

SUBCOMMITTEE ON
HEALTHCARE & TECHNOLOGY
THE CREATING JOBS THROUGH SMALL BUSINESS
INNOVATION ACT OF 2011

HEARING
BEFORE THE
COMMITTEE ON SMALL BUSINESS
UNITED STATES
HOUSE OF REPRESENTATIVES
ONE HUNDRED TWELFTH CONGRESS
FIRST SESSION

HEARING HELD
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HEARING ON THE CREATING JOBS THROUGH SMALL BUSINESS INNOVATION ACT OF 2011

THURSDAY, APRIL 7, 2011

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
SUBCOMMITTEE ON HEALTHCARE AND TECHNOLOGY,
Washington, DC.

The Committee met, pursuant to call, at 10:00 a.m., in Room 2360, Rayburn House Office Building. Hon. Renee Ellmers [chairwoman of the subcommittee] presiding.

Present: Representatives Ellmers, Richmond and Peters.

Chairwoman ELLMERS. Thank you all for being here with us this morning as we discuss legislative legislation to reauthorize the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs.

I would especially like to express my gratitude to each of the witnesses who have taken time out of their busy schedules to be with us today. And on a personal note I would also like to thank Chairman Graves for giving me the opportunity as a freshman to chair this Subcommittee. That was very generous of him and the staff as well. They are so incredibly helpful and it is an honor to be sitting in this position, especially since this is my very first Subcommittee. So thank you all. And I will remember you always very fondly.

STATEMENT OF CHAIRWOMAN ELLMERS

Chairwoman ELLMERS. Small businesses are a major driver of high technology innovation and economic growth in the United States generating significant new jobs, new markets, and high growth industries. In this era of globalization, optimizing the ability of small businesses to develop and commercialize new, highly innovative products is essential for U.S. competitiveness and national security. This is why programs like SBIR and STTR are so important.

Created in 1982, the SBIR program was designed to increase the participation of small, high tech businesses in federal R&D endeavors. The driving force behind its creation was predicated upon the belief that while technology-based companies under 500 employees tended to be highly innovative, and innovation being essential to the economic well-being of the United States, these businesses were, excuse me, underrepresented in government R&D activities. By including qualified small businesses in the nation's R&D effort, SBIR grants and contracts stimulate innovative new technologies to help agencies meet the specific research and development needs of the nation in a wide variety of areas, including health, energy solutions, and defense.

It has been said that nobody has a patent in good, new ideas. While that is true, it can be difficult for an innovator or a small company with limited resources to take that idea and manufacture it into a new product or process. Programs like SBIR provide a bridge between product conception and marketability, a step of vital importance for innovative ideas to become reality. The new technologies and discoveries that come out of this program go a long way to keep the United States competitive edge in the world marketplace. And the SBIR program is the kind of public-private partnership that is essential to the continued growth of our economy.

In 2007, the National Research Council (NRC) of the National Academies of Science completed one of the most comprehensive examinations of the SBIR program. The study found that the SBIR program provides substantial benefits for participating small businesses at all agencies in a number of different ways. According to the NRC's study, the SBIR program is a significant job creation engine and considerable factor in the founding of new companies, helps to provide partnering and networking opportunities for small businesses, and provides the impetus to start projects that otherwise would not have gotten off the ground.

There is a very strong case for reauthorization of the SBIR and STTR programs. The discussion draft of legislation to reauthorize these programs that we have before us goes a long way toward modernizing and improving the SBIR and STTR programs. They have a proven track record of creating jobs, advancing innovative science in the marketplace, and solving federal agency problems. Our legislative goal is to strengthen these programs to ensure efficient use of taxpayer dollars that help create more jobs by targeting the best science. Moreover, the bill does not cost anything but rather sets aside 2.5 percent of all federal extramural research dollars for small businesses to compete for. Among other things, the draft would reauthorize the SBIR and STTR programs for three years, increase Phase I and Phase II award sizes for both programs, allow for greater participation of small companies regardless of their financial structure, and enhance data collection for the programs to help us provide accurate and consistent oversight.

Again, thank you all for being here today. I am eager to hear the testimony of our witnesses and I look forward to working with you, Ranking Member Richmond and Chairman Graves and Ranking Member Velázquez of the full Committee to reauthorize these important programs.

I now yield to Ranking Member Richmond for his opening statement.

