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FULL COMMITTEE HEARING ON LEGISLATIVE INITIATIVES TO STRENGTHEN AND MODERNIZE THE SBIR AND STTR PROGRAMS

HEARING

BEFORE THE

COMMITTEE ON SMALL BUSINESS
UNITED STATES
HOUSE OF REPRESENTATIVES

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FULL COMMITTEE HEARING ON LEGISLATIVE INITIATIVES TO STRENGTHEN AND MODERNIZE THE SBIR AND STTR PROGRAMS

Wednesday, June 17, 2009

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Committee met, pursuant to call, at 10:04 a.m., in Room 2360, Rayburn House Office Building, Hon. Nydia M. Velázquez [Chairwoman of the Committee] presiding.

Present: Representatives Velázquez, Moore, Dahlkemper, Nye, Clarke, Bright, Halvorson, Graves, Akin, Luetkemeyer, and Thompson.

Chairwoman VELÁZQUEZ. I call this hearing of this House Small Business Committee to order.

An innovative economy is a resilient economy. After all, the ability to adapt has helped our country bounce back from countless recessions. The best example of this is the downturn of the 1990s, during which an army of innovators brought us economy recovery and an IT revolution. Not surprisingly, that revolution was led by small firms.

Today, as we continue to work our way out of recession, we can look to that same small business community. With the proper tools they can help lead us the way back to prosperity.

For years, the SBIR and STTR programs have helped entrepreneurs do what they do best, pioneer new products. Nearly 35 years after they were first drafted, these programs will spur innovation. In fact, we can thank SBIR for everything from needleless insulin patches to wireless technology for BlackBerrys. Those innovations are more than everyday conveniences. They represent growth in our economy and countless homegrown jobs.

But while SBIR and STTR are inherently valuable programs, they are in need of modernization. Today, we are going to take steps to not only update these programs, but to enhance them.

I think we can all agree that a lot has changed in the last few years. Our economy has transformed and so have the needs of small firms. Yet, regardless of those changes, neither SBIR nor STTR has been updated in nearly a decade.

The legislation we are examining this morning will turn that around. It will modernize the programs to reflect today's economy and will enhance them to boost commercialization.

Just as importantly, this bill is going to cut through the programs' red tape. To begin, it authorizes an agency to create fast track programs. Doing so will eliminate funding delays for Phase Two awards, streamlining the R&D process and allowing innovators to spend more time in the lab.

Entrepreneurs are prolific inventors. In fact, they churn out 14 times more patents than big businesses do. But there is a process for turning dreams into products and many good ideas get lost along the way. By creating commercialization benchmarks, we are placing new emphasis on bringing products to market. We are also improving communication between SBIR officers and purchasing agencies. That way, entrepreneurs will know what the agencies are looking for and will have a better shot at bringing their projects to the marketplace.

As any inventor will tell you, commercial appeal isn't always enough. R&D is an expensive process; entrepreneurs often lack the capital to see it through. The legislation we are discussing today recognizes that and promises small firms increased financial freedom. It is no secret that capital is scarce these days, which is why all options should be on the table. This bill gives entrepreneurs, not Washington bureaucrats, the final say on how their firms are financed.

While both SBIR and STTR are critical programs, their value has historically been limited to certain regions. Through workshops and local marketing campaign, we are going to change that—outreach in rural regions and amongst underrepresented communities, such as women, minority and veterans will expand our R&D programs. Tools like training workshops and podcast seminars will help these groups do everything from select a purchasing agency to file an SBIR application. That is important because higher program participation means a deeper talent pool and ultimately more products brought to market.

In the last few years, our country has faced profound challenges. Today, we stand at a crossroad on a wide range of issues from health care reform to energy policy. In addressing this obstacle, one thing is very clear: We need a new approach. That why this morning's legislation is so important. It invests in America's innovators, entrepreneurs who realize that with a little ingenuity, we can turn the page on the old way of doing business and usher in a new era of prosperity.

[The information is included in the appendix.]

Chairwoman VELÁZQUEZ. With that, I look forward to hearing from today's witnesses, and I want to take this opportunity to thank all of you in advance.

And I now yield to Mr. Luetkemeyer for an opening statement.

Mr. LUETKEMEYER. Good morning. And thank you, Madam Chairwoman, for holding this hearing. And thank you to all of the witnesses who have taken their time with us this morning.

This hearing represents this committee's continuing work to complete legislation reauthorizing and modernizing the Small Business Innovation Research and Small Business Technology Transfer programs. For over 25 years, these two programs have provided invaluable support to our nation's cutting-edge small businesses. The grants provided by these programs have kick-started small compa-

nies to help fight disease, protect our nation's warfighters and increase crop yields.

In today's economy, more engineers, researchers and technicians work for small businesses than at any other time in our nation's history, and many of them have ideas for products or a process that can improve various facets of our lives. The problem these innovators face lies in bringing those ideas to fruition. This is where SBIR and STTR have had a tremendous impact on providing the initial seed funding to research and develop these ideas into concrete plans. The programs have helped launch thousands of companies and grow countless others.

Winning an SBIR or an STTR grant not only provides initial funding for development of an idea, it often validates the initiative and spurs private investment. In times when banks and traditional lending institutions are tightening their purse strings, we ought to be looking at ways to spur such investment. The SBIR and STTR programs are exactly the type of government programs that provide such a service.

The SBIR and STTR programs offer competition-based awards to stimulate technological innovation among small firms while providing government agencies new, cost-effective technical and scientific solutions to meet their diverse needs.

The development of this program is not only critical to the unique needs of each of the participating Federal agencies, but also to our national economy. Small businesses invigorate the U.S. economy by introducing new products and cheaper ways of doing business, sometimes with substantial economic benefits. They play a key role in introducing technologies to the market, often responding quickly to new market opportunities. Some of the greatest technological innovations came from small business owners, tinkering in their own laboratories or in their workshops. These two programs provided these innovators the opportunity to grow their ideas into practice, provide jobs and improve our economy.

We are confident that the legislation drafted by our committee will maintain the integrity of the program while not limiting participation. We must work to find an appropriate solution that funds the best science while wisely investing taxpayer dollars.

With that, Madam Chair, I look forward to continuing our work on this issue, and I yield back.

Chairwoman VELÁZQUEZ. Thank you.

Chairwoman VELÁZQUEZ. And now I welcome Dr. Scott Koenig. He is the President and chief executive officer of MacroGenics, a research firm in Rockville, Maryland. Mr. Koenig has been with MacroGenics since September 2001. MacroGenics is developing therapies to treat cancer, autoimmune disorders, allergy and infectious diseases. Welcome.

STATEMENT OF SCOTT KOENIG, M.D., Ph.D.

Dr. KOENIG. Thank you. Good morning, Chairwoman Velázquez, members of the committee, ladies and gentlemen. I am President and CEO of MacroGenics and Chairman of the Board of Applied Genetic Technologies Corporation. I am appearing before this committee on behalf of Biotechnology Industry Organization.

I am a scientist, physician and entrepreneur. For the past 25 years I have worked at the NIH and in the biotechnology industry.

I have seen the importance and impact of the SBIR program in the biotechnology industry firsthand. But sadly, from my perspective, current rules have inhibited and interfered with the growth and survival of the small, private biotechnology companies in the development of promising technologies of products due to the inability of venture-backed companies to participate in the SBIR program.

Let me provide an example. AGTC is a small, private biotechnology company in Alachua, Florida, developing cutting-edge product candidates to treat and cure different genetic diseases using adeno-associated viral vectors. The company, by all parameters, is small. They have seven employees, no product revenues and large capital requirements to advance their programs through the early stages of preclinical and clinical development. They have raised $37 million from venture capitalists to date, and because of their capital structure, they are ineligible to receive SBIR funds.

AGTC received several SBIR grants from 2001 to 2003 for three different projects to advance treatments for rare diseases and expand the technology platform. These were projects that were either too early in the development cycle or targeted to too small a patient population to be of interest to the financial investors.

In 2003, the company applied for an SBIR Phase One/Two grant that was initially approved for award with excellent reviews, but had to be withdrawn due to the VC ownership. This grant would have advanced a treatment for Pompe's disease, a fatal genetic disorder that in many cases causes the death of infants by 1 year of age. No investors were willing to fund this early-stage work on Pompe's. To date, 6 years later, no further work has been done on this program. This is a small company, doing promising work, whose innovation pipeline is hindered by the current SBIR eligibility rules.

The National Research Council's 2009 report stated that restricting access to SBIR funding for firms that benefit from venture investments would, thus, appear to disproportionately affect some of the most commercially promising small innovative firms and that the current SBIR eligibility rules have the potential to diminish the positive impact of the Nation's investments in research and development in the biomedical area.

Advancing science now through the valley of death has never been more important than it is right now as numerous small biotechnology companies are being forced to shelve promising therapy as a result of the current economic crisis. In fact, in just the last 5 months, at least 40 U.S. biotech companies have either placed drug development programs on hold or cut programs altogether. These programs include therapies for HIV, cervical cancer, multiple sclerosis, diabetes and lots of others.

The impact of the current economic crisis on small biotechnology companies has been and continues to be severe. According to the latest data, 45 percent of small biotech companies have less than 1 year of cash remaining, and a recent joint study by BIO and Thompson Reuters indicates that the majority of biotech investors

are changing their investment approaches towards lower-risk projects.

I appreciate the opportunity to discuss the much-needed changes in the current SBIR program. My recommendations can be grouped into three general areas:

First, increase competition for SBIR grants and provide awards to small companies with the best science and most promise to benefit the public. SBIR plays a critical role in aiding these small biotechnology companies navigate through this valley of death where the concept is too high-risk for private market support.

BIO supports the provisions in the SBIR reauthorization legislation that would reinstate eligibility for small biotechnology companies that are majority venture backed. This would ensure that the most competitive pool of applicants and that grants awarded will be based on the projects that show the most promise in bringing breakthrough therapies to the public.

Second, clarify SBIR eligibility rules to make them easier to understand and increase transparency regarding the program's operation. Currently, the application of affiliation rules often results in small companies with 50 employees being affiliated with hundreds of other employees of companies simply because the companies share a common investor.

BIO supports provisions in the SBIR reauthorization legislation that would create a more rational and effective affiliation process. Specifically, BIO supports language to clarify minority investment by venture capital operating companies that does not make the company an affiliate for purposes of determining size.

Finally, third, maintain agency flexibility to make certain SBIR programs continue to serve the needs of individual agencies. BIO supports provisions of the SBIR reauthorization bill that would protect an agency's ability to fund commercialization programs and determine when it is appropriate to exceed award amounts.

As the National Academy of Science's 2009 report made clear, SBIR should continue to rely on agency managers' judgment, experience and understanding of mission needs to effectively administer the SBIR program.

Thank you very much for your time.

Chairwoman VELÁZQUEZ. Thank you.

[The statement of Dr. Koenig is included in the appendix.]

Chairwoman VELÁZQUEZ. Now I welcome Ms. Mary B. Dwight. She is the vice president of government affairs for the Cystic Fibrosis Foundation in Bethesda, Maryland. The Cystic Fibrosis Foundation founded in 1955, was established to provide the means to cure and control cystic fibrosis.

Welcome.

STATEMENT OF MARY B. DWIGHT

Ms. DWIGHT. Thank you, Madam Chairwoman, and thank you, members of the committee. It is my privilege to speak about the important role of the SBIR program and the development of therapies for cystic fibrosis and other serious life-threatening diseases.

Cystic fibrosis is a fatal genetic disease that affects 30,000 Americans. It is one of more than 7,000 rare or orphan diseases that impact over 30 million Americans.

At the Cystic Fibrosis Foundation, we recognize the additional hurdles that we face to develop therapies to treat this disease. As a rare disease, the small market makes it less likely that companies will pursue promising therapies. As a life-threatening disease, we do not have time to wait.

To overcome this hurdle, the foundation pioneered a new business strategy, dubbed Venture Philanthropy, through which we directly invest, much as a venture capitalist would, in research and development for CF therapies. We collaborate with biotechnology and pharmaceutical firms, large and small, to reduce their financial risk and enable them to join our effort to cure CF. In the past 5 years, we have invested over $660 million in our research and medical programs.

Through this aggressive research program, we have made significant progress in the treatment for CF. When the foundation was established in 1955, children with the disease were not expected to see kindergarten.

Today, the median survival is more than 37 years, but no one in this room would say that that life expectancy is acceptable. We have more to do. And we continue to work with innovative companies to pursue therapies, to treat both the symptoms of cystic fibrosis, as well as promising products to target the genetic disease itself.

In working to advance innovative drug development for those that suffer with the disease, our Venture Philanthropy model mirrors the success of the SBIR program. We applaud the committee for a steadfast support of this important resource for innovative research and ask that you continue to develop this program so it may foster research for cystic fibrosis and other rare diseases.

SBIR grants offer critical financial resources for promising therapies that may not have high potential for commercialization, but are nonetheless vital to people with rare disease. The story of our recent partnership with Alnara Pharmaceuticals illustrates how funding either through our Venture Philanthropy model or the SBIR program can advance promising therapies that would otherwise be abandoned by the market. We believe that Alnara, a small company in Cambridge, Massachusetts, would be well suited to develop an enzyme for cystic fibrosis, yet this indication was not a part of their business model. The foundation reached out to Alnara with the offer of financial support.

Consider Alnara's principal products like the trunk of a tree, established and well funded from a variety of sources, including the venture capitalists Dr. Koenig mentioned. We asked Alnara in effect to grow a new branch for cystic fibrosis. Our funding, or SBIR program funding as well, provided the company the stability it needed to take on the increased risk of this new branch. The result was a positive new direction for the company, for new jobs and a promising new treatment for people with cystic fibrosis.

We thank the committee for recognizing the importance of the SBIR program to rare disease research through the reauthorization's call for a special focus on rare-disease-related topics.

SBIR grants provide the necessary capital and stability companies need to pursue promising new approaches or to grow new branches of their established business models. This support is es-

sential to foster more therapies for rare disease, as these therapies are often secondary products or new uses for the companies' larger, more commercialized products.

In our fight against CF, we are fortunate to have so many therapies to pursue, yet we are still racing the clock to develop new CF therapies. Despite our successful fund-raising efforts and our promising pipeline, we cannot pursue all of the research opportunities before us without help and without partners. Many of our colleagues in the fight against rare disease are not as fortunate as we and are even less able to foster promising research.

Congress has reaffirmed its commitment to support innovative research for orphan diseases by creating incentives for companies to develop orphan drug products and by providing discretionary funding for research on orphan disease, including SBIR.

