the keynote speaker at technology and economic development events.

Through the years Ms. Eskesen has served on the boards of several technology development organizations. A skilled and informed analyst, she has also worked with a range of organizations regionally, nationally and internationally which are engaged in encouraging the growth of small technology based companies.

Extensively involved with a small group of others in passage and subsequent implementation of the original SBIR enabling legislation in 1982, Ms. Eskesen has testified frequently before Congressional committees of matters of consequence to the SBIR community. She was the leading advocate in 1986 for the first SBIR re-authorization; was extensively involved in drafting the 1992 re-authorization legislation which continued, expanded and modified this important small business resource and was a key player in development and implementation of strategies to achieve final passage well in advance of sunset. Through the years, her knowledge, efforts and counsel have been key in almost every situation in which effective functioning of SBIR has required support from political attack through agency management decisions. Currently, her major focus is finding appropriate resolution to the highly contentious issue of SBIR participation of VC funded firms.

FINANCIAL DISCLOSURE:

To whom it may concern: Neither the development of the databases which underpin this discussion nor the operations of the Innovation Development Institute are, or have in any manner, been supported by federal funding nor by external contributions from any source.

Chairman EHLERS. Thank you very much, and I should remind the Members that witnesses—before we started, if you will watch the lights, green means you have time, yellow means hurry up, and red means the trap door opens underneath your chair. So, all right. Next, we will go to Dr. Cohen. The first Dr. Cohen. Is your microphone on?

STATEMENT OF DR. RON COHEN, PRESIDENT AND CEO, ACORDA THERAPEUTICS, INC.

Dr. RON COHEN. Thank you very much for the opportunity to present today. I am Ron Cohen. I am a Board-certified doctor of internal medicine, and founder and CEO of Acorda Therapeutics, which is a small, privately held, venture backed biotech firm in Hawthorne, New York. Prior to founding Acorda 10 years ago in 1995, I was part of the startup team of another biotech company, which eventually we took public, which dealt with growing skin and liver and other tissues for transplantation.

The mission of Acorda is to develop and bring to market therapies that restore neurological function to people with spinal cord injuries, multiple sclerosis, and related conditions that damage or affect the nervous system. Currently, my company has a drug product in—we have just begun a Phase III clinical trial, the final stage, which we hope will finally prove efficacy of a drug that restores the walking ability and strength in people with multiple sclerosis.

In addition, we have a small, about a dozen dedicated scientists, who are working on bringing other therapies to the clinic, notably a protein therapy that has shown in animal models the ability to grow new nerve connections in animals with spinal cord injuries and various brain injuries, and to restore various functions in an unprecedented manner, including walking, bladder function, and visual function. We are also working on therapies to repair the nerves that have lost their insulation in people with multiple sclerosis.

All of these are quite promising. We are doing all this with 59 employees, which I believe would be considered a small company under any rational standard. For the first four years of our company's existence, I worked out of my second bedroom, and then, a sublet office of a friend. I took no salary, and so this was a classic entrepreneurial story. Since we were able to raise our first venture capital round in 1998, we have raised approximately $132 million in venture capital, plus another $8 million in grants and corporate partnerships.

I currently have 35 venture capitalists who have seen fit to invest in my company. The biggest single owner among them owns 10 percent of the company, and the others own five percent or less apiece. I believe, therefore, that in the 19 years I have been in biotech, I have a reasonable perspective on what makes our industry go, what makes it successful, and the role of the venture capitalist in it, as well as SBIR grants, of which my firm has been awarded several over its lifetime.

I believe there is a fundamental misunderstanding afoot about the proper role of VCs, and also, an erroneous attempt to equate VC ownership with big company ownership. The two notions are extremely distinct. Venture capital is simply a pooling of funds from scores, hundreds, or even thousands of individuals to form an efficient way of allocating that capital for investing in high risk, high reward propositions. The SBIR grant program has proved to be an essential gap filler in the progress of technology from the scientist's bench to the patient's bedside, or to product.

Because there is an early stage of technology, particularly in biotech, where it takes 10 to 15 years to bring a product from idea to market, if at all successful, there is an initial gap where the idea is there, the technology may be partly formed, but it is too early for a venture capitalist to invest, because it is too high risk. Now, venture capitalists take very high risks in biotech. For 250 products that enter clinical trials, only one, on average, will emerge as a successful therapy. So, even if venture capitalists were to invest only in clinical stage products, they are still taking a huge risk. The fact is, they invest in preclinical products, too, but there is that window that requires other funding to create proof-of-principle and direction for the venture capitalist.

That is the window that the SBIR program fulfills, and if I had not been able to get SBIR and also an ATP grant early on, my company would not be here today. Our therapy for MS would not be in Phase III trials, and we would not have these promising other therapies in our pipeline, absolutely. Indeed, if one looks at the SBIR program, to get a Phase II grant, which is where you begin to get substantial funds, a million dollars or two, rather than the Phase I grants, which are about $100,000 to $200,000, one of the requirements is that the recipient have proved the ability to raise private funding. And so, in many ways, the current interpretation is at odds with the actual operation of the Phase I and Phase II program.

To exclude venture backed companies, therefore, is to exclude companies that have actually proved themselves to be the most efficient at developing products, because the venture capitalists hire the best physicians, the best scientists, the best patent attorneys,

to review each company's business. And those that pass that grade are the ones that get invested in. The SBIR grants allow competitive, smart entrepreneurs and scientists to bring their products to the point where they can run the gauntlet of VC due diligence successfully.

If this interpretation currently is to stand, it will chill our industry. We have already seen a survey from the Biotech Industry Organizations showing that over half of the companies that previously have been applying for SBIR grants are no longer applying, as a result of this interpretation. I have heard personally from directors of various divisions at the NIH that the quality of grant applications for SBIR is now going down, because of this chilling effect. So there are fewer grants, and perversely, the very companies that are the most competitive are the ones who are no longer applying and getting these grants, where the government's return on investment, as it were, would be expected to be the highest.

So in summary, the SBIR grant has played a critical role in the technological advancement and the economic advancement of this country, which are the envy of the world. Within the biotech industry, and companies such as mine, if I have a Phase III that costs tens of millions of dollars to run through clinical trials, that is where my investors are putting their money. So even though I have raised $140 million, I have $20 million left, and all of it is dedicated to the later stage programs. If I can get SBIR grants to fund my nerve growing technology, and I can prove that it works, the venture capitalists will put in the scores of millions of dollars that it will take me to get it the rest of the way and bring it to people.

But without the SBIR program, even within my company that has raised so much money, I cannot move those programs forward. Thank you very much.

[The prepared statement of Dr. Ron Cohen follows:]

PREPARED STATEMENT OF RON COHEN

Key Points:

- The biotechnology industry is unique in that it takes at least several hundred million dollars and an average of 10–15 years to develop a drug from concept through to market. Biotechnology companies therefore must rely on venture investment as well as grant sources for sufficient funding.
- By imposing an unnecessary restriction against venture capital owned small business, the SBIR program is denying talented scientists the opportunity to develop new therapies and medical technologies at an early stage, to achieve sufficient proof of principle so that venture capitalists will be willing to invest in them. This exclusion is not consistent with the purpose of the SBIR program, which is to stimulate small businesses that will commercialize important technological developments.
- A prohibition against venture capital owned companies is stifling innovation by lowering the number of applicants and making the SBIR program less competitive. It also is impeding the ability of the National Institutes of Health, which provide most of the SBIR grants received by biotechnology companies, to accomplish their mission of improving the health and medical care of the American people.
- I support 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 percent U.S. ownership and control requirement.

Good Morning. My name is Dr. Ron Cohen. I am the Founder, President and CEO of Acorda Therapeutics. Acorda is a privately held biotechnology company located in Hawthorne, New York. My company's mission is to develop and market therapies that restore neurological function to people with spinal cord injury, MS and related conditions of the nervous system.

I would like to thank the Members of the Committee for the opportunity to comment on the current obstacles to participation in the Small Business Innovation Research (SBIR) program by businesses that are majority-owned by venture capital companies.

As you know, the biotechnology industry is unique in that it takes a large amount of capital—at least hundreds of millions of dollars—to develop a drug from concept through to market. These costs are simply too high for individuals to fund. Biotechnology companies must rely on venture investment and grant sources for sufficient funding.

Small biotechnology companies often rely on SBIR Phase I and Phase II grants to fund cutting edge research in areas that most venture capitalists would consider too early stage to fund. However, according to the current eligibility standards, a business must be at least 51 percent 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 problem facing the biotechnology industry is that the SBA's Office of Hearings and Appeals has interpreted the term "individuals" to mean human beings. There is no definition of the term "individual" in the law that established the SBIR Program. The SBA's current interpretation of "individuals" excludes venture capital companies.

This exclusion is not consistent with the purpose of the SBIR program, which is to stimulate small businesses that will commercialize important technological developments. Not only does this interpretation go against Congress' original intent for the program, but it is likely also to stifle innovation by lowering the number of applicants and making the SBIR program less competitive.

A recent survey conducted by the Biotechnology Industry Organization (BIO), of which Acorda is a member, shows that SBA's interpretation is preventing many small biotechnology companies from participating in the SBIR program. More than 70 percent of the companies surveyed were privately owned small businesses with fewer than 50 employees. However, many of these companies were deemed ineligible to receive a SBIR grant due to their venture capital funding. In the past five years, 62 percent of the survey respondents, comprising both public and private companies, had applied for SBIR grants. Half of these applicants were denied grants due to the current interpretation of the size standards.

Finally, more than 60 percent of the privately-held companies surveyed reported choosing not to apply for SBIR grants at all due to perceived eligibility concerns.

The results of BIO's survey illustrate the negative impact that the exclusion of VC-backed companies is having on the biotechnology industry and on medical innovation. In imposing this unnecessary restriction, the SBIR program is denying talented scientists the opportunity to develop new therapies and medical technologies at their early stages, to achieve sufficient proof of principle to attract venture capitalists to invest in their later stages of development. It also is impeding the ability of the National Institutes of Health, which provide most of the SBIR grants received by biotechnology companies, to accomplish their mission of improving the health and medical care of the American people. In the end, even the best science requires long, risky and expensive development to be translated into usable therapies, something that only companies are equipped to do effectively.

I believe Acorda exemplifies Congress' original intent with respect to the SBIR program. We currently employ 59 full-time associates, most of whom are highly educated and skilled. Acorda has received several grants through the SBIR program and these grants have been critical to our ability to develop technologies that have the potential to benefit people living with spinal cord injury and multiple sclerosis. Our lead clinical product, Fampridine-SR, is a novel therapy that is the first shown in clinical trials to improve neurological function, such as walking and strength, in people with MS. SBIR grants supported early proof of concept data for this product and helped persuade venture capitalists to support subsequent stages of development. These venture capitalists have provided well over $140 million in investment capital to date, already providing the SBIR program with an outstanding "return" on its investment. Acorda recently has begun a large-scale, pivotal trial of Fampridine-SR in MS.

It is important to understand that even small businesses that have raised large amounts of investment capital can still put SBIR grants to productive use. Typically, such companies' invested venture capital is earmarked for the very expensive

later stage projects that require tens to hundreds of millions of dollars to complete. But these same companies often have earlier stage projects, as well, that the venture capital investors are unwilling to fund. Yet, because such companies have built an infrastructure of talented professionals to develop their later stage programs, and also have developed networks of venture capital investors, they are uniquely positioned to successfully develop their earlier stage programs, as well. SBIR grants can and do provide the "proof of principle" required by these early stage projects, even within "well-funded" companies, to persuade the venture capitalists to fund subsequent stages of development.

I support 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 percent U.S. ownership and control requirement. This change would allow greater participation in the SBIR program and help to sustain important programs at small companies so they reach the point where novel therapies can enter the clinic and potentially save lives.

This change would ensure that small businesses with ownership structures similar to mine would be able to benefit from this important program and pursue research efforts that are critical to improving our nation's health, maintaining its technological leadership and advancing its economic well-being.

Thank you.

BIOGRAPHY FOR RON COHEN

Founder, President and CEO, Acorda Therapeutics

Dr. Cohen previously was a principal in the startup of Advanced Tissue Sciences, Inc., a biotechnology company engaged in the growth of human organ tissues for transplantation uses. Dr. Cohen received his B.A. degree with honors in Psychology from Princeton University, and his M.D. from the Columbia College of Physicians & Surgeons. He completed a residency in Internal Medicine at the University of Virginia Medical Center, and is Board Certified in Internal Medicine.

Dr. Cohen is Chairman Emeritus and Director of the New York Biotechnology Association (NYBA). He also serves as a Director Zymenex A/S, as a member of the Scientific Advisory Board of the Daniel Heumann Fund and as a member of the Columbia-Presbyterian Health Sciences Council.

Chairman EHLERS. Mr. Cohen.

STATEMENT OF MR. JONATHAN COHEN, PRESIDENT AND CEO, 20/20 GENE SYSTEMS, INC.

Mr. JONATHAN COHEN. Thank you, Mr. Chairman. Good afternoon. I am Jonathan Cohen, founder and CEO of 20/20 Gene Systems, a small biotechnology company based in Rockville, Maryland, that was founded in 2000, and is focused on developing and bringing to market innovative diagnostic products for biodefense, cancer, and autoimmune diseases.

We currently have eight employees, and have raised over $2 million in investment from both individual investors, often referred to as angels, as well as some small venture capital money, and some corporate investment, and have won about a half a dozen SBIR awards, and the SBIR program has played a vital role in our company's success to date.

While Dr. Cohen and I share a last name, we do not share a common vision as to the propriety of having companies owned by venture capital firms participating in the SBIR program. I am here to strongly discourage Congress from passing any legislation that would permit institutionally owned companies, and I believe a company owned by one or more VCs is an institutionally owned company, from accessing the tiny 2.5 percent set aside, that this Congress established for small companies owned by individuals.

Now, to the extent that Acorda Therapeutics and other companies owned by institutions deserve federal support for their R&D, and I believe in many cases they do, for technology that is very high risk, or for which the markets are unpredictable or small, biodefense, orphan diseases, they should be entitled to that money, but it should come out of the other 97.5 percent of the Federal R&D pie, in my opinion. To do otherwise will have a dramatic effect on the large numbers of biotech startups that are individually owned, particularly those that have the misfortune of—I started my company in March of 2000, about a week before the so-called bubble burst, and the last five years have been a very, very difficult time for biotech startups.

I believe that if Congress were to change the size standards, as has been proposed, that substantial numbers of biotech start-up companies will go out of business, and let me explain why. The SBIR process, particularly at the NIH, is extremely resource intensive. It costs my company—it takes about six weeks for full-time Ph.D.s to work on a Phase I SBIR application, and twice that amount of time for a Phase II. If I have to—if our company has to compete with Ron's company that has raised $132 million, they have the ability to prepare more applications in a more cost-effective manner than we do, and I am deeply concerned that that 2.5 percent of the pie will effectively be one percent or .5 percent. That is the consequence that I fear most.

Now, why should that be of concern to this Congress? I believe strongly that both institutionally owned biotech companies and individually owned biotech companies play a very important role in our economy and in our healthcare system, but it is a distinct role, and over the last five years, the venture capital community has overwhelmingly invested in late stage drugs for large markets. That is not a criticism. Those are very important products, and the products that we heard about from the last witness deserve substantial funding. But there is a lot more to biotechnology than blockbuster drugs. Bioterrorism defense, ag biotech, research tools, platform technologies, vaccine development. These are fields that, by and large, have been ignored by, certainly, the large venture capital firms, and we need this 2.5 percent set aside. It is extremely important to enable those smaller companies to bring products to market.

Let me just give you one example. Our company, at the height of the anthrax incident that affected Capitol Hill in 2001, we developed and brought to market an important product called BioCheck, that is used—right now, it is used by about 200 first responder organizations throughout the country, including about a dozen federal agencies, to screen suspicious powders. It was used at the Kerry campaign headquarters a week before the Democratic Convention, and it was used at the Bush campaign headquarters right before the elections. We would not have been able to bring that product to market if we had been majority owned by venture capital firms, because they would have perceived the markets as too small and the risks too high.

So the small, individually owned biotech companies are a community of companies worth protecting. Yes, venture owned companies should be entitled to obtain federal support for certain areas

of high risk, high impact R&D, but that should come out of the other 97.5 percent of the Federal R&D pie. And there are, by the way, increasing programs at the NIH to address that. In my written testimony, I attached an article from the Wall Street Journal last week that talks about how the NIH is beginning to fund early stage clinical trials for even large companies like Eli Lilly. This is a trend, by the way, that this Congress should encourage, and I would look forward to working with this committee and its staff in developing new programs that support deserving programs from large companies that do not destroy the small, innovative biotechnology companies.

Thank you for considering my testimony this afternoon.

[The prepared statement of Mr. Jonathan Cohen follows:]

PREPARED STATEMENT OF JONATHAN COHEN

Good afternoon. I am Jonathan Cohen,[1] founder and CEO of 20/20 GeneSystems, a small biotechnology company based in Rockville, Maryland focused on developing and bringing to market innovative diagnostics for biodefense, cancer, and auto-immune diseases. Before starting 20/20 in 2000 I worked as in-house counsel for two publicly traded biotechnology companies.

As a company with eight employees owned by about a dozen individuals and a few institutional investors, the SBIR program has played a vital role in 20/20's progress and success. We are deeply concerned, however, that if the SBIR size standards were changed to permit companies owned and controlled by large venture capital firms to qualify for this small pool of funding we could loose our ability to continue to bring innovative products to market. Hundreds of small and biotech companies like 20/20 throughout the country could be put out of business by this change. We therefore urge that the size standards for this program be left intact and that companies that are not small businesses (as traditionally defined) instead look outside this 2.5 percent set-aside for appropriate and needed government support.

Likely Consequences of the Proposed Change to SBIR Size Qualifications

Because the SBIR application process is so resource intensive, especially at the NIH, opening up the program to companies owned and controlled by deep-pocketed investment houses presents a genuine risk that a significant percentage of available funds will be siphoned away from the very companies for which the SBIR program was created to support. In other words, the 2.5 percent set aside for small companies (as they have been traditionally defined) could quickly become one percent or 0.5 percent. There would be several key consequences of this change.

First, it would shift funding away from areas of research underway at many small companies that is critical for public health and national security but out of favor with Wall Street. This includes biodefense, vaccine development, diagnostics, platform technologies, research tools, orphan disease therapies, agricultural biotechnology, environmental biotech, etc. For example, just after the anthrax mailings here on Capitol Hill in 2001 our company developed a novel method of screening suspicious powders and brought it to market the following year. Today our *BioCheck*™ test kit is routinely used by more than 300 federal, State, and local first responder organizations nationwide. Had we been owned and controlled by one or more large VC firms it is highly unlikely that this popular and important product would have been permitted to be developed and commercialized due to the relatively small market it addresses and liability risk as would be perceived by our large corporate owners.

Second, it would decrease support for high-impact, high-risk innovative research which small, independently owned companies historically excel at in favor of lower risk product development favored by most VCs today. The following observation by John F. Wong, Ph.D. who writes a monthly "Wall Street Biobeat" column in *Genetic Engineering News* accurately describes the current state of biotech investment:

[1] Jonathan Cohen is President & CEO of 20/20 GeneSystems, Inc., Rockville, MD (www.2020gene.com). The views expressed herein are his own and do not necessarily represent those of the company or its shareholders. He can be reached at jcohen@2020gene.com or 240–424–9424.

> The biotech industry seems to be at a crossroads as it enters the second half of its 50-year cycle. **With the focus now on developing products that are already in clinical development, the industry appears to be moving away from its core strength of research and innovation.**
>
> Frustrated by not reaping the benefits of the genomic and proteomic revolution of the 1990s, **biotech investors now seem to be more risk adverse. Their investment strategy is to focus on investing in companies with products in late stages of clinical development, which they believe will receive FDA approval.** (Emphasis added)[2]

This phenomenon was reiterated last week by several leading venture capitalists attending the annual meeting of the Biotechnology Industry organization:

> "In the late 1990s, investors were willing to back early-stage technology phases of biotechnology," said Jim Barett, an analyst and general partner of New Enterprise Associates. "Now the investment community is moving toward later-stage projects. That means that early-stage projects are having difficulty raising money in this environment of risk discounting."[3]

However, what's best for Wall Street is not always best for America. VCs play a critical role in support of important segments of the biotechnology industry but blockbuster drugs are not the only need of our health care system. Diagnostics and new platform technologies, for example, receive little interest from large VCs but are essential for both biodefense and the emerging field of "personalized medicine" where the optimum therapies are tailored to patients based on their genetic disease profile.[4] Small biotech companies supported by the SBIR program are making major advancements in these important areas of R&D.

Furthermore, as reported by *Business Week* in March, individual Angel investors are filling some of the funding gap in high-risk early stage biotech investing that has been vacated by VCs, pouring nearly $2 billion into biotech last year, up more than 60 percent from 2002 (Attachment). Having raised over $2 million from Angels I can report, however, that this is very time consuming process that relies on the SBIR program to keep our R&D advancing and to provide these non-professional investors with independent validation of our technology.

Third, it would likely discourage the VC community from deploying the staggering $50 billion in unspent funds sitting in their coffers[5] *by relying on SBIR grants rather than making follow-on investments in their portfolio companies.* The proposed eligibility changes would simply be giving more "snow to the Eskimos."