[The information follows:]

STATEMENT OF RANKING MEMBER RICHMOND

Mr. RICHMOND. Thank you, Chairwoman Ellmers.

First, let me thank all of the witnesses for being here—Dr. Koenig, Dr. Link, Dr. Brewer, and Mr. Norem—for taking time out and coming to testify today on an issue that is very important and has the ability to continue to move this country forward not just in terms of innovation but the products that are created and the technology that is developed, make this country a better place,

saves lives, and all of those things that are very important to us, not only that but it also creates jobs. So thank you for doing that.

And Madam Chairwoman, small businesses have always been our nation's greatest innovators, developing new products and technologies. Whether it is new computer software or lifesaving medicine, small firms are vital to the technological breakthroughs that keep America competitive. The Small Business Innovation Research program has been an important mechanism for enlisting small firms to meet the U.S. government's research needs.

In my home state of Louisiana, entrepreneurs are receiving SBIR grants from NASA to work on geographic mapping technologies from Homeland Security to improve disaster response and from the National Science Foundation to improve online distribution of video content. Just yesterday I met with the president of Tulane University, Dr. Scott Cowen, who is also in my district, that informed me that their commercialization efforts are currently underway at Tulane thanks to SBIR.

In addition to Tulane in my district, the New Orleans Bio Innovation Center acts as a business incubator helping budding entrepreneurs turn ideas into products. The Bio Innovation Center is a cornerstone of Louisiana's commitment to nurturing biotechnology within the state. It is a component entity of a larger leadership of the Greater New Orleans Biosciences Economic Development District, now referred to simply as the Bio District New Orleans.

Beneficiaries of the work done in New Orleans' Bio District have made it clear that a sustained, longer term of reauthorization of SBIR is a priority for their membership. It is also a priority for me.

The discussion draft before the Committee represents an important first step in moving forward to reauthorize this initiative. How we go about modernizing SBIR will determine whether small firms continue making these kinds of valuable contributions to the American economy. As we develop this legislation and begin working with our Senate counterparts, we should keep a number of goals in mind for the program.

I have a central focus when it comes to SBIR. It is vitally important to reach an agreement that prioritizes a long-term reauthorization. The frequent short-term reauthorizations are disruptive to the planning efforts of SBIR stakeholders. The program is a proven job creator and a growth engine for small business. It is time to move forward.

I am satisfied that the draft bill, which we will be discussing today, mostly addresses my priorities with the SBIR program. I have identified other areas where I believe the bill could be strengthened. As the legislative process moves forward I warmly embrace the opportunity to work with my colleagues and our chairwomen on both sides to make sure that this piece of legislation can be one that the SBIR stakeholders are proud of.

Madam Chairwoman, risk-taking and innovation are prized values in America's entrepreneurial culture. Some of the most significant technological advancements that forever changed how we live our lives were developed not in the laboratories of big corporations but in the backyards and garages of entrepreneurs. The SBIR program is an important tool for fueling this creativity and in the process creating new jobs.

During the recession, while big companies were laying off its employees, it is estimated that the SBIR program helped spark the creation of more than 1,300 new enterprises. As the U.S. economy regains its footing, innovation will be crucial and SBIR grants can be a key ingredient in that equation. For all those reasons, it is important that while we are taking the painstaking care to reauthorize this program in a manner that works for our nation's small businesses.

I look forward to a thorough discussion today of the draft legislation and I want to thank the witnesses again for testifying. And with that, Madam Chairwoman, I yield back.

[The information follows:]

Chairwoman ELLMERS. Thank you, Mr. Ranking Member. And it is going to be a pleasure serving on this Subcommittee with you. Thank you so much.

If additional members have an opening statement prepared, I ask that they be submitted for the record. I would also like to take a moment to explain to you the timing light system. You will each have five minutes to deliver your testimony. The light will start out as green. When you have one minute remaining the light will turn yellow. Finally, it will turn red at the end of your five minutes. I ask that you try to keep to this time limit but I will be lenient if you are close to finishing. So, thank you.

STATEMENTS OF GLENN NOREM, EXECUTIVE CHAIRMAN, TOTUS LIGHTING SOLUTIONS, INC., ON BEHALF OF THE AUSTIN, TEXAS CHAMBER OF COMMERCE; DR. TERRY BREWER, PRESIDENT, BREWER SCIENCE, INC.; DR. ALBERT LINK, PROFESSOR, DEPARTMENT OF ECONOMICS, BRYAN SCHOOL OF BUSINESS AND ECONOMICS, UNIVERSITY OF NORTH CAROLINA, GREENSBORO; DR. SCOTT KOENIG, PROFESSOR, UNIVERSITY OF NORTH CAROLINA AT GREENSBORO, ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION.