Congress can do even more for these small but deserving patient populations by designating 10 percent of the SBIR grants for orphan disease research and development. Guaranteeing this funding would answer a financing problem facing innovative small businesses. With Congress' support, small business would be in a better position to move beyond basic research on an orphan drug product and commercialize products that can improve the health of millions of people with rare disease.

I thank the committee for your time and look forward to answering your questions.

Chairwoman VELÁZQUEZ. Thank you, Ms. Dwight.

[The statement of Ms. Dwight is included in the appendix.]

Chairwoman VELÁZQUEZ. Our next witness is Mr. John Stocker. He is the Senior Vice President of Federal Solutions for Lynntech, located in College Station, Texas. Lynntech is a research and technology development company with a 20-year history of successful innovations in energy, water and health.

Welcome.

STATEMENT OF JOHN J. STOCKER

Mr. STOCKER. Thank you very much, Madam Chairwoman, Mr. Luetkemeyer, members of the committee. It is with great pleasure that I appear before you today to offer Lynntech's views on the proposed legislation to reform the Small Business Innovation Research program.

As the Chairwoman noted, Lynntech is headquartered in College Station, Texas. We are the largest SBIR contractor in the State and one of the largest in the country.

The legislation that we are reviewing this morning has been the product of very hard work and thought generated by your staff, Madam Chairwoman. Contrary to the comments of the opposition, this legislation has not been rushed through a process of dictatorial powers, but rather through the input of all parties to ensure that change is accomplished in a thoughtful way and as a result of the input from stakeholders.

As a result, Lynntech, I would be pleased to note this morning, is announcing its intention of forming a new coalition of SBIR companies that agree with our view that reform requires access to all capital sources and that technology transition should be the centerpiece of the program. This new coalition will be known as the

Council on Small Business Innovation and Research and is intended to provide SBIR firms an opportunity to present alternative viewpoints to the Congress on issues of the day.

As we have stated many times before, we believe that last year's debate focused on the wrong set of issues. SBIR firms need the opportunity to access all sources of capital to be successful and the one principle that should be guiding the program, and that is moving technology into the marketplace.

Ownership of SBIR companies by venture capital firms should not be guiding our discussion regarding reform of the program. In fact, venture capital firms and other private capital resources should be available to SBIR firms to grow their technology development efforts. The only ground rule should be that large corporations should not directly benefit from a small business program. The issue that debate should be focused on, in Lynntech's opinion, is that of technology transition.

Let me comment for a moment on the venture capital issue as it is identified in the proposed legislation. The legislation does, in fact, address the issue of capital sourcing by allowing SBIR companies majority owned by venture capital firms the opportunity to compete for SBIR contracts.

Let me underline the word ″compete.″ Madam Chairwoman, your critics frequently state that your objective is to obtain 100 percent control of the SBIR market by a majority of VC-owned firms. The proposed legislation does not say that. What it does do is to allow for the competitive marketplace to be opened to those small businesses that would otherwise qualify where their majority ownership lies in the hands of venture capital firms.

Also, contrary to your critics, you do not allow unfettered access to this market for large VC firms. Large VC firms can comprise no more than 20 percent of an SBIR company. No SBIR firm would be opposed to a major company such as Pfizer, Lockheed or Boeing taking a stake in their company if there existed the possibility of eventually transitioning technology to the marketplace.

In fact, Lynntech is concerned that its ability to raise capital in the private markets could be damaged by the continued prohibition on majority ownership by VC firms. If Lynntech had had a capital infusion that would have transferred majority control to a VC firm, it would no longer be eligible for SBIR and the country would be effectively denied the achievement of new systems and technologies that improve the safety and well-being of the country.

On technology transition, Lynntech is pleased that Title II of the proposed legislation clearly indicates that the policy of the Congress is that the SBIR program should focus on the development of projects that have potential for transitioning to the market. Lynntech applauds this objective and believes it is key to the efforts undertaken for SBIR reform.

The proposed legislation further establishes a reporting mechanism for Federal agencies to report on the success of their commercialization efforts. This last provision is especially key, as much of the reform debate has been hampered by inadequate data.

The proposed legislation also establishes a process whereby technology transition efforts would be supported by Phase Three funding. The definition of that—of what constitutes Phase Three is

clearly outlined, and the agencies are given a number of tools to use in the achievement of Phase Three objectives.

There are a couple of concerns that we have in regard to the legislation. We would like to see the allocation for SBIR funds to be increased, and we have also commented in regard to the authorization period being extended for more than a period of 2 years.

Despite these minor concerns, however, Lynntech believes, in general, the proposed legislation goes a long way to achieving the SBIR reforms that are so desperately needed. Thank you.

Chairwoman VELÁZQUEZ. Thank you, Mr. Stocker.

[The statement of Mr. Stocker is included in the appendix.]

Chairwoman VELÁZQUEZ. Our next witness is Ms. Li. She is the Chief Resource Officer and Acting Chief Operations Officer at PD International, an applied think tank and solutions provider located in Baltimore, Maryland. Ms. Li is testifying on behalf of the United States Women's Chamber of Commerce. The U.S. Women's Chamber of Commerce was founded in 2001 to increase economic growth opportunities for women.

Welcome.

STATEMENT OF NING LI

Ms. LI. Thank you, Madam Chairwoman, ranking members of the committee. I am here today as a member of the U.S. Women's Chamber of Commerce, representing our 500,000 members. Over three-quarters of our members are small business owners, many of whom are active contributors to high-tech innovations, including research and development for both the Federal and commercial sectors.

My firm, PD Inc., is an innovative technology firm and hands-on small business. The firm was founded in 2001 for the purpose of inventing technologies that are the first to effectively solve existing technical problems that are of significant social and economic impact.

Since the year 2004, PD Inc. has devoted major resources into the R&D activities of voting technology. Our research has focused on the holistic design of a new-breed voting machine that would address problems existing in current voting technologies in order to accommodate all stakeholders, such as election officials, voters and the Federal Government, in their need of having an easy to use, easy to manage, accurate, fair, transparent and verifiable election process.

One of the major subcomponents of our design is an essential innovation in addressing security problems, which have been the major contributor to social controversy and the public scrutiny in the past years. At the beginning of 2008, we identified that the SBIR opportunity at the National Science Foundation could be of benefit to our specific innovation.

The SBIR application process is complex in its requirements of documentation, one of which is a letter from the existing potential customer or—an existing or potential customer to support the invention of such technology. However, our customers would generally be county and municipal election officials who, as public sector personnel, cannot endorse a product or technology marketed by a particular commercial entity. We did not have enough time to

allay any endorsement-related concerns; therefore, we decided not to file our application at that point.

In the latter half of 2008, we proved that the prototype built of our product is economically viable and there hasn't been such a device in the commercial space. At this point, we are beyond Phase One in the R&D process, but we still need money to build it. Phase Two of the SBIR award would solve our funding needs; however, we are not eligible to apply because we haven't gone through Phase One. If we apply for Phase One, it is not only dishonest, it also would waste precious human and monetary resources to repeat procedures that have already been done.

We recommend that small enterprises which are able to secure independent validation of their technology should be allowed to bypass Phase One and apply directly for Phase Two assistance.

We support legislation that does not permit business to evade Phase One of the SBIR program, but does allow an exception to be granted for companies that can demonstrate to agencies SBIR proposal evaluators that the company has fully completed Phase One work.

For example, SBIR program participants that have already demonstrated proof of concept utilizing their own financial resources in addition to having acquired a validation through peer review conducted by recognizable subject matter experts should be allowed to opt out of Phase One and go directly to Phase Two. This would save the innovators time and enable them to adhere to their schedule of innovation. Meanwhile, it also helps, saving taxpayers money.

Other recommendations, acquisition of the services of a patent attorney should be recognized by all Federal agencies as eligible expenditure under both Phase One and Phase Two. Efforts should be put into place to protect small business rights to intellectual property. Regulations should bind the large industrial partners of SBIR program recipients to protect small innovators' interests in intellectual property during the process of applied research collaboration.

A standard NDA agreement should be drafted by SBA, which large prime personnel would be required to sign before requesting small businesses disclose their intellectual property information. And a code of conduct should be established to regulate large prime personnel behavior.

SBA should work with SBIR's recipients and perhaps with the U.S. Patent and Trade Office to assist businesses with the filing of patent applications.

We strongly support the venture capital provisions detailed in the legislation under consideration, which permits SBIR awardees to receive venture capital, venture capital partnership vital to linking small businesses, innovation and research to capital market opportunities.

We must make sure there are safeguards within the legislation, the regulation and the practical application of the rules to protect small business from exploitation by larger businesses and the venture capitalists. We support maintaining majority ownership and board representation by the small firm.

Thank you again for the opportunity to provide input here today. We applaud the work of this committee to energize research and

innovation within the small business community and assist with the transfer of this innovation to Federal Government and commercial sectors. Thank you.

Chairwoman VELÁZQUEZ. Thank you, Ms. Li.

[The statement of Ms. Li is included in the appendix.]

Chairwoman VELÁZQUEZ. And now I recognize Mr. Akin for the purpose of introducing our next witness.

Mr. AKIN. Thank you, Madam Chairwoman. It is a pleasure to have Derek Rapp here testifying before this committee today. Derek is CEO of Divergence, Incorporated, a science-based company that focuses on solutions and the prevention and control of pest infections and infestations. The company's technologies have applications in plant protection, animal health and human health.

Prior to joining Divergence, Derek worked for Monsanto for 12 years where he held several positions, including Director of Mergers and Acquisitions. During his time in that position, he led divestitures with proceeds totaling roughly 2 billion.

Prior to that position, Derek led the company's acquisition and licensing program in the plant biotechnology and seeds area, leading several major acquisitions totaling more than 2.5 billion, as well as numerous licensing transactions.

Derek is a member of the board of directors of the St. Louis Regional Chamber and Growth Association, was chairman of the Plant and Life Sciences Network for RCGA in 2008. He is also a board member of Missouri Biotechnology Industry Association and the St. Louis Life Sciences Project.

Derek, I appreciate all the hard work you do in St. Louis, and I look forward to your testimony today. Welcome to Washington, D.C.

STATEMENT OF DEREK K. RAPP

Mr. RAPP. Good morning. Thank you, Congressman Akin and Madam Chairwoman and Committee. Thank you very much for the opportunity to appear before you today.

I am going to speak just briefly with regard to my views on the SBIR program and its importance. As you will hear, I am a strong proponent of the continued awarding of SBIR grants. Such grants have made and continue to make a fantastic difference for Divergence, and I have no doubt for thousands of other companies as well.

First, a bit of background. Divergence is a life science startup company—in Congressman Akin's district, in fact—with 23 full-time employees. Our research is focused on discovering safe and effective products for plant protection, animal health and human health. Most of products in development arising from Divergence's research are focused on the identification, treatment and prevention of parasitic infections caused by round worms, also known as nematodes.

Divergence began operations in 1999 and has raised approximately $36 million since its inception. Roughly 60 percent of this amount has come from equity investors, both individuals and venture capital firms; 20 percent has come from corporate relationships, and the final 20 percent, upwards of $7 million, has come from research grants.

Of these research grants, $5.5 million has come in the form of SBIR grants. Divergence has received nine grants from the National Science Foundation, nine grants from the U.S. Department of Agriculture and seven grants from the National Institutes of Health. In all, Divergence has received 15 Phase One grants, eight Phase Two grants and two follow-on grants.

A life sciences company faces many challenges and its investors often take sizeable financial risks. The science is difficult and the time line to significant value creation is usually lengthy. SBIR grants play three major roles for companies. First, they lessen the risk to investors by reducing the shareholder dilution and increasing the funds available for early-stage projects. This means that more companies get started and that more companies reach the proof of concept stage with their research.

Second, SBIR grants provide a validation of the science. The fact that the granting process includes peer review as a component of the program is quite significant. Investors, potential employees, collaborators and others respect this rigorous review process.

Third, SBIR grants provide an incentive and a source of pride to the scientific employees. The work in life sciences companies is long, difficult and often frustrating. Word of receipt of a grant provides real boosts to a team.

SBIR grants provide important benefits for our society as a whole, too. As the name suggests, they foster innovation in impactful market areas.

In each grant application, a company is asked to describe its scientific concept, any preliminary data that may have generated to date and the resources it will call on to undertake its science if the grant is funded. The company is also asked to discuss the markets it hopes to target and the way it anticipates getting its products to the market place. Hence, the program is designed to reward companies that are innovative and impactful.

Such innovation is essential for the U.S. to remain a world leader in life sciences, and the benefits to our citizens, indeed to people throughout the world, of the products that arise from such research are incalculably large.

For all these reasons, I find SBIR grants quite compelling, and therefore I strongly encourage Congress to reauthorize the funding of SBIR grants.

I look forward to the opportunity to engage with you this morning in a dialogue about the SBIR program and the pending legislation. To be clear, however, I am not an expert on the intricacies of the granting program or governmental agencies. My strongly held views are on the basic need to fund innovation and research institutions and companies.

I thank you very much for your attention and your efforts.

Chairwoman VELÁZQUEZ. Thank you, Mr. Rapp.

[The statement of Mr. Rapp is included in the appendix.]

Chairwoman VELÁZQUEZ. I would like for the members of the panel to comment on the legislation that we have before the committee today.

The legislation is designed to encourage more small firms to respond to SBIR research solicitations. Can you comment on what

provisions of the bill will contribute to greater number of small companies applying for SBIR awards?

Dr. Koenig.

Dr. KOENIG. Madam Chairwoman, I think that the most important component of this bill is rectifying and changing the 2003 ruling allowing majority-owned venture companies to now participate in this process. This will make this a much more competitive program. You will get the best science, the best companies involved in this program.

I think that this rule has taken a fantastic program and damaged it. And I think that by reinstituting that change alone you will now open up the opportunity for the program to be much more successful, more companies benefiting, and the country benefiting from it.

Chairwoman VELÁZQUEZ. Ms. Dwight.

Ms. DWIGHT. We would echo those comments as well. The VC changes really do strengthen the program.

As a founder of biotechnology and pharmaceutical research, we often look to the presence of VC funding as proof of concept in a way. We cannot do it alone, and especially as a philanthropy organization, we should not do it alone. So the fact that a company has a promising therapy that has been validated by venture capital funding as well really does indicate to us that we are on the right horse, and we need to work with them in partnership.

So the VC funding changes in the new bill really will strengthen the SBIR program to allow those companies, including very small ones, that have very promising therapies to move forward.

Chairwoman VELÁZQUEZ. Mr. Stoker, I just would like to move to my next question I would like to address to you.

In the discussion of how to treat venture capital investment in the SBIR program, some have proposed placing a cap on the amount of funds that an agency can devote to venture-backed SBIR awards.

What is your view of this idea and what potential problems might this create, if implemented?