Finally, it would hurt regions of the country with a small life science investor base, such as Maryland, to the benefit of Boston and San Francisco that are home to many seasoned biotech VCs. At the Maryland Technology Development Center (MTDC) in Rockville, a county operated facility that houses one of the largest numbers of biotech start-ups in the mid-Atlantic region not a single biotech company has raised a first round of venture capital since we became tenants there in 2001 but most have been funded through the SBIR program. The biotech entrepreneurs at the MTDC overwhelmingly oppose BIO's efforts to change the SBIR size standards.[6] Yet many of these companies are quite productive, and, like 20/20 have managed to develop and launch innovative successful biotechnology products with the support of the SBIR program, as well as Angel and some smaller institutional investors.

Simply put, a company owned and controlled by one or more large VC firms is not a small business and should not be entitled 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

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[2] *Genetic Engineering News,* March 1, 2005, page 60.

[3] "Investors: Show us the Drugs," *Business Gazette,* June 24, 2005.

[4] The new paradigm of individualized medicine—strongly being pushed by the FDA—will likely create demand for drugs to "niche" diseases, as defined by molecular profiling, with significantly smaller markets than traditional "blockbuster" drugs. This will likely increase the role of smaller biotech companies which can focus on smaller markets than large companies.

[5] Dow Jones VentureOne, March 2005.

[6] It should be pointed out that BIO does not represent or speak for the entire biotechnology industry and certainly not most small companies. At best it speaks only for its membership which is heavily weighted by very large companies that are either publicly traded or have completed several large rounds of institutional investment. I was a member of BIO a few years ago and took part in several of its committee meetings. I was stunned by the extent to which these forums were dominated by professional lobbyists employed by large pharmaceutical companies and how few small company entrepreneurs took part in these meetings. In my view BIO lacks standing to address issues impacting small, individually owned companies since that community is so under-represented in its membership and leadership.

a dime," take substantial risks, and address smaller and less predictable markets, including those unpopular on Wall Street. To permit this change would essentially take the "S" out of SBIR.

Large Entities Should Look Beyond SBIR

Proponents of changing longstanding definitions of "small business" are "barking up the wrong tree" by pressing for changes to the SBIR size standards when they should instead be focusing their efforts on the other 97.5 percent of the federal R&D pie 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 last few years. Today there is an expanding number of programs available to businesses of all sizes at the NIH and other agencies for high-risk, high-impact R&D or the development of products with small or unpredictable markets such orphan drugs or vaccines to bioterror agents. These programs collectively have substantially more funding available than the SBIR program. For example, as reported last week in *The Wall Street Journal,* the NIH is beginning to offer to pay for and carry out early clinical trials of high-risk experimental drugs for certain diseases for which improved therapies have been lacking for decades. (Attachment) Pharmaceutical giant Eli Lilly is among the companies reportedly taking part in this new program.

Congress should encourage this trend and consider new initiatives, open to companies of all size, that help bridge the growing "valley of death" between basic discoveries and delivery to patients of innovative drugs, devices, and diagnostics.[7] At the same time, the integrity of programs like SBIR that safeguard the viability and productivity of our nation's small risk taking biotech entrepreneurs must be protected.

Thanks for considering my testimony today.

BIOGRAPHY FOR JONATHAN COHEN

In 2000 Jonathan Cohen founded 20/20 GeneSystems, Inc. a biotechnology company dedicated to developing novel diagnostic products for biodefense, cancer, and auto-immune diseases. In 2004 he was one of three nominees for the "Entrepreneur of the Year" award from the Technology Council of Maryland. As CEO of 20/20 he lead the company in raising over $2.5 in investment capital, procuring over $1 million in Federal Government contracts and grants, and launching two innovative technology products, one for biodefense and another for life science research. The company currently has two diagnostic products in its development pipeline, one for biodefense (radiological biomarkers) and another for predicting the efficacy of targeted cancer therapies.

Prior to starting 20/20 served as General and Patent Counsel of Oncor, Inc., which pioneered the first gene-based cancer diagnostic approved by the FDA. In that capacity he facilitated numerous corporate alliances and technology licensing transactions.

Mr. Cohen is a registered patent attorney with over 14 years experience in biotechnology patents and licensing matters. He has a Master of Science degree in Biotechnology from Johns Hopkins University in addition to a law degree from American University. Mr. Cohen previously served on the Patent Committee of the Biotechnology Industry Organization and is an active member of the Government Affairs Committee of the Technology Council of Maryland.

He is a former volunteer firefighter and Emergency Medical Technician.

Chairman EHLERS. It is delightful to see such unanimity among the witnesses. The buzzers that you heard indicate we have votes going on on the Floor. I think we can get your testimony in, Dr. Nacy, if you don't linger on it, and then, we will have to recess and return.

[7] This could include a new Advanced Healthcare Technology Development Program, modeled after the NIST ATP program, focused on supporting innovative platform technologies that improve disease diagnosis and therapy selection, drug development, and clinical research. Funding for high-risk technology development is severely lacking from both the NIH and private investors despite the significant impact this can have on our nation's health care system. At least 10 percent of the NIH budget should be set aside for high-impact technology development in fields not supported by VCs or corporations.

STATEMENT OF DR. CAROL A. NACY, CHIEF EXECUTIVE OFFICER, SEQUELLA, INC.

Dr. NACY. Thank you, Mr. Chairman, for hearing me through, and thank you, Committee Members, for offering me the opportunity to give you my perspective on the effect of the current interpretation of the law on both my company and on my industry.

Sequella, Inc. is an eight year old biopharmaceutical company developing products for tuberculosis, a disease that is a global health threat of awesome proportions. In the world, two billion people, out of a total six, that is one out of every three people in the world, has tuberculosis. And 15 percent of these people will come down with this disease in their lifetime, in the next 30 to 50 years. That is 300 million people with tuberculosis. Annually, there are now over 10 million new cases of TB every year, and over two million deaths. TB is an aerosol transmitted disease. It is of concern to the United States, because it is a listed biothreat agent.

Although we have indigenous tuberculosis under control in our country, we exist in a global economy, and we import tuberculosis into the United States inside of people who travel here for business or for pleasure, or to immigrate permanently as citizens from areas in which tuberculosis has literally overwhelmed public health systems. In fact, all over Asia, China, India, South America, and Africa, only on this continent and in Australia do we not have an overwhelming TB problem.

We risk having tuberculosis walk across our borders in a drug-resistant form that would totally annihilate our public health control systems. And I will just give you one example of how quickly this can occur. In New York City, once we had block grants, they shut down a $50 million a year TB control program that, for the city itself, and within three years of the closure of that program, multi-drug-resistant TB epidemic occurred in New York City that cost $1 billion and two years to get under control. TB is definitely not a disease that you want to underestimate.

Sequella was established as a for-profit company in 1997 to solve the problem that the U.S. Public Health Service, in the form of the CDC and the NIH, recognized as a time bomb, the reasserting of control for resurgent TB in New York City and in the other urban areas of this country, was hampered by the fact that products for control of TB are 50 to 100 years old. Although TB was the number one killer of U.S. citizens prior to 1950, the antibiotic era made us complacent. So, Sequella was established to reverse the industry trend of no attention to tuberculosis.

We have been financed over the last eight years through Founder and Director equity investments, investments by angel investors, and a variety of competitive scientific research grants, including grants and contracts from the SBIR program. We have competed for and received SBIR funding for diagnostics, devices, vaccines, and drugs, all focused on TB. And the total amount of funding in the SBIR grant contract program that we have received to date is over $6.5 million—and I have given you a table on page 2—out of a total of $18 million raised for my company.

Despite the healthy success of the SBIR grant competition, we will require $10 million in additional funds over the next two years to complete the clinical trials of a brand new diagnostic that can

actually detect active TB, and initiate the clinical trials of a brand new drug that, in animals, is both more effective and quicker acting than the current treatment of six to nine months.

The SBIR programs at NIH are designed to stimulate the research and development of products for diseases of interest to our Federal Government regardless of the commercial interests in such products. TB is such a disease. It is a U.S. problem with little ongoing commercial effort. The amount of money and the structure of the SBIR program means that the costs of identifying and developing new products for this devastating disease are only begun with the SBIR program. The overall costs for getting something into the clinic is $2 to $5 million just for the animal studies, and anywhere from $30 million to $150 million for the clinical trials. We have to find the money somewhere to get the product out that we started with the SBIR program.

I don't know of anyone who is interested in providing me with $150 million total amount of money, unless it is the venture capital groups who understand high risk and high reward. The VC money is clearly for——

Chairman EHLERS. Excuse me.

Dr. NACY. Yes, sir.

Chairman EHLERS. Hold that thought. We will have to recess and go vote, and we will pick up with you.

Dr. NACY. Okay.

Chairman EHLERS. Give you a little extra time when we return.

[Recess.]

Chairman EHLERS. I apologize for the interruption. It happens here frequently. Dr. Nacy, we were in the midst of your testimony. Actually, we were at the end, but I will give you a little, a couple——

Dr. NACY. Thank you.

Chairman EHLERS. I will give you a couple minutes to add whatever additional thoughts you wanted to express.

Dr. NACY. I basically wanted—oh, I am sorry. Go ahead.

Chairman EHLERS. And we will go to Dr. Abramson. And I, unfortunately, have to go to another meeting, but we will import someone else to chair this meeting during that time, and I apologize in advance for having to leave.

Dr. Nacy.

Dr. NACY. Yes, I just wanted to mention what the impact of this current interpretation of the law regarding SBIR programs means to Sequella. We are currently not venture financed. For the last two years, I have been raising money in the venture community. I have finally gotten two people who are—who believe that tuberculosis is an appropriate company focus for Sequella, and are interested in financing us.

I hope to close the financing by the end of the summer, but at the same time, I have my SBIR grants that both exist, and I have two applications in that have been approved, but not yet funded, and will be funded by the end of the year, worth $2 million to the company. And so, of course, these—this interpretation affects my company specifically, but also affects every other company that is in the process of trying to commercialize products. The SBIR moneys and the VC moneys don't commingle. They are used sequen-

tially. The SBIR moneys are used to identify new and potential products that will be useful to mankind, and the VC money is used to get them clinically evaluated and bring them to commercialization. And so, not having the access to both sides of that equation means that I will either commercialize what exists today, and forget ever developing any new products for TB in the future, or I will continue to identify products that will never make it to patients, and basically, that—this has put me within a rock and a hard place. The venture money will be specifically for the clinical trials of the new TB drug, and if there is anything left over, for the new TB diagnostic.

I just also wanted to rebut the issue of the 2.5 percent for companies. We really can only compete as companies for the SBIR grant, and it is very, very difficult to access the rest of the money from the NIH programs, because we do not do hypothesis-driven research. We do product development, which is guided by FDA rules and regulations, and there is not a lot of flexibility in what we can do when we develop a new drug. So, we are not competitive. I, as a scientist, sit on review boards for the grants for R01 grants, and in fact, just finished one last Thursday, in which no company was actually awarded or approved for grant funding. All academics. As it probably should be, because we do have the SBIR program, as long as we are not yet venture financed.

I think the country, and I think the government, will only benefit if the best product-oriented science is funded, and it will only benefit if that product-oriented science ends up with a product that can be used by patients. I think the two sides of that equation have to be together. The venture financing is critical for getting products out there. The SBIR grant program is critical for innovation in the early stage research.

And I think that I would like just, then, to close and thank you for the opportunity to present this opinion.

[The prepared statement of Dr. Nacy follows:]

PREPARED STATEMENT OF CAROL A. NACY

Points:

- Medical R&D SBIR Programs (NIH, DOD) were designed to initiate R&D on products for diseases of importance to the U.S. public health. Program requires companies to (a) show evidence of follow-on funding for product commercialization and (b) commercialize a product from at least one Phase II grant (or no more SBIR grants can be awarded).
- Sources of follow-on funding are limited in the high-risk clinical phase of product development because of the cost of these development tasks (hundreds of millions of dollars): VC are virtually only source of capital in this quantity.
- SBIR and VC moneys do not co-mingle: they are used sequentially for research (SBIR) and clinical trials/commercialization (VC): both are essential to bring products to marketplace for use by physicians/patients.
- SBIR grants should focus on the best science, regardless of VC financing of companies.

Mr. Chairman and Committee:

Thank you for offering me the opportunity to provide information about the impact of the ruling on eligibility of VC-backed companies for SBIR grants on my company and my industry.

Sequella, Inc. is an eight-year-old biopharmaceutical company discovering and developing products for the diagnosis and control of tuberculosis (TB), a global health

threat of truly awesome proportions: two billion people (one of every three in the world) are infected with the bacterium today, and 15 percent of these people (or 300 million) will come down with fulminant and lethal TB in their lifetime, the next 30–50 years. There are now nearly 10 million new cases of TB every year and over two million deaths annually. TB is an aerosol-transmitted debilitating disease that is listed as a biothreat agent of concern to the U.S. Government.

Although we have indigenous TB almost under control in our country, we exist in a global economy and we import TB on a daily basis inside people who travel for business or pleasure or immigrate for permanent citizenship from areas of the world that are overwhelmed by this disease. Until we solve the global problem of TB, our country is at risk for the importation of drug-resistant TB from elsewhere that will quickly undermine our public health efforts at control. Just one example: New York City closed down their $50 million/year TB control program in the late 1980s. Within three years of closure, New York City underwent a mini-epidemic of TB and drug-resistant TB that cost the city over $1 billion dollars and two years to control. TB is not a disease to ignore or underestimate.

Sequella was established as a for-profit company in 1997 to solve a problem that the U.S. Public Health Service (CDC and NIH) recognized as a time-bomb: the re-asserting of control for resurgent TB in the 1990s in New York City and other urban centers in the U.S. was strongly hampered by the techniques available to diagnose and treat the disease, techniques which are 50–100 years old. Although TB was the #1 killer of U.S. citizens prior to 1950, the antibiotic era of 1950–1990 allowed us to become complaisant about infectious diseases, and no new antibiotics were discovered or developed for TB since mid-1970s. Sequella was established to reverse this industry trend.

Sequella has been financed over the last eight years through Founder and Director equity investments, investment by Angel investors, and a variety of competitive scientific research grants, including grants and contracts from the SBIR program at the National Institutes of Health (NIH). We have competed for and received SBIR funding for diagnostics, devices, vaccines and drugs, all focused on TB: the total amount of funding under the SBIR grant/contract program alone was about $6.5 million (see Table 1), out of a total of $18 million raised overall for the company.

Table1. *List of SBIR grant awards to Sequella, Inc.*

Grant	Type	Title	Submitted	Awarded	Per Year	Duration	TOTAL ($)
R43A143812	SBIR	Antibody-based Diagnostic for TB in non-human primates	12/15/97	9/1/98	$100,000	6 months	$100,000
R43AI/GM46094	SBIR	Shikimate Enzymes as Novel Tuberculosis Drug Targets	12/15/98	7/1/99	$100,000	1 year	$100,000
R43AI46062	SBIR	Electronic Monitoring of Compliance with TB Chemotherapy	12/15/98	9/31/00	$300,000	1 year	$300,000
R43AI48973	SBIR	Commercial Development of the Bronx Box	8/1/00	2/15/01	$300,000	1 year	$300,000
R43AI49608	SBIR	A new Tuberculin for the Diagnosis of TB	8/1/00	9/15 01	$300,000	1 year	$300,000
R43AI50271	SBIR	A rapid lateral-flow Test for TB in Nonhuman Primates	12/1/00	9/15/01	$168,000	1 year	$168,000
R43AI50273	SBIR	Transdermal Test for Active TB	12/1/01	9/15/02	$300,000	1 year	$300,000
N43AA23006	SBIR	Transderm noninvasive monitor	3/1/02	9/14/03	$100,000	1 year	$100,000
R44AI48973	SBIR	Commercial Development of Bronx Box Phase II	9/30/02	12/31/04	$600,000/yr	2+ year	$1,300,000
R43AI051832	SBIR	BCG + Hsp TB Vaccine	3/15/03	5/15/04	$300,000	1 year	$300,000
N44AA33009	SBIR	Transdermal noninvasive monitor Phase II	9/25/03	9/24/05	$469,575/yr	2 years	$939,150
R44AI50271	SBIR	A rapid lateral-flow Test for TB in Nonhuman Primates Phase II	9/25/03	9/24/05	$986,375/yr	2 years	$1,972,751
R43AI060250	SBIR	Dipiperidine Drug Class	9/1/04	9/1/05	$300,000	1 year	$300,000

Despite the healthy success of SBIR grant competition, Sequella will require over $10 million in additional funds in the next two years to complete the clinical trials of its new and more effective diagnostic and initiate the clinical trials of its new drug that, in animals, is both more effective than existing drugs and shortens the treatment time for cure.

The SBIR programs at NIH are designed to stimulate research and development of products for diseases of interest to the Federal Government, regardless of commercial interests in such products. TB is such a disease: a U.S. problem with little ongoing commercial effort. The amount of money and structure of SBIR grants ($75K–$300K Phase I; $750K–$2M Phase II) is sufficient only to start the process of drug, diagnostic, or vaccine discovery and development. The overall costs of development of a new product from the time that the research looks promising is overwhelmingly large, and the money to cover these costs is extremely difficult to find:

— Preclinical toxicity studies for drugs/vaccines range from $2M–$5M in cost/product candidate
— Clinical trials for a single drug/vaccine range from $30M to $150M/product, depending upon indication

Non-SBIR money is clearly required to bridge the funding gap to get a product to the patients it is to serve: the only source for that large an amount of money going to a high-risk venture such as drug development (with one in 5000 success rate) is venture capital (VC). VC money is for clinical development and commercialization, not the high-risk discovery research or early translational research before the clinic: research into new targets of interest to government is last on priority list with VC money, and rightly so. They must push companies to develop a product revenue stream so that they can exit their high-risk investment with an acceptable return on investment.

Specific impact of the eligibility ruling: Sequella, Inc. has two SBIR grant applications (a Phase I for $300K and a Phase II for $1.6M) that are in a queue for funding in this FY 2005. Funding is expected by late summer. Sequella is also completing its first VC financing to fund the clinical trials of the new TB drug and the new TB diagnostic that were developed with NIH SBIR and other grant funds. The loss to Sequella of the ~$2M SBIR grants for its portfolio products NOT ready for clinical trials will be a significant loss to the company and will not be replaced by VC financing. Without SBIR support, we would not have spent the time and energy on TB, a disease that is not considered a commercial opportunity in the U.S. Without the grant support in the future, our remarkable research success in finding new diagnostics, drugs, and vaccines for important non-commercial diseases of importance to the U.S. will stop.

In Sequella, and I suspect in most other small biotechnology companies, the SBIR and VC money will not co-mingle, but will be used sequentially for product development: research (SBIR) funding will drive new product identification; commercialization (VC) funding will bring the identified product to market for use by patients. Both sources of capital are critical for product success. Most VC-backed biotechnology companies remain small businesses (many of them very small: Sequella has only 17 employees), and the addition of VC to the Board or VC commercialization funds to the treasury does not make them any larger or less in need of discovery research funding.

I have heard comments that the SBIR set-aside moneys are only 2.5 percent of grant support available at the NIH. I continue to review grants for the NIH in non-SBIR programs, and I can tell you from personal experience that companies do not compete well in this arena. The reason? We do not do hypothesis-driven research. Our research is governed by rules and regulations of the FDA for product development, and even the discovery research we do does not address fundamental biology, but product-oriented processes not amenable to review by academicians who drive the R01 granting processes at the NIH.

Competition with other small business industries does not exist for NIH SBIR programs: only biotechnology/biopharma companies compete for the dedicated small business set-aside moneys from NIH and DOD for medical research. Thus, the argument that VC-backed small biotechnology companies in medical research are unfairly competing for small business funds in general is erroneous: only science-based companies can compete for the NIH/DOD medical research funds. Although having VC investment provides an opportunity to be a successful company that commercializes products, VC investment does not provide a scientific advantage for companies: science is reviewed for its merits, not its financial backing. Good science that is competitive can come from VC-backed companies or companies that are not VC-backed. Sequella is an example of the latter: we have been highly successful at grant competitions, although we are not yet VC financed. I am absolutely sure that we will be as competitive when we have VC funding. Competition is based on scientific merit, and for the best science to prevail, we should all (VC-backed or not) be in the mix.

The country will only benefit if all the best product-oriented science is funded, but it will also only benefit if that science is transformed from a promise to a product, and that will happen most efficiently in VC-backed companies with sufficient funds to make it though the costly clinical development process.

Thank you again for the opportunity to express my views before the Committee.

BIOGRAPHY FOR CAROL A. NACY

DATE AND PLACE OF BIRTH: 14 January 1948; Tokyo, Japan.