Chairwoman ELLMERS. Okay. At this moment I would like to start off with Mr. Glenn Norem. He serves as executive chairman and cofounder of Totus Solutions. I am hoping I said that correctly. Okay. Incorporated. His company provides advanced lighting and security solutions for safety, security, and surveillance applications primarily to government agencies. Mr. Norem has also served as executive chairman of eeParts, Incorporated. He received a Bachelor of Science degree in Electrical Sciences and System Engineering from Southern Illinois University and an M.B.A. from University of Chicago's Booth School of Business. Thank you for being here today.

STATEMENT OF GLENN NOREM

Mr. NOREM. Thank you. Good morning, Chairwoman Ellmers and Ranking Member Richmond, members of the Subcommittee and ladies and gentlemen. It is an honor to be up here before you, and I commend your Committee for the contributions that you have had to the growth of our economy, the creation of new jobs, and the fostering of innovation in the United States. Thank you for the introduction.

Totus was founded in April of 2009. We manufacture intelligent lighting-based security platforms that are deployed and establish electronic security grids to protect the citizens of our country, strengthen our defenses, and to improve the response to incidents in their jurisdictions. I am also the founder of eeParts, a supply chain services company with operations in Texas and in China. I cofounded ViewCast prior to that, a provider of streaming and media technologies. Prior to ViewCast, I was general partner of two successful venture capital firms focused on early stage and start-up investments.

Totus was started by two serial entrepreneurs, again, to build these security platforms. It is an integration of secure wireless communications, video surveillance, and sensor monitoring arrays. The surveillance and sensor grids enable customers to provide an advanced level of physical security to their installations and superior response to incidents that occur in their jurisdictions. I am also here representing the Austin Chamber of Commerce. The Austin Chamber represents a five county region in central Texas and more than 2,400 businesses with a wide range of industries and sizes.

Entrepreneurs, innovation, and access to capital. Certainly not all small businesses require investment capital from third party resources to be successful, and many successful firms have been built solely with money from friends and family and from individual investors. However, many emerging growth companies require significantly more capital and will receive that from one or more venture capital funds. It has been my professional experience that the relationship between entrepreneurs and the venture capital professionals has contributed to unparalleled success of innovation and jobs for our nation in the last 30 years.

The seeds of our nation's venture capital industry actually began with the Small Business Administration and their SBIC programs in the 1970s. Venture-backed companies generally benefit from both the venture capital's money, their investment, and the business development expertise of their professionals as the entrepreneurs strive to grow our businesses in today's fast paced, globally competitive environment.

The SBIR program has fostered innovation and new job creation, and it is important to Totus as it is with many other small businesses in this country because it keeps us and enables us to stay close to our federal agencies, such as the Department of Defense, Department of Homeland Security, to create solutions to meet the critical needs of their organizations and the missions to protect our citizens.

The SBIR program is a powerful catalyzer for innovation and a driver of the American economy. As an example of that, my co-founder and colleague, Steven Chen previously founded 3eTI and was a recipient of Phase I, Phase II, and Phase III SBIR grants which led to the invention and commercialization of the first FIPS-140 secure wireless technologies, products that were used by the Department of Defense and other U.S. agencies. Historically, our country has benefitted greatly from the successes of our entrepreneurs as they grew in new businesses, high tech businesses with innovative products creating new companies, new industries, and new jobs that have been proven to be vital to our economy.

New company formation and access to capital has been difficult in the last few years. To fulfill our ambitious goals, new companies like Totus require both talent and investment capital. In the formative stages, the investments need to be secured before the firm recruits talent. Unfortunately for Texas, the current SBIR rules handicap our access to investment capital by prohibiting our participation in the SBIR program if we accept venture capital investment.

While we have been successful in raising debt and equity capital from individuals, the high visible stock market crashes of the last decade have had a negative effect on individual investors that have historically provided angel capital. What that means for Totus, like many other small businesses hindered by the current situation, is that we spend more executive time and resources raising capital which translates to slower growth for our businesses and limits the creation of new jobs.