Mr. STOCKER. Madam Chairwoman, in Lynntech's view, placing artificial caps on the participation of any small business in this program, I think creates problems in the agencies. There will be substantial questions about interpretation of the cap, there will be questions in regard to how the accounting process is being managed for ensuring that the cap is honored.

Frankly, in many agencies, Madam Chairwoman, they have problems enough with identifying how many dollars go to the SBIR program. There are countless instructions, memos and directives, for example, from the office of the comptroller at OSD in making sure the services are properly complying with the general thrust of SBIR. So by putting a VC cap in place, you are just complicating the problem.

Chairwoman VELÁZQUEZ. Thank you.

Dr. Koenig.

Dr. KOENIG. We agree with that assessment. I mean, the National Research Council report says that getting flexibility in the system, allowing the agencies to make that decision to then fund

them at the appropriate level, will end up giving a better result. And we support that notion.

Chairwoman VELÁZQUEZ. Okay.

Ms. Li, in your testimony you raised an important issue about whether Phase One is always necessary in the SBIR program.

Can you elaborate on your views regarding this issue?

Ms. LI. Thank you, Madam Chairwoman.

SBIR Phase One practice essentially is an organized peer review process. So what is required is, a small business has to recommend a name—names of two well-known subject matter experts to the program engineer who is in charge of the subject that you are submitting your proposal to. The process can be done by the small businesses themselves.

Basically, we would—we suggest possibly a standard affidavit form—and the evaluation form can be downloaded from SBA Web site—that we can attach to our proposal and send to the subject matter experts, because our research activity would know who are the subject matter experts.

The reason we are asking for this is because it would offer the flexibility in our schedule. Again, we are—by all means, we are enterprise, we are not academic institution. So we have other responsibilities. We have responsibility to serve our customers, to make profits. So sometimes these activities get into the way of doing SBIR.

Of course, they ideal scenario is, our inventors would like to spend all of their time in the lab; but currently, because of the way—we have to survive; we need to do those business activities, as well as doing innovation.

So that will offer us a lot of flexibility in conducting our innovation.

Chairwoman VELÁZQUEZ. Okay.

Dr. Koenig, since the SBIR program was last reauthorized, a number of agencies have made jumbo SBIR awards that exceed statutory levels. Many argue that such awards provide agencies with the flexibility to fund the research they view as most productive.

What is your perspective on this issue?

Dr. KOENIG. We believe quite strongly that, again, the agencies should be the determinant of the size of the award and there be certain circumstances when the award should be greater than the guidance.

In the end, the Agency is in the best position to decide what is in the best interest of the program towards getting that program towards commercialization. So I think putting it in the hands of the Agency makes a lot of sense.

Chairwoman VELÁZQUEZ. Okay.

Mr. Stocker, provisions of the legislation authorize initiatives to help SBIR grantees overcome the so-called ″valley of death″ and commercialize their research. In your opinion, will these provisions bridge this gap and result in more SBIR-funded research in the marketplace?

Mr. STOCKER. Madam Chairwoman, I think the legislation goes a long way towards addressing that problem. It cites a number of tools the agencies could utilize for helping to bridge that gap.

We think the most significant one, because we are largely a defense contractor, is that most of the acquisition managers are totally unaware of the innovations that are being undertaken in the SBIR program. So we think that the guidelines that are provided in the legislation will generate a process where we hope change will take place. And certainly with the reporting requirements you now have in the bill, I think you will be able to follow it as well.

Chairwoman VELÁZQUEZ. Okay.

And, Ms. Dwight, SBIR eligibility rules force small firms to choose SBIR funding or VC funding when, in fact, many growing small companies require both.

Can you clarify how a change to the SBIR eligibility rules will help advance the objectives of the program?

Ms. DWIGHT. As I mentioned in my testimony, what we see in the companies that we partner with for the cystic fibrosis therapies is that they need a variety of resources to bring a therapy to market.

Often our grants may be one of the larger ones they get or maybe one of the smaller ones. Our grants range from—anymore from around an average of about $1 million to, in some cases, $80 million for one promising therapy. So when you have that much money going into a company to bring something to patients, it requires a vast majority of resources, and SBIR can be a really valuable tool to bring into the mix for development.

So we strongly support the idea that SBIR can be one of many resources for a company, not the only one.

Chairwoman VELÁZQUEZ. So let me ask you, are you concerned that increasing also the average SBIR grant size will mean that fewer SBIR grants will be available to small businesses?

Ms. DWIGHT. No. In fact, we applaud the increased grant size. The reality is, I think the current grant size is often inadequate to bring a therapy to the next stage. And it really is, the larger grant size will enable the company to more accurately focus on the therapeutic development.

Chairwoman VELÁZQUEZ. Okay.

Now, your turn, Mr. Graves.

Mr. GRAVES. Thank you, Madam Chair. I want to thank all of you for being here today. I apologize for being a little late, but I know some of you come a long ways and I appreciate it very much.

My first question is for Mr. Stocker, and it is a friendly question. But I see you formed a new association to advocate for SBIR and for VC funding, and I would like for you to just expand a little bit on why you felt it necessary to come up with a new association.

Mr. STOCKER. Largely because of the fact that the recognized associations that have commented on the policy issues associated with not only this legislation, but in the past do not reflect the views of our company. And we have discovered other SBIR firms that share our concern about not having adequate recourse to multiple sources of capital as well as public financing, as in the SBIR program, and the need to see SBIR as an important tool in technology transition.

The current organizations out there have stated flatly that commercialization is not the centerpiece of this program. We firmly disagree with that.

Mr. GRAVES. Thank you very much. Very well said.

Mr. Rapp, my second question is to you. In your written testimony you touched on why small companies tend to be more innovative than larger ones. Can you expand on that a little bit?

Mr. RAPP. Certainly. And thank you.

It goes to a fair extent, my opinion, to a concept of risk and assumption of risk. A small company is inherently forced to take some pretty significant risks and therefore is willing to, I think, think more broadly and doesn't have the baggage of institutional memory or projects that are already in existence to shed before it can go on and do new things.

So it is a combination of trying to reward its investors who are taking significant risks in the first place and then also that lack of institutional baggage.

Understand that when an investor invests in a company like ours, that party is looking for a return of perhaps 10 times on its investment. When an investor invests in a major, publicly traded company, obviously they are hoping that they beat the market, which is not anywhere close to a 10X return in almost every case.

So it is just a question of matching the opportunities with the risk profile for the investment in the first place.

Mr. GRAVES. Thank you.

Madam Chairman, thanks for having the hearing. It just explains even more why we need the changes to SBIR.

Chairwoman VELÁZQUEZ. Thank you.

Mr. Nye.

Mr. NYE. First of all, I would like to thank Chairwoman Velázquez for her leadership on the issue, and thank you also, Ranking Member Graves, for all of your leadership in helping us to modernize this program—which I think clearly we have established has done some good in terms of promoting small business innovation and just needed some tweaks to let it do even better.

As the subcommittee Chair of the Subcommittee on Contracting and Technology, we have also had some hearings on the same issue. We have heard some great things about the benefits of the program.

I had the opportunity to speak at a breakfast to about a 1,000 participants in the U.S. Navy's SBIR program a couple of weeks ago, and they gave it high marks.

I have—and I want to thank you particularly, the panelists, for making the trip here today, but also for being the ones who are out there on the front lines making this program work in practice, producing the innovations and creating the jobs out in the marketplace—indeed the whole reason why we create and are concerned about making sure that we get this program right.

I think most of my questions have been satisfied by your testimony in some of the other questions answered. But I have seen heads nodding at various times during one or the other of your testimony. I just want to see if you can sort of show me, by a show of hands, if you all agree that making it easier for our venture capital to play a role and dovetail with the SBIR program is helpful. And then, if you don't, if you could tell me why.

If you agree that is helpful, if you would raise your hands.

That looks like everybody agrees with that. That is the impression I was getting.

Again, I just want to thank you all for the hard work that you are putting into creating the innovation that drives our economy, and I look forward to continue working with all of you other small business and foundation representatives and our chairwoman, making this program even better.

Thank you. I yield back.

Chairwoman VELÁZQUEZ. Thank you.

Mr. Luetkemeyer.

Mr. LUETKEMEYER. Thank you, Madam Chairwoman. For Ms. Dwight, a couple of questions.

What kind of criteria do you use for the investments that you make in the various companies to do research for you?

Ms. DWIGHT. We base it on a variety of criteria. The fundamental guidance for us is that there are promising therapies for cystic fibrosis, do we believe that a compound or a small molecule or whatever sort of basic research is promising and something worth taking an extra shot on goal against the fight against the disease.

Once we get through that process and look at the viability of the science, we also want to look at the viability of the company that we may be partnering with. And as I mentioned before, venture capital is also a great marker of us that we have a viable partner, that we have someone that has been proven to know how to take that science, that promising science, and move it towards commercialization and towards the patient.

So it really is a combination of both science analytics and unless business prowess and ability to move the therapy into the next phase.

Mr. LUETKEMEYER. How do you look at the science, though? Did you have some scientists on your staff? Do you have some sort of doctors that understand and can look at this and see that this has got potential?

I mean, I am not a scientist, so I am just kind of curious.

Ms. DWIGHT. I am not either. So I can brag on our very well-respected scientific team.

We have a medical team and it is actually an independent entity below the Cystic Fibrosis Foundation called Cystic Fibrosis Foundation Therapeutics. We have medical doctors and bench scientists on staff and also many folks around the country advising us on the promise of the therapies.

And, really, the foundation is recognized as the leader in cystic fibrosis research, convening many of these scientists together. Through evaluations internally and also through these expert panels nationwide, we are able to look at what is going on in cystic fibrosis research. And also, I think particularly as I mentioned in my statement, this is a rare disease. So typically something may come as a promise for cystic fibrosis from the bench science.

But in many cases, some of the therapies that have been most promising for cystic fibrosis may not have originated as a therapy for cystic fibrosis. They may have been a molecule that was developed for something else in its entirety, and someone along the way said, You know what, this might work for us.

So we are able to look at the science through our experts and also through our business model of Venture Philanthropy with grants provided; say, Why don't you come and try and work this with us, we think the science here has promise; we think this may be something that may work for a disease you may not even have heard of, so we are going to bring you to the table with funding and experts in the science area to say, Let's try it for cystic fibrosis.

And we are very fortunate in that we have over 30 therapies in our product development pipeline that have yielded some promise for this disease and over—more than four are in patients today because of that willingness to take a new risk.

Mr. LUETKEMEYER. I appreciate your patience. I can hear it in your voice.

There was kind of a common theme among all of you this morning with regards to the size of the awards or the grants from the different programs. Each of you said it needed to be larger.

I guess my question would be this: If you have a finite pool of money, would you rather have larger awards and fewer, meaning you may not get anything for your projects, or would you rather keep it the same to make sure that we maximize the ability of each of you to be able to get some dollars for your particular program?

Let's start with Dr. Koenig.

Dr. KOENIG. In the end, it is not the actual number of grants that are awarded. You obviously have to have an award that is going to have an impact on the business and that can lead to that commercialization. And so, therefore, I think that that should again be a decision that can be tied to the conditions of the company.

The agencies should have impact on that, so the absolute number of grants is not the critical part, making sure that the amount of money is fitting with the costs of the ongoing research that are required in today's dollars to make an impact on that company and getting that company towards commercialization.

Ms. DWIGHT. One of the things we applaud the committee for is language in the bill that calls for a special focus on rare or orphan diseases. Again, as I mentioned in my testimony, many times a rare disease is overlooked and the commercialization opportunities for it are less. It is a small population.

And so we have asked that you all consider increasing the ability of the grants program to look for opportunities to support these noncommercialized opportunities for rare disease and set aside a specific amount for orphan or rare disease product development, because it one place that the government really can and has in the past, through other legislative initiatives, played a critical role in bringing therapies to market that might not otherwise ever be developed for small patient populations.

Mr. STOCKER. Let me jump in here and make a comment that is slightly different from the prevailing view you have heard thus far.

We do agree that contract award sizes need to be increased. I can't tell you what the number of Phase One, Phase Two reviews that I have been in, particularly with DOD technical monitors where there has been substantial hand-wringing over the fact that

these award values are so small, not very much work can be done. So there is no question that the award sizes should be increased.

But I would also argue that the allocation level needs to be increased as well. It has been set at 2.5 percent for many, many years. It needs to be looked at as—increased to the 3.75 percent, we have proposed, in part because of the fact that more funding that is made available to the SBIR program means all of the innovations that we are talking about here today can be achieved. And the important thing is that it is not new budget authority.

So within the confines of whether there is an emerging PAYGO legislation or not, this could fit into both PAYGO and within the existing budget authority as is currently established.

Chairwoman VELÁZQUEZ. Time has expired.

Mr. Moore.

Mr. MOORE. Thank you, Madam Chair. And I would like to join the Chair and all of our fellow panelists who have welcomed you and thank you for coming here today.

My first question, I would like to focus on the larger economic benefit of the SBIR and STTR programs. In my home State of Kansas, 55,000 people are employed by nearly 1,300 bioscience establishments, some of which are small businesses that have used the utilized the SBIR program.

For example, Pinnacle Technology in Lawrence has used SBIR money to develop a wireless neurochemical biosensor that researchers use.

It is estimated for each SBIR dollar awarded, $5 of economic benefit accrue in the local economy. Kansas companies received $76.9 million in SBIR grants from 2000 to 2002, producing approximately $385 million in economic benefit.

You all are small business owners. Do you believe that SBIR grants allow you the necessary flexibility to hire appropriate staff, make purchases and participate in the local economies of your communities?

Do any of you care to comment?

Dr. Koenig?

Dr. KOENIG. In the development of biotechnology products, the SBIR program by itself, as has been illustrated and discussed earlier, is insufficient by itself to get through the regulatory process and approval of these programs. We do believe that they have a huge impact on the local economy, but if that is the only vehicle to getting that product to the market, almost every company would fail.

So, again, having that program in place with the opportunity to provide supplemental grants will not only be additive, it will be synergistic in terms of the whole ability of that company to ultimately commercialize and be successful.

Mr. MOORE. Does any other panelist have a response?

Mr. Rapp?

Mr. RAPP. I would say, the Phase Two grants, the larger grants, are particularly the ones where a company's employment decisions are going to be affected.

To be quite honest with you, for a 6-month grant, by the time you take out administrative expenses associated with the grant, you may be talking about $60- to $80,000. You can't responsibly

hire somebody for that period of time, and therefore, the larger grants and the longer-term grants are the ones that are going to have more of an effect on hiring moves, I would say.