MARITAL STATUS: married, five children

HOME ADDRESS: 2233 Q Street, NW, Washington, DC 20008; Tele: 202–299–0106; Fax: 202–299–0107; E-mail: carolnacy@sequella.com

EDUCATION:

1966–1977 Catholic University of America, Washington, DC

- 1966–1970 A.B., Biology
- 1972–1975 M.S., Microbiology
- 1975–1977 Ph.D., Microbiology

1976–1978 Department of Rickettsial Diseases, Walter Reed Army Institute of Research, Washington, DC; Nation Academy of Sciences NRC Postdoctoral Research Associate

BRIEF CHRONOLOGY OF EMPLOYMENT:

1998–present Sequella, Inc., 9610 Medical Center Drive, Suite 200, Rockville, MD; Founder, CEO and Chair, Board of Directors (Company focused on products for TB)

1997–1998 Anergen, Inc., 301 Penobscot Drive, Redwood City, CA; Chief Scientific Officer (Company focused on products for autoimmune diseases)

1993–1997 EntreMed, Inc., 9610 Medical Center Drive, Suite 200, Rockville, MD; Consultant (1997); Executive Vice President and Chief Scientific Officer (1995–1997); Senior Vice President for Research (1993–1995) (Company focused on cancer)

1976–1993 Walter Reed Army Institute of Research, Washington, DC

- 1988–1993 Program Director, GS–15 (SES Trainee), Immunotherapy of Infectious Diseases; Assistant Chief, Department of Cellular Immunology; and Task Area Manager, Broad Army Program on Immunomodulators in Biological Defense
- 1986–1988 Program Manager, GS–14, Immunity to Leishmania; and Assistant Chief, Department of Immunology
- 1980–1986 Microbiologist, GS–12 and GS–13, Department of Immunology
- 1978–1979 Microbiologist, GS–12, Department of Rickettsial Diseases
- 1976–1978 NRC National Academy of Sciences Post-doctoral Research, Associate, Department of Rickettsial Diseases

1979 Laboratory of Parasitology, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD; Visiting scientist

1975–1977 Trinity College, Washington, DC (see teaching experience); Instructor, Microbiology

1970–1972 Branch of Infectious Diseases, National Institute of Neurological Diseases and Stroke, National Institutes of Health, Bethesda, MD; Microbiologist, GS–5

TEACHING EXPERIENCE:

1983–1993 Lecturer, Immunology Course, Military Medical Science Fellowship Program, Walter Reed Army Institute of Research, Washington, DC

- 1985–86 MAJ Charles Davis, MC USA: *"Isolation and characterization of the lymphokine that induces macrophage resistance to infection with obligate intracellular parasites."*(see publications 63 and 64)
- 1990–1991 MAJ Wayne Jonas, MC USA: *"Cytokine therapy of aerosol Francisella tularensis infections in mice."*
- 1987–1993 Advisor, research manuscript preparation by Medical Science Fellows

1982–1993 Advisor, Microbiology and Immunology, National Research Council/National Academy of Sciences, Post-doctoral Resident Research Associateship Program, Walter Reed Army Institute of Research, Washington, DC

1983–1985 Dr. Beverly A. Mock: *"Genetic control of susceptibility to cutaneous and systemic Leishmania major infections in mice."* (see publications 41,42,43,46,52,56,65,114)

1987–1988 Dr. Reiko Nakamura: *"Characterization of an EL–4 derived suppressor factor for macrophage cytostatic effects against Mycobacteria."*

1989–1991 Dr. Barbara Nelson: *"Effect of Transforming Growth Factor*β *on lymphokine induction of macrophage effector activities,"* (see publications 81,84,87,93,94,95,101)

1989–1991 Dr. R.B. Narayanan: *"Development of protective monoclonal antibodies for Francisella tularensis infections of mice."* (see publications 106,107,116,118,122,124)

1989–1992 Dr. David Leiby: *"Purification of the lymphokines that induce macrophage resistance to infection with Leishmania major."* (see publications 81,85, 95,96,98,103,104,111,113)

1990–1993 Dr. Karen Elkins: *"Cellular immune responses during Francisella tularensis infections."* (see publications 103,104,105,109)

1992–1993 Dr. Ephram Getachew: *"Induction of antimicrobial activities in human monocytes."* (see publications 121, 127)

1986–1988 Post-doctoral Advisor, Medical Research Council of Canada, Ottawa, Canada

1986–1988 Dr. Miodrag Belosevic: *"Characterization of the resistance of activated macrophages to infection with obligate intracellular parasites."* (see publications 58,60,61,63,64,69,74,76,77,83,94)

1980–present Professor, Adjunct, Catholic University of America, Washington, DC

1981–1984 Masters Thesis, Anne H. Fortier: *"Characterization of macrophage populations that become infected with the protozoan parasite, Leishmania major."*

1984–1986 Ph.D. Dissertation, Anne H. Fortier: *"Leishmania tropica infection of P/J mice: analysis of systemic disease and macrophage function in a mouse strain with characterized macrophage defects."*

1987–1988 Masters Thesis, Matthew Seguin: *"Role of Kuppfer cells in murine infections with Plasmodium berghei."*

1987–1989 Masters Thesis, Huong Cao: *"Differential induction of macrophage class II histocompatibility antigens by IFN? and Interleukin-4."*

1989–1993 Master's Thesis, Xioyan Fan: *"Tumor Necrosis Factor* α *synthesis and secretion: regulation in macrophages infected with the Human Immunodeficiency Virus."*

1991–1993 Ph.D. Dissertation (Committee Member), Heidi Link: *"T cell specificity repertoire induction by alternate forms of the CS protein of Plasmodium berghei."*

1994–1997 Ph.D. Dissertation, Adonia Pappathanassiu: *"Factors that regulate angiogenesis."*

1994–1996 Thesis Advisor, Johns Hopkins University, Baltimore, MD

1994–1996 Master's Thesis, Antonio Ruiz: *"Cytokine circuits in angiogenesis: interaction of bFGF and cytokines for enhanced proliferation of endothelial cells."*

1994–1997 Professor, Adjunct, Howard University, Washington, DC

1994–1997 Ph.D. Dissertation, Jacinta Uzoamaka Aniagolu: *"Characterization of anti-cholesterol antibodies: implications for atherosclerosis."*

2001–present Adjunct Professor, George Washington University, Department of Tropical Medicine and Microbiology, Washington, DC

1988–1990 Reader: Master's Thesis, Lisa Medvitz: *"Association of two genetic traits, defective macrophage killing of Schistosoma mansoni schistosomula and defective production of macrophage activating lymphokines, in P/N mice."*

1980–1995 Faculty, Wet Workshop on Macrophage Activation, Annual Meeting, Society for Leukocyte Biology

1974–1976 Instructor, Department of Biology (General Microbiology), Trinity College, Washington, DC

1972–1975 Graduate Teaching Assistant, Department of Biology, Catholic University of America, Washington, DC

Academic Honors:

1966–1970 Full Scholarship, Catholic University of America, Washington, DC
1971 National Aeronautics and Space Administration Special Fellowship
1974 National Science Foundation Student-originated Studies Grant
1975 Sigma Xi Excellence in Research Award
1976 Outstanding Graduate Student, Catholic University of America
1976 Who's Who in American Colleges and Universities
1976–1978 National Academy of Sciences/National Research Council Resident Research Associateship
1983 Young Investigator Award for Excellence in Research, Reticuloendothelial Society
1986 Election, Fellow of the American Academy of Microbiology
1994 Honorary Life Member, Society for Leukocyte Biology
2000 Women in Discovery, Texas A&M University
2002 Lifetime Achievement in Science, Catholic University of America
2003 Dean's Development Board, Catholic University of America

Associations:

Society of the Sigma Xi (1978)
American Society for Microbiology (1974)
American Society for Tropical Medicine and Hygiene (1979)
Reticuloendothelial Society/Society for Leukocyte Biology (1979)
American Association of Immunologists (1980)
American Academy of Microbiology (1986)
American Society for Cancer Research (1994)
New York Academy of Sciences (1997)

MEMBERSHIPS IN SCIENTIFIC SOCIETIES AND RESEARCH PANELS:

Offices in National and International Associations:

American Society for Tropical Medicine and Hygiene
Appointed:
1993–1994, Nominating Committee
1995–1998, Scientific Program Committee

Society for Leukocyte Biology
Elected:
1987–1991, Secretary
1991–1992, President-Elect
1992–1993, President
1993–1994, Council

Appointed:
Publications Committee (1986–89)
Monograph Series Committee (1991)
President's Advisory Committee (1991)
Nominating Committee (Chair), (1995)

Editorial Responsibilities:
EDITOR: *SLB Newsletter* (1992–1995)

Honors:
Young Investigator Award for Excellence in Research, 1983
Honorary Life Membership, 1994

American Society for Microbiology
Elected:
1985–1986, Co-Chair, Immunology Division
1986–1987, Chairman, Immunology Division
1988–1990, Divisional Group I Representative
1994–1995, President-Elect
1995–1996, President

1996–1997, Past-President, Member of Council

Appointed:
1990–1992, Foundation Lecturer
1992, Ad Hoc Committee on Ethics and Integrity in Publications
1994–1996, Foundation Lecturer
1996–1999, Committee on Awards, Abbott Laboratories Lifetime Achievement Award
1995–1999, Committee on Centennial Heritage

Editorial Responsibilities:
Infection and Immunity
Editor, Parasitic and Fungal Diseases (1990–1993); Host response and inflammation (1993–1995)
Associate Editor (1984–1988)

Honors:
Fellowship in the American Academy of Microbiology (1986)

American Association of Immunologists
Appointed:
1992–1996, Publications Committee

Editorial Responsibilities:
Journal of Immunology
Editor, Immunoparasitology (1987–1991)
Associate Editor (1986–1989)

Member, Editorial Boards:
Journal of Immunology
Editor, Immunoparasitology (1987–1991)
Associate Editor (1986–1989)
Journal of Clinical Immunology
Associate Editor (1989–1993)
Journal of Leukocyte Biology
Associate Editor (1986–present)
Infection and Immunity
Editor, Parasitic and Fungal Diseases (1990–1992)
Editor, Host response and inflammation (1993–1996)
Associate Editor (1984–1988)
Invited (Ad Hoc) Reviewer for:
Immunobiology
Journal of Clinical Investigation
Proc. of the National Academy of Sciences
EMBO
American Journal of Tropical Med. and Hygiene
Cellular Immunology
Journal of Molecular Parasitology
Journal of Infectious Diseases

Global Health Panels:

World Health Organization (1985–87), Study Group on Immunology and Chemotherapy of Leishmaniasis

World Health Organization, Stop TB Alliance (2001–present), Working Group, TB Vaccines

World Health Organization, IVR (2001–2004), Scientific Advisory Group, Vaccines

World Health Organization, Stop TB Alliance (2002–present), Working Group, TB Diagnostics

World Health Organization, IVR (2002–present), Scientific Advisory Group, TB Diagnostics

Ad Hoc review of grants or contracts for:

Experimental Immunology Study Group, National Cancer Institute

Immunology of Parasitic Diseases, Biodefense and Emerging Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD

National Science Foundation, Washington, DC

Medical Research Council of Canada, Ottawa, CANADA

Canadian Cystic Fibrosis Foundation, Toronto, Ontario, CANADA

Advisory Boards and Review Panels

Ad Hoc Member, Advisory Board (1993), Cytokine Division, CBRL, Federal Drug Administration, Rockville, MD

Panel Member, Review Board (1996), NIAID Extramural Tuberculosis Program Review: Priorities for Tuberculosis Research, National Institutes of Health, Bethesda, MD

Member, Advisory Board (1997–2002), National Research Council, National Academy of Sciences, Washington, DC

Panel Member, Review Board (1997), NIDR Infectious Diseases Planning Workshop, National Institutes of Health, Bethesda, MD

CORPORATE BOARDS OF DIRECTORS

Director and Chair of Board (1997–present), Sequella, Inc., 9610 Medical Center Drive, Suite 200, Rockville, MD

Director (2001–present), Chair of Board (1999–2001), ASM Resources, 1335 Connecticut Avenue, Rockville, MD

Director (2001–present), TolerGenics, Inc., 9610 Medical Center Drive, Suite 230, Rockville, MD

Director (2003–present), Social and Scientific Systems, 8757 Georgia Avenue, 12th Floor, Silver Spring, MD

Director (2003 npresent), Women in BIO, Rockville, MD

Director and Treasurer (2003–present), Sequella Foundation, Inc., 9620 Medical Center Drive, Suite 220, Rockville, MD

Director and Chair of Board (1997–2003), Aeras Global TB Vaccine Foundation, (AKA Sequella Global Tuberculosis Foundation, 1997–2003), 9610 Medical Center Drive, Suite 220, Rockville, MD

Director (2001–2002), Member, Advisory Board (1998–2000), Life Sciences Research Organization, 9650 Rockville Pike, Bethesda, MD

Director, (1996), Cytokine Sciences, Inc., Denver, Colorado

CORPORATE HONORS

2002 Fast Company: Top 50 Innovators in the World (#6)

2003 Best Business Plan, VaBio Investor Conference

2005 Top 100 Women in Maryland, Daily Record

GRANT SUPPORT

Detection of Pathogens by Flow Cytometry, Small Business Technology Transfer Program Phase I (STTR); $100,000 (15 Aug 94–14 Aug 95); PI.

Self MHC class II beta chain vaccine for diabetes, Small Business Innovation Research Program, Phase I (SBIR); $100,000 (1 Sept 98–Mar 99), co-PI, I five percent, no salary.

Diagnostic for non-human primate tuberculosis, Small Business Innovation Research Program, Phase I (SBIR); $100,000 (1 Sept 98–Mar 99), PI.

Lateral Flow Serologic Test for TB, SBIR grant, Phase I; $168,000 (15 Jul 01–14 Jan 02), PI.

Transdermal Patch for Active TB, SBIR grant, Phase I; $300,000 (15 Sep 01–14 Sep 02), PI.

High Throughput Screening of TB Drugs, R01 grant from the NIH, $565,000 (15 Sep 01–14 Sep 04), PI.

A Second-generation Patch Test for Detection of Active TB, U01 grant from NIH, $1,660,000 (15 Aug 03–14 Aug 2007), PI.

Lateral Flow Serologic Test for TB, SBIR grant, Phase II; $1,600,000 (29 Sept 03–28 Sept 05), PI.

PATENTS

Identification of Infection by Flow Cytometry (No. 08/330,533)

Compositions and Methods for Treating Cancer and Hyperproliferative Disorders (No. 5919459)

Method of diagnosis and treatment of atherosclerosis using anti-cholesterol antibodies (No. 96944237)

CONSULTING ARRANGEMENTS

1998–2002 Battelle Corporation, 505 King Avenue, Columbus, OH; (Nonspecific immunity for defense against Infectious Diseases)

1997–1999 Oncogene Sciences, Inc., 106 Charles Lindbergh Blvd., Uniondale, NY; (Drug development for Infectious Diseases)

1997–1998 MIMC, Inc., 1401 Rockville Pike, Rockville, MD; (Development of new concepts for pre-clinical CRO)

MANAGEMENT EDUCATION:

Senior Executive Service (SES) Development Program, U.S. Civil Service:

Dec 91 Utilizing Human Resources
Jan 92 Reviewing Implementation and Results
May 92 Strategic Planning and Executive Leadership
Jul 92 Administering Money and Material Resources

Other:

Apr 93 FDA Regulatory Compliance
Jul 04 Finance and Accounting for Non-financial Managers

COMMUNITY ACTIVITIES:

1990–1993 Coordinator, Hands-on Science After School Program, Burning Tree Elementary School, Bethesda, MD

1993–present Maryland High Technology Council

PUBLICATIONS:

135 papers published in journals and books.

RESEARCH INTERESTS:

Immunity to infectious agents, specifically intracellular pathogens and agents that grow in macrophages; cytokine regulation of macrophage function; regulation of endogenous mechanisms for control of disease; tuberculosis.

Chairman EHLERS. Thank you very much. Dr. Abramson.

STATEMENT OF DR. FREDERIC D. ABRAMSON, PRESIDENT AND CEO, ALPHAGENICS, INC.

Dr. ABRAMSON. Thank you very much, Mr. Chairman. This is obviously an issue on which reasonable people agree to disagree reasonably. I am Frederic Abramson, founder and CEO of AlphaGenics, a small life sciences firm in Rockville.

I founded AlphaGenics in 1999 to use genetic information to develop innovative products for consumers. Two products under development now include JeneJuice, a sports drink that is custom blended based on a person's genetic makeup, and SkyGene, a handheld electronic device that lets people share information about their genes for personality and other non-disease social information. We have also identified a new way in which the right mix of nutrients in a person's diet could prevent influenza.

I also teach in the Master's degree program in biotechnology at Johns Hopkins, where I teach economics, finance, creating the biotechnology enterprise. My Ph.D. is in human genetics, from Michigan. I have a Masters of Management from MIT, where I was a Sloan Fellow. I also am an attorney. I am admitted to the patent bar and the bar of the U.S. Supreme Court.

The essential point that I want to make here is that the small business ownership standards, as these relate to SBIR awards, is

that no change should be made in the current interpretation of the law. In other words, biotech companies that are majority owned by VC should not be permitted to compete for SBIR funds. Any change that permits venture owned small businesses to compete for SBIR will jeopardize biotechnology innovation as we know it today. There are three central reasons why no change should be made.

The first point is that changing the rule will open the door to large companies and venture capitalists who can form syndicates and spin off entities to do the research, funded by SBIR, that they normally would fund themselves. There won't be any meaningful way to distinguish ownership, about who is eligible and who isn't, so a Fortune 1000 company could be part of a syndicate that would own a small company and get SBIR funding to fund their research that they would otherwise do in-house. More important, their vast resources which they have at their disposal means they can assemble the better looking teams to compete for SBIR in the evaluation process. They will have powerful academic credentials, and this actually increases their unfair advantage in the competitive process at NIH. If I were head of R&D of a Fortune 1000 company, I would take every research project that came to me, work to get it syndicated, and spin it out in one of these small businesses to get SBIR funding.

Secondly, under the current rules, VCs have a choice between owning 49 percent or 51 percent of a business, and under one choice, not competing by SBIR, or the other choice, competing. These two percentage points is what separates prudence from greed. Under the current rule, the investor has a fair choice to make, and they can make the choice based on their own assessment of the risks.

The ownership percentages also relate to valuation for the business. That is, what is a company worth when someone invests in it? There are several ways to calculate valuation, but fundamentally, the most powerful way valuation is determined is the negotiating position of the parties. If a VC owned firm can compete for SBIRs, the VC can drive a bargain in which they drive down the valuation of the small business to get a better deal.

Finally, there is a practical question, and a practical issue. VCs today are not putting the money in early stage bio. They have moved downstream into later stage companies, because these investments are more attractive and lower risk. Many of the companies they invest in, as noted earlier by another witnesses, have already obtained SBIR funding, which gives them a more attractive profile for funding. VCs also are only a small percentage of the total bio funding. Angel investors and corporate investment constitute a major portion of the bio investment profile. Most of these deals don't have the investor taking control of the business. So, this is really—the current stand and the current rule is consistent with the longstanding policy that small bio companies need a chance to prove their value to become attractive to investors, not the other way around.

So, to summarize, Mr. Chairman, there is an Olympic sized swimming pool of funds available from NIH and DOD that every company in the United States can compete for, and large companies can get funds to innovate in science and technology. And we

know organizations like Harvard, Cal Tech, Yale, Boeing, Lockheed-Martin, and IBM all compete for these. Congress realized years ago that small companies need a special kind of pool, a wading pool, if you will, to compete in.

And what we want here, and the VC backed firms are asking for, these are, you might call, young adults. They don't like swimming in the big pool with the big guys, because it is hard to swim in, so they want to get over in the baby pool with the little guys, to get what is there.

It is well documented that most of America's innovation comes from small companies. Permitting venture backed companies to obtain SBIR funds will siphon off the funds that small companies need, and will erode America's competitive position in the world as we know it.

I thank you for the opportunity to share these views, and I will answer any questions.

[The prepared statement of Dr. Abramson follows:]

PREPARED STATEMENT OF FREDRIC D. ABRAMSON

My name is Dr. Fredric Abramson, founder and CEO of AlphaGenics, a small life science firm located in Rockville, Maryland.

I founded AlphaGenics in 1999. AlphaGenics uses genetic information to develop innovative products for consumers. Two products now under development include JeneJuice, a sports drink that is custom blended based on a person's genetic makeup, and SkyGene, a hand-held electronic device that lets people share information about their genes for personality and other non-disease social information. We have also identified a new way in which the right mix of nutrients in a person's diet could prevent influenza.

I also teach in the Master's of Biotechnology program at Johns Hopkins University. I teach courses in economics, finance and creating the biotechnology enterprise. My Ph.D. is in Human Genetics from the University of Michigan. I have a Master's of Management from MIT, where I was an Alfred P. Sloan Fellow, and I hold a law degree from American University. I am is admitted to the U.S. patent bar and the bar of the United States Supreme Court, among others.

The essential point for the Small Business ownership standards as these relate to Small Business Innovative Research funds is that no change should be made to the current interpretation of the law. In other words, biotech companies that are majority owned by VCs should not be permitted to compete for SBIR funds. Any change that permits venture owned small businesses to compete for SBIR will jeopardize biotechnology innovation as we know it today. There are three central reasons why no change should be made.

The first point is that changing the rule will open the door to large companies and venture capitalists spinning off and owning small companies to obtain SBIR funds. There is no meaningful way to distinguish what kind of majority ownership is not eligible. Each of the Fortune 1000 companies can create these eligible subsidiaries to cash in on the small business funding. Worse, their vast resources means they will be able to assemble better looking teams with powerful academic credentials, which will increase their unfair advantage in obtaining NIH funds. If I were head of R&D for a Fortune 1000 company, I would spin out virtually every bio project into a subsidiary to get SBIR funding.