In conclusion, it is most confounding to me that the venture capital-supported companies have been barred from participating in the SBIR program because the entrepreneurs, the SBIR program, and the venture capital community at-large have been solidly aligned in their interest in commercializing technology, in their missions with spurring innovation, and in the growth of new, commercially successful businesses. It is well understood that entrepreneurs and their companies are dependent on access to capital, and no other single factor more thoroughly determines whether a business will be successful.

I trust that my comments have both reaffirmed both the value of the SBIR program and the need to remove barriers or obstacles to access to capital for entrepreneurs as we seek to secure capital from all available sources.

Thank you for this opportunity to appear before the Committee.
[The statement of Glenn Norem follows:]

**HEARING TESTIMONY**

**GLENN NOREM
EXECUTIVE CHAIRMAN
TOTUS SOLUTIONS, INC.**

ON BEHALF OF

THE GREATER AUSTIN CHAMBER OF COMMERCE

BEFORE THE

**HOUSE OF REPRESENTATIVES COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON HEALTHCARE & TECHNOLOGY**

“CREATING JOBS THROUGH SMALL BUSINESS INNOVATION ACT OF 2011”

APRIL 7, 2011

Introduction

Good morning Chairwoman Ellmers and Ranking Member Richmond, Members of the Subcommittee, ladies and gentlemen. It is an honor to appear before your Committee today to testify about the Small Business Innovation Research (SBIR) program. The Members of this Committee are to be commended for your contributions to the growth of our economy, to the creation of new jobs, and to fostering innovation in the United States of America.

My name is Glenn Norem, and I am the Executive Chairman and co-founder of Totus Solutions. I am here representing Totus Solutions and the Austin (Texas) Chamber of Commerce.

Totus Solutions, founded in April 2009, is the manufacturer of intelligent, lighting-based security platforms that are deployed to establish electronic security grids to protect the citizens of our country, at home and abroad, and to strengthen our defenses and improve the response to incidents that occur in our communities.

I am also the founder of eeParts, a global provider of supply-chain services with operations in Texas and in China. Previously, I co-founded another innovative, systems-based company, ViewCast, a provider of streaming media technologies. Prior to ViewCast, I was a general partner of two successful venture capital funds focused primarily on investing in start-up and early-stage companies.

Totus Solutions

Totus Solutions was founded by two “serial” entrepreneurs to engineer, manufacture, and market intelligent, lighting and security platforms, based on energy-saving light emitting diodes (“LED”). Totus’ *Guardian Security Platforms™* are the integration of secure wireless communications, video surveillance, and sensor monitoring technologies on an intelligent LED lighting platform.

Surveillance and sensor grids enable customers to provide an advanced level of physical security and a superior response to incidents and situations that arise in their jurisdictions.

Totus’ *Guardian Security Platforms™* provide a highly-reliable, integrated security platform that enables the rapid, affordable deployment of surveillance and sensor grids to monitor pedestrian and vehicular traffic, campus activity, and to provide for perimeter security.

The Greater Austin Chamber of Commerce

The Austin Chamber of Commerce represents a 5-county region in Central Texas and more than 2400 businesses from a wide range of industry sectors and sizes. The Chamber administers Opportunity Austin, an economic development initiative launched in 2004 aimed at fostering job-creating investment in the region that would generate 72,000 new jobs and increase payroll by \$2.9 billion in 5-years. The Austin regional business community committed \$14.4 million to implement the strategy, and today, regional employment growth has far surpassed expectation, adding an estimated 123,400 new jobs to Austin's economy and increasing regional payroll by \$5.6 billion.

Through an agreement with the state, the Austin Chamber also manages the Texas Emerging Technology Fund's (ETF) Central Texas Regional Center for Innovation Commercialization (RCIC) which covers a 15-county region and facilitates capital formation for technology startups to fund innovation. Additionally under the auspices of the Greater Austin Technology Partnership, the Chamber is executing a new major initiative to harness the expertise of Austin's technology gazelles and galvanize their stewardship to ensure Austin's innovative and entrepreneurial communities continue to thrive.

Entrepreneurs, Innovation, and Access to Capital

Certainly not all small businesses require investment capital from third-party sources to be successful; and many successful firms have been built with capital solely from friends and families or from individual investors. However, many emerging-growth firms that require significant investment capital will receive an investment from one or more venture capital funds.