But I would also say that all of these programs stimulate the near-term activities that you hope then lead to the kinds of collaborations or venture capital funding subsequently that will bring that product forward and ultimately through that so-called ″valley of death″ and into commercialization.

There hasn't been a lot of focus here today, I feel, on Phase Three as the agencies seem to refer to it, that period after the grant time. And let us not kid ourselves. These grants are great, but you still have a lot of work to do afterwards in order to get something to the marketplace; and those collaborations and subsequent funding are essential.

Mr. MOORE. Sure. Any other comments?

I am sorry, Ms. Li, did you have a comment?

Ms. LI. I very much agree with all of the panelists. I agree with Mr. Rapp that Phase Three, actually—we need a lot of assistance in that.

I was not supposed to mention this, but—

Mr. MOORE. Go ahead.

Ms. LI. For example, I have a colleague, he has developed this wonderful technology that can help to put off the wildfire through DOD solicitation.RPTS MERCHANTDCMN MAGMER

Ms. LI. DOD has their application in this particular technology, and large prime contractors also are very interested in the application in the DOD arena. But this particular technology can be used for the betterment of human life, and so—you know, to save lives. And so I feel there has to be some assistance in some way to help us to realize it.

Mr. MOORE. Thank you

Chairwoman VELÁZQUEZ. Will the gentleman yield for a second?

Mr. MOORE. Certainly.

Chairwoman VELÁZQUEZ. Mr. Rapp, we, too, are concerned about Phase Three and the lack of funding; and this why in the bill for the first time we authorize funding of $27.5 million for Phase Three.

Mr. RAPP. And I appreciate the beginning of focus there. And I had simply mentioned this conversation, but I am glad. Thank you very much.

Mr. MOORE. The second question, very briefly. In 2004, the Kansas State legislature passed and then Governor Sibelius, now HHS Secretary Sibelius, signed the Kansas Economic Growth Act of 2004, which, among other things, created the Kansas Bioscience Authority. The KBA has worked to, and has been successful, in creating partnerships between public-private and academic entities. To what extent has receiving any SBIR grants allowed you to pursue other sources of funds? Does the SBIR grant confirm a measure of credibility to other potential investors? Anybody? Mr. Rapp?

Mr. RAPP. Without a doubt, in our case. We received SBIR funding before we ever did our first major equity round, actually; and that was an instant validation for us. It was an NIH grant. And for us to be able to tell would-be investors that we already had re-

ceived that money was a stamp of approval on our science. So you bet.

Mr. MOORE. Very good. Anybody else?

Ms. DWIGHT. We would just echo that as well, that many of the companies we partner with that is seen as a marker of viability, much as any other funding would be as well.

Mr. MOORE. Thank you very, very much.

I yield back my time, Madam Chair.

Chairwoman VELÁZQUEZ. Mr. Akin.

Mr. AKIN. Thank you, Madam Chair.

I think what I am picking up from all of your testimony is, first of all, the SBIR money is—in a way, it is kind of pump priming. It isn't the thing that provides all the water in the well but gets you started, and it gives you that sort of a certification and all.

I was particularly interested in, Mr. Rapp, your background had been buying and selling and these various kinds of businesses, start-up, high tech kinds of things. How common is SBIR, an SBIR kind of a situation with the start-ups? Is it something that you see that is constantly a pattern that everybody started there or had some of that in their beginning, or is it maybe one out of two or one out of three, one out of four? How commonly do you see those? Just because it seems like you have had—for a good many years, you have had a picture of this kind of business.

Mr. RAPP. I don't have statistics, certainly, but my—I would say to you that success in this sort of program and attention to it, it comes as a result of a mind-set within the company, a focus on this as an opportunity.

And I think the companies that have their roots in academia, or some of the people come out of academia, are more inclined to be thinking about these sorts of grants because they are more accustomed to applying for or seeing their labs in academic institutions apply for grants for their funding in the first place.

Mr. AKIN. So it is more common in high-tech types of areas, you would say, then?

Mr. RAPP. I would certainly say that. And I would say it is more common in companies where, again, there is just an academic history perhaps associated with some of the founders. But a significant percentage of the life sciences companies are trying for them. We are in an incubator in St. Louis, and I would say well more than half of our companies are applying, and probably close to half have received grants over time.

Mr. AKIN. Thank you.

Others?

Mr. KOENIG. I agreed with your comment that the SBIR is pump priming, but it does more than that. I think it is a diversification derisking strategy as well. Many of the venture capitalists will provide money for later stage programs, particularly in this environment. And so this is an opportunity for the SBIR to fund some additional research projects that could evolve into another project that the venture capitalists will continue to fund. So I think that it is both pump priming but also derisking and diversifying.

Mr. AKIN. Thank you.

Anybody else?

Mr. STOCKER. One of the things that we found is that the SBIR program gives you an opportunity to move beyond proof of concept and begin development of prototypes. It is those prototypes that will eventually attract the interest, as I mentioned earlier, of acquisition managers, prime contractors and investors; and you need those prototypes to show them that there is in fact a product that will emerge from this process.

I would also point out that the reason the Phase Three effort is so important is that you may have proof of concept, you may have a prototype that will give you the framework of what that product will look like. The Phase Three effort will really allow you to apply system design efforts to it and to have a fully definitized prototype that can be ready to go into manufacturing at the end of Phase Three.

Mr. AKIN. So we can have basically all the good ideas in the world, but if you can't actually get them over the finish line—I think what I heard, a pretty good consensus also on our panel, was something to the effect that, even with limited supplies of money, from a government point of view probably quality would be the thing you would choose, that you really want a good fit, you want to have all the parameters right so that you are getting the good outcomes that you are shooting for, and how many of them may not be the best way of judging but, rather, whether or not it is really using the tool in the most appropriate way to really achieve a viable kind of operation. Is that a good—

I think my time is up. I thank you, Madam Chair.

Chairwoman VELÁZQUEZ. Thank you.

Mrs. Dahlkemper.

Mrs. DAHLKEMPER. Thank you, Madam Chair; and I want to thank the witnesses today.

I just want to kind of talk a little bit on the other side of the issue with the venture capitalist businesses. My understanding from all of your answers is that you are all in support of providing majority owned venture capitalist businesses the opportunity to fully participate in all SBIR programs. But there has been the other side of the coin. There is many who do not believe that this is a good thing.

I come from the Third District of Pennsylvania in the northwestern part of Pennsylvania. We don't have a lot of venture capitalists in my district, but what we do have is some great small businesses who are working on innovative research. And the concern that has come in front of me is that—it is a concern that there will be less money available, funding available, for those who are truly small businesses.

I guess I want to just bring that up and ask you if you think this could truly hurt small businesses if we open this up, and maybe if we need to have some limits for a time to see to kind of gauge the impact that this has on truly small businesses. Because I think there could be consequences. When you look at these venture capitalists, they have staff and ability to be on the front end helping these small firms to a point that might put them at a disadvantage to a small firm that doesn't have the staff. Mr. Rapp, could you maybe address this as a small business then?

Mr. RAPP. It is interesting. So Divergence is a company that does have venture capital ownership. But I would say VCs own about a quarter of Divergence at this point. Our dealings with the agencies when we are applying for grants are quite directly with the agencies, not through VCs or anybody else.

So in terms of an advantage that comes, maybe there is some validation, some reverse validation. Just as SBIR has provided some validation as we were receiving funding from them, perhaps the fact that the VCs and other sophisticated parties believe in what we are doing helps us. But, otherwise, I don't see the process working in that direction so much, to be honest with you. So, from our standpoint, I don't have a strong feeling that we would put others at a disadvantage. Because when we are scrambling to put together that grant application we feel like we are doing it on our own.

Mrs. DAHLKEMPER. Do you think there would be any value in having some sort of short-term limit so we could gauge the impact on other small businesses or not?

Mr. RAPP. The limit would be of what sort? Sorry.

Mrs. DAHLKEMPER. Well, it could be a limit for the first few years on putting a cap on the ability for VCs to enter into these grants so that you could gauge the impact of the consequences on other—

Mr. RAPP. Well, at least speaking from the perspective of life sciences, that chasm is still so large between any funding that we are going to receive from an SBIR grant and the ultimate commercialization that we need all the help we can get; and we are going to have to do a lot more after that, too. So it is not as if this makes it easy for us to roll right on through. So as far as limits on the participation and all, I don't see how that is going to be that broadly helpful.

Mrs. DAHLKEMPER. I know, Dr. Koenig, you obviously want to answer.

Mr. KOENIG. I appreciate the sensitivity of your particular home district, but, in the end, there is a limited amount of funds in this program; and, ultimately, what you want is competition to be such that the programs that are selected are the best ones that will ultimately end up becoming commercialized and helping the citizens of this country.

The example I gave in my testimony of a company in Florida that is seven employees, has no revenues, and is far away from commercialization, despite the fact that it is a majority owned, I think it is the paradigm of the best example of a small company. And so to use that rule or to limit it I think in the end is going to ultimately hurt the program in general.

Mrs. DAHLKEMPER. Ms. Li, did you want to address that?

Ms. LI. I very much see the side of your story. Because I had a learning curve in the past year. I realized that we have very limited venture capitalists in our area as well; and we are certainly a little disadvantaged in the sense that we are not an academic institution, we have limited grant writing experience, we learn as we go.

But, at the same time, because if we don't get a grant from SBIR we have to get some money to build our stuff. So I go to Northern Virginia, and I found a venture capitalist. I am going to have a

meeting with them next week. I feel the difficulty, but maybe go draw some venture capitalists to your State. Maybe that will be helpful.

Mrs. DAHLKEMPER. Okay. Thank you.

My time is up. I yield back.

Chairwoman VELÁZQUEZ. Mr. Thompson.

Mr. THOMPSON. Well, thank you, Madam Chairwoman and ranking member, for your leadership in reworking the current SBIR program.

I am from Pennsylvania. Pennsylvania has been a fairly active State, with 761 SBIR awards over the life of the program. In my district, the Fifth, Pennsylvania alone has 75 awardees over the life of the program. Those 75 awardees were 297 awards, and those 297 awards totaled $102.5 million. So it is a lot of innovation investment. It is a great program and certainly looking at ways to continue to improve it.

Dr. Koenig, with the recent economic conditions in the country that we have had, and it kind of looks like it has kind of touched all parts of our economy, have you seen venture in angel capital, that well, dry up at all?

Mr. KOENIG. Absolutely. Definitely. Just the impact right now on companies that I described, in terms of the available cash that they have remaining, almost half of the companies have less than a year of cash. And these are public companies. If you talk about the private companies, it is even worse.

What I have seen is a shift, that the venture capitalists, where they are funding many of the companies, they are now beginning to place bets and having greater reserves for these companies. Because they know it is going to take much longer to get to commercialization. And so, in the end, there is going to be lots more companies failing as a result of the inability to continue to get funding from these sources.

Mr. THOMPSON. I think it probably goes without saying that especially in these tough economic times and that impact certainly emphasizes the importance of the SBIR program.

Mr. KOENIG. Without a doubt.

It is funny. I recall when I was head of research in MedImmune, and MedImmune was one of the most successful biotech companies in this country and, actually, in the world and was awarded an SBIR One/Two funding. And I remember commenting specifically that I called the SBIR program the jewel of the government. I really believed at that time that the government did everything right. And when the rules changed in 2003 I was very upset about that, because I have seen the value of the impact of this program on what it could do in terms of the lives of people in this country, the development and successes of a company and the development of very important products that are making differences in the lives of individuals.

Mr. THOMPSON. Ms. Dwight.

Ms. DWIGHT. I just wanted to address that as well.

Again, as a funder of promising therapies, our goal is to bring therapeutics for cystic fibrosis into the market and into patients. And we work with a host of companies, ranging from very small

companies just out of academia, 5, 10 employees, to very large pharmaceutical companies.

The story I told you in my testimony about Alnara Pharmaceuticals I think really illustrates the importance of this program now in this current economic time. I mentioned that Elmira Pharmaceuticals was a company that we had our eye on. They produced enzymes, which is something most people with cystic fibrosis must take, but they didn't produce a cystic fibrosis enzyme. We thought we had a product where the company funding had actually dried up; they were going bankrupt. We knew that there was hope for cystic fibrosis in this company's product; and so we needed to partner it with a larger, more stable company that could carry it through and, using our funding, could utilize it as a new branch of their business model. And the result was a positive for everyone, for our patients, first and foremost, but also for the company. They were able to bring new employees in, they were able to bring some of the employees who had been working on their product at a smaller company, and an SBIR funding would have been essential as well in that model.

Mr. THOMPSON. Just real quickly a follow-up to Mrs. Dahlkemper's question. It is probably an unfair question, because you all are working with venture capital.

Is there anything that you see that would be a safeguard to make sure that those small businesses—especially in rural Pennsylvania; our districts are very similar—who may not have access to venture capital? I think of all the programs we have we only have two that we have been able to have that connection. Are there safeguards to make sure that the competing ground remains kind of fair and equitable for those rural small businesses that do not have access to that kind of a resource?

Mr. STOCKER. Mr. Thompson, it is a question that has come up, and a number of small SBIR firms have been concerned about now having to chase after venture capital to ensure that they can remain in the game. We think it is an unfounded fear.

As I mentioned earlier, the caps and the application of the caps presents special problems within each of the agencies. We think it is poor public policy. The fact that a venture capital firm is resident in Silicon Valley doesn't mean they can't come to rural Pennsylvania and invest in a project there.

I think the problem is that there is two issues. One, there is a great misunderstanding of what a venture capital fund is. The National Academy of Sciences study that was just recently completed indicated that SBIR firms without VC funding were actually more successful at commercializing than were VC-backed companies. And it may be that may change in the future, but that was certainly the case in the past.

The second thing that needs to be done—and this legislation provides for that. It provides for tools that will require the agencies to report back in terms of actual contract behavior showing what has happened in the community between VC-backed firms and non-VC-backed firms. And, secondly, it provides for an opportunity to have SBIR companies be introduced to outside potential funding sources. And I will give you a good example of that, and I will be brief.

We are working with the Air Force Research Lab right now at Wright-Patterson Air Force Base in Dayton who has selected Lynntech as a company that will be introduced to a number of venture capital companies that are being brought to AFRL so that those firms can see the kinds of technologies that the Air Force has been paying for. That is exactly the sort of framework that we have been talking about needs to be done on a more consistent basis across all of the services and, frankly, across all of the agencies.

And so that fear that has been expressed by your colleague from Pennsylvania can be addressed; and with a greater awareness, greater knowledge, a greater access to tools, that fear will dissipate.