Second, under the present rule, VCs have a choice: take 49 percent ownership and compete for SBIR funds, or take 51 percent or more control and develop the company on your own. These two percentage points is what separates prudence from greed. Under the current rules, an investor has a fair choice to make. Take control of the small business and be excluded from SBIR competitions, or take a minority interest and let the small business compete with others. That's a fair choice.

Related to ownership percentages is the area of valuation. That is, what is a company worth when someone invests in it? There are at least four well recognized ways to calculate valuation. But perhaps the most powerful is the negotiating position of the parties. If VC owned firms are allowed to compete for SBIR, it will mean that VCs can demand and get a larger percentage ownership for the same investment dollars. This lowers the valuation, and in effect devalues the contribution of the founders.

Finally, there is the practical the issue of where VCs are putting their money in biotechnology. For the past few years, virtually no VC investment went into early or seed stage bio companies. Why? Because the risks are higher than investing in later stage companies. Indeed, many of the later stage investments became attractive BECAUSE they obtained SBIR funding, not the other way around. Factually, the VCs are only a small percentage of early and seed stage bio funding. Most of the early stage funding comes from angels and from corporate-strategic alliances. And most of these deals do not have the investor taking control of the small business. Again, this is consistent with the long standing policy of giving small bio companies a chance to prove their value to become attractive to investors, not the other way around.

To summarize, there is a large Olympic-sized adult swimming pool of federal dollars for every company in the U.S. This pool funds innovations in science and technology, and organizations such as Harvard, Johns Hopkins, Cal Tech, Boeing, Lockheed-Martin and IBM have been able to develop innovations with this funding. However, Congress realized that the small companies, the early stage companies have trouble getting funding in this pool. So Congress created a wading pool called the SBIR program. Small companies in this pool compete against other small companies.

The VC backed firms are teenagers who don't like swimming in the adult pool. So they want the rules changed so they can get into the wading pool with the little guys, who will be forced out.

Since it is well documented that a substantial source of America's innovation comes from these start-up small businesses, permitting venture backed companies to siphon off SBIR funds will, in my opinion, erode America's competitive technology position in the world.

Thank you, and I am happy to answer any questions.

BIOGRAPHY FOR FREDRIC D. ABRAMSON

Dr. Abramson is taking the lead in developing genetic-information based consumer products to improve the lives of ordinary people. He comes to this emerging field, which he calls Directive Genomics, with four decades experience in a broad variety of business, scientific and educational activities. These range from developing advanced computer software that reduced hospital-acquired infections to operations & marketing in the recording industry. His scientific work included developing a computerized tracking system to deal with Dengue Fever in the Caribbean, demonstrating that women can produce antibodies to synthetic steroids, and analyzing over half-million pregnancy outcomes to show that roughly 75 percent of all human pregnancies result in a spontaneous fetal death. He worked on federal and state policy, including U.S. Department of Health Education and Welfare Secretary Joseph Califano's national policy review of alcohol abuse programs, the Nuclear Regulatory Commission's measure of inspector objectivity, a policy analysis of future technology in emergency medical services for the U.S. Department of Transportation, scientific experiment selection for NASA's Spacelab, and Chaired the Maryland Governor's Commission on Workers Compensation Laws.

His business activities include founding the Association for Medical Emergency Informatics, Inc. (publisher—U.S. DOT emergency medical services training materials), United Software Associates, Inc. (publishing European source computer software in the American market), and the Fit America Research Center (research on weight loss). His work experience additionally includes retail sales, wholesale distribution, rock and roll show promotion, manufacturing of sheepskin seat covers for sports cars and industrial elastomer products.

Dr. Abramson is recognized as a gifted teacher and lecturer, and was named Teacher of the Year in the Johns Hopkins Master's program in biotechnology, where he teaches courses in the economics of biotechnology, creating the biotechnology enterprise, financial development, and legal aspects of biotechnology. He also is an adjunct in the Hopkins graduate program in information technology. He previously held full-time academic appointments at the University of Kentucky Medical School (Assistant Professor of Community Medicine) where he founded and directed the Research Design Biostatistics Laboratory, and the American University, Washington, D.C. (Associate Professor of Management) where he taught business strategy and organization development. He taught MBA students as an adjunct in the Executive Program at Loyola College in Baltimore and the Georgetown University School of Business.

Dr. Abramson holds his Ph.D. in human genetics from the University of Michigan (1972) and a Master of Science in Management from MIT (1977) where he was an Alfred P. Sloan Fellow. He also received degrees from the University of Pennsyl-

vania (A.B. mathematical biology, 1963), University of Rochester (M.S. biology, 1965), and the American University Washington College of Law (J.D., 1987). He is admitted to the bars of Maryland and the District of Columbia, and to practice before the United States Supreme Court and the United States Patent Office.

DISCUSSION

Chairman EHLERS. Thank you all very much for your comments. I—when I walked in, I was happy to see you all engaged in vigorous conversation with each other. Perhaps we should just appoint you to go to another corner and resolve the problem and come back.

But while sitting here, I have generated a half-dozen ideas of my own about what we might do. I will not announce those at this time, but I certainly appreciate your stimulating testimony.

I apologize that I have to leave for another meeting, and normally, I would never do that when I am chairing a committee, but in this case, we are trying to solve the pension problems, which of course, as Mr. Baird says, we will never see me again. But I certainly appreciate your testimony, in case I am not back before you leave. Thank you very, very much for coming, and you have made a major contribution to the discussion.

With that, I am pleased to turn over the chair to Dr. Schwarz, who was a practicing physician for many years, and since most of you talked about life sciences, he is eminently suited to chair the remainder of the meeting.

Thank you.

Mr. SCHWARZ. [Presiding] The gentleman from Oregon, Mr. Wu.

Mr. WU. Thank you very much, Mr. Chairman.

I was reading these summaries, and I am in the process of asking for the statute. Well, I have requested the statute, but it hasn't come yet, and it seems to me that asking some questions of first impression might help here, or at least might help me, and that is when I looked at the language of some of these secondary materials, this requirement about the recipient being a citizen or a resident, which has subsequently been interpreted to require a real person, other than an entity, that seems to be a drafting error more than anything else. I mean, that seems to be the kind of language that Congress typically inserts to say we want an American to be doing this, and the unintended consequence is that it has been interpreted to mean a natural person and exclude institutions.

Do you all have any comments on that? Dr. Cohen.

Dr. RON COHEN. Thank you, Mr. Wu. I would support that entirely. It seems, just historically, that the intent was to ensure majority ownership by American entities, American people. With respect to venture capitalists, having dealt with 35 venture capitalists in my company, I will tell you, I am not sure I understand what the argument is about, because after all, what is venture capital? A venture capital firm is a bunch of limited partners, it is a partnership, of people with high net worth, and also institutions, such as pension funds and 401Ks and so on, who pool their money for the purpose of investing in high risk, potentially high reward endeavors. So, it does represent American individuals in a very real sense.

Mr. WU. Well, Dr. Cohen, you will forgive me if I truncate your answer. I take that as a yes, you agree, and thank you, and that others might not. I would be interested in hearing your perspective.

Mr. JONATHAN COHEN. I have a very different perspective, if I may. I can't comment on what the original intent of Congress was in using this——

Mr. WU. But that is what I am going to, what Congress drafted in 1982, or passed in 1982, probably drafted between, I don't know, '80, '82, '79, '82, however long it was worked on.

Mr. JONATHAN COHEN. I suspect they were deliberate when they used the term individuals, because—and I don't think this is splitting legal hairs. I believe there is a profound difference between an individual, a living, breathing person, and a pension fund. And let me give you, if I may, just one concrete example. There is an emerging trend, and I cited an article from Business Week, and that I entered into the record, a very encouraging trend in biotechnology the last few years is there is an increased interest on the part of angel investors, particularly what are called disease angels, in other words, people that invest in startup biotech companies, in part for return for investment.

Mr. WU. Mr. Cohen, I understand that. I understand that, but if that is the case, how do you account for interpretation between 1982 and 2003 when venture capital funds were included? It wasn't until 2003 that VC funds were excluded, at least that is my understanding.

Mr. JONATHAN COHEN. I suspect it was an oversight.

Mr. WU. This is a matter of statutory interpretation. There seems to have been a 21-year period when it was interpreted another way.

Mr. JONATHAN COHEN. I think it was—I suspect, and I am not sure, but I suspect it was an oversight, and nobody had asked for, perhaps no one had asked the SBA for an interpretation. What happens with a lot of these, when we get the grants, we are asked to check a box. And a lot of entrepreneurs perhaps check the box, and didn't consult with counsel, and perhaps over the years, there were recipients of SBIR that were, in fact, ineligible. That does not, in my view, mean that that is the way it should be in perpetuity. I think the program has grown, and also, as the amount of venture capital has gone down, that perhaps demands on the program have gone up, and this has gone to the forefront, but I suspect that the term "individual" was a deliberate one, and in hindsight, it is an appropriate one. And a company that is individually owned is different than——

Mr. WU. My light has turned yellow here, so—and you will forgive me——

Mr. SCHWARZ. Mr. Wu, the Chair will be happy to grant you the time you need to continue your questioning.

Mr. WU. Well, thank you very much, and Dr. Abramson, when you said let us stick with the original rules, I mean, the original rules seem to be the way that they were interpreted from '82 to '93. And then, there is this change from '93, I am sorry, 2003 to now, and so, if you are advocating for a return to the status quo ante, it seems like, you know, the 21 year interpretation seems to be a little bit more stable one.

Dr. ABRAMSON. I would say that there was no prior interpretation. I think no one interpreted it one way or the other. It was left open, with the assumption that somehow, institutional ownership was excluded. It would be obvious if Congress created a carve-out for small business, and the small business could be owned, by a majority, by an institution, a non-natural entity, it would, in effect, eviscerate the purpose of creating the carve-out.

I would agree with Jonathan that what probably happened in nobody raised the question, asked the question, because up until, certainly from the '80s through the mid-90s, the role of venture capital, particularly in bio, was relatively small. I mean, Amgen and Genetech go back into the '80s, but we are talking about venture capital as a growth industry taking place in the '90s. It appears that somewhere along the line, someone said wait a minute, what is the interpretation we should be using? And that is where the definitive statement was made, well, this language would exclude the VCs. So, in our view, we are arguing that the prior interpretation was a non-interpretation. When it was finally asked, the interpretation was natural person means natural person.

Mr. WU. Dr. Eskesen, it seems only fair to give you a chance to comment.

Dr. NACY. I just—a small business is a small business. I am 17 person business at the end of my venture financing, hopefully at the end of this summer, I will be a 17 person business. I will be a small business. The venture capital money will not provide for a research program in my organization. I am still a small business, no matter what the venture capitalists have invested in me, it is a small business. I am not sure I understand what the distinction is between venture capital-backed companies and non-venture capital-backed companies who hope to be venture capital-backed.

Mr. JONATHAN COHEN. I just want to point out that there seems to be an awful lot of energy and potentially acrimony poured into this debate, and I would encourage you all to think about this as the pool is big enough for everybody. I mean, in 2003, we are looking at, my understanding is, what, $1.7 billion, and in the current fiscal year, we are looking at $2 billion or more, and this is up from a $44 million, some odd dollar figure in 1982. We are looking at a 1.2 percent split in 1982, and a 2.5 percent split today. I mean, you know, when I was dealing with the technology segment of our economy, you know, one of the fundamentally different ways of looking at the world in that technology, in that business segment, was that you know, if you grow the pie, there is enough room for everybody, and I guess I find an absence of that approach, at least today, and I hope that it will be restored at some point, and Mr. Chairman, I thank you for your indulgence, and the little bit of extra time. Appreciate it.

Mr. SCHWARZ. Very welcome. The gentleman from Washington, Mr. Baird.

Mr. BAIRD. I thank the Chairman. I thank the witnesses, and my distinguished Ranking Member, as well, for his astute comments, insightful comments.

This issue was brought to my attention by a company, a laser company in my district, BioLasers, world leaders. And the incredible capital it takes to do some of these things, be it biotech, be it

lasers, be it any of the high technology, one of the things that has struck me is the enormous size of fiscal infrastructure, physical infrastructure we have to have to make very small things, and especially in high tech.

I am interested in your experience, in terms of the funding you need, and it is relevant, because to say that we want innovation in high technology areas, but we are going to exclude venture capital, it seems to me that you significantly exclude some of the high capital intensive activities that we—that may generate the very kind of innovations and create the jobs we hope SBIR will do. I open that up to the panelists.

Ms. ESKESEN. If I could respond, sir, to go back to the question that Mr. Wu posited, the——

Mr. BAIRD. Now, wait a second. You are going to have to answer my question on my time. I mean——

Ms. ESKESEN. Well, I will, because I need to answer his in order to answer—I need to answer his to——

Mr. BAIRD. I am just funning with you.

Ms. ESKESEN.—answer yours. The precipitating action that caused this interpretation to occur involved a company in Utah who had a $16 million investment. They were "turned in" by a competitor, who argued that they were not any longer a small firm because they were majority owned by a venture capital community, or by a venture capital fund. In fact, in this particular case, the venture capital investment was 90 percent of the company was owned for that $16 million. And the point is a very basic one, and it speaks directly to the issue that you are raising, sir.

We are not talking at all about excluding venture capital-funded firms. What we are talking about fundamentally is the value that that VC is placing on the company when they make that initial investment. In this particular instance, the person who negotiated the deal was actually very proud of himself.

Mr. BAIRD. I am going to cut you off there. I think you raised a good point. My question, more broadly speaking, is a general question about the amount of capital that is involved, either for a Stage III type clinical trial, or other kinds of innovation, so that we get a general sense, because let us say we are talking 50 percent of $5 million. $5 million in this town isn't all that much, but if you are a business, it is a lot of money. But it is a hell of a lot of money when we are talking 50 percent of $60 million or $100 million, because some of the factories and plants you need to do some of this research are expensive, for a Stage III clinical trial.

I am going to ask Dr. Cohen or Dr. Nacy to talk a little bit about the kind of capital intensive activities you are involved in.

Dr. RON COHEN. Thanks very much. It currently is estimated that the cost for the average drug to develop from the laboratory bench to the patient's bedside is on average, about $1 billion from beginning to end. Now, I grant you that that takes all comers, including the big pharmaceutical industries, and it includes a lot of overhead costs and so on. But even under the best of circumstances, within the biotech industry itself, it is a minimum of $300 million, $250 to $300 million, and often $400 or $500 million to get to the point where you have a success, if in fact, you ever have a success.

Mr. BAIRD. So in effect, if we—to the extent that we reduce venture caps percentage, and mind you, in the bill we are talking about, no single venture cap firm could own more than 50 percent. A consortium could, or an amalgam could, maybe better put. But the point is, if you exclude venture cap, where do you get the rest of the money to do this kind of operation? Are you not, de facto, excluding certain areas of technology or certain kinds of research if you say that venture cap can't be more than 50 percent, because where else do you get that kind of money?

Dr. NACY. That is—may I speak to that?

Mr. BAIRD. Please.

Dr. NACY. I just want to ask anybody who is sitting on the committee whether they would want to give Carol Nacy and Sequella $30 million and not have any control over the way I use my money. In the SBIR program, we are controlled over how we use our money. We apply—we have to meet certain milestones, and it has to be on the product that we applied for. Venture capital has the same requirements, and they want to make sure if they put $30 million into my company that I am using that $30 million the way they like it, and it is in clinical trials, and in late stage product research. It is not in the early, innovative stages of a high risk venture that one in 5,000 might end up at registration.

So, when we talk about 51 percent control, 51 percent control is simply to make sure that their money is used by my company in an appropriate way. They don't have control of the company, necessarily. They have control of the stock, and they can vote at the stockholder's meeting. But the way we structure our boards, we have control of our companies. They have a lot of say in the company, because they have one or two or three board members of a total, but they don't have the majority board members.

Mr. BAIRD. That is a helpful way——

Dr. NACY. So they have control of the company, and—but they want to control the money, so their shareholder ownership is in a majority ownership, so that if we should make a very bad decision on how to use their money, they can reverse that at the shareholder meeting.

Mr. BAIRD. Dr.—Mr. Cohen or Dr. Abramson, what is wrong with my reasoning?

Dr. ABRAMSON. The issue is not whether there is valuable research being done by the companies that are here, or other companies in biotech, or that they shouldn't be funded. Certainly, there is a phenomenal amount of ongoing research that has potentially incredible benefits coming out of the pipeline.

The issue here is where the starting point is for innovation, and how do we support that. In the technology incubator that I am located in, and——

Mr. BAIRD. Let me—but my question is, let us suppose you are in an industry where—but the nature of the industry is hugely capital-intensive, and so you cannot do the innovation in that industry without the capital for the machinery. I mean, just get a chip——

Dr. ABRAMSON. It is not a question of doing innovation. It is a question of commercializing innovation. The innovation of discovering a drug takes place in the early stage. The Phase II, Phase III clinical trials are devoted to validating and ensuring that the

drug is safe and effective, and can be used by the public. The innovation has already taken place in the discovery and research stage.

So, the purpose of SBIR is to stimulate the very early stage, when the idea is generated in the scientist's mind, and needs to get to the bench to be proven. Now, in the incubator we are located in, there are about 20 bio companies. Only about a third of them are able to successfully compete for SBIR money. That means two thirds are not. Now, either the two thirds of those scientists are just cosmically stupid, and investing their time on things that are bad ideas, or the pool of money that Mr. Wu talked about isn't large enough to sustain that level of innovation. So, people working on eye research or cancer research or other areas that may be innovative, but can't be funded today, with the existing pool, would have a greater difficulty in getting funded. Now, once an SBIR takes place, and I have proven my idea, and I have proven the basic science, and I go to Phase II, and I get some ability to take it to the next level, at that point, it is incumbent on me to go out to the community, the funding community, which includes VCs, other corporations, whatever, to raise the funds necessary to take it to market.

Human Genome Sciences, the very famous company in our area, is now taking the drugs it is developing and teaming with large pharma companies to take it to market. Human Genome Sciences raised $2 billion. I would love to have $2 billion to work with. But the fact is, you are absolutely right——

Mr. BAIRD. But they are now, presumably if they raised it through venture cap, they are ineligible for SBIR.

Dr. ABRAMSON. Well, they raised it publicly, in a public market. They have gotten products to a point where they can start testing in Phase III, but in order to lay off their risk, because these are substantial risks, no question about it, they are teaming with larger, even larger companies——

Mr. BAIRD. Why is a public offering more sacrosanct than venture cap?

Dr. ABRAMSON. I am not sure it is.

Dr. NACY. It is a series staged way of funding your company.

Mr. BAIRD. Yeah. That is what I understand. My question is if our goal—look, my goal is to innovate, create jobs, and inspire competition. And that is my focus, and to the extent that we nitpick on some of the other elements, I think we have lost focus. Dr.—or Mr. Cohen, I wanted to ask you.

Mr. JONATHAN COHEN. Yeah, and I share those goals. But I do not believe the pool is currently big enough. The pay lines have gone up, the bar has been raised. The last few years, and last year, particularly, it has been harder to get SBIR funding, and Frederic and I are in the same facility. I have seen over the last few years a lot of companies, a lot of good companies, go under. And that pool is going to get an awful lot smaller if H.R. 2943 is passed as written, because by my back of the envelope calculations, about 80 to 90 percent of the biotech industry would be eligible for this slender 2.5 percent of the pie.

It will hurt innovation, in my view.

Mr. BAIRD. Thank you. I had further questions, but I will yield back.

Mr. SCHWARZ. Thank you, Mr. Baird. Mr. Miller, the gentleman from North Carolina.

Mr. MILLER. Thank you. I am reminded of the old line about university faculty politics, that the reason faculty politics are so bitter is that the stakes are so small. It does seem that the reason that this debate is so vigorous, I won't say bitter, is because we are doing so little to help companies through the valley of death, to help that very expensive, high risk effort to get ideas from research all the way into the marketplace.

Mr. Cohen, Jonathan Cohen, made that point in his testimony, and pointed to a couple of models, ATPR being one of them, excuse me, ATP being one of them, which is a source of patient capital. What do you all think, do you all think we are doing enough, and what else can we do to try to get research-based products into the marketplace through this very tortured process, tortured and expensive?

Dr. ABRAMSON. If I may comment, I think two—several things. One, for example, the ATP program. Congress has repeatedly unfunded—I think it is funded this year only for ongoing programs. There is no new money. So, Congress can stimulate this innovation in these high risk areas by funding things like ATP. That would be one thing.

Another is, and Dr. Nacy is correct, in part, that the culture of NIH is very academic oriented, and not oriented towards transferring the benefits of research into the mainstream, and delivering it. And so, to the extent Congress can help shape the NIH culture to allow companies like Sequella to compete for the 97.5 percent of the funds with Yale and Harvard and Hopkins, so that they can take these products into the marketplace, that would be invaluable.

Mr. MILLER. I am sorry. Say that again.