It has been my professional experience that the symbiotic relationship between entrepreneurs and the venture capital professionals that assist small businesses in their investment portfolios (providing both the essential investment capital for growth and their business development expertise) has contributed to the unparalleled success of innovation and jobs for our nation in the last 30 years. The contributions of venture capital in 2009 alone accounted for 21% of the U.S. GDP¹, which is even more surprising when you take into account that most venture capital companies are small businesses with fewer than 12 employees² and much less access to capital than commonly believed.

¹ Venture Impact: The Economic Importance of Venture Backed Companies to the U.S. Economy -A joint study by the National Venture Capital Association and IHS Global Insight Copyright 2009.

²Venture Funding and the NIH SBIR Program. National Research Council (US) Committee for Capitalizing on Science, Technology, and Innovation: An Assessment of the Small Business Innovation Research Program; Wessner CW, editor. Washington (DC): National Academies Press (US); 2009.

The seeds of our nations' venture capital industry actually began with the Small Business Administration and its Small Business Investment Companies (SBIC) programs of the 1970's and the many SBIC professionals that later managed venture capital funds.

Venture capital-backed companies generally benefit from both the venture capital investment and the business development expertise of the venture professionals as the entrepreneurs strive to grow their business in today's fast-paced, globally-competitive environment.

The SBIR Program Fosters Innovation and New Job Creation

The SBIR program is important to Totus, and many other small businesses across the country, because it enables us to work closely with the federal agencies such as the Department of Defense and the Department of Homeland Security to create solutions to meet the critical needs of their organizations and their missions to protect our citizens.

As the largest funder of federal research and development in the country, the SBIR Program is a powerful catalyzer for U.S. innovation and a driver of the American economy. SBIR grants have funded many successful projects that sparked the growth of numerous, innovative products when fully commercialized. These new companies have created new jobs, new technologies, and, sometimes, entirely new industries in our country.

As an example, my colleague and co-founder of Totus Solutions, Steven Chen, was previously the founder of 3eTI Corporation, a recipient of Phase I, Phase II, and Phase III SBIR awards which led to the invention and commercialization of the first FIPS-140 secure, wireless (WiFi) communication product for use by the Department of Defense and other U.S. Agencies. As an example, this (FIPS-140) secure, wireless technology has enabled the rapid and economical deployment of mission-critical communications for the U.S. Navy and other federal agencies where wireless communications had been previously prohibited because of the poor security of commercial WiFi systems.

Previously isolated from their command when they penetrated the deepest holds of a foreign ship, today Navy Seals utilize secure wireless communication relay points (dropping them like bread-crumbs along their path) to communicate their activities back to the command center when they are asked to board a foreign vessel at sea. Tomorrow, firefighters will rely on similar technology for command and coordination when they enter a burning building.

The Totus management team firmly believes that the Small Business Innovation Research program will be important to the success of our business – because it keeps us close to the ever-changing needs of our federal, state, and local government customers and the agencies charged with protecting them.

Many entrepreneurs, like the founders of Totus, start new businesses based on innovative product concepts. Historically, our country has benefited greatly from the successes of our entrepreneurs as they grew new, "high tech" businesses with innovative products and services, creating new companies, new industries, and new jobs that have proven to be vital to our economy.

New Company Formation and Access to Capital

To fulfill our ambitious goals, new companies, like Totus, require both talent and investment capital. In the formative stages, the investment needs to be secured before the firm recruits and retains its talent. Unfortunately, for Totus, the current SBIR rules handicap our access to investment capital by prohibiting our participation in the SBIR program if Totus were to accept venture capital investment.

While we have been successful in raising debt and equity capital for Totus from individuals (accredited investors), the highly-visible stock market “crashes” of the last decade have had a negative effect on the individual investors that have historically provided “angel investment” capital.

What this means to Totus, like many other small businesses hindered by the current situation, is that we all spend more executive time and resources raising capital because it is generally secured in smaller amounts from individual investors – which translates to slower growth of our businesses and limits the creation of new jobs.

Conclusion

In conclusion, it’s most confounding that venture capital-supported companies have been barred from participating in the SBIR programs... because the entrepreneurs, the SBIR program and the venture capital firms are solidly aligned in their interests in advancing and commercializing technology, in their missions of spurring innovation, and in growing new commercially, successful businesses. Venture funding seems to be positioned as a liability rather than an asset to entrepreneurs and to a potential SBIR funding recipient.