Mr. RAPP. If I may, also—in terms of leveling the playing field, also ensuring that there are resources for any applying company to really make sure that they understand what goes into a grant application. The relationships that we have developed with the different agencies with our program managers have been really important for us, both in advance of an application and then subsequently. So making sure that the agencies understand the importance of assigning someone to that company and that they are responsible, in effect, for shepherding things through for that company is going to be how you level the playing field. Because then you make sure that you are not relying or that the company isn't relying on some third party for their sophistication.

Mr. THOMPSON. Thank you.

Chairwoman VELÁZQUEZ. Mrs. Halvorson.

Mrs. HALVORSON. Thank you, Madam Chairman—I apologize. I feel so far away from you I probably should have moved over there—Madam Chairman and Ranking Member Graves.

I want to thank all of you for being here, and sorry I was a little late. But I noticed in all your testimony you talked about how successful these programs were since their inception and how we now have the opportunity to both reauthorize them and enhance them. So I am very pleased that one of the bills under consideration is the World Technology and Outreach Act, which is going to seek participation for rural areas as well as women and veterans. But I would like to hear further from any of you on the panel what you think we need to do or what you plan to do with regards to outreach or how do we get more participation from those areas.

Mr. RAPP. One little thing, and, again, I am looking at it just from the single company perspective. But I have seen in the State of Missouri someone who has been charged with the responsibility for working with companies as they apply for grants. So whether that is done at the Federal level or at the State level, I am not sure what is the right way.

But again getting back to my comment to Congressman Thompson, the idea that there would be resources that would help that company make a sophisticated application is I think really important. You feel like you are somewhat in a game—I will be honest with you—when you are writing up an application and you want to make sure you understand the rules of the game.

Mrs. HALVORSON. Well, and also someone said that the rules changed in 2003. Was that for the good? I think Dr. Koenig said that.

Mr. KOENIG. Yes. As I indicated, I thought it was for the bad, not for the good.

Mrs. HALVORSON. Can you explain that for us?

Mr. KOENIG. Yes. I think what happened is that companies that were receiving SBIR funds were no longer now eligible to receive those SBIR funds. So, as a result, since that time—and the NIH has nice documentation—the number of grant applications have gone down. There has been a general sense that the quality of the applications have gone down. So some of the more potentially successful companies with the best technology are now excluded from this process, and I think what we need to do is change that so that they now can become again part of that process.

Mrs. HALVORSON. And one last question. So have you let us know that? I am sure—and I am new, but have you let anybody know that we need to change that so more people have an opportunity to use the funds?

Mr. KOENIG. I think that is a large part of the testimony from this panel today. I think there was a consensus that the greatest impact would be to change that rule to allow now for the venture-backed companies to again participate in that program.

Mrs. HALVORSON. Because most people are telling me now they are fearful that there is not going to be enough in there because we have expanded it to rural, women, veterans.

Mr. KOENIG. I think, again, it is going back to what it was. So I think that, in the end, we are getting now back to a more even playing field and ultimately having the best companies compete for the limited resources here, which I think is in the interest of the country.

Mrs. HALVORSON. Thank you, Madam Chairman—or Mr. Chairman. I yield back.

Mr. MOORE. [presiding.] Thank you for recognizing there was a change up here in the chair.

Mrs. HALVORSON. I had to take a double-check.

Mr. MOORE. Any other questions by any of the members of the Committee here?

If not, I want to thank all of the panelists who appeared here today to testify and answer our questions. We very much appreciate that.

I want to thank my fellow panel members on both sides for the questions that they have asked; and I think this has been very, very helpful.

I ask unanimous consent that members will have 5 days to submit a statement and supporting materials for the record.

Without objection, so ordered.

This hearing is now adjourned and, again, thanks to all.

[Whereupon, at 11:34 a.m., the Committee was adjourned.]

NYDIA M. VELAZQUEZ, NEW YORK
CHAIRWOMAN

SAM GRAVES, MISSOURI
RANKING MEMBER

Congress of the United States
U.S. House of Representatives
Committee on Small Business
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STATEMENT
of the
The Honorable Nydia Velazquez, Chairwoman
House Committee on Small Business
Full Committee Hearing on Legislation Modernizing SBA's SBIR and STTR Programs
Wednesday, June 17, 2009

An innovative economy is a resilient economy. After all, the ability to adapt has helped our country bounce back from countless recessions. The best example of this is the downturn of the mid 1990's, during which an army of innovators brought us economic recovery *and* an IT revolution. Not surprisingly, that revolution was led by small firms. Today, as we continue to work our way out of recession, we can look to that same small business community. With the proper tools, they can help lead the way back to prosperity.

For years, the SBIR and STTR programs have helped entrepreneurs do what they do best--pioneer new products. Nearly thirty years after they were first created, these programs still spur innovation. In fact, we can thank SBIR for everything from needleless insulin patches to wireless technology for Blackberrys. Those inventions are more than everyday conveniences--they represent growth in our economy and countless homegrown jobs. But while SBIR and STTR are inherently valuable programs, they are in need of modernization. Today, we are going to take steps to not only update these programs, but to enhance them.

I think we can all agree that a lot has changed in the last few years. Our economy has transformed, and so have the needs of small firms. Yet regardless of those changes, neither SBIR nor STTR has been updated in nearly a decade. The legislation we are examining this morning will turn that around. It will modernize the programs to reflect today's economy, and will enhance them to boost commercialization. Just as importantly, this bill is going to cut through the program's red tape. To begin, it authorizes agencies to create fast-track programs. Doing so will eliminate funding delays for Phase Two awards, streamlining the R&D process, and allowing innovators to spend more time in the lab.

Entrepreneurs are prolific inventors. In fact, they churn out 14 times more patents than big businesses do. But there is a process for turning dreams into products, and many good ideas get lost along the way. By creating commercialization benchmarks, we're placing new emphasis on bringing products to market. We're also improving communication between SBIR officers and purchasing agencies. That way, entrepreneurs will know what the agencies are looking for, and will have a better shot at bringing their projects to the marketplace.

---more---

As any inventor will tell you, commercial appeal isn't always enough. R&D is an expensive process, and entrepreneurs often lack the capital to see it through. The legislation we're discussing today recognizes that, and promises small firms increased financial freedom. It's no secret that capital is scarce these days, which is why *all* options should be on the table. This bill gives entrepreneurs-- *not* Washington bureaucrats-- the final say in how their firms are financed.

While both SBIR and STTR are critical programs, their value has historically been limited to certain regions. Through workshops and local marketing campaigns, we're going to change that. Outreach in rural regions and amongst underrepresented communities--such as women and veterans-- will expand our R&D programs. Tools like training workshops and podcast seminars will help these groups do everything from select a purchasing agency to file an SBIR application. That's important, because higher program participation means a deeper talent pool and, ultimately, more products brought to market.

In the last few years, our country has faced profound challenges. Today, we stand at a crossroads on a wide range of issues, from healthcare reform to energy policy. In addressing these obstacles, one thing is very clear--we need a new approach. That's why this morning's legislation is so important. It invests in America's innovators, the entrepreneurs who realize that--with a little ingenuity-- we can turn the page on the old way of doing business, and usher in a new era of prosperity.

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Opening Statement
Ranking Member Sam Graves
House Committee on Small Business
Hearing: *Legislative Initiatives to*
Strengthen and Modernize the SBIR and STTR Programs
June 17, 2009

Good morning. Thank you, Madam Chairwoman, for holding this hearing and thank you to all of the witnesses who have taken their time to be with us this morning. This hearing represents this Committee's continuing work to complete legislation reauthorizing and modernizing the Small Business Innovation Research and Small Business Technology Transfer Programs. For over 25 years, these two programs have provided invaluable support to our nation's cutting-edge small businesses. The grants provided by these programs have kick-started small companies to help fight disease, protect our nation's war fighters, and increase crop yields.

In today's economy, more engineers, researchers, and technicians work for small businesses than at any other time in our nation's history and many of them have ideas for products or process that can improve various facets of our lives. The problem these innovators face lies in bringing those ideas to fruition. This is where the SBIR and STTR have had a tremendous impact. By providing the initial seed funding to research and develop these ideas into concrete plans, the programs have helped launch thousands of companies and grow countless others. Winning an SBIR or STTR grant not only provides initial funding for the development of an idea, it often validates the initiative and spurs private investment. In times when banks and traditional lending institutions are tightening their purse strings, we ought to be looking at ways to spur such investment. The SBIR and STTR programs are exactly the types of government programs that provide such a service.

The SBIR and STTR programs offer competition-based awards to stimulate technological innovation among small firms while providing government agencies new, cost-effective, technical and

scientific solutions to meet their diverse needs. The development of this program is not only critical to the unique needs of each of the participating federal agencies, but also to our national economy.

Small businesses invigorate the U.S. economy by introducing new products and cheaper ways of doing business, sometimes with substantial economic benefits. They play a key role in introducing technologies to the market, often responding quickly to new market opportunities. Some of the greatest technological innovations came about from small business owners tinkering in their laboratories and workshops. These two programs provide these innovators with an opportunity to grow their ideas into practice, provide jobs, and improve our economy.

I remain confident that legislation drafted by our Committee will maintain the integrity of the program while not limiting participation. We must work to find an appropriate solution that funds the best science while wisely investing taxpayer dollars. With that, Madam Chair, I look forward to continuing our work on this issue and yield back.

HEARING TESTIMONY

SCOTT KOENIG, M.D., PH.D.

PRESIDENT AND CHIEF EXECUTIVE OFFICER

MACROGENICS INC.

ON BEHALF OF THE

BIOTECHNOLOGY INDUSTRY ORGANIZATION

BEFORE THE HOUSE OF REPRESENTATIVES COMMITTEE ON SMALL BUSINESS

"LEGISLATIVE INITIATIVES TO STRENGTHEN AND MODERNIZE

THE SBIR AND STTR PROGRAMS"

June 17th, 2009

Good morning Chairwoman Velázquez, Ranking Member Graves, Members of the Committee, ladies and gentleman. I am Scott Koenig, President and Chief Executive Officer of MacroGenics Inc and Chairman of the Board of Applied Genetics Technology Corporation (AGTC). I am appearing before this Committee on behalf of the Biotechnology Industry Organization (BIO). BIO represents more than 1,200 companies, academic institutions, state biotechnology centers and related organizations in all 50 states.

I am a scientist, physician, and entrepreneur and have worked at both the NIH and in the biotechnology industry for the past twenty-five years. During my career I have held positions including Senior Vice President of Research at MedImmune Inc., co-founder and CEO of MacroGenics Inc, and Board member of AGTC. During this time I have been involved in the development of multiple biological products, such as a therapy to prevent a fatal respiratory viral illness in premature infants, a vaccine to prevent cervical cancer, and a number of other promising biological therapeutics still in development such as treatments for juvenile diabetes, West Nile virus infections, and many types of cancer. I have seen the

importance and impact of the SBIR program in the biotechnology industry, not only on fostering the growth of fledgling companies during some of the most challenging times in their business cycles, but in enhancing the advancement of important products to the marketplace. Sadly, from my perspective, current rules have inhibited and interfered with the growth and survival of small private biotechnology companies and the development of promising technologies and products due to the inability of venture-backed companies to participate in the SBIR program. Let me provide an example of each with two quite different outcomes for programs developing vital treatments for children.

In the early 1990's, MedImmune was a small biotechnology company in Gaithersburg, MD, founded in 1988, funded by venture capitalists, which became a publicly-traded company on NASDQ in 1991. One of the lead programs in the company at the time was a monoclonal antibody to prevent a viral infection called respiratory syncytial virus (RSV) in neonates. The research and development of this program was funded by SBIR Phase 1 and 2 grants. This funding was critical in supporting the company and the research program. Today, this product called Synagis, the first and only FDA-approved monoclonal antibody product to prevent an infectious disease, has been used in over 600,000 children. MedImmune was acquired by AstraZeneca in 2007, one of the largest acquisitions of a biotechnology company by a pharmaceutical company. MedImmune now employees thousands of highly skilled professionals. If current SBIR rules prevailed at that time when MedImmune's scientists first applied for an SBIR grant, MedImmune would have been ineligible to receive those SBIR funds and it would have significantly impacted the development of that program and the company.

Contrast that outcome with AGTC. Today, AGTC is a small private biotechnology company in Alachua, Florida, developing cutting-edge product candidates to treat and cure different genetic diseases using adeno-associated viral (AAV) vectors produced from their propriety manufacturing process. The company, by all parameters, is small. They have seven employees (recently downsized from 13 because of financial circumstances), rent space in a university subsidized lab, have no product revenues, and have large capital requirements to advance their programs through early stages of pre-clinical and clinical development. They have raised $37M from venture capitalists to date and because of their capital structure are ineligible to receive SBIR funds. All of the venture capital funds are being used to support two early clinical stage programs at the company and there is no additional capital available to support other promising avenues of research. AGTC received several SBIR grants from 2001-2003 for three different projects to advance treatments for rare diseases and expand their technology platform. The results from this research were valuable in advancing the company's mission. These were projects that were either too early in their development cycle or targeted to too small of a patient population to be of

interest to financial investors. In 2003, the company applied for a Phase I/II SBIR grant that was initially approved for award with a very good score and excellent reviews, but the application had to be withdrawn due to circumstances of VC ownership. This grant would have advanced a treatment for Pompe disease, a fatal genetic disorder that in many cases results in death of infants by one year of age. No investors were willing to fund this early stage work on Pompe. To date, six years later, no further work has been done on this program.

Currently, the company is working on one of the most promising programs to treat blindness in children caused by genetic disorders. The first eye disorder being addressed is Leber's congenital amaurosis (LCA), a rare retinal disease affecting a few thousand patients in the U.S. An initial clinical trial has resulted in the restoration of partial sight in the first legally-blind patients with the inherited defective gene when they were treated with the AAV vector containing the normal form of the gene. This ground-breaking work using the company's AAV vector product candidate, as well as studies conducted by other investigators, was published recently in *Human Gene Therapy* and the *New England Journal of Medicine*. AGTC is starting additional clinical trials to test this promising therapy in patients with LCA with its current funds. However, the company desires to generate and test other gene replacement candidates for four other genetic eye diseases, particularly those with larger number of affected individuals, but cannot do so because resources are unavailable and they are unable to apply for SBIR grants for the high risk, but likely rewarding approach to treating these debilitating eye disorders.

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

The SBIR program is an important component in the foundation and growth of new biotechnology-based companies and we ask that this funding vehicle be available to companies after they raise venture capital so that we can continue to develop these life-changing products. This policy is supported by the 2009 National Research Council's 2009 report "Venture Funding and the NIH SBIR Program." This study

found that "...restricting access to SBIR funding for firms that benefit from venture investments would thus appear to disproportionately affect some of the most commercially promising small innovative firms..." and that the current SBA eligibility rules have "...the potential to diminish the positive impact of the nation's investments in research and development in the biomedical area." The report recommends that the SBA ruling be repealed or modified so that majority-venture funded companies with significant commercial potential can compete for SBIR funding.