Dr. ABRAMSON. The companies represented here, for example, should be able to compete at NIH for funding to get their products through Phase I, Phase II, and Phase III clinical trials, which are very expensive. Jonathan mentioned a program, of a shared program to lower the risk, lower the costs. More work needs to be done to get the funds necessary. It is really unfair for a company the size of Dr. Nacy's to have to try to figure out how to raise $100 million to deliver something with the value of the solution she is working on.

This is precisely the role of where the Federal Government and its resources can make selective choices to help us all.

Dr. RON COHEN. I am going to differ, and say that it is absolutely right and proper that Dr. Nacy's company or mine, or any of ours, be compelled to compete for the funding we get, based on the merits of what we have to offer to society. That is the system I grew up with, and I love that system. And I am willing to throw in my lot with that system.

As to your question about are we doing enough, I can't answer that, because really, at the bottom, it seems to me it is a question of what is society interested in investing for its future well-being. So, how much does our society want to invest, and I draw a distinction between invest and handouts or charity. Because in a real sense, I think the SBIR has been one of the most successful of our government's programs precisely because it is an investment based

on competitive grant reviews by some of the leading scientific minds in the world of the various grants that come in. And those grants that get funded have passed through that gauntlet successfully, and have been deemed meritorious, and one sees the results.

Ms. Eskesen quoted some figures earlier, where companies that have gotten SBIR grants have gotten venture capital investment at 10 to one ratio. Well, that alone tells you that this has been successful, because of all the jobs that are created, the technology that has been advanced, and generally, the contribution to the commonwealth. So, I don't know if we are doing enough or not. I don't know what that magic number is, but I will tell you that I am well satisfied with the way the SBIR program is administered.

Could we use more funding? Sure. If you ask me as an entrepreneur, I will always say sure, we would love to have a bigger pool, and to promote more innovation. But at some point, you do wind up with a lowering of the overall quality, right, so the more competitive the grant process, the higher the quality of what you get out.

Mr. MILLER. There are several kind of fingers raised to speak, but Dr. Cohen, I don't think anyone is suggesting, I am certainly not suggesting, that we set aside a substantial amount of money, simply ring a dinner bell, and say who wants some money, we got some.

Dr. NACY. But if you did that, we would be there.

Mr. MILLER. Everyone here would be—everyone in the room would be, yes. And everyone in America. Yes.

Ms. ESKESEN. In my written testimony, I made the point that there is a profile that a company has to present in order to be of interest to a venture capitalist, and that profile is a large market potential, and the significant likelihood within a relatively short time framework of a liquidity event, an IPO or an M&A. I think you have to recognize there is a big percentage of SBIR involved companies who will never be eligible for venture capital, because they don't fit that profile.

And a major concern to me, that is really rolled into this VC issue, is that we have a serious deficit of the availability of transitional funding for the development of technology. We have very effectively, through the extreme competitiveness of SBIR, created the funding for the research and for the development. We have not created that second D, which is the demonstration of the technology, which is often necessary for it subsequently, then, to make it to commercial condition.

For those companies that have VC eligibility, they are often able to use part of that money to transition. But even if we resolve this divisive issue, we are still left with the very basic problem of where does the capital come from that will enable the companies who are not VC eligible, and it is a lot of firms. Our estimates are that we are looking at—we have 47,000 issued patents in the SBIR community. If you look at that that have some potential market, could be being used, our estimates are that it is worth somewhere $50 and $60 billion, but the vast majority of it at this point is sitting on the shelves, because the resources that are required to transition that technology are not there. The problem is far more fundamental, it seems to me, than just the availability of venture capital.

Mr. MILLER. If the Chair is being reasonably forgiving——

Mr. SCHWARZ. The Chair is being more than reasonably forgiving, so please continue, Mr. Miller.

Mr. MILLER. Mr. Cohen, I think you had your——

Mr. JONATHAN COHEN. Thank you, and Representative Miller, I think you have really put your finger on the core issue here. We in the biotech sphere are clearly not doing enough.

We are not doing enough, because we are not making sufficient progress in the war on cancer. We are not developing countermeasures to bioterrorism fast enough, and I believe if there is one message that I am hearing from this testimony today, and from this panel, is that there is a need for something new.

We need a new program, particularly at the NIH, although it could cross into other agencies, such as NIST, to fund high risk, high impact technology development, not basic research, but technology development, that companies of all shapes and sizes, and universities, and federal agencies, for that matter, can compete for, that can help us move research to patients, and put products into the strategic national stockpile.

I have been giving this quite a bit of thought, and I would be happy to reconvene with you or your staff, but I do think ATP is a very good starting point. And I regret that the program is not entirely popular with all of the Members of Congress. I think that is regrettable, but what is important, I think, about that program, and where it differs from SBIR is it contemplates companies of different sizes, and it has different levels of matching funds. So, it may very well be that a large company or a medium sized company should get federal support, but we might ask, in that case, for example, some level of match from their investors. That—this goes, perhaps, beyond the scope of the hearing today, but I would strongly encourage this committee and this Congress to continue to look at that issue, because from my perspective, the stakes couldn't be higher.

Mr. MILLER. Go ahead, sir.

Dr. RON COHEN. You know, this is, perhaps a happy milestone, because I find that Mr. Cohen and I are in complete agreement on this point.

I would like to just amend my earlier response, and say that while I cannot comment, myself, on what is the appropriate level of investment, certainly some sort of panel or study might be convened to look at that question, but I will say that in fact, currently 97.5 percent of the NIH budget is allocated for what is called hypothesis-driven research, very important, basic, discovery research. 2.5 percent is allocated for applied research or practical drug development, or other technology development from that research.

It is an interesting question as to whether that is the right ratio there, and it is an interesting question that Mr. Cohen raises as to whether there is a series of funding vehicles that one could create to invest at different stages of development. So SBIR for proof-of-principle, let us say an ATP-like program, which we did get one ATP grant, so I am well familiar with it, to get it the next step of the way.

Mr. MILLER. Chairman, just one more.

Mr. SCHWARZ. Okay.

Mr. MILLER. Given the chair's extreme indulgence. Early on, I am in my second term now, but early on, I met with folks from Duke University, which I think is some measure of what I am willing to do to serve in Congress, and they said that they were—the sacrifices that I am willing to make. They said that Bayh-Dole worked great. Bayh-Dole worked great. They had lots of patent lawyers on staff. They immediately got patent protection for any ideas coming out of their research. They had the pipeline established. They could get products to what you call the liquidity event. And it was working great, and the profits that came from those products that had made their way to the marketplace was going back to fund that whole stream, that whole pipeline.

I then talked to folks from smaller universities, less well endowed universities. North Carolina A&T, an historically black college or university in Greensboro, but also, a research university. University of North Carolina, Greensboro, much less well endowed than Duke University, but also, a research university. They said yeah, Bayh-Dole is working great for Duke. It is not working for us at all. We can't get products from research to a liquidity event. We can't—we don't have the funds to establish the pipeline.

Is that your own experience as well, particularly for smaller—Dr. Abramson, I think you distinguished Harvard from—or some other similar university from other universities doing research. Any thoughts on that topic, Dr. Nacy?

Dr. NACY. I think it is very difficult to educate scientists as to what is a product and what isn't a product, and I am 30 years into my scientific career. I am an actual scientist who went into business 12 years ago. It is hard. Smaller universities do have a difficult time getting reasonable patents written, and supporting those patents until somebody comes along and says yes, we can commercialize this. And even if they say yes, it is usually a startup company like mine, in which I like to have all my technologies come in with no costs to me, because I have no money to pay for them. So, I can put everything that I have in the way of money into their development.

Universities need some upfront payments, and this is—it is a very cumbersome system that we have in the United States right now. I, for 18 years, was at Walter Reed Army Institute of Research. I hated the Bayh-Dole Act when I was there. It created problems with collaborations with the NIH and with other people.

I am now on the other side of the story. I love it in one sense, and I am frustrated by it in another, because I think young universities or small universities, whether they are research or not, are never going to have the right kind of resources to provide the right kind of advice to their scientists and their patent attorneys to actually get commercialized product.

By the way, may I just mention one more thing. Not all science is good, and not all scientists are good.

Mr. MILLER. All right.

Dr. NACY. And so, not all science should be funded, and that is why the competitive process is really so important.

Mr. MILLER. And we are getting back to the dinner bell issue again. I don't think anyone wants to suggest that we have someone ring a dinner bell and say, who wants money, we got some. That

they are—of course, there should be standards, and they should be rigorous. But there were——

Mr. SCHWARZ. Go ahead.

Mr. MILLER. There were other hands. I just wanted to see if anybody else wanted to address that.

Dr. RON COHEN. Yeah, just to amplify, indeed, smaller universities have, almost by definition, less research going on, are less likely to come up with the sort of research that would come out of a Harvard or a Stanford or a Duke, which is not to say that they won't come up with meritorious research. It is a matter of just size and volume. But it is the case that when their scientists do come up with something meritorious, their infrastructure is not equipped, as Duke or Harvard would be, to take advantage of it. And what does that mean? That means having the technology transfer infrastructure with appropriate business and legal people, first of all, to patent the discoveries in a timely way. So, you need to have that knowledge and those people, and the money to do it, and then, to have the connections with the venture capital and other funding communities and entrepreneurs to be able to go and license that technology to them, so that they can go and develop it. That is where those universities have difficulty, because they just don't have the funds and the infrastructure to take full advantage of the discoveries that come out of their labs, even when they do come out of their labs.

Dr. ABRAMSON. Congressman, if I may add, I speak to the economic development people around the country on a regular basis, and there is an interesting thing happening right now, particularly in the bio field. Regions of the country are becoming aware of the need to build their own ability to commercialize biotechnology. At the BIO meeting in Philadelphia, I actually talked with people from North Carolina who talked about Research Triangle, but then talked about areas outside of the Research Triangle that are working to develop their own infrastructure to attract technology, but also, to commercialize what is being done at other universities.

So, I would have to say that what—the points here are correct, but what is happening is that around the country, people are aware, more and more, that they have to begin developing this. And one of the things they do, interestingly enough, is they put on small, local conferences for these local companies from, say, Carolina A&T, to get SBIR funding. And they do it, because these companies that they are talking to are early stage startups without many resources, coming out of a small university, not a whole lot of local capital, maybe some angel money. And they are talking to the—helping them to compete with the larger, more established players. So, in fact, this is happening, and I would go back to my original point.

Having the rule to allow the larger companies come in would make it more difficult for these smaller areas to actually develop their infrastructure at all.

Mr. MILLER. Mr. Chair, I am going to ask that you proceed——

Mr. SCHWARZ.—Mr. Wu, who I believe is going to yield to the gentleman from Washington, Mr. Baird.

Mr. WU. Yes. It is my intention to yield the majority of my time to Mr. Baird, but first, I just wanted to—we have a key triangula-

tion on at least one issue, that Dr. Cohen, Mr. Cohen, and I all believe in the concept of leverage, and that the more leverage we get, the better off we are. I am glad we are making steps forward in this. But it is good that we have achieved this. I am still somewhat concerned about what statutory basis the Small Business Administration had in its interpretation, and this is something that I intend to take up with counsel from the Small Business Administration, and see what kind of statutory basis they did have, and what the language, precise language was, that—which was used in 1982. I have been perusing the statute, and thus far, have found little statutory basis for their interpretation, but I remain educable.

And forgive me for being hung up on such small things, but something else I heard during the course of testimony is the repeated referral to award sums in the range of $1.5 to $2 million, and it is my read of the statute that it says $100,000 in Phase I, and $750,000 in Phase II. Do you all know how NIH is achieving a larger number, when the statute, at least on its face, seems to state something different?

Dr. NACY. I don't know how they are doing it, but I am very grateful that they are, because you can get almost nothing done for $100,000 in biotech——

Mr. WU. I understand. We are talking about small sums of money——

Dr. NACY. Don't change that part.

Mr. JONATHAN COHEN. The $100,000 is for—up for Phase I, and that does seem to obtain, in my company's experience. Phase II, there are some grants that are in the $700,000, $750,000 range, but clearly, there are some that are between $1 and $2 million. I don't know what they do that with the statute. I am not an expert——

Mr. WU. Well, I am all in favor in flexibility in interpretation, and achieving what innovation needs, but we need some level of statutory compliance, and sometimes returning to the statute and revising it may be necessary. I am just concerned that we live in an era when our Attorney General, when he was counsel to the President, apparently wrote a memo that the President doesn't need to follow the statutes of the United States, but I am getting further afield, and I am going to yield the balance of my time to Mr. Baird.

Mr. SCHWARZ. Mr. Baird.

Mr. BAIRD. Thank you. I thank the Chair.

Mr. SCHWARZ. I am a little disappointed that I am not hearing more about Michigan and OU and UW and University of North Carolina here, but I note that Dr. Abramson is a University of Michigan graduate, as am I. So, we are not too bad out there, are we?

Dr. ABRAMSON. No.

Mr. SCHWARZ. In fact, quite good.

Dr. ABRAMSON. Quite good.

Mr. SCHWARZ. Mr. Baird.

Mr. BAIRD. I thank the Chair. If I were to look at this issue more broadly, my concerns are sort of in three parts. One is the issue before us today, and I think it is appropriate that we focus on that. That has to do, within my judgment, the need to expand, or actu-

ally not expand, maybe return to the eligibility of VC based firms to compete with SBIR. The other two sides are the needs that you have just articulated. We have, in fact, with legislative staff here, have been working for the better part of a year now on essentially establishing a Phase III element of the SBIR program that would address some of these very concerns. Perhaps additional funding or additional percentage, et cetera, but I think it is a point well taken. So, on the one hand, I think we need to, in my judgment, assure that venture cap firms have access to this.

Second, I think we need to expand and create, possibly, this Phase III element to actually get products to market. The other side to the coin, and I would like some commentary on that, there are also concerns, and I know Mr. Gutknecht and I have discussed this. I can't speak for him, but I know we have discussed the issue, and you hear it out there, that there are companies that exist, basically on repetitive SBIR granting, and that the actuality that they ever bring something of use to our society to the fore, other than maybe employing a few people for the short-term until their next SBIR grant is funded, that is out there, and I think it is a valid concern, and I wonder if people could comment on that. Given that we have a finite pool, making sure that people who are going to compete for that pool actually do something worthwhile for society.

Dr. Nacy.

Dr. NACY. In the NIH program, which is where the biotech companies generally look for their SBIR funds, if you have had a number of Phase I and Phase II programs, you are not eligible for any additional SBIR grants, unless you have commercialized at least one product in the process.

And now, I am not sure that they tell you how many grants you can get before you commercialize something, but they are now asking in Phase II grants for a commercialization scheme and a funding scheme that is associated with commercialization, to ensure that we are compliant with that part of the regulation.

Mr. BAIRD. And part of the reason I—earlier, it was mentioned that it is getting harder to get SBIR funding. My take on that is probably that is good, given these concerns I have heard.

Dr. ABRAMSON. And there are really two other issues here, which really are related to the issue before the committee. Scientists, by their nature, aren't trained to be businesspeople, and programs like MIT and Hopkins and so on, are working to transition the scientist to a more businesslike mentality. So, many of the people who receive SBIR awards just don't have the acumen and the knowledgebase to actually take it through the steps of commercialization. So——

Mr. BAIRD. I think that is a good point, but I certainly hear of people who have the acumen and knowledge to get SBIR funds, but don't actually have any intent but to chase SBIR funds repeatedly.

Dr. ABRAMSON. Well, that is the other side—the other flipside. There is also, obviously, there are what you might call boutique kind of firms, and they live off the SBIR funding. But there is another element, which is also on the NIH side. The bulk of the NIH review still takes place with scientists who are allied with academics or NIH. They themselves have very little experience in com-

mercialization, so there is a skewness in terms of what really is commercializable or not.

Mr. BAIRD. A good point.

Dr. ABRAMSON. So, we end up with kind of a trap here.

Mr. BAIRD. Other comments on that?

Mr. JONATHAN COHEN. I would just like to reiterate Frederic's point. I think, as part of looking at this whole process holistically, we really do need to look at the NIH process, the review process. And I do think that may, in part, contribute to what some perceive as a poor commercialization rate on the part of companies.

We also have some funding from DOD, although it is not SBIR funding. It is biodefense funding, and it is striking to me the difference between the DOD and NIH. The DOD process was a very rigorous, probably a more competitive process, because we were competing against the Lockheed-Martins of the world, and academia, and so forth. So, it was a rigorous process, but it was structured in a way, and the way they are managing that, we have monthly reports, we have quarterly meetings. They want a deliverable. They are managing taxpayers' money toward a deliverable, and I think what the NIH did with the program, at least from my observation, is they basically said—they took the same machinery that they used to review academic grants—which may be appropriate, I am not qualified to say—and applied it to businesses. And it is a square peg in a round hole.

So, I think we need to take a fresh look at that review process to see if, in fact, it can be improved.

Mr. BAIRD. I have heard very similar things from folks, that there is a much different level of oversight or management, depending on which entity is providing the SBIR funding. Other final comments before I yield back?

Dr. RON COHEN. I would—I have heard of companies of the sort you describe, sort of chasing SBIR grants, but I don't have the facts and figures. It would be interesting to see if it is anything more than a very, very tiny minority of recipients, which is what I suspect it would be, and it is an issue, and should be addressed, probably, separately. But overall, it occurs to me, listening here, that one of the things that was very impressive to me and my colleagues in the ATP grant process, and I realize it has been in and out of favor, but this is an element that was really quite compelling, was that in a 40-page grant, about 20 pages were the science and the technology, and how we were going to develop, and the other 20 pages were a business plan. And when the grants were reviewed, these are, you know, $2 million or up, they had people with industry experience actually passing judgment on the business plan side as much as the technology people were passing judgment on the technology side. So, when you got the grant, what that said was, we deem this to be not only scientifically exciting and technologically exciting, but also, that your team and your plan are sufficiently realistic that you might actually get this to market and prosper. Something that may be worth considering.

Mr. BAIRD. I know others want to comment, but in deference to my chair, I will yield back, unless he wants to allow that.

Mr. SCHWARZ. Why don't you, Mr. Baird, go ahead and finish, and we will bring it to a close when you finish your questioning.

Dr. NACY. I just want to say, just from the NIH perspective, that the list of reviewers from my previous grants in the last two years have changed dramatically. We now have a lot of people from industry on those committees reviewing the grants. So, I think the NIH recognized that they were getting a lot of academic——

Mr. BAIRD. So, there has been evolution in that.

Dr. NACY. There is—it is an evolving process, and now, I would say about 80 percent of the people are from industry, and it is improving the comments that we get back as part of the review.

Mr. BAIRD. Ms. Eskesen.

Ms. ESKESEN. I have been involved in SBIR for a long time, and this issue of the proposal mills is a myth and a fiction that has absolutely no basis in fact, and really, it realistically should be allowed to die.

Mr. BAIRD. Well, I would tell you that people—I would dispute that vigorously. I am familiar with people who have left SBIR mills to found valid, successful companies, and I have 100 percent confidence in the veracity of their personal statements and personal experience. So, it may not be as rampant as some may assert, but I have personal knowledge of people who have worked in those kind of settings that have received repeated SBIR funds, and have never produced anything of substance, of use to the public. So, with that, I will yield back the balance of my time.

Mr. SCHWARZ. Thank you very much, Mr. Baird, and thank you, I want to thank the panel for being here. I do not have any questions, but I am very interested in, for instance, what you might be doing, Ms. Eskesen, with Microbacteria tuberculosis, simply because I lived for five years, I am sorry. You are not doing anything——

Ms. ESKESEN. I am——

Mr. SCHWARZ. Yeah. Yeah—not to your knowledge. But I am very interested in that, having lived in an endemic tuberculosis area for five years in Southeast Asia, and with a tubercular positive rate of probably about 70 percent, where I was, in any event. And also, very interested in what Dr. Cohen is doing with spinal cord and—I will ask you a couple of questions about embryonic stem cells, perhaps, when we are done here today, having been a very strong supporter of the embryonic stem cell bill, which just passed the House and is now in the Senate, and being a physician of now 41 years duration myself.

So I thank all of you for being here, and before we bring the hearing to a close, I want to thank our panelists for testifying before the Subcommittee. It has been a great hearing. The witnesses have given the Committee a great deal to consider.

If there is no objection, the record will remain open for additional statements from Members, and for answers to any follow-up questions the Subcommittee may ask the panelists. Without objection, so ordered.

The hearing is now adjourned.

[Whereupon, at 4:40 p.m., the Subcommittee was adjourned.]

Appendix 1:

Answers to Post-Hearing Questions

Answers to Post-Hearing Questions

Submitted to Ann Eskesen, President, Innovation Development Institute, Swampscott, Massachusetts

These questions were submitted to the witness, but were not responded to by the time of publication.

Q1. If a firm is more than 51 percent owned by one or more venture or institutional investors, would you consider your business to be controlled by these investors?

Q2. Aside from the issue today, what other recommendations would you make on how the SBIR program could be improved? For example are the Phase I and Phase II award levels sufficient? Also what are your thoughts on Phase III funding?

Q3. What is your assessment of how NIH is managing its SBIR program? What could NIH do better?

Q4. You have heard the arguments made by Dr. Nacy and Dr. Cohen on why their company should be able to compete for SBIR awards. Why do you think they should not be able to compete for SBIR awards?

Q5. What is your opinion of the Advanced Technology Program (ATP)?