It is well understood that entrepreneurs and their young companies are dependent on access to capital; and no other single factor more thoroughly determines whether a new business will thrive or fail. The limitation of access to any source of capital seems counter intuitive to the process of fostering innovation and encouraging the growth of small businesses.

I respectfully suggest to the Committee to also be aware of the details in a “compromise solution” on the issue of percentage ownership and venture capital participation or any requirements that will require regular monitoring of the venture-investor’s portfolio of investments beyond the SBIR recipient for program compliance. The “unintended consequences” may add a significant burden to the entrepreneurs, the SBIR recipient company, and the SBIR Program administrator to “police” the rules... thereby stifling both innovation and job creation.

I trust that my comments affirm both the value of the SBIR program and the great need to remove barriers or obstacles to access capital for entrepreneurs as they seek to secure capital from *all* available sources of funding, including venture capital.

Thank you again for the opportunity to appear before this Committee. I look forward to answering your questions.

Chairwoman ELLMERS. Thank you, Mr. Norem.

Next we have Dr. Terry Brewer, who is president and founder of Brewer Science headquartered in Rolla, Missouri. Founded in 1981, Brewer Science, excuse me, is the discoverer of original solutions for the world's leading manufacturers of computer chips, sensors, LEDs, displays, and other microelectronics devices. Under his leadership, Brewer Science has grown from only three to 300 employees. Dr. Brewer has served on many boards and committees, particularly related to the area of innovation. He is one of the founders of Jordan Valley Innovation Center and serves on the Board of Springfield Innovation, Incorporated. Thank you for your testimony, Dr. Brewer.

STATEMENT OF TERRY BREWER

Dr. BREWER. Good morning, Chairwoman Ellmers, Ranking Member Richmond, and the members of the Subcommittee.

Thank you for the opportunity to appear here today to discuss the impact and the value of the SBIR program. I am Terry Brewer. I am president of Brewer Science, Incorporated in Rolla, Missouri, and I am appearing here today as a founder and owner of a small business that sustains high technology innovation.

I founded Brewer Science in 1981 and based it in Rolla, Missouri. Brewer Science is a major innovator of high technology processes used to create ultra small circuits that enable devices, such as tablet computers from which I am talking, smartphones, digital cameras, flat panel devices, and LEDs. The stringent requirements of these products provide Brewer Science with opportunities to leverage the company's knowledge and creative capabilities to provide the needed advanced technologies for both government and private sectors. Our product line encompasses unique chemicals, processes, and equipment that are used to give devices more capability in less space at a lower cost.

Like many entrepreneurs, I started the company with a novel concept, but with little cash. By using another company's extra lab space, creating a unique business approach, and accessing the support of programs like SBIR, Brewer Science has grown to nearly 300 employees. We are now the largest private employer in Phelps and the surrounding counties, Missouri, with sales offices all across Asia and Europe to access worldwide markets with our U.S. manufactured products.

Additionally, we are making significant headway in the development of next generation semiconductors using breakthrough processes and materials, such as carbon nanotubes in our facilities in Rolla and Springfield, Missouri. Over the past three years, this small, privately held high tech company located in rural Missouri has grown into a strong innovator and exporter of products used by every major integrated circuit manufacturer in the world. We have participated in the SBIR program with a high degree of success, including the commercialization of multiple disruptive technologies. The global competitors from countries that provide large government subsidies for the research and development programs require us to utilize programs such as SBIR which is needed now more than ever.

The founders of the SBIR program had a great vision to support and grow a true national treasure, innovation generated and sustained by American small business. In fact, American small businesses have become the most powerful innovating force on earth and it is this ability to not only invent but to provide sustained innovation that is the hallmark of this effort.

Since receiving our first SBIR award in 1984, the microelectronics industry has benefitted from many Brewer Science technologies facilitated by the program. It has helped us create and sustain high value jobs en route to influencing the development of modern electronic devices as we know them today.

So how do you calculate the impact of Brewer Science and its effect on the microelectronics industry? It is really not possible. From local jobs to advances in global microelectronics, Brewer Science innovations have made a difference in the way we live. But we are only one example of how funded innovation drives this kind of change. There are many more stories like ours that also confirm the value of the SBIR program.