The role of the SBIR program in bringing breakthrough therapies to the American people is a matter of record. There are 252 FDA approved biologics that have been developed by 163 companies. Thirty-two percent of those companies have received at least one SBIR/STTR award. Despite the past successes, the ability of the SBIR program to provide critical funding for medical research projects will remain hampered, unless SBIR reauthorization updates the program to address the current realities facing small, innovative American companies.

As you know, Congress created the SBIR program in the early 1980's because it recognized that promising, early stage scientific research all too often failed to be funded through the markets because it was viewed as too high risk. This failure of the markets is often referred to as the "valley of death." Advancing science through the valley of death has never been more important than it is right now as numerous small biotechnology companies are being forced to shelve promising therapies as a result of the current economic crisis. In fact in just the last five months, at least 40 U.S. public biotech companies have either placed drug development programs on hold or cut programs all together. These programs include therapies for HIV, cervical cancer, multiple sclerosis, and diabetes.

For more than twenty years, small, domestic biotechnology companies competed for SBIR grants. In addition to providing funding, these grants were a powerful signal to the private sector that a company's research was compelling and possessed scientific and technical merit. However, in 2003 the Small Business Administration's Office of Hearings and Appeals (OHA) ruled that a biotechnology company, Cognetix, did not meet the SBIR size standard because multiple venture capital investors, in the aggregate, owned more than 50% of the company's stock. The ruling, which is not based on the SBIR statutory language, ignores the realities of the marketplace where small biotechnology firms must raise hundreds of millions of dollars to conduct capital-intensive research. On average, it is estimated that it takes between 8 and 12 years to bring a biotechnology therapy to market and costs between $800 million and $1.2 billion. In the case of my company, MacroGenics, our most advanced program in late stage-clinical testing is a monoclonal antibody to treat juvenile diabetes which was first developed in the early

1990's. It may come to the marketplace no earlier than three years from now after review by the FDA if the safety and clinical testing are favorable, more than 20 years from the initial discovery of the molecule. Small biotech firms typically have less than 50 employees, no product on the market, and must raise considerable funds through a combination of angel investors and venture capital firms in order to make a therapeutic commercially available to patients.

The impact of the current economic crises on small biotechnology companies has been and continues to be severe. According to the latest available data, 30 percent of small, publicly-traded biotechnology companies are now operating with less than 6 months of cash on hand, almost double the number of cash-starved companies compared to 2007. Forty-five percent of these companies have less than 1 year of cash remaining. The total capital raised by the industry in 2008 has seen a steep decline (down 55% compared to 2007).

The SBIR program has always been critical to helping innovative biologic therapeutic development programs traverse the "valley of death" and move towards a publicly available product. A role that has never been more critical than it is today. A recent joint study by BIO and Thompson Reuters found that the current economic crisis has forced over 80 percent of biotech investors to change their investment approaches. They can no longer afford the high risk that is characteristic of investment in biotech. The decline of the biotech industry jeopardizes not only America's patient population, but also America's competitive edge in the 21st century global economy. The importance of restoring eligibility to small biotechnology companies has never been clearer.

SBA has stated that the ownership rule is meant to be a proxy for determining that a company is domestic. However, the use of capital structure as a proxy for determining domesticity and the subsequent OHA ruling has had the unintended consequence of excluding a sizeable portion of U.S. biotechnology companies that would otherwise be eligible to participate in the program. Even more alarming is the fact that NIH SBIR applications have decreased 40 percent since 2004, about the time that SBIR-participating agencies implemented the new SBA restriction on majority VC-financed companies.

Small biotechnology companies generally possess a collection of research projects with one lead product and an average of 5 other therapies or candidates in early stage/pre-clinical research. Typically, a biotechnology company will begin fundraising for its lead product in development. Companies generally raise between $5 million and $15 million in their first round of venture financing, an amount that often results in multiple venture capital companies collectively owning more than 50% of the company. This is especially the case with very young companies whose valuation may reflect their high-risk, early stage

nature. Typically, no single venture capital company will own more than 15 to 25 percent of the company's equity.

Despite the extensive fundraising a biotechnology company undertakes for their lead product, these funds are not interchangeable, and are tied to very specific milestones to support the lead product's development. As such, in order to develop secondary or tertiary candidates/therapies, a company has to find secondary sources of fundraising capital. At the very earliest stages of development other sources of financing, such as SBIR grants, have been instrumental in advancing research and development in biotechnology. This phenomenon is described in the 2009 NAS study which explains that biologic drug development is not a linear process and has to be examined not just as SBIR funds for firms, but SBIR funds for projects. The NAS data illustrates how SBIR funds are complementary to venture capital funds and may be used to develop early-stage research projects distinct from a company's lead research project.

Opportunity to Strengthen/Restore SBIR Program

I appreciate the opportunity to discuss much-needed changes to the current SBIR program. I believe these changes would strengthen the program and ensure that it is funding the best small biotechnology businesses that are working on innovative programs which have the most potential to benefit the public. My recommendations can be grouped under three general goals. First, increase competition for SBIR grants and, as such, foster innovation and commercialization by small companies with the most promise. Second, clarify SBIR eligibility rules to make them easier to understand and increase transparency regarding the program's operation. Third, maintain agency flexibility to make certain the SBIR program continues to serve the needs of individual agencies.

I will briefly discuss each of these important goals.

Increase Competition and Foster Innovation and Commercialization by the Best Small Companies

SBA's 2003 ruling that excludes majority venture-backed companies inhibits the SBIR program from receiving the most competitive pool of applicants possible and stifles the ability of SBIR to carry out its mission to fund projects that will improve public health and have the most commercial potential.

The current SBA interpretation would deem eligible a public company with 499 employees and significant, perhaps hundreds of millions of dollars in revenue. However, a private company like AGTC, with 7 employees, no annual revenue, and $37 million in venture capital by multiple venture capital funds equaling over 75% of the company's equity, even though no one venture capital firm has more than 26%

of total equity, is ineligible. Among BIO emerging companies, a significant number are ineligible, the majority of which would apply for SBIR funding if they were able. These companies are working on breakthroughs for the treatment of diseases such as Alzheimer's, lupus, and cancer.

The National Institutes of Health (NIH) have documented disturbing trends since the 2003 ruling. Applications for SBIR grants at NIH have declined by 11.9 percent in 2005, 14.6 percent in 2006, and 21 percent in 2007. Additionally, the number of new small businesses participating in the program has decreased to the lowest proportion in a decade.

Small biotechnology companies have high and intense capital needs (over $1 billion) and an unusually long development time of 5-12 years. The vast majority of biotechnology companies raise between $5 million and $15 million in their first round of venture financing for their lead product(s), an amount that usually results in the venture capital firms collectively owning more than 50% of the company. However, the investment group usually consists of several firms, none of which owns more than 15-25% of the company.

SBIR plays a critical role in aiding small biotechnology companies in their early stage research to navigate through the "valley of death" where the concept is too high-risk for private market support. This has never been more important as the "valley of death" is only getting wider in these difficult economic times.

BIO supports the provisions in the SBIR reauthorization legislation that would reinstate eligibility for small biotechnology companies that are majority-venture backed. These provisions include reasonable limitations on the role of corporate venture capital investors and majority ownership by a single venture capital company. This will ensure the most competitive pool of applicants and that grants awarded will be based on projects that show the most promise in bringing breakthrough therapies to the public.

Clarify SBIR eligibility rules to make the application process more straightforward and user-friendly

It is equally important that the reauthorization clarify SBA affiliation regulations. Under current SBA regulations, when determining the size of a business, the SBA considers the number of direct employees at the business as well as affiliated businesses' employees. Businesses are affiliates of each other if the SBA determines that another business has either affirmative or negative control. Current regulations state that a venture capital company that holds a minority share in another business can be considered an

affiliate of that business. If the SBA determines a venture capital company is affiliated with the business, not only are the employees of the venture capital company included in the size determination but so are the employees of other businesses in which the venture capital firm is invested.

As a result of these affiliation rules, a small company with 50 employees could be deemed to be affiliated with hundreds of other employees of companies with which the small company has no relationship whatsoever, simply because the companies share a common investor. It is important to note that this can be the case where the VC investor owns a minority stake in the small business applying for SBIR.

Not only are these affiliation rules nonsensical, the manner in which they are applied is often a mystery to the small business applying for the SBIR grant. As a result, a small company may certify in good faith that it is eligible for an SBIR grant, only to later find out that the SBA has affiliated it with a large number of employees at other unrelated companies, thus making the small business ineligible.

BIO supports the provisions in the SBIR reauthorization legislation that would create a more rational and effective affiliation process regarding determinations about an SBIR applicant's investors' portfolio companies. Specifically, BIO supports language to clarify that minority investment by a venture capital operating company does not make that company an affiliate for the purposes of determining size. This common-sense provision will provide clarity and peace of mind for small business entrepreneurs looking to participate in the SBIR program.

Maintain Agency Flexibility

BIO also supports maintaining agency flexibility in the SBIR program. One of the great strengths of the SBIR program is that Congress provided the affected departments and agencies with flexibility in establishing the program. Maintaining flexibility in the program is also supported by a National Research Council 2007 report which states, "...flexibility is a positive attribute in that it permits each agency to adapt its SBIR program to the agency's particular mission, scale and working culture."

The reality is that various government agencies may structure their SBIR program in different ways to meet differing agency needs. This is a good thing, so long as the original goals of the SBIR program are preserved. Certain agencies, for example, may need the flexibility to award larger grants, if the project they are funding is in an area where research is typically more expensive. This is sometimes the case for biotechnology companies researching therapies that are especially novel or cutting-edge. For this reason, BIO does not believe that a hard cap should be applied to the SBIR grant amounts.

Additionally, any caps on SBIR grants, if imposed, should apply to particular SBIR phases and should not apply to the entire amount that the agency spends on a particular project. The NIH, for example, has chosen to implement a commercialization assistance program for those companies who may need extra funding before they can attract private dollars. A hard dollar cap in the SBIR program could threaten such a program and this would be, in BIO's opinion, very unfortunate.

BIO supports provisions in the SBIR reauthorization bill that would protect an agency's ability to fund commercialization programs and determine when it is appropriate to exceed award amounts. As the NAS 2009 report made clear, SBA should continue to rely on agency managers' judgment, experience, and understanding of mission needs to effectively administer the SBIR program.

CLOSING REMARKS

Congress can continue to support the United States biotechnology community by allowing the government to partner with small biotechnology companies that have promising science but need additional resources at key stages of development not readily available in the private capital markets. SBIR should be an aggressively competitive program that fulfills federal research and development goals of bringing breakthrough public health discoveries to the public. BIO believes that the modernizations to the SBIR program being considered by the committee will help to accomplish these important objectives.

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STATEMENT OF MARY B. DWIGHT

VICE PRESIDENT OF GOVERNMENT AFFAIRS

CYSTIC FIBROSIS FOUNDATION

BEFORE THE HOUSE COMMITTEE ON SMALL BUSINESS

ON THE SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

JUNE 17, 2009

Statement of Mary B. Dwight
Vice President of Government Affairs
Cystic Fibrosis Foundation
Before the House Committee on Small Business
On the Small Business Innovation Research (SBIR) Program
June 17, 2009

Chairwoman Velazquez, Congressman Graves and members of the Committee, thank you for the invitation to testify on behalf of the Cystic Fibrosis Foundation. It is my privilege, in particular, to speak about the important role of the Small Business Innovation Research (SBIR) program in the development of therapies for cystic fibrosis (CF) and other serious and life-threatening illnesses.

The CF Foundation is *the* leader in the search for a cure for cystic fibrosis. To develop new therapies for CF and accelerate progress toward a cure, it has pioneered a strategy of "venture philanthropy."

We made the decision to pursue a venture philanthropy model out of necessity. First, we could not accept the fact that children born with CF in 1955 often did not live to attend elementary school, and we recognized that for people with this disease, every second counts.

Second, while our progress since the Foundation's founding has been steady, it is not adequate. The life expectancy for people with CF is still far below the national average, and children are still dying each day from this disease.

Third, because the CF population is small, those companies that are successful in product development are far less likely to pursue the development of CF drugs that have an exceedingly small market for such products.

The needs of CF patients and the economics of CF drug development necessitated an aggressive and creative approach. By applying business concepts and collaborating with the biotechnology and pharmaceutical industry, the CF Foundation has quickened the pace of drug discovery and development. In the past 14 years, four cystic fibrosis therapies have been developed with support of the CF Foundation: Pulmozyme®, TOBI®, azithromycin, and hypertonic saline. The time taken for the development of Pulmozyme® – five years from test tube to use by cystic fibrosis patients – was less than half the industry average. In addition, our research and development program has yielded a robust pipeline of 30 potential therapies.

At the heart of this effort is the Therapeutics Development Program, through which the CF Foundation functions much as a venture capitalist would, directly investing in the research and development of new CF therapies. We have invested over $660 million in our research and medical programs, and in 2009 we will invest $26 million in CF research at biotechnology companies for the development of new drugs. Our venture philanthropy approach, recognized by the National Institutes of Health (NIH) and by

publications such as *Business Week, Harvard Business Review, USA Today, Forbes* and *The New Yorker,* encourages private firms to become engaged in CF research and development by addressing some of the risk associated with the small patient population and the resulting limited market.

Through this aggressive research program, the CF Foundation has made significant progress in the treatment of CF. The median age of survival is now more than 37 years, more than double what it was just 25 years ago, and more than seven times what it was when the CF Foundation was established in 1955. Yet we have more to do. The pipeline of 30 potential therapies includes some aimed at treating the symptoms of the disease and others intended to correct the genetic defect that causes CF. Testing these therapies and others will require substantial resources, and it is imperative that all potential sources of funds be available to advance research and development of these treatments.

We are fortunate to have so many therapeutic targets to pursue, yet we are racing the clock to develop new CF therapies. Despite our successful fundraising efforts, we cannot pursue all of the promising research opportunities before us without help and without partners. Other research foundations engaged in basic, translational and clinical research are facing challenges similar to ours. Those foundations that are successfully moving new compounds through testing are struggling during the recession, and those with fewer compounds in clinical tests face challenges in financing their basic research efforts intended to identify such compounds. In short, all research foundations are attempting to meet the needs of their patients for new therapies in a daunting economic environment. The need for strong partners, including partners who have SBIR funding, has never been greater.