ANSWERS TO POST-HEARING QUESTIONS

Submitted to Ron Cohen, President and CEO, Acorda Therapeutics, Inc.

These questions were submitted to the witness, but were not responded to by the time of publication.

Q1. As a small business with less than 500 employees, or in your case less than 100 employees, if you raise a round of venture financing would you say that all of your fund-raising needs have been satisfied? Are you able to pursue all of the projects and business leads you would like to pursue with this venture financing?

Q2. Given the 10 to 15 years of work and hundreds of millions of dollars it takes to complete testing and gain approval of a biotechnology therapy, venture capital investment is often a necessity for many biotechnology companies. If biotechnology companies receive venture capital for their research and development, why is it necessary for these companies to also receive SBIR grants?

Q3. If a firm is more than 51 percent owned by one or more venture or institutional investors, would you consider your business to be controlled by these investors?

Q4. The SBA recently issued a Final Rule (69 Fed. Reg. 70180) that amended SBIR eligibility requirements to allow grant awardees to be 51 percent owned and controlled by another business, as long as the other business is itself at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. Does this Final Rule solve the eligibility concerns by VCC-backed biotechnology companies?

Q5. The Small Business Administration (SBA) has been holding a series of Public Hearings across the country to address two topics: (1) the restructuring of small business size standards; and (2) the possible participation of small businesses majority-owned by venture capital companies in the SBIR program. These hearings follow the SBA's announcement that they are considering whether an exclusion from affiliation rules for venture capital companies (VCCs) should be provided in size determinations for eligibility in the SBIR program. Would this exclusion solve the eligibility concerns by VCC-backed biotechnology companies?

Q6. Aside from the issue today, what other recommendations would you make on how the SBIR program could be improved? For example are the Phase I and Phase II award levels sufficient? Also what are your thoughts on Phase III funding?

Q7. What is your assessment of how NIH is managing its SBIR program? What could NIH do better?

Q8. What is your response to those who say that changing the current venture capital participation rules would fundamentally change the structure of the SBIR program?

Q9. What is your opinion of the Advanced Technology Program (ATP)?

ANSWERS TO POST-HEARING QUESTIONS

Responses by Jonathan Cohen, President and CEO, 20/20 Gene Systems, Inc.

Q1. If a firm is more that 51 percent owned by one or more venture or institutional investors, would you consider your business to be controlled by these investors?

A1. Yes. The owners of a company have ultimate control of that company even if they choose to delegate some or all of that control to a hired CEO and management team. Based on my experience VCs and other institutional shareholders usually delegate day-to-day operations of the firm to the management team. However, if the company fails to meet the expectations of the owners, or the management team does not have the full confidence of the owners, either the CEO is replaced or the owners will begin to micro-manage some or all of the company operations.

In business controlling the majority of stock is equivalent to controlling the operations of the company. I base this opinion on my experience as in-house counsel for two biotechnology companies that were owned and controlled by institutional investors. This is so even in the case of syndicate investing by multiple VCs wherein no one VC owns a majority of stock but they do so collectively. In such cases one or more "lead" investors act on behalf of the syndicate.

Q2. Aside from the issue today, what other recommendations would you make on how the SBIR program can be improved? For example are the Phase I and Phase II award levels sufficient? Also what are your thoughts on Phase III funding?

What is your assessment of how the NIH is managing its SBIR program? What could NIH do better?

A2. The NIH SBIR program is a critically important program but one in significant need of improvement. Weaknesses of the program may be summarized as follows:

- Favors low-risk, incremental research rather than highly innovative technology development that is a core competency of small tech companies.
- Relies almost entirely on university professors for review and scoring of grant applications. Typically these reviewers lack product or technology development expertise.
- Gives too much weight to "grantsmanship" and extensive preliminary data. Gives too little weight to the innovation of the technology or the medical significance thereof, or the track record of the management team in bringing products to market.
- The NIH mistakenly treats the 2.5 percent SBIR set-aside as a ceiling rather than a floor. Even institutes that rely heavily on small companies to advance their mission (e.g., the new Bioengineering Institute which receives 30 percent of its grant applications from small businesses) limit their SBIR pool to 2.5 percent.
- STTR set aside of 0.3 percent is much too small due powerful potential synergies between small companies and nonprofit medical centers with access to patients and patient samples.
- Since NIH staff do not normally participate in the application review there is no mechanism to obtain reliable feedback on the likelihood of success before significant resources are invested in the application process.
- Phase I funding ($100,000) is too small for most biotech projects.
- Gap between Phase I and II can last years.

To remedy these shortcomings and improve the NIH SBIR program I would offer the following recommendations:

1. **Design and implement an NIH SBIR application and review system geared specifically for small businesses rather than universities. Retain program managers with product/technology development expertise and empower them to help guide funding determinations and manage ongoing projects.**

The NIH SBIR program utilizes the same review committees that are used for evaluating academic research programs. These reviewers tend to place undue weight on good grant writing and preliminary data rather than the significance of the technology and the applicant's ability to bring needed products to market. The Department of Defense SBIR program and the ATP program have review processes more

appropriately geared to commercialization that should become models for the NIH SBIR program.

One odd feature of the NIH SBIR program is the "Chinese wall" between grant reviewers and program managers. This system presumably is designed to protect university grant applicants but has no value in the SBIR program. In the Army SBIR program, for example, funding decisions are typically made by Program Managers in consultation with two subject matter experts, one inside the government the other outside. This arrangement permits SBIR applicants to get useful feedback from the funding agency on prospective applications before investing significant recourses in the application process.

2. Increase the NIH set-aside for SBIR and STTR

The SBIR statute requires applicable federal agencies to expend *not less than* 2.5 percent of their R&D budgets with small business concerns. 15 USC 638(f). Unfortunately, this floor has been interpreted by the NIH to be a ceiling. While 2.5 percent may be a correct set aside for many agencies it is too small for the NIH. Most disease treatments today are being advanced by small biotech companies.

The STTR program, which is directed to the transfer of technology from universities and non-profit research institutes to small businesses, is arguably more significant in the health care context than in other areas of technology. Thus the 0.3 percent STTR set aside is woefully inadequate for the NIH since and should be raised to at least 2.0 percent.

3. Expand the size and duration of Phase I awards

Most biotech projects require a longer award period and greater award amount than those commonly allowed under the Phase I SBIR program. Budgets of up to $250,000 costs per year and time periods of up to two years for Phase I should be routinely permitted. To permit these larger amounts to be available to more applicants, companies should be limited to total SBIR support per year (Phase I and Phase II) of $1 million. Companies deserving of federal support beyond this cap should seek it through funding mechanisms outside of the SBIR pool.

4. Implement a Preliminary Application Process to Lower the Cost of Failure

Due to the over emphasis on "grantsmanship" and preliminary data the NIH SBIR application process is very expensive. It can cost a small company nearly $20,000 to prepare and submit a well written Phase I application while facing a success rate of only about 18 percent. This costly process literally drives many small companies out of business and wastes government resources as well.

To remedy this problem the NIH should adopt a preliminary application process along the lines of that employed by the Department of Homeland Security's HSARPA program. There, a five-page white paper is first submitted by applicants and evaluated by the HSAPA staff who provide a written assessment of the likelihood of success if a full application is submitted. This process painlessly rules out all but the most competitive applications and saves significant time and money for both the applicant and the government.

5. Permit Phase I recipients with matching funds to apply early for Phase II

The DOD SBIR program has implemented a Fast Track process for SBIR projects that attract matching funds from an outside investor for the Phase II effort (as well as for the interim effort between Phases I and II). Under this program companies may submit their Fast Track application within 150 days of receiving their Phase I contract and these applications are given expedited review by DOD.

This model should be adopted by NIH as it encourages private investment and helps bridge the gap between Phase I and II which can often last one or more years.

6. Encourage private investments in SBIR recipients through tax credits (in lieu of Phase III funding)

The idea of Phase III funding is problematic because it would siphon away funding available for Phases I and II. Instead I believe Congress should encourage private investment in small business technology developers through a new SBIR investor tax credit. Such a program—modeled after the New Markets Tax Credits Program—would permit taxpayers to receive a credit against federal income taxes for making qualified equity investments in companies that have received a Phase II award. The credit provided to the investor would total 40 percent of the cost of the investment credit from their federal income taxes that would accrue over four years. The maximum total credit available from combined investments in any one company

would be limited to two times the value of the Phase II award. Thus, for example, a recipient of a $500,000 Phase II award could attract an additional $1 million in private capital that would earn those investors $400,000 in tax credits over four years.

This model provides a more cost-effective way to leverage taxpayer dollars than additive grants and has proven successful in those states (Ohio, North Carolina, Maryland) that offer similar investor tax credit programs.

Q3. You have heard the arguments made by Dr. Nacy and Dr. Cohen on why their company should be able to compete for SBIR awards. Why do you think they should not be able to compete for SBIR awards?

A3. More than 20 years ago Congress astutely recognized that small businesses developing innovative products and technologies have unique strengths that can help our economy and society but also important limitations that put them at a disadvantage in competing for federal support. Thus, a small set-aside (now 2.5 percent) for small businesses seeking certain federal R&D funding programs was deemed warranted.

The law that created the SBIR program begins with this declaration of Congress' policy in establishing the program:

> The expense of carrying on research and development programs is beyond the means of many small business concerns, and such concerns are **handicapped** in obtaining the benefits of research and development programs conducted at government expense. These small business concerns are thereby placed at a **competitive disadvantage.** This weakens the competitive free enterprise system and prevents the orderly development of the national economy (emphasis added). [15 USC 638(a)]

Entities owned by large venture capital firms typically have access to substantial financing and other assets and are neither handicapped nor disadvantaged in competing for federal R&D programs. Hence they do not require the benefits of a set aside, especially one as small as the 2.5 percent SBIR set aside.

On the other hand, companies of various sizes and ownership structures should be able to compete for federal support for certain high risk, high impact R&D for which adequate private capital is unavailable. This support should not, however, be drawn from the SBIR pool but rather the other 97.5 percent of the agency R&D budget.

Q4. Your company 20/20 GeneSystems has institutional investors. What are institutional investors and how do they differ from VC investors? Don't your investors also push you to develop marketable products?

A4. Our company is currently majority owned by more than a dozen individual "Angel" investors and our founders and minority owned by three institutional investors. These three institutional investors include one venture capital fund, a Japanese company that has marketing rights to our products in Asia, and a law firm. Collectively we have raised about $2.5 million in private equity to date.

The fact that our company is majority owned by individuals rather than institutions has a profound impact on our priorities, culture, and method of operations. Individuals invest in companies for multiple reasons, some of which go beyond financial return. This is particularly the case in biotech where "disease Angels" have become an increasingly important source of early stage capital. These high net worth individuals invest not only in hopes of earning a solid return but also to advance treatments to particular diseases that they care about personally. In contrast, managers of funds made up of large corporations, pension funds and the like have a fiduciary duty to disregard their personal interests and seek to maximize the financial return for their shareholders.

In 2001 we introduced a product called *BioCheck*™ that is now routinely used by over 300 first responder organizations and federal agencies to screen suspicious powders. I am convinced that had we been majority owned by large institutional investors rather than individuals we would not have been able to launch this product due to perceived liability risk and unpredictable markets.

Q5. In your remarks I noted that you refer to large VC investors as the problem. What is the difference between a large VC investor and a small VC investor? How do you define a large VC investor?

A5. A "large VC" is a fund (typically organized as a limited partnership) that is majority owned by corporations. These corporations (limited partners) typically include pension funds, Fortune 500 companies, or insurance companies.

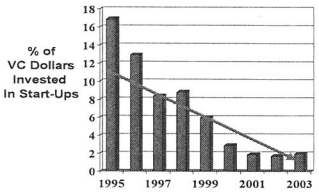
A "small VC" is a fund that is majority owned by high net worth individuals. (I would put Angel clubs in the same category as small VCs.) Under current SBA rules, a company majority owned by a small VC is eligible to participate in the SBIR program.

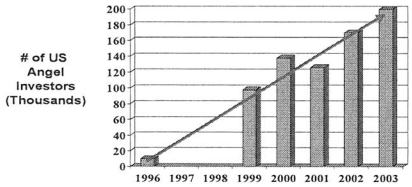
Today individual "Angel" investors—not venture capital firms—are the primary source of early stage capital for most biotech start-ups in the U.S. This was the subject of a March 7, 2005 feature story in *Business Week* titled "Where VCs Fear to Tread: Angel investors are filling a critical gap by providing early backing for biotechs."

The following data compiled by Boston Millennia Partners, a leading life science VC firm illustrates how Angel investors in early stage companies are growing relative to VCs:

Growth of Angel Investors

• Angel Organizations grow as VCs invest less in Start-Ups:





• Cumulatively, Angel Organizations invest large amounts of capital:

	2003		2004	
	Dollars	Deals	Dollars	Deals
Venture Capital Firms	$18.9B	2,834	$20.9B	2,876
Angel Investors	$18.1B	39,000	$22.5B	48,000

Source: NVCA, UNH Center for Venture Research, NASVF, and PWC-MoneyTree
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www.bmpvc.com

Boston Millennia*Partners*

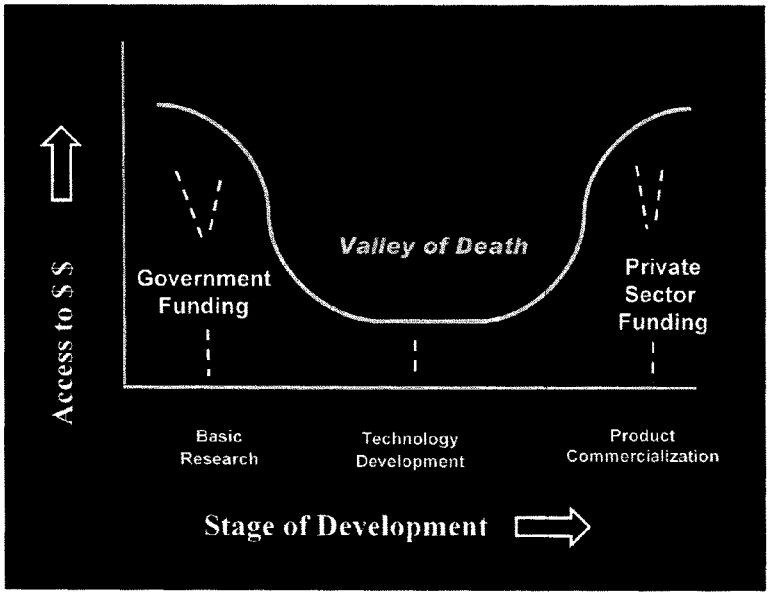
I believe it is proper for companies that are majority owned by small VCs—not large VCs—to access the SBIR program.

Q6. You recommend that Congress develop new initiatives, open to companies of all sizes to bridge the growing "valley of death" between basic discoveries proof-of-concept. Could you give us some examples of what you envision? Are you familiar with the Advanced Technology Program (ATP)? If so, should the Federal Government support programs like this and others like it?

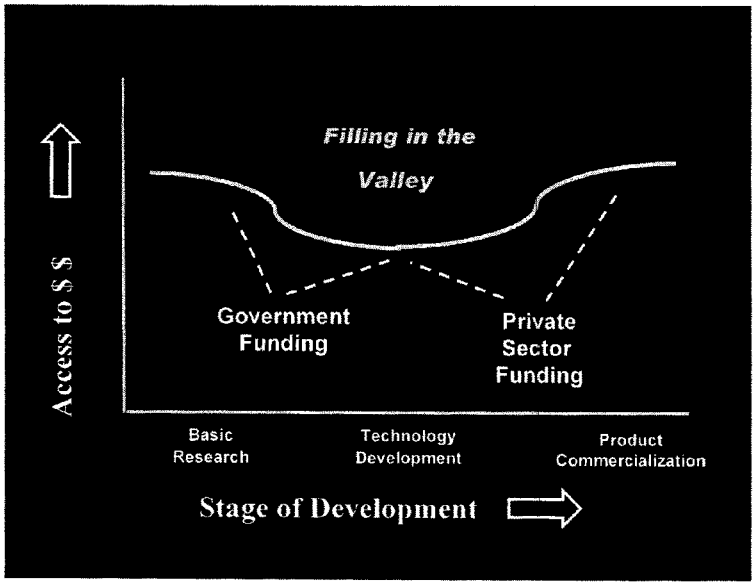
A6. Biomedical innovation in America today is "stagnant" according to the FDA.[1] Significant improvements in outcomes for patients with cancer, Alzheimer's disease, spinal cord injury and other maladies have changed little over the past 30 years. The problem according the FDA's 2004 *Critical Path* Report is that "the applied sciences needed for medical product development have not kept pace with the tremendous advances in the basic sciences." The report provides the FDA's analysis of the "pipeline problem" namely, the recent slowdown, instead of the expected acceleration, in innovative drugs and diagnostics reaching patients. According to the report, despite the explosion of bioscience and genomics research over the past ten years the number of new drug applications submitted to the FDA has actually declined. significantly.

I am convinced that this slowdown in biomedical innovation is a direct result of the "valley of death" phenomenon. Today nearly all public funding is allocated for basic research while most private capital is flowing towards late stage, lower risk product development. This "barbell" effect has resulted in a huge gap—a valley of death—that has effectively stalled biomedical innovation in the U.S. today:

[1] See *Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products.* (www.fda.gov/oc/initiatives/criticalpath)



To help fill this gap and create a "valley of life" a two pronged approach is needed: (1) shift a greater portion of government funding towards high-risk product and technology development and (2) use tax credits as an incentive for higher risk private sector investments in early stage companies:



The investor tax credit concept was discussed above as a proposed private sector alternative to Phase III funding.

Regarding government funding, Congress should set as a benchmark that about one-third of the NIH budget (extramural and intramural) should be dedicated to R&D that can be applied or translated into the development—within about five to seven years—of tangible products that fill critical unmet patient needs. To that end the NIH will need new programs that support high risk, high impact technology development by companies of all size as well as non-profit research institutes and universities. Such programs at other agencies have proven to be very successful including DARPA (Defense), ATP (NIST), In-Q-Tel (CIA), and HSARPA (Homeland Security). The National Cancer Institute has stated that the DARPA and HSARPA models "could be highly appropriate to accelerate the development of the advanced cancer technologies needed to achieve the NCI's 2015 goal.[2]

Funding decisions and management of such a program would be the responsibility government program managers experienced in moving advanced technology from concept to market in a timely manner. These programs would be open to companies of all size, as well as nonprofit research centers and medical schools that can offer a path to bringing the products to market through a licensing program, etc.

At the June 28, 2005 Hearing the otherwise divided panel of biotech CEOs seemed united on one issue: that there is clear a need for a new ATP-like program dedicated specifically to advanced biomedical product and technology development (see transcript pages 71–73). To that end *I would propose that a new "Advanced Healthcare Technology Development" program be created that would be jointly administered by the NIST and NIH.*[3] NIST, with its considerable expertise in the physical and material sciences and engineering, would focus on applications directed to innovative platform technologies that cut across multiple disease areas. The NIH would focus on novel applications of innovative technologies in specific disease areas.

Q7. What is your opinion of the Advanced Technology Program (ATP)?

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[2] NCI Roundtable, "Leveraging Multi-Sector Technology Development Resources and Capabilities to Accelerate Progress Against Cancer," January 2004, page 24.

[3] I have had many discussions with persons in industry and government about the idea of such a joint program and have received unanimously positive feedback. At the request of the Science Committee or any Member I would volunteer to help work on a detailed proposal.

A7. While I have no direct experience with the ATP program the feedback I have received from counterparts at other companies about the program has been extraordinarily positive. Companies seem much more enthusiastic about the ATP program than any other government support program that I am aware of. The most important unique attribute of NIST ATP is its emphasis on high risk technology innovation which today receives almost no support from either the venture capital community or the NIH.[4] A new report issued in August by the FDA and the Association of American Medical Colleges on the decline of innovative drugs noted the lack of platform technology development as a key problem:

> Another problem arises from declining biotechnology industry development of platform technology (fundamental scientific tools used in drug discovery), largely because venture capitalists no longer are interested in funding such research.. . .The creation of new technology platforms is critical to the long-term survival of the bio-pharmaceutical industry and may require more support from government agencies and in the pharmaceutical industry to sustain this field.[5]

Also the ATP places heavy emphasis on the ability of awardees to bring their technology to market. It is very important that Congress restore funding to the ATP and use it as a model for other federal R&D programs.

I believe ATP would serve as an excellent model for the aforementioned proposed Advanced Healthcare Technology Development program that would be jointly administered by NIST and NIH.

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[4] "For a few years in the late 1990s, prior to the bursting of the "genomics bubble" in 2000, Wall Street was very supportive of platform technologies. Five years later there remains no sign of interest returning to this space. New platform technologies will be essential for the emergence of "personalized medicine" wherein therapies are tailored to patients based on genomic and proteomic biomarkers.

[5] "Drug Development Science: Obstacles and Opportunities for Collaboration" page 10.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Carol A. Nacy, Chief Executive Officer, Sequella, Inc.

Q1. As a small business with less than 500 employees, or in your case less than 100 employees, If you raise a round of venture financing would you say that all of your fundraising needs have been satisfied? Are you able to pursue all of the projects and business leads you would like to pursue with this venture financing?