In driving this change, it is important to distinguish between science and innovation. While appropriate science contributes to meaningful innovation, the value of the SBIR program is more than just finding the best science. Science does not create jobs. Businesses focused on sustainable innovation and development do create jobs. The SBIR founders were right. Small business innovation research empowers government funding to move great innovations forward to solve technical challenges through commercialization and manufacturing thereby achieving economic growth.

The founders of the SBIR program intended for American small business to generate jobs and technical growth. However, investment firms driven strictly for financial gain are not always aligned with this focus. I recognize that monetary support is critical for small business growth, but while investment firms can provide support for small businesses, their driving purpose may not always align with SBIR objectives. Any changes in the SBIR legislation should be sensitive to these concerns.

In conclusion, the visionaries of the SBIR program anticipated the increasing need for sustained innovation from the U.S. small businesses. As our nation struggles with challenging economic times there is no better vehicle to get us through than American small business innovation. No better vehicle.

While there are differences and distractions associated with the passage of this bill, I encourage the Subcommittee to remember the essence of what this program supports and how valuable SBIR is to supporting these efforts. That essence is the creation of technology-based jobs in the United States.

[The statement of Terry Brewer follows:]

Testimony of Dr. Terry Brewer
Brewer Science, Inc.
Rolla, Missouri

Before the
United States House of Representatives
Committee on Small Business
Subcommittee on Healthcare and Technology
April 7, 2011

Introduction:

Chairwoman Ellmers, Ranking Member Richmond, and members of the Subcommittee, thank you for the opportunity to appear here today to discuss the impact and value of the SBIR program. I am Terry Brewer, President of Brewer Science, Inc., in Rolla, Missouri, and I am appearing here today as a founder and owner of a small business that sustains high-technology innovation.

Brewer Science:

I founded Brewer Science in 1981 and based it in Rolla, Missouri. Brewer Science is a major innovator of high-technology processes used to create ultra-small circuits that enable devices such as tablet computers, smart phones, digital cameras, and flat-panel monitors and TVs. The stringent requirements of these products provide Brewer Science with opportunities to leverage the company's knowledge and creative capabilities to develop the needed advanced technologies for both government and private sectors. Our product line encompasses unique chemicals, processes, and equipment that are used to give devices more capability in less space for lower cost. They are also used in new alternative green energy products such as high-brightness LEDs destined to replace conventional light bulbs.

Like many entrepreneurs, I started the company with a novel concept but little cash. By using another company's extra lab space, creating a unique business approach, and accessing the support of programs such as the SBIR, program Brewer Science has grown to nearly 300 employees. We are now the largest private employer in Phelps County, Missouri, with sales offices across Asia and Europe to access worldwide markets for our U.S.-manufactured products.

Our mission is to innovate and sustain advanced processes and products for the dynamic demands of electronics and related industries. Our covenant is to ensure that Brewer Science products are the most reliable in the industry. We are also driven to continually improve product quality, manufacturing systems, and customer care.

Additionally, we are making significant headway in developing the next generation of semiconductors using breakthrough processes and materials, such as carbon nanotubes, in our facilities in Rolla and Springfield, Missouri.

Over the past 30 years, this small, privately held, high-tech company located in rural Missouri has grown into a strong innovator and exporter of products used by every major integrated circuit manufacturer in the world. We have participated in the SBIR program with a high degree of success, including the commercialization of multiple disruptive technologies. Receiving no venture capital funding, we rely on our people, our ideas, and a limited programs number of programs such as the SBIR program to support continued, leading-edge growth and innovation. This combination will lead to the development of the next generation of microelectronics technologies here in the United States.

With global competitors from countries that provide large government subsidies for their research and development, programs like the SBIR program are needed now more than ever. As a U.S. company competing in fierce, global markets, we must fight to secure a technology leadership position that requires increasing investments in innovative solutions to provide our customers, both commercial and government, with the latest microelectronic technology advantages.

Small Business Innovation Research Program:

History:

The founders of the SBIR program had the great vision to support and grow a true national treasure: innovation generated and sustained by American small businesses. In fact, American small businesses have become the most powerful innovating force on earth, and it is this ability to not only invent, but to provide sustained innovation that is a hallmark of this effort. However, even though the SBIR program has shown great value in supporting growth through innovation, the program may be in jeopardy because of distractions that take away from the core of its purpose: the successful commercialization of high-technology concepts through small businesses.