The SBIR program reflects our fundamental philosophy of building viable and creative partnerships to accelerate the development of new therapies. SBIR grants are particularly important for companies pursuing the early discovery phase of drug development, a period of research for which it is especially difficult to secure funding. SBIR-funded research entities often enjoy a productive synergy between SBIR funding and venture capital funding. Small biotechnology companies are able to use SBIR funds in combination with funding from other sources, including non-profit organizations like the CF Foundation, to overcome the most vulnerable stages of development. Likewise, biotechnology companies that secure SBIR funds make themselves more attractive to outside investors.

SBIR grants often offer critical support for innovative early-stage research, much as our venture philanthropy support does. Like our model, SBIR grants provide the support companies need to prove their research concept. Once a company passes this hurdle, investors are more willing to invest to bring therapies to market.

The SBIR program has been a success, and the need for it has never been greater. We urge some changes to the administration of the program to ensure that it meets its fundamental goals and supports research in fields that would otherwise be neglected because of small markets or obstacles to research.

The current ownership rules for small businesses must be revised. In addition, the program rules should be amended to dedicate a percentage of SBIR funds to research on orphan diseases, as early stage research on these diseases is understandably not an attractive target for pharmaceutical and biotechnology companies. We applaud the House Small Business Committee for its past and ongoing efforts to address each of these issues.

Amend Ownership Rules

One of the chief obstacles in our quest for a cure for CF is the availability of adequate financing for research and development of new treatments. Historically, access to SBIR funding has contributed to the ability of biotechnology companies to remain engaged in CF product development.

Unfortunately, in recent years the CF Foundation has directly observed a decline in the number of firms that are engaged in CF research and are also receiving SBIR funding. Some firms with promising CF therapies report that they are disqualified from receiving SBIR funds due to their receipt of venture capital support. Although there appears to be some disagreement about the overall impact of the ownership rule on the number of SBIR applications submitted by medical research entities, the direct experience of the CF Foundation suggests that the impact has been significant.

While we understand the need to ensure that the SBIR program truly supports small business entities and protects against abuses of the program, we find that the ownership rule has had the no doubt unintended impact of disqualifying from the SBIR program those small business entities that hold the greatest promise of partnering with the CF Foundation to bring new therapies to market. It has been our experience that those small businesses that are able to obtain venture capital funding are our strongest partners, yet those partners still need both CF Foundation and SBIR support to be able to advance their development work. As we previously described, our therapeutic development model requires support from a variety of sources. The loss of any source of financing can have a significant adverse impact.

We applaud the efforts of the Committee to address the ownership rule through legislative change and agree that the focus should be on the control of the small business rather than strictly on venture capital investment. We can again cite the experience of the CF Foundation to underscore that our potential partners that have lost SBIR eligibility clearly meet other requirements of a small business entity, including the fact that they retain independence in management and other decisions. In our experience, the SBIR ownership rule is disqualifying small businesses that are the intended target of the program.

Our experience is supported by findings from a National Research Council report on venture funding and the NIH SBIR program. This report concluded that the ownership

rule disproportionately affects firms with demonstrated potential for commercializing their drug products. The report found that firms that had venture funding were less likely to bring their products to market than those firms that were not venture-funded. When the venture-funded firms did commercialize their products, they were much more likely to generate substantial sales from their SBIR-funded projects.

The CF Foundation considers its best partners those that have been able to attract venture capital investment and SBIR funding. Venture capital funding, like SBIR funding, is often an indication that a small company has a strong and sophisticated management and development team. This factor, combined with the availability of venture capital and SBIR funds to supplement those provided by the CF Foundation can define these firms as solid R&D partners, with an increased likelihood of success.

Provide a Special Focus for Orphan Diseases

Twenty-five years ago, Congress recognized the need to encourage research and development related to rare diseases – those affecting fewer than 200,000 Americans – by passing the Orphan Drug Act. Since that time, Congress has reaffirmed its commitment to this research by creating incentives to companies that develop orphan drug products and providing discretionary funding for research on orphan diseases. These initiatives have proven successful, as measured by the development of new therapies for a number of rare diseases.

The existing rare disease research programs could be significantly strengthened by ensuring the availability of funds for orphan disease research and development through SBIR. This funding would help reduce a financing problem facing companies that are moving beyond basic research on an orphan drug product but are not yet able to commercialize their product.

The risks related to the research and development of new therapeutic products are substantial and far greater for development of an orphan drug than a conventional drug. The rewards for development of an orphan drug are also limited by the size of the market. This combination of factors argues against industry involvement in orphan drug research, so incentives must be created for drug development companies.

The venture philanthropy efforts of the CF Foundation have been essential in attracting companies to orphan drug research as well as keeping companies in the field. Our support alone is not adequate to retain the attention of those who have shown interest in CF research or to encourage new entities to join the effort. Although we pride ourselves on our successes, we are acutely aware that there are many diseases that do not enjoy the strong private and venture philanthropy support that the CF Foundation provides for cystic fibrosis.

An appropriate solution to this problem would be to set aside a portion of SBIR funds at NIH for support of biotechnology companies focused on orphan disease research and

development. We believe that a set-aside total of 10 percent of SBIR funds at NIH would represent an important investment in rare disease research. This approach is fully consistent with the fundamental goals of the SBIR program to increase the commercial application of federally supported research and to stimulate technological innovation in the private sector. We also believe this modest targeting of funds to rare diseases might have the added benefit of encouraging applications from small business entities that have a specific interest in rare diseases but have never been SBIR applicants.

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The Cystic Fibrosis Foundation lends its strong support to reauthorization of the SBIR program. This program facilitates partnerships that are critical for development of new treatments for CF and hundreds of other diseases. Targeting a modest portion of SBIR funds to rare disease research holds the potential of attracting new companies to rare disease research and providing new therapies to patients with few options and in dire need of new treatments.

We look forward to the opportunity to talk to you in greater detail about these proposals.

TESTIMONY OF JOHN J. STOCKER
SENIOR VICE-PRESIDENT
LYNNTECH, INC.

Before

THE HOUSE SMALL BUSINESS COMMITTEE

On

Reform of the Small Business Innovation Research Program

Washington, D.C.
17 June 2009

Madame Chairwoman Velazquez, Mr. Graves and Members of the Committee, it is with great pleasure that I appear before you today to offer Lynntech's views on the proposed legislation to reform the Small Business Innovation Research Program (SBIR). Lynntech, headquartered in College Station, Texas, is the largest SBIR contractor in the State and one of the largest in the country.

Let me take a moment to thank you, Madame Chairwoman, for your leadership on this issue. It is certainly not easy to create consensus on an important program like this when so much of the debate has been formed out of emotion, rather than from clear and rational debate. You are to be congratulated for persevering in the face of negativity.

The proposed legislation is also the product of hard work and thought generated by your staff. Contrary to the comments of the opposition, this legislation has not been rushed through a process of dictatorial powers, but rather from the input of all parties to ensure that change is accomplished in a thoughtful way.

Lynntech would also like to announce its intention of forming a new coalition of SBIR companies that agree with our view that reform requires access to all capital sources and that technology transition should be the centerpiece of the program. This new coalition will be known as The Council on Small Business Innovation and Research (CSBIR) and is intended to provide SBIR firms an opportunity to present an alternative viewpoint to the Congress on the issues of the day. This action, which has been undertaken within the past few days, we believe will lead to an organization of sufficient size to lend credence to its views.

For the moment, Lynntech will articulate its views on behalf of that coalition of interests. As noted earlier, Lynntech is one of the largest SBIR firms in the country and has a wide diversity of research projects and patents that it currently holds. While two-thirds of Lynntech's research dollars are sourced out of the Defense Department, we have performed research for nearly all of the agencies that control SBIR dollars. Lynntech was founded in 1989 by two former faculty members of Texas A&M University. Lynntech's primary objective is to intensify its efforts to transition the many technologies the company has developed into the marketplace. These technologies are concentrated in the areas of electrochemical synthesis, energy storage and conversion, chemical/biological defense systems, and environmental remediation.

As a result, Lynntech's interest in the debate regarding the SBIR Reform legislation is quite high as our efforts to transition technologies will be driven by the framework of future reforms.

As we have stated many times, we believe that, with all due respect, that last year's debate did not focus on the right set of issues. SBIR firms need the opportunity to access all sources of capital to be successful in the one principal that should guide the SBIR program and that is the success of moving technology into the

marketplace. Ownership of SBIR companies by venture capital firms should not be guiding our discussion regarding reform of the program. In fact, venture capital firms and other private capital resources should be available to SBIR firms to grow their technology development efforts. The only ground rule should be that large corporations should not directly benefit from a small business program. The issue that the debate should be focused on, in Lynntech's opinion, is that of technology transition.

The VC Issue

The proposed legislation does, in fact, begin to address the issue of capital sourcing by allowing SBIR companies majority-owned by venture capital firms the opportunity to compete for SBIR contracts. Let me underline the word, compete. Madame Chairwoman, your critics frequently state that your objective is to attain 100% control of the SBIR market by majority VC-owned firms. The proposed legislation does not say that; what it does do is to allow for the competitive marketplace to be opened to those small businesses, that would otherwise qualify, where their majority ownership lies in the hands of venture capital firms.

Also, contrary to your critics, you do not allow unfettered access to this market for large VC firms. Large VC firms can comprise no more than 20% of the SBIR company. No SBIR firm would be opposed to a major company such as Pfizer, Lockheed, or Boeing taking a stake in their company if there existed the possibility of eventually transitioning technology to the marketplace.

In fact, Lynntech is concerned that its ability to raise capital in the private markets could be damaged by the continued prohibition on majority ownership by VC firms. If Lynntech had had a capital infusion that would have transferred majority control to a VC firm, it would no longer be eligible for SBIR and the country would be effectively denied the achievement of new systems and technologies that improve the safety and well-being of the country.

Therefore, the proposed legislation makes it clear that in all other respects the SBIR firm must continue to meet the size standards of the SBIR program with the one caveat that it can have up to 20% of its capital provided by large corporate entities.

Again, as long as the program is not opened up to participation by large corporate entities, Lynntech believes that ownership should not be the central issue of the reform effort.

Technology Transition

Lynntech is pleased that Title II of the proposed legislation clearly indicates that the policy of the Congress is that the SBIR program should focus on the development of projects that have potential for transitioning to the market.

Lynntech applauds this objective and believe it is key to the efforts undertaken for SBIR reform. The proposed legislation further establishes a reporting mechanism for Federal agencies to report on the success of their commercialization efforts. This last provision is especially key as much of the reform debate has been hampered by inadequate data.

The proposed legislation also establishes a process whereby technology transition efforts would be supported by Phase III funding. The definition of what constitutes Phase III is clearly outlined and the agencies are given a number of tools to use in the achievement of Phase III objectives.

Lynntech supports the authorization of funds for this Phase III effort, although we would argue that additional resources will be needed and believe that a $100 million authorization would go a long way for supporting continued development. The proposed legislation also permits the creation of a funding vehicle that will help defray the cost of managing the SBIR program. This will help offset the complaint often heard that SBIR is simply a "tax" on appropriated dollars.

The proposed legislation also fosters increased contacts between local economic development organizations, prime contractors, and venture capital companies. All of these efforts are intended to increase the knowledge base of the technologies and innovations that have been developed by SBIR firms and are vitally needed in order for those firms to eventually commercialize their work.

In order to ensure that the program objectives of attainment of maximum technology transition, Lynntech believes that standards must be set as to how many contract awards are made without successful transition to Phase II or Phase III efforts. The proposed legislation does, in fact, seek to address this issue.

Finally, Lynntech has long argued that the SBIR program should be part of a broader Federal Government program to support research and development. The proposed legislation would direct the establishment of an interagency policy committee that would set policy for the SBIR/STTR program, collect data, and analyze the impact of this legislation.

Programmatics

Lynntech also supports the retention of Phase I, but agrees with the objective of allowing some privately funded research to compete for Phase II awards. The proposed legislation allows for this step to be undertaken.

Award caps are increased to $250,000 for Phase I and $2 million for Phase II contracts in the Committee proposal. This is also long overdue as Lynntech has observed the frustration of both the Government technical monitors and our own researchers at the small size of the awards. Not enough research can be conducted within the present award sizes.

Concerns

There are a couple of shortcomings with the proposed legislation as is presently configured.

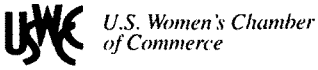
First, the allocation of extramural R&D funds has not been increased for the SBIR program. The current level of 2.5% is no longer adequate to underwrite the myriad of worthwhile projects that the SBIR community can undertake. Lynntech believes that an increase of the allocation to 3.75% would make some sense.

Second, the SBIR program would only be extended for two years. Lynntech believes that this would be a mistake as it normally takes two years for the dollars to be allocated and contracts awarded. A five year authorization would allow for sufficient date collection and analysis to allow the Committee to fully see the impact of their proposed changes. Therefore, Lynntech would support a five year re-authorization.

Summary

Despite a couple of concerns, Lynntech believes that, in general, the proposed legislation goes a long way to achieving the SBIR reforms that are so desperately needed. The twin objectives of achievement of multiple sources of capital and accelerating the technology transition process have been addressed in the proposed legislation. Lynntech is also confident that a middle ground on the allocation increase and the extension of the authorization can be achieved.

We thank you for the opportunity to present our views.



Testimony
of
Ning Li
PD Inc.
on behalf of the
U.S. Women's Chamber of Commerce

Before the House Small Business Committee

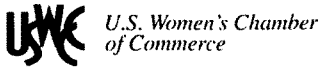
"Legislative Initiatives to Strengthen and Modernize the SBIR and STTR Programs"
June 17, 2009, 10:00 AM

Chairwoman Velázquez, Ranking Member Graves, Members of the Committee. I am here today as a member of the U.S. Women's Chamber of Commerce representing our 500,000 members. Over three-quarters of our members are small business owners, many of whom are active contributors to high-tech innovation including research and development for both the federal and commercial sectors.

My firm, PD Inc., is an innovative technology firm and a Small Business Administration designated HubZone Small Business, located in Baltimore, Maryland. The firm was founded in 2001 for the purpose of inventing technologies that are the first to effectively solve existing technical problems that are of significant social and economic impact. I am especially pleased to have the opportunity to provide testimony for the Committee today as my firm has had direct experience with the SBIR program.

Since the year 2004, PD Inc. has devoted major human and monetary resources into the R&D activities of voting technology. Our research has focused on a holistic design of a new breed voting machine that would address problems existing in current voting technologies in order to accommodate all stake-holders, such as election officials, voters, and the federal government, in theirs needs of having an easy to manage, easy to use, accurate, fair, transparent, and verifiable election process. One of the sub-components of our design is an essential innovation in addressing security problems which have been a main contributor to social controversial and public scrutiny in the past years.