A1. No to both parts of the question: The high cost of drug development (many hundreds of millions of dollars) means that I will likely have several venture financing rounds under my belt at Sequella before I will have product on the market. The initial round of venture financing (Series A) that I hope to close before the end of 2005 will be applied to the clinical trials of two of our products close to registration or human testing: a Phase III trial (efficacy in human population) of a new TB diagnostic to be used outside the U.S. and a Phase I trial (safety only, no efficacy) of a new TB drug to shorten treatment in the U.S. from six months to fewer than six months (we hope). Additional funding will be required to determine if the new drug actually can shorten treatment time, and those are the expensive efficacy trials (Phase II and Phase III). Additional funding rounds will be required for these later trials.

In addition to clinical trials of the new diagnostic for ex-U.S. use and the new drug that will be funded by the Series A financing, Sequella has a pipeline of new and important technologies and drugs that will not be funded by the Series A (or subsequent Series B) venture round(s). We have a second generation of the ex-U.S. diagnostic that is being readied for regulatory submission to the U.S. FDA, we have two other anti-TB drugs (both work against multi-drug resistant TB, a Class C bioweapon) that are ready for formal preclinical toxicity studies that precede human clinical trials, we have a technology that enables physicians to determine the antibiotics to which a TB organism is susceptible in two days (rather than the current technique that takes up to 12 weeks) that is ready for predicate testing in a field setting, and we have a wristwatch-like device that can help patients take their drugs correctly and inform physicians when they do not (a compliance monitor). None of these drugs, diagnostics, or devices will be commercialized by the Series A or future Series B venture financing. All of these pipeline technologies have been financed, are currently financed, or we have applied for financing for them through SBIR grants and contracts. Without access to the extra-VC funds that are supplied by the SBIR program, our pipeline will dry up, and the U.S. and rest of world will be the poorer for not having these resources for identification and control of TB.

Q2. Given the 10–15 years of work and hundreds of millions of dollars it takes to complete testing and gain approval of a biotechnology therapy, venture capital investment is often a necessity for many biotechnology companies. If biotechnology companies receive venture capital for their research and development, why is it necessary for these companies to also receive SBIR monies?

A2. See above answer for application of venture capital money: there is little to no money in the venture capital community today for the early discovery and development research that underlies product identification and clinical development. Venture money now goes to late-stage technologies. Innovation occurs in the earliest stages of research, not at the late stages where we must comply with a complex set of FDA rules and regulations to assure safety and efficacy of products in humans. No innovation can happen once you move to clinical trials. Building successful companies, and contributing to the U.S. economy with jobs, products, and revenues, requires both innovation and clinical development. We will stunt the innovation required to solve such complex issues as bioweapon defense, cancer, global infectious diseases that impact U.S. public health if every time we move one product into clinical trials funded by venture capital we stop the innovation process in a company. Companies that can successfully navigate the high-risk process of product identification and development should be supported by our government at every possible level, including at the most fundamental level for product success, early-stage research. The program that exists to support that early-stage, high-risk innovation is the SBIR program.

Q3. If a firm is more than 51 percent owned by one or more venture or institutional investors, would you consider your business to be controlled by these investors?

A3. It is difficult to actually control the day-to-day functions of a company, even if you own more than 51 percent of that company, although there may be companies where such is the case.

It is rare to find a single venture capital firm ready to assume ALL the risk of financing a particular biotechnology company, given our spectacular failure rate. They generally invest through consortia of VC in order to minimize and share risk. The term sheets that I have seen from venture capital consortia, both in my present company, my past two companies, and in the industry in which I work, provide for the lead (the VC company who contributed the highest percentage of money to the consortium) and perhaps one other venture investor to have a seat on the corporate Board. The standard format is to reconfigure the company Board to have two representatives from the venture groups, two representatives selected from the company (usually CEO) and the pre-financing Board, and one independent Board member. Thus, control is balanced by in-house and independent interests, including venture interests.

The ownership percentage could provide a level of control at the shareholder level and would be exercized at the annual shareholders meeting, where Directors are elected and changes to the architecture of the company are voted upon.

Finally, a certain amount of leverage on how VC funds are utilized (and thus the immediate directions of the company) can be assumed from the acquisition of capital from any venture group: clearly they are investing their money in certain aspects of the company that they believe will lead to product and sales, giving them a return on their investment. In this sense, they are just like the SBIR program: a SBIR grant is given to innovate around a certain set of scientific assumptions and data, and you cannot use SBIR money for other unrelated innovations that you have not spelled out in advance. Everybody wants to know that their money is used "appropriately."

Q4. The SBA recently issued a Final Rule (69 Fed. Reg. 70180) that amended SBIR eligibility requirements to allow grant awardees to be 51 percent owned and controlled by another business, as long as the other business is itself at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the U.S. Does this Final Rule solve the eligibility concerns by VCC-backed biotechnology companies?

A4. No, not really. If we could select the VC who were willing to invest in us, and if there was complete transparency in the identity of the Limited Partners of funds that would allow us to make informed choices that complied with this rule, then perhaps it would be sufficient. In reality, however, we do not have financing choices. It is hard enough to get a single VC to agree to lead a financing round (as they assume the responsibility for due diligence and risk assessment), and it costs so much to bring a biotech product to market that we cannot afford to turn down anyone who takes the inherently high-risk approach of financing us. That's why VC are able to strike such good deals: we need their money. Supply and demand.

Q5. The SBA has been holding a series of Public Hearings across the country to address two topics: (1) the restructuring of small business size standards; and (2) the possible participation of small businesses majority-owned by venture capital companies in the SBIR program. These hearings follow the SBA's announcement that they are considering whether exclusion from affiliation rules for VCC-backed companies should be provided in size determinations for eligibility in SBIR program. Would this exclusion solve the eligibility concerns by VCC-backed biotechnology companies?

A5. If the "affiliation rule" implies that the head-count for my company (17 persons at present), once venture-backed, would also include the head-count of the VC group itself and all of their portfolio companies, then that rule should be revoked in all cases. My 17-person company gets no benefit whatsoever, financial or business, from any other company in an investor's portfolio, whether we are talking VC or high net worth individual. But a change in that rule would not solve the other interpretation, that VC do not count as individuals (even though they and their limited partners are controlled by individuals) in the 51 percent individual ownership issue. That's a separate and equally problematic stance that should be changed.

Q6. Aside from the issue today, what other recommendation would you make on how the SBIR program could be improved? For example, are the Phase I and Phase II award levels sufficient? Also, what are your thoughts on Phase III funding?

A6. There is never enough money! The traditional $75,000 for Phase I (six months), $750,000 for Phase II (two years) is a drop in the bucket for both money and time in biotech product development, where even a simple diagnostic kit takes $5–$10 million and 4–6 years to get to market. The NIH has an extraordinary SBIR program that recognizes both the time and the cost of product development, and this has greatly helped in driving products to commercialization. The ability of certain

government institutions to shift SBIR funding amounts to meet their goals would be a good innovation for the SBA and the SBIR program in general. Regarding Phase III money, I would certainly avail Sequella of the opportunity to compete for such funds, if available. Phase III would be particularly useful for Company products that are not of interest to VC, but are of interest to the U.S. Government and the originating Company.

Q7. What is your assessment of how NIH is managing its SBIR program? What could NIH do better?

A7. I have experience primarily with NIAID at the NIH. I find their administration of the SBIR program to itself be innovative (they have a special SBIR–AT–NIAID program that is excellent, and they are currently experimenting with the idea of Phase III funding for certain of the technologies that they determine are important for their mission). They have moved from primarily academic reviewers of SBIR grants to predominantly industry scientists, with a resulting increase in insights into the common problems of product development and the science of translational research. This results in better critiques and makes revised grants all that much stronger. Other Institutes at the NIH should adopt many of the innovations that NIAID has in place or is exploring.

Q8. What is your response to those who say that changing the current venture capital participation rules would fundamentally change the structure of the SBIR program?

A8. That's a bit disingenuous. The SBIR program did not have restrictions on VCC-backed companies for its first 20 years (1983–2003), then the rules changed for the last two years. The preponderance of time and evidence of the structure of the SBIR program is in favor of the VCC-backed company participation as the norm.

Q9. Your company is located in Maryland. What are your thoughts on Mr. Cohen's comments that changes to the rules for VC investments would be bad for Maryland biotech companies?

A9. Mr. Cohen is entitled to his opinion. However, the argument he proposes for no-change is one of competition. Lower the number of eligible participants and increase the probability of funding.

I actually find that offensive. I am looking for the best science when I review grants, and I don't actually care whether the person has other funding as well, or who supplies that funding. I want the science to be sound and the plan to be feasible. There is a lot of science that is flawed: not all science should be funded. There are many scientists/start-up companies who cannot make a cohesive and comprehensible plan to move that science forward: not all scientists/companies should be funded. Competition is what drives innovation and hones great science. I am not venture financed at the moment, and I have no fear that, should the rule be changed, I will compete successfully for additional SBIR grants no matter who is in the applicant mix. And if my current percent success rate begins to decline, I will not blame VCC-backed companies, but my own scientists for having not made crystal clear the innovation and importance of the products we work on. It's all about good science that underpins good products.

Q10. What is your opinion of the Advanced Technology Program (ATP)?

A10. I like the concept, but at present the ATP program is set up more for engineering and environmental technologies than biotechnology. It would be nice to have an ATP program dedicated to biotech.

ANSWERS TO POST-HEARING QUESTIONS

Submitted to Frederic D. Abramson, President and CEO, Alphagenics, Inc.

These questions were submitted to the witness, but were not responded to by the time of publication.

Q1. If a firm is more than 51 percent owned by one or more venture or institutional investors, would you consider your business to be controlled by these investors?

Q2. Aside from the issue today, what other recommendations would you make on how the SBIR program could be improved? For example are the Phase I and Phase II award levels sufficient? Also what are your thoughts on Phase III funding?

Q3. What is your assessment of how NIH is managing its SBIR program? What could NIH do better?

Q4. You have heard the arguments made by Dr. Nacy and Dr. Cohen on why their company should be able to compete for SBIR awards. Why do you think they should not be able to compete for SBIR awards?

Q5. What is your opinion of the Advanced Technology Program (ATP)?

Appendix 2:

Additional Material for the Record

PREPARED STATEMENT OF THE NATIONAL VENTURE CAPITAL ASSOCIATION

The following testimony is submitted on behalf of the National Venture Capital Association, a trade organization representing approximately 470 venture capital firms in the United States.

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. This segment of the economy, the entrepreneurial segment, is the true differentiator for the U.S. in terms of global competitiveness. U.S. companies originally funded with venture capital now represent 11 percent of annual GDP and employ over 10 million Americans. Companies that were originally funded with venture capital dollars include: FedEx, Genentech, Intel, Cisco, Amgen, Apple, Starbucks, Amazon, e-Bay and Google.

We respectfully submit testimony today on behalf of those venture-backed companies that are developing innovative technologies to improve the quality of our lives and raise our standard of living. Historically, 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 and simultaneously build viable businesses that will bring these innovations 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.

For the last two years, we have received calls from our member firms alerting us to situations in which an SBIR grant has been denied because the company has venture investors. As a result, several of these companies have shelved research projects, laid off scientific teams, or scaled back operations.

Venture investment, which has measured more than $350 billion during the past 20 years, has vastly improved the quality of our lives by bringing innovation to the market place. On the life sciences side, more than one in three Americans has directly benefited from a venture capital backed innovation. Medical devices such as the pacemaker, the MRI, and the pulse oximeter as well as pharmaceuticals such as ENBREL for arthritis, Herceptin for cancer and Integrilin for coronary disease were all brought to market through venture capital investment.

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 business so that promising discoveries can be brought to market.

There is a myth that says 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 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. And 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 company is 51 percent owned by venture capital firms. The result: additional research is stalled or permanently shelved and the SBA has missed a tremendous opportunity to support a promising innovation.

There is another myth 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 Jer-

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

[2] *Journal of Health Economics,* Vol. 22, p. 151.

sey, 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 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 there is a small venture capital presence, often numerous venture firms must 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 low 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.

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, and this requires allowing venture financed companies to once again compete. 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.

Last week, Congressmen Graves, Baird, Honda and Inslee introduced H.R. 2943. This legislation puts into law a clarification of SBIR eligibility requirements for venture backed start up companies. The NVCA applauds their efforts and encourages quick action on this legislation. 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. NVCA believes this legislation addresses this spiraling problem.

Thank you for the opportunity to express NVCA's views on these vital issues.

Venture Capital Investment Flows to All 50 States

Since 1984, venture capitalists have invested the following amounts:

> $10 billion
- California
- Massachusetts
- Texas
- New York
- Colorado
- New Jersey
- Washington
- Pennsylvania

Between $1 billion and $10 billion
- Virginia
- Florida
- Illinois
- Maryland
- North Carolina
- Connecticut
- Minnesota
- Ohio
- Oregon
- Arizona
- Tennessee
- Missouri
- New Hampshire
- Utah
- Michigan
- South Carolina

Between $500 million and $1 billion
- Alabama
- Wisconsin
- Indiana
- Louisiana
- Kentucky
- Kansas
- Oklahoma

Between $100 million and $500 million
- Rhode Island
- Maine
- Nebraska
- Delaware
- Mississippi
- Hawaii
- Nevada
- New Mexico
- Iowa
- Vermont
- Idaho
- Arkansas
- Alaska

Less than $100 million
- Montana
- West Virginia
- South Dakota
- North Dakota
- Wyoming

NVCA
National Venture Capital Association

PREPARED STATEMENT OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

This statement is submitted by the Biotechnology Industry Organization (BIO), an organization representing over 1,100 companies, universities, research institutions, state biotechnology associations and affiliates in 50 states.

BIO applauds the Subcommittee for holding a hearing on the Small Business Research Innovation (SBIR) grant program. While BIO represents many established companies in the industry, the vast majority of BIO members, over eighty-five percent, are small, emerging companies with fewer than 500 employees. In fact, more than fifty percent of the companies in the biotechnology industry have fewer than 50 employees. The SBIR program has played a critical role in providing necessary financing for small biotechnology companies. Unfortunately, however, an interpretation by the Small Business Administration (SBA) of the eligibility requirements for the SBIR program has prevented the majority of BIO members from participating in the program.

To qualify for SBIR grants, a small business applicant must meet certain eligibility requirements. The size and ownership requirements—or "size standard"—limit eligibility to those companies that: (i) are at least 51 percent owned and controlled by one or more *individuals* who are citizens of, or permanent resident aliens in, the United States and (ii) have no more than 500 employees, including any affiliates.

However, on January 10, 2001, the SBA Office of Hearings and Appeals ruled in *CBR Laboratories, Inc.* that the definition of "individuals" was limited to natural persons and could not include an entity such as a venture capital company (VCC). Two years later, this new interpretation of "individuals" resulted in the denial of a SBIR grant to Cognetix, Inc. because the company was venture capital-backed in excess of 51 percent. Other biotechnology companies subsequently have also been denied SBIR grant money or have opted to delay their submissions in the hopes that this issue will be re-considered. As a result, work on life-saving and life-enhancing technology is being postponed. (See Attachment)

Before most biotechnology products can become commercially available, years of work and hundreds of millions of dollars of capital are required to complete testing and gain product approvals. While there are many different funding strategies, the typical form of investment in promising, early-stage companies is venture capital. Such capital comes primarily from VCCs, whose interests are usually owned by a combination of individual investors, business entities and pension funds. After the initial seed funding is invested in support of basic R&D, a typical biotechnology company seeks venture capital investments to allow it to expand R&D and eventually launch commercial operations. Because of the significant funding required to bring biotechnology products to market, very few biotechnology companies are capable of commercializing their technologies without significant VCC backing.

In our industry, even the relatively small amount of money a company will raise in its first round of financing (Series A), $5–$8 million, generally will result in the new investors—usually a collection of venture funds—owning more than 50 percent of the company. Indeed, based on a survey of our members, it is clear that for the majority that have raised venture funding, the ownership structure is such that the collection of venture investors and other outside investment groups own more than 50 percent of the company.

In the biotechnology industry, there is a specific need for both SBIR and VCC funding. The lengthy and costly clinical development process for biotechnology requires investment that is out of reach for most small business entities. Limiting government support for this type of R&D to firms without VC funding as a main source of additional financing effectively cuts out smaller firms with excellent science foundations. This restriction risks delaying the discovery and development of promising new therapies for cancer, diabetes, Parkinson's and, significantly, many disease areas where there is less commercial focus, like tuberculosis or diseases that would qualify for an orphan drug classification.

While almost all of our member companies 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 Phase I and Phase II grants to fund cutting edge research in areas where venture capital and other sources of financing are difficult to obtain. This is typically the case for companies that need early-stage funding for proof-of-concept, while they are putting together their initial rounds of financing. SBIR grants also have been very useful to early-stage biotech companies to fund research on programs different from the lead programs around which they have raised their venture financing. Many companies will raise a venture round that is deliberately sized to the amount of funds needed to advance a lead program because the amount of money required is usually relatively high and the company

does not want to take on more debt and dilution than necessary. While they are working on these lead programs, they often come across new potential indications or new project opportunities that they will want to test before attempting to raise additional money. The SBIR program is ideally suited for this purpose, because the company already has demonstrated that it can successfully raise follow-on financing—one of the key criteria in evaluating an SBIR Phase II grant proposal.

BIO conducted two surveys this year to understand the nature and scope of this problem for our industry. The results of both surveys confirm that SBA's current SBIR size standard is severely limiting and discouraging small biotechnology companies from participating in the SBIR program.

Of the respondents to the first survey, 62 percent (public and private companies) had applied for SBIR grants over the last five years. Exactly half of these applicants were denied grants either immediately because they could not meet the SBIR size standard owing to their ownership structure, or subsequently, because of an adverse determination regarding their size. Interestingly, over 60 percent of privately owned companies chose not even to apply for SBIR grants because of perceived eligibility concerns.

The second survey, conducted earlier this month, was designed to measure the larger impact the eligibility ruling is having on our overall membership and the industry. Of the 274 companies surveyed, 25 companies reported having been turned down from the program, and 55 percent of the respondents said they are no longer applying for SBIR grants. Importantly, 34 percent of the respondents said they delayed or canceled a research project due to the SBIR ineligibility. These projects included a promising new drug for lupus, cell therapy for delayed wound healing in diabetes, and therapies to protect cells and organisms against anthrax and radiation exposure.

The legislative history makes it abundantly clear that Congress intended for the SBIR program to assist small businesses to commercialize their creations and products and to *stimulate small U.S.-owned firms to produce innovative technologies.* Congress very clearly recognized and endeavored to encourage the symbiotic relationship between VCCs and small technology firms. For example, an entire section of the relevant Committee Report details the importance of encouraging private investment. The Committee concluded that:

> providing small firms with R&D seed money. . .will encourage additional private investment in these firms. The agency-wide SBIR program outlined in the legislation should facilitate the ability of participating firms to attract venture capital as well as other financial commitments from the private sector.[1]

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 workshop to the marketplace. Moreover, Congress even created a Phase II SBIR preference for companies that attracted venture capital investment by providing:

> *special consideration in the funding review of Phase II proposals to applicants who are successful in attracting private capital commitments to pursue commercial applications of the federal research.* This special consideration is given by awarding extra points of merit to those proposals that have attracted private sector commitments for follow-on funding.[2]

It is BIO's belief that restoring the eligibility of majority venture-owned companies and granting the VCC exclusion from affiliation would *not* adversely affect the ability of small business concerns without such private capital to compete for SBIR awards. However, restricting VCC-backed companies from participating in the grant program *will* have a significant negative impact on the quality of applications and the type of science that will be studied. The United States' global leadership in biotechnology will be threatened if the Federal Government's role in promoting critical research and development through programs such as the SBIR program is limited.

BIO has no desire to limit the SBIR grant program so small biotechnology companies without venture capital funding will be ineligible. On the contrary, BIO believes that the enormous promise of biotechnology research and development merits exploration and investment on a variety of fronts and by a 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 biotechnology are limitless, unless we choose to limit them by limiting who can participate in this venture.

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[1] See S. Rep. No. 97–194, 97th Cong., 1st Sess. 1981, reprinted in, 1982 U.S.C.A.A.N. 512.

[2] Committee Report at 7–8 (emphasis added).

Preventing such limits includes removing barriers to participation in the SBIR program. To do this, BIO urges a revision of the SBIR eligibility requirements to reflect Congress' original intent to encourage awards to small businesses that have successfully attracted outside investors. BIO supports H.R. 2943, the *Save America's Biotechnology Innovative Research (SABIR) Act,* introduced by Rep. Sam Graves (R–MO). This bill would amend the Small Business Act to require SBA to broaden its SBIR Small Business Size Standard, to permit appropriate venture capital financing by venture capital funds that are (1) not dominant and (2) not controlled by a large pharmaceutical or other company. BIO stands ready to assist the Subcommittee in ensuring that the U.S. remains the global leader in the field of biotechnology. We thank you for your time and attention to this matter.

ATTACHMENT

SAMPLE PROJECTS CANCELED OR ON HOLD AS A RESULT OF SBIR INELIGIBILITY DUE TO VENTURE BACKING

Protection Against SARS Virus

A company has developed a therapy against the SARS virus that is several hundred times better than other compounds that have been reported. This therapy will provide protection against spread of SARS virus within an individual and, as a consequence, the spread of virus between individuals. The therapy is directed toward those who have been exposed and can be used to contain the spread of the disease. Support for this potential therapeutic is needed to provide animal testing resources, manufacturing, formulation, and other toxicity testing before being brought for human clinical trials.