At the beginning of 2008, we discovered the SBIR program and identified that the SBIR opportunity at the National Science Foundation could be of benefit to our specific innovation. The SBIR application process is complex in its requirements of documentation, one of which is a letter from an existing or potential customer to support the invention of such technology.



However, our customers would generally be county and municipal election officials who, given that they are public sector personnel, cannot "endorse" a product or technology marketed by a particular commercial entity. Therefore, the state and local election officials who we had contacted, and who had initially displayed a good bit of enthusiasm when we first described the features of our design, later were reluctant to provide the correspondence that we needed to complete the SBIR application. As the application deadline was rapidly approaching, we did not have enough time to follow-up with these election administrators to allay any endorsement-related concerns. Therefore, we decided not to file our application at that point.

Our research continued in the latter half of 2008. We proved that the prototype we built is economically viable and there hasn't been such a device in the commercial space. At this point we were beyond Phase I in the R&D process, but we still need money to build it. Phase II of the SBIR award would solve our funding needs. However, we are not eligible to apply because we haven't gone through Phase I. If we apply for Phase I it is not only dishonest it also would waste precious human and monetary resources to repeat procedures that have already been done.

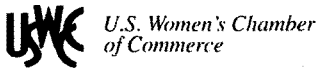
Our experience has motivated us to recommend to the Committee that small enterprises, which are able to secure independent validation of their technology, should be allowed to bypass Phase I and apply directly for Phase II assistance. We support legislation that does not permit businesses to evade Phase I of the SBIR program, but does allow an exception to be granted for companies that can demonstrate to agency SBIR proposal evaluators that the company has fully completed phase one work.

For example, SBIR program participants that have already demonstrated "proof of concept" utilizing their own financial resources, in addition to having acquired validation through peer review conducted by a recognized subject matter expert, should be allowed to "opt out" of Phase I and go directly into Phase II. Such an expert could be affiliated with an accredited academic or research institution. This would save the innovators time, and enable them to adhere to their schedule of innovation.

Our experience also leads us to the following additional recommendations.

Acquisition of the services of a patent attorney should be recognized by all federal agencies, as an eligible expenditure under both Phase I and Phase II.

Efforts should be put into place to protect small businesses' rights to intellectual property. The U.S. Small Business Administration (SBA) should be directed to promulgate regulations, which would be binding on the large, industrial partners of SBIR program recipients, to protect small innovators' interests in intellectual property during the process of applied research collaboration. For example, a standard Non Disclosure Agreement (NDA) could be drafted by the General Council Office of SBA, which large prime personnel could be required to sign before requesting small business innovators disclose their intellectual property information.



A code of conduct should be established to regulate large prime personnel's behavior when it comes to handling small business innovators' intellectual property.

SBA administrators should also direct all the participating federal agencies to proactively assist their SBIR program recipients' efforts in protecting their intellectual property.

Additionally, SBA should set aside resources to work with SBIR recipients, and perhaps also with the U.S. Patent & Trademark Office (USPTO), to assist these businesses with the filing of patent applications.

We strongly support the venture capital provisions detailed in the legislation under consideration which permits SBIR awardees to receive venture capital. Venture capital participation and partnerships are vital to advancing innovation and linking small business innovation and research to capital and market opportunities.

However, we must make sure there are safeguards within the legislation, the regulations and the practical application of the rules and relationships to protect small businesses and the SBIR program from exploitation by larger businesses and venture capitalists. We support clearly maintaining majority ownership and board representation by the small firm. And, we need rules and practical methods to protect innovation, intellectual property rights, and assist with patent services.

Thank you again for the opportunity to provide input here today. We applaud the work of this committee to energize research and innovation within the small business community and assist with the transfer of this innovation to the federal government and commercial sectors.

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Written Testimony for
The U.S. House of Representatives
Committee on Small Business

"Legislative Initiatives to Strengthen and Modernize the SBIR and STTR Programs"

June 17, 2009
10:00am
2360 Rayburn House Office Building

Derek K. Rapp
Chief Executive Officer
Divergence, Inc.
893 North Warson Road
Saint Louis, MO 63141
www.Divergence.com

Madam Chairwoman and Committee Members:

Thank you for the opportunity to appear before the House of Representatives Committee on Small Business and to offer my testimony to address the initiatives to strengthen and modernize the SBIR and STTR programs. My name is Derek Rapp, and I am the CEO of Divergence, Inc., a biotechnology research company located in St. Louis, Missouri.

I am a strong proponent of the continued awarding of SBIR grants. Such grants have made and continue to make a fantastic difference for Divergence.

First, I will provide a bit of background. Divergence has 27 full time employees who are focused on discovering safe and effective products for plant protection, animal health, and human health. Divergence's expertise lies in disciplines such as genomics, bioinformatics, parisitology, and nematology. Divergence has discovered both chemicals and plant genes that have the potential to be commercialized in various markets. Most of the products arising from Divergence's research are focused on the identification, treatment, and prevention of parasitic infections caused by roundworms (also known as nematodes).

Parasitic nematodes cost growers an estimated $7-9 billion in the U.S. each year, as much as $100 billion each year worldwide. These losses come in the form of reduced crop yields caused by the weakening of crops as a result of damage done to the plants by parasites. Parasitic nematodes are also a major problem for animals and humans causing significant morbidity.

Life sciences companies often have a much longer product development cycle than a typical small business, as they must conduct the initial discovery research, perform several years of product safety testing, and wait for a multi-year approval process in order to bring products to market. For example, many different sources estimate that the average time for a new drug to reach the market from the time of its discovery is between 10 and 15 years. As a small business focused on research and development in the life sciences, Divergence has a business plan that allows for funding of research during the significant amount of time it takes to get a product to market. Divergence funds operations through private investments, third party licensing and research agreements, and grant funding. Divergence relies on all of these funding sources to maintain operations.

Divergence began operations in late 1999 and has raised roughly $21 million in equity financing during its nearly ten years in business. Investors include a group of sophisticated angel investors along with two venture capital funds. Corporate relationships for licensing and research have added more than $7 million in revenue. The final source of funding for the Company has come through grants, totaling nearly $7.6 million since inception. In addition to SBIR grants, Divergence has benefited from significant funding from the National Corn Growers Association.

The relationship that NCGA and Divergence have had for the past several years has been extremely positive, and, we hope, will lead to new yield-increasing technologies reaching the market for corn growers in the coming years.

A significant portion of grant funding to Divergence (approximately $5.5 million) has come in the form of SBIR grants through the National Science Foundation, the National Institutes of Health and the United States Department of Agriculture. Divergence has applied for 48 SBIR grants in total, and 25 of these applications have been funded. Of these 25 funded applications, 15 were Phase I grants, 8 were Phase II grants, and two were follow-on grants (one NSF Phase IIB grant and one NIH Manufacturing Assistance Program grant).

Such funding does come at a cost however. Writing and submitting an SBIR grant is a time-consuming and expensive proposition for a company. We estimate that our team typically spends 120 to 150 hours writing and assembling an application. That time translates to more than $10,000 in salary. In addition, the time it takes to work on the application takes our scientists away from the bench, slowing the progress they are making on their research. This represents a significant commitment of time for a small business, especially when applying for a Phase I grant that may result in an $80,000 award from USDA or $100,000 from NIH or NSF.

A life sciences company such as Divergence faces many challenges. First, we have to identify a significant need that can be addressed. Second, we must be innovative, identifying a solution that is feasible, novel, and superior to all others throughout the world. It may seem arrogant or presumptuous to demand of ourselves the development of the world's premier product, but this is the necessary mindset in our markets which are global and which allow for the flow of intellectual property rights through collaborations with parties worldwide. Once we have discovered a strong product candidate, there remains extensive product development work to do, as well as toxicology and environmental testing. These efforts require tens of millions of dollars and many years before commercialization.

A shareholder takes significant financial risks in investing in a privately-owned life sciences company. As discussed, the timeline for product development is quite long, the demands for capital are high, and science poses many challenges. This is significant since in the case of a privately-held company, a shareholder has little opportunity for liquidity of his or her investment. Hence, less than half of such companies succeed, at least to the point of delivering significant returns to their investors. Any activities that a company can take to increase its chances for success and decrease shareholder dilution will help a company attract the necessary capital to succeed. The SBIR grants do exactly that.

SBIR grants play other important roles for small companies in addition to improving opportunities for financing. They provide a validation of the science. The fact that the granting

process includes peer review as a component of the program is quite significant. Investors, potential employees, collaborators and others respect this rigorous review process.

SBIR grants also provide an incentive and a source of pride to scientific employees. The work in such companies is long, difficult, and often frustrating. For every positive result, there may be several negative ones. Word of receipt of a grant provides a "shot in the arm" for a team.

I hope I have made the case for why SBIR grants matter so much to companies and their investors. However, I recognize that for you to believe that these grants are worth funding, you also need to know that they benefit the public more broadly. Importantly, for the application processes in which Divergence has been involved, there have been several questions for the applicant to answer regarding the impact of the work. We are asked about market size, competitive alternatives, currently available products, and commercial plans. Hence, the reviewers should be able to determine whether the project has social worth and whether it will lead to a product that has a good chance of reaching the market.

Additionally, there is general benefit to our economy to see innovation. Innovation is essential for the world to tackle major problems. Innovation is also essential for the U.S. economy to remain competitive with other countries around the world in the area of life sciences. Agriculture, and human healthcare, and veterinary medicine are global markets, and due to their attractiveness and social importance, many countries place a high priority on research into these markets. Small companies are an important source of innovation, and SBIR grants can enable such innovation here in the U.S. There are certain reasons why, arguably, small companies are especially innovative. Small companies often have higher tolerances for risk than larger companies, and smaller companies are not saddled with institutional momentum around existing projects that compete with new projects for resources. Hence, small companies are often more able to respond to changes in the technological and commercial landscapes. Of course, large companies can be and are a source of innovation also.

It is a time of great excitement and also of great responsibility for those of us in life sciences. Agriculture is under tremendous pressure to achieve improved yields and ensure the availability of crops for uses in food, feed, fiber, and fuel. Close to one billion people in the world are malnourished. Arable land has been decreasing at an annual rate of .3%, and global population has been increasing at an annual rate of 1.2%. Hence, the world needs annual productivity increases of 1.5% simply to hold even, not to mention providing additional food to the malnourished people of the world. The situation actually becomes even more challenging when we consider the fact that demand for agricultural output is actually increasing at a faster rate than general population trends. This is true for two main reasons. First, dietary habits are changing in certain regions, primarily Asia, toward increased protein consumption. This change requires additional crops to be grown for the feeding of the animals that will be the source of the protein.

Additionally, society increasingly is utilizing agricultural output for non-food applications – e.g., fuels and fibers. For example, in the United States, roughly a third of corn production will be used for ethanol in 2009. In all, global demand for agricultural outputs (food, feed, fuel) will double between 2000 and 2050. More efficient and safe agriculture must therefore be a high priority for U.S and international interests, and control of pests, including nematodes, is an important part of the equation.

I would like to address some specific items envisioned in the various currently proposed pieces of legislation associated with SBIR grants.

Sections 3 and 4 of the "SBIR and STTR Enhancement Act" are focused on enhancing a company's activities as it moves from Phase I to Phase II in the granting process. I applaud this move. If a project is sound enough to have received Phase I funding and leads to solid data for a Phase II application, it probably should be funded. A company that is failing at this step, for whatever reason, is missing out on a key opportunity; therefore, so too is our country, since this suggests that Phase I dollars did not lead to downstream projects. I would encourage the agencies to consider what are the most helpful ways to assist companies attempting to receive a Phase II grant. Merely generating some market research data and reviewing the business plan will not be sufficient in many cases, especially when the review work is done by someone who lacks expertise in the specific markets for which the funded project is targeted. Suggestions on how to advance the science and sophisticated, market-savvy assistance with the commercialization plan would be helpful. Doing this work in ways that are not overly burdensome on the recipient companies would also be appreciated, as the current processes demand a great deal of time and energy from the companies.

Section 12 of this act provides for an increase in the sizes of Phase I and Phase II awards. I recognize that there are trade-offs associated with larger awards – more grants funded versus more impactful grants. I am supportive of the proposed increase. The larger amounts would allow for more research to be completed in the Phase I stage, thus allowing for more thorough results and providing for a better supported Phase II application. The higher amounts for Phase II grants would also allow for significant progress to be made toward commercialization. Small businesses often do not have the funds to spend on the research and testing needed to bring a product to market; the larger grants would certainly help. In addition, small businesses typically apply some of their own funds towards a funded research product in order to complete the research as the Phase I or Phase II funds are often insufficient to cover the costs. The increased amounts would allow a small business to fund more fully the research with grant dollars so that they can then utilize their own funds for costs which are unallowable in a grant such as patent expenses.

Section 13 deals explicitly with the idea of a company being eligible for multiple Phase II grants simultaneously. If projects for SBIR funding are legitimately separate from one another, funding them both should certainly be deemed appropriate.

Section 3 of the "Investing in Tomorrow's Technology" Act relaxes the limitations on grant eligibility regarding venture capital firm ownership. Admittedly, this constraint has not posed problems for Divergence as our ownership profile has always been somewhat skewed toward individual investors as opposed to firms. Still, I acknowledge that a company that has multiple venture capital firms owning stakes in it should qualify for SBIR grant funding in many cases, and venture capital firms will respond favorably to their companies' receipt of grants, just as any investors would. In Divergence's case, the receipt of grant funds helped us reach the point of receiving venture capital investment. The relationship between grant money and venture capital is an important one.

I would like to make one additional point. For all of the good that the SBIR program does, it is important that all of us remember one thing that the program does not do, at least not in many cases. It does not take many products to the point of commercialization. The time period from the end of Phase II funding ends until commercialization of a product is almost always long. In the case of the life sciences industries, it is likely to last several years. As Congress contemplates funding for SBIR's, I hope that consideration will be given to helping companies bridge the large gap between discovery research and product commercialization. It is essential that the SBIR's continue to receive funding, so I am not trying to shift the focus from SBIR's. However, for the full impact of the program to be realized, there has to be sufficient support even after Phase II.

In summary, Divergence and many other small businesses are working hard to provide solutions to many of the challenges the United States faces today. As I have discussed, the work is difficult, and there are many obstacles that such companies need to overcome. Our scientists and our businesses need the support of the SBIR program and its program managers. We feel very strongly that the SBIR/STTR program provides an enormous value to small businesses, and thus, we enthusiastically support its extension.

Thank you for giving me the opportunity to convey this information and provide my views to this committee. Also, thank you for your efforts on behalf of a major piece of the American economy – small companies conducting innovative research toward the discovery and development of valuable, novel products.

Derek K. Rapp
Chief Executive Officer
Divergence, Inc

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