Protection Against Anthrax Infection

A company has discovered that a potential drug that is effective in protecting organs from the injury caused by lack of oxygen or too much oxygen is also effective in protecting animals against anthrax infection. Survival of the animals was increased significantly after anthrax infection in an animal model with compound treatment. This provides the therapeutic opportunity to slow or prevent some of the initial damage to the infected person and provide an increased time for antibiotics to become effective. Support for additional animal testing of the compound in conjunction with antibiotics would provide the evidence needed to proceed toward clinical development.

Therapy to Decrease Injury Due to Stroke or Heart Attack

A potential drug has been discovered that decreased the size of injury by 50 percent to the heart and to the brain in separate models of heart attack or stroke. The compound was delivered at the time when the blockage is released which is the therapeutically relevant time of application. By reducing the size of injury by 50 percent, the long-term deleterious effects due to a stroke or heart attack should also be reduced allowing a better functional recovery. Support is needed to advance this compound for additional animal testing for potential toxicities which is required before advancing into human clinical trials.

Novel and New Approaches for Anti-cancer Drugs

A company has developed a technology and demonstrated that it can discover anti-cancer agents that will attack cancers by new and different approaches than have been previously reported. Cancer cells can be killed by activating an internal cell suicide signal which is normally off. This company has developed a procedure to identify the many different ways by which this cellular suicide signal can be turned on. These new anti-cancer agents act in ways that are totally different from current drugs and attack cancers by different avenues. One of the potential drugs the company has discovered is highly selective for breast and colorectal cancers and does not affect normal cells or other types of cancers, and it may be anticipated that it would have less toxic side effects. Grant support would increase the speed of identification of other interesting drugs and their novel pathways to bring them more rapidly toward clinical development.

Stem Cell Research to Treat Chronic Wounds

A small publicly-traded biotechnology company did not qualify for a $1.0 million SBIR grant to study the potential benefit of adult stem cells for treating chronic wounds, for which there exists a major unmet medical need. The NIH approved the research, however because a majority of the company's major shareholders are U.S.-based investment funds, the company had to withdraw its application since it could not show that greater than 50 percent of its shares were held by individual U.S. citizens.

Technology for Rapid HIV Detection

A company was working to develop a rapid test for HIV for quicker earlier detection. This proposal has been shelved due to the great costs and troubles anticipated with being unable to receive sufficient grant funding.

Plastic Atomic Force Microscope (AFM)

A company has developed manufacturing concepts that could result in significant decreases in costs of certain types of scientific instrumentation. In particular, this

company wishes to develop a low cost AFM for more general use than the higher price research grade instruments currently in place. This proposal has been abandoned.

Multi-analyte Arrays for HIV Detection

This proposal was to use the ultramicroarray technology to construct capture domains against all of the major HIV proteins and their antibodies on a single chip. This will enable simultaneously detection from very small sample volumes. This was just submitted as an RO1 (not a business grant program), which reduces probability of funding significantly.

Detection of Human Cytokines for Cancer Therapy

Based on mouse models, this proposal was to detect biomarkers for cancer using an ultra-miniaturized platform that translates into minimal invasiveness and enhanced utility. This proposal has been abandoned.

Cancer Biomarker Detection

This proposal was to use the company's ultra-miniaturized biomarker detection platform (the company has detected PSA—and cancer biomarker—from just four cells) to cancer detection and monitoring and to enhance laser capture micro-dissection capabilities (the ability to do protein analysis on very small numbers of cells). This proposal has been abandoned.

Staph A Heteropolymer for Prevention and Treatment of Staphylococcus Aureus Bacteremia

The Staph A HP heteropolymer will be developed for prevention of infection in hemodialysis, cancer, HIV and other patients receiving a catheter and who are at risk for infection.

HIV Heteropolymer Therapeutic

A company plans to undertake a study to evaluate whether a heteropolymer containing an HIV specific non-neutralizing antibody can clear a Simian/Human hybrid HIV like virus from infected cynomolgus monkeys. The HIV heteropolymer will be developed as a therapeutic treatment for HIV infected individuals to be used to supplement existing treatments.

Candida Heteropolymer Therapeutic

A company plans to develop a Heteropolymer drug for the treatment of bloodborne Candida infections.

Human Polyclonal Antibodies in Genetically Modified Pigs

Production of fully human polyclonal antibodies in genetically modified pigs—Pigs are engineered using cloning technology to make potent human antibodies as a new class of therapeutics for infectious disease applications, for antibiotic resistant infections, and biowarfare countermeasures.

Vitality Chromosome

A mini-chromosome for soybean containing a set of genes to increase expression of omega-3 fatty acids, and phytosterols to improve oil quality for human consumption of soy oil products.

Identity Preservation for Consumer Products in Modified Crops

Development of a panel of visually and genetically coupled markers for identifying specialty traits in crops for consumer use, such as plastics, pharmaceuticals or nutritional products. Autonomous mini-chromosomes carrying value-added traits would also carry linked sets of unique PCR markers and near ultraviolet or visible pigments for easy identification of product specific crops to assist in identifying preservation, processing and distribution control.

Mini-chromosome for Ethanol Production From Corn

A mini-chromosome for corn containing genes for three enzymes that would improve the conversion efficiency of plant materials, including grain, stover and cellulosic materials from other plant sources.

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Environment, Technology, and Standards, Committee on Science, House of Representatives

For Release on Delivery
Expected at 3:00 p.m. EDT
Tuesday, June 28, 2005

FEDERAL RESEARCH

Observations on the Small Business Innovation Research Program

Statement for the Record of Anu K. Mittal, Director
Natural Resources and Environment Team

GAO-05-861T

June 28, 2005

GAO
Accountability-Integrity-Reliability
Highlights

Highlights of GAO-05-861T, a statement for the record to the Subcommittee on Environment, Technology and Standards, Committee on Science, House of Representatives

FEDERAL RESEARCH

Observations on the Small Business Innovation Research Program

Why GAO Did This Study

Since it was established in 1982, GAO has consistently reported on the success of the Small Business Innovation Research (SBIR) program in benefiting small, innovative companies, strengthening their role in federal research and development (R&D), and helping federal agencies achieve their R&D goals. However, through these reviews GAO has also identified areas where action by participating agencies or the Congress could build on the program's successes and improve its operations. This statement for the record summarizes the program's successes and improvements over time, as well as the continuing challenge of assessing the long term results of the program.

www.gao.gov/cgi-bin/getrpt?GAO-05-861T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Anu K. Mittal, (202) 512-3841, mittala@gao.gov.

What GAO Found

Between July 1985 and June 1999, GAO reviewed, reported, and testified on the SBIR program many times at the request of the Congress. While GAO's work focused on many different aspects of the program, it generally found that SBIR is achieving its goals to enhance the role of small businesses in federal R&D, stimulate commercialization of research results, and support the participation of small businesses owned by women and/or disadvantaged persons. Participating agencies and companies that GAO surveyed during the course of its reviews generally rated the program highly.

GAO also identified areas of weaknesses and made recommendations that, if addressed, could strengthen the program further. Some of these concerns related to (1) duplicate funding for similar, or even identical, research projects by more than one agency, (2) inconsistent interpretations of extramural research budgets by participating agencies, (3) geographical concentration of awards in a small number of states, and (4) lack of clarification on the emphasis that agencies should give to a company's commercialization record when assessing its proposals. Most of GAO's recommendations for program improvement have been either fully or partially addressed by the Congress in various reauthorizations of the program or by the agencies themselves.

One issue that continues to remain somewhat unresolved after almost two decades of program implementation is how to assess the performance of the SBIR program. As the program has matured, the Congress has emphasized the potential for commercialization as an important criterion in awarding funds and the commercialization of a product as a measure of success for the program. However, in 1999, GAO reported that the program's other goals also remain important to the agencies. By itself, according to some program managers, limited commercialization may not signal "failure" because a company may have achieved other goals, such as innovation or responsiveness to an agency's research needs. GAO identified a variety of reasons why assessing the performance of the SBIR program has remained a challenge. First, because the authorizing legislation and the Small Business Administration's (SBA) policy directives do not define the role of the company's commercialization record in determining commercial potential and the relative importance of the program's goals, different approaches have emerged in agencies' evaluations of proposals. Second, GAO found that it has been difficult to find practical ways to define and measure the SBIR program's goals in order to evaluate proposals. For example, the authorizing legislation lacks a clear definition of "commercialization," and agencies sometimes differed on its meaning. Finally, GAO reported that as the emphasis on commercialization had grown, so had concerns that noncommercial successes may not be adequately recognized. For example, program managers identified various projects that met special military or medical equipment needs but that had limited sales potential.

Mr. Chairman and Members of the Subcommittee:

We are pleased to have the opportunity to comment on the Small Business Innovation Research (SBIR) program. Since the program's inception, we have consistently reported on its success in benefiting small, innovative companies, strengthening their role in federal research and development (R&D), and helping federal agencies achieve their R&D goals. However, through these reviews we have also identified areas where action by participating agencies or the Congress could build on the program's successes and improve its operations. Over the life of the program these recommendations have largely been implemented. This statement will discuss the program's successes as well as the continuing challenge of assessing the long term results of the SBIR program.

As a competitor in the global economy, the United States relies heavily on innovation through research and development. The potential of small businesses to be sources of significant innovation led the Congress to increase government funding for R&D projects with commercial potential that are conducted by small high-technology companies. In this context, the Small Business Innovation Development Act of 1982 established the SBIR program to stimulate mission-related technological innovation, use small businesses to meet federal R&D needs, foster participation by minority and disadvantaged persons in technological innovation, and increase private sector commercialization of innovations derived from federal R&D.[1] The act provided for a three-phased program: phase I to determine the feasibility and scientific and technical merit of a proposed research idea; phase II to further develop the idea, taking into account its commercial potential; and phase III to commercialize the resulting product or process with no further SBIR funding.

The original program was reauthorized in 1986, extending the program's expiration date from 1988 to 1993.[2] In 1992, it was reauthorized by the Small Business Research and Development Enhancement Act to expand and improve the program, to emphasize its goal of increasing private sector commercialization, to increase participation by small businesses, and to improve the government's dissemination of program-related information.[3] In addition, the act increased funding for phase-I and phase-

[1]Pub.L. No. 97-219 (1982).

[2]Pub.L. No. 99-443 (1986).

[3]Pub.L. No. 102-564 (1992).

II proposals to $100,000 and $750,000, respectively, with adjustments once every 5 years for inflation and changes in the program. The program was again reauthorized in 2000 by the Consolidated Appropriations Act of 2001,[4] which directed the Small Business Administration (SBA) and participating agencies to, among other things, expand the scope of publicly available information on specific grants and to annually report on their SBIR programs. In addition, the act requires award recipients to provide information to help SBA evaluate the program. The SBIR program is currently scheduled to expire on September 30, 2008.

Current law requires every federal department with an R&D budget of $100 million or more to establish and operate a SBIR program funded by a set percentage of that agency's extramural R&D budget—originally 1.25 percent and now 2.5 percent. In addition, agencies with R&D spending above $20 million are directed to establish goals for financing small business R&D projects at levels higher than the previous year. As of fiscal year 2004, 12 federal agencies participated in the SBIR program, including the departments of Agriculture, Commerce, Defense (DOD), Education, Energy, Health and Human Services (HHS), Homeland Security, Housing and Urban Development, and Transportation; the Environmental Protection Agency; the National Aeronautics and Space Administration (NASA); and the National Science Foundation (NSF). Each agency manages its own program, while SBA plays a central administrative role, such as issuing policy directives and annual reports for the program. Awards from three agencies—DOD, National Institutes of Health, and NASA—account for the majority of SBIR funds. From its inception in fiscal year 1983 through fiscal year 2003, federal agencies have awarded over $15 billion for more than 76,000 projects.

SBIR Program Has Generally Met Its Goals

Between July 1985 and June 1999, we reviewed, reported, and testified on the SBIR program many times at the request of the Congress. While our work focused on many different aspects of the program, we generally found that SBIR is achieving its goals to enhance the role of small businesses in federal R&D, stimulate commercialization of research results, and support the participation of small businesses owned by women and/or disadvantaged persons. Participating agencies and companies that we surveyed during the course of our reviews generally

[4]Pub. L. No. 106-554 (2000).

rated the program highly. Specific examples of program success that we identified include the following:

- *High-quality research.* Throughout the life of the program, awards have been based on technical merit and are generally of good quality. For example, in 1989 we reported that according to agency officials, more than three-quarters of the research conducted with SBIR funding was as good as or better than other agency-funded research. Agency officials also rated the research as more likely than other research they oversaw to result in the invention and commercialization of new products. When we again looked at the quality of research proposals in 1995, we found that while it was too early to make a conclusive judgment about the long-term quality of the research, the quality of proposals remained good, according to agency officials.

- *Widespread competition.* The SBIR program successfully attracts many qualified companies, has had a high level of competition, and consistently has had a high number of first-time participants. Specifically, we reported that the number of proposals that agencies received each year had been increasing. In addition, as we reported in 1998, agencies rarely received only a single proposal in response to a solicitation, indicating a sustained level of competition for the awards. We also found that the agencies deemed many more proposals worthy of awards than they were able to fund. For example, the Air Force deemed 1,174 proposals worthy of awards in fiscal year 1993 but funded only 470. Moreover, from fiscal years 1993 through 1997, one third of the companies that received awards were first-time participants. This suggests that the program attracts hundreds of new companies annually.

- *Effective outreach.* SBIR agencies consistently reach out to foster participation by women-owned or socially and economically disadvantaged small businesses. For example, we found that DOD's SBIR managers participated in a number of regional small business conferences and workshops that are specifically designed to foster increased participation by women-owned and socially and economically disadvantaged small businesses.

- *Successful commercialization.* SBIR successfully fosters commercialization of research results. At various points in the life of the program we have reported that SBIR has been successful in increasing private sector commercialization of innovations. For example, past GAO and DOD surveys of companies that received SBIR Phase II funding have determined that approximately 35 percent of the projects resulted in the sales of products or services, and approximately 45 percent of the projects

received additional developmental funding. We have also reported that agencies were using various techniques to foster commercialization. For example, in an attempt to get those companies with the greatest potential for commercial success to the marketplace sooner, DOD instituted a Fast Track Program, whereby companies that are able to attract outside commitments/capital for their research during phase I are given higher priority in receiving a phase II award.

- *Helping to serve mission needs.* SBIR has helped serve agencies' missions and R&D needs. Agencies differ in the emphasis they place on funding research to support their mission and to support more generalized research. Specifically, we found that DOD links its projects more closely to its mission. In comparison, other agencies emphasize research that will be commercialized by the private sector. Many of the projects DOD funded have specialized military applications while NIH projects have access to the biomedical market in the private sector. Moreover, we found that SBIR promotes research on the critical technologies identified in lists developed by DOD and/or the National Critical Technologies Panel. Generally agencies reviewed these listings of critical technologies to develop research topics or conducted research that fell within one of the two lists.

Improvements Made to the SBIR Program Over Time

We have also identified areas of weaknesses and made recommendations that, if addressed, could strengthen the program further. Many of our recommendations for program improvement have been either fully or partially addressed by the Congress in various reauthorizations of the program or by the agencies themselves. For example,

- *Duplicate funding.* In 1995, we identified duplicate funding for similar, or even identical, research projects by more than one agency. A few companies received funding for the same proposals two, three, and even five times before agencies became aware of the duplication. Contributing factors included the fraudulent evasion of disclosure by companies applying for awards, the lack of a consistent definition for key terms such as "similar research," and the lack of interagency sharing of data on awards. In response to our recommendations, SBA strengthened the language agencies use in their application packages to clearly warn applicants about the illegality of entering into multiple agreements for essentially the same effort and developed Internet capabilities to access SBIR data for all of the agencies. In SBA's view, the stronger language regarding the illegality of seeking funding for similar or identical projects addresses the need to develop consistent definitions to help agencies determine when projects are "similar."

- *Inconsistent interpretations of extramural research budgets.* In 1998, we found that while agency officials adhered to SBIR's program and statutory funding requirements, they used differing interpretations of how to calculate their "extramural research budgets." As a result some agencies were inappropriately including or excluding some types of expenses. To address our recommendation that SBA provide additional guidance on how participating agencies were to calculate their extramural research budgets, the Congress in 2000 required that the agencies report annually to SBA on the methods used to calculate their extramural research budgets.

- *Geographical concentration of awards.* In 1999, in response to congressional concerns about the geographical concentration of SBIR awards, we reported that companies in a small number of states, especially California and Massachusetts, have submitted the most proposals and won the majority of awards. The distribution of awards generally followed the pattern of distribution of non-SBIR expenditures for R&D, venture capital investments, and academic research funds. We reported that some agencies had undertaken efforts to broaden the geographic distribution of awards and that the program implemented by the National Science Foundation had been particularly effective. Although we did not make any recommendations on how to improve the program's outreach to states receiving fewer awards, in the 2000 reauthorization of the program, Congress established the Federal and State Technology Partnership Program to help strengthen the technological competitiveness of small businesses, especially in those states that receive fewer SBIR grants.

- *Clarification on commercialization and other SBIR goals.* Finally, in response to our continuing concern that clarification was needed on the relative emphasis that agencies should give to a company's commercialization record and SBIR's other goals when evaluating proposals, in 2000 the Congress required companies applying for a second phase award to include a commercialization plan with their SBIR proposals. This requirement partially addressed our concern. Moreover, in the spring of 2001, SBA initiated efforts to respond to our recommendation to develop standard criteria for measuring commercial and other outcomes of the SBIR program, such as uniform measures of sales and developmental funding, and incorporate these criteria into its Tech-Net database. Specifically, SBA began implementing a reporting system to measure the program's commercialization success. In fiscal year 2002, SBA further enhanced the reporting system to include commercialization results that would help establish an initial baseline rate of commercialization. In addition, small business firms participating in the

SBIR program are required to provide information annually on sales and investments associated with their SBIR projects.

Assessing the Performance of the SBIR Program Remains a Challenge

One issue that continues to remain somewhat unresolved after almost two decades of program implementation is how to assess the performance of the SBIR program. As the program has matured, the Congress has emphasized the potential for commercialization as an important criterion in awarding funds and the commercialization of a product as a measure of success for the program. However, in 1999, we reported that the program's other goals also remain important to the agencies. By itself, according to some program managers, limited commercialization may not signal "failure" because a company may have achieved other goals, such as innovation or responsiveness to an agency's research needs. We identified a variety of reasons why assessing the performance of the SBIR program has remained a challenge.

- First, because the authorizing legislation and SBA's policy directives do not define the role of the company's commercialization record in determining commercial potential and the relative importance of the program's goals, different approaches have emerged in agencies' evaluations of proposals. As a result, the relative weight that should be given to the program's goals when evaluating proposals remains unclear. Innovation and responsiveness to an agency's needs, for example, may compete with the achievement of commercialization. In the view of many program managers, innovation involves a willingness to undertake R&D with a higher element of risk and a greater chance that it may not lead to a commercial product; responsiveness to an agency's needs involves R&D that may be aimed at special niches with limited commercial potential. Striking the right balance between achieving commercial sales and encouraging new, unproven technologies is, according to the program managers, one of the key ingredients in the program's overall success.

- Second, we found that it has been difficult to find practical ways to define and measure the SBIR program's goals in order to evaluate proposals. For example, the authorizing legislation lacks a clear definition of "commercialization," and agencies sometimes differed on its meaning. This absence of a definition makes it more difficult to determine when a frequent winner is "failing" to achieve a sufficient level of commercialization and how to include this information in an agency's review of the company's proposal. Similarly, efforts to define and measure technological innovation, which was one of the program's original goals, have posed a challenge. Although definitions vary, there is widespread

agreement that technological innovation is a complex process, particularly in the development of sophisticated modern technologies.

- Finally, we reported that as the emphasis on commercialization had grown, so had concerns that noncommercial successes may not be adequately recognized. For example, program managers identified various projects that met special military or medical equipment needs but that had limited sales potential. These projects would be helpful in reducing the agency's expenditures and meeting the mission of the agency but may not be appropriately captured in typical measurements of commercialization. In general, we found that program managers valued both noncommercial and commercial successes and feared that the former might be ignored in emphasizing the latter.

To help evaluate the performance of the program, in the 2000 reauthorization of SBIR, Congress required SBA to develop a database that would help the agency collect and maintain in common format necessary program output and outcome information. The database is to include the following information on all phase II awards: (1) revenue from the sale of new products or services resulting from the SBIR funded research, (2) additional investment from any non-SBIR source for further research and development, and (3) any other description of outputs and outcomes of the awards. In addition, the database is to include general information for all applicants not receiving an award including an abstract of the project.

In conclusion, Mr. Chairman, our work has shown that, overall, the SBIR program has been successful in meeting its goals and that the Congress and the agencies have implemented actions to strengthen the program over time. However, an assessment of the program's results remains a challenge because of the lack of clarity on how much emphasis the program should place on commercialization versus other goals.

For further information, please contact Anu Mittal at (202) 512-3841 or mittala@gao.gov.

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