Value:

Since we received our first SBIR award in 1984, the microelectronics industry has benefited from many Brewer Science technologies facilitated by the program. Over the past 27 years, this support has enabled Brewer Science to contribute to the integration of this technology into the IC (integrated circuit – microelectronics) industry. It has helped us create and sustain high-value jobs en route to influencing the development of modern electronic devices as we know them today.

So, how do you calculate the impact Brewer Science has made on the microelectronics industry? It's not possible. From local jobs to advances in global microelectronics, Brewer Science innovations have made a difference in the way we live. But, we are only one example of how funded innovation drives this kind of change. There are many more stories like ours that also confirm the value of the SBIR program.

Challenges:

In driving this change, it is important to distinguish between “science” and “innovation.” While appropriate science provides the foundation for meaningful innovation, the value of the SBIR program is more than just funding “the best science.” Science alone does not create jobs, businesses focused on sustainable innovation and development do. The founders had it right: “Small Business Innovation Research” empowers government funding to move great innovations forward to solve technical challenges through commercialization, thereby achieving economic growth.

Concerns about expanding the program regarding minority participation and achieving geographic parity are legitimate, but realistically cannot be addressed when the existence of the program is at risk. To increase parity and participation, the program must be continuous and must be continually improving.

The founders of the SBIR program intended for American small businesses to generate jobs and technology growth. However, investment firms driven strictly by financial gain are not always aligned with this focus. I recognize that monetary support is critical for small business growth. While investment firms can provide support for small businesses, their drive and purpose may not always align with SBIR objectives. Any changes in SBIR legislation should be sensitive to these concerns.

Metrics:

We must realize that the true value of the SBIR investment is not the number of patents or papers produced, but the economic benefits supported by the resulting innovation. Sustained innovation, not just invention, adds value to society. We must measure and reward those companies that provide these results. I encourage the Subcommittee to undertake this task during the reauthorization process.

Conclusion:

In conclusion, the visionaries of the SBIR program anticipated the increasing need for sustained innovation from U.S. small businesses. As our nation struggles with challenging economic times, there is no better vehicle to get us through than American small business innovation. While there are differences and distractions associated with the passage of this bill, I encourage the Subcommittee to remember the essence of what this program supports and how valuable SBIR is to supporting these efforts.

Thank you for your interest and for allowing me to share my perspectives with you and I would be pleased to answer any questions.

Chairwoman ELLMERS. Thank you, Dr. Brewer. Thank you for your testimony.

I now yield to Ranking Member Richmond who will introduce our next witness.

Mr. RICHMOND. Madam Chairwoman, it is my pleasure to introduce Dr. Albert Link.

Dr. Link is a professor of Economics at the University of North Carolina at Greensboro with a focus on science and technology policy. He received his Ph.D. in Economics from Tulane University and is currently the Editor-in-Chief of the Journal of Technology Transfer. He has written many articles on the SBIR program, and Dr. Link is a member of the research team for the National Research Council's Committee for Capitalizing on Science, Technology, and Innovation, an assessment of the Small Business Innovation Research program.

As a Tulane graduate, it is my pleasure to introduce Dr. Link. Dr. Link.

Mr. LINK. Thank you.

STATEMENT OF ALBERT LINK

Mr. LINK. Good morning, Chairwoman Ellmers, Ranking Member Richmond, and members of the Subcommittee.

The pollen season has arrived in North Carolina. So if you would excuse me.

It is a privilege to be here and I thank you for the opportunity. The observations that I offer to you this morning are more general than those from Mr. Norem and Dr. Brewer. The insight that they offer from a company perspective is enlightening and extremely important.

If I may speak at a more general level, the SBIR program has had, and I expect it to continue to have, a significant impact on the technological foundation of our economy, thus reinforcing the economy's potential for continued and sustained growth.

Defending this statement is not difficult at an aggregate level. The evidence is clear that the benefits to society outweigh the costs of the program. In other words, a benefit cost analysis calculated under very conservative assumptions shows that the ratio of social benefits to SBIR funding costs far exceeds one.

Turning to two specifics, employment growth and commercialized new technologies, both of which are of economic importance and both of which are directly linked to SBIR funding. After I briefly remark on each I will comment on the common thread between them, namely Phase III funding. Employment growth is not an explicit objective of the SBIR program, but it is definitely an important issue, especially in the current economic environment.

The average annual rate of employment growth in SBIR-funded companies over the past decade has far exceeded the growth rate of the economy as a whole. The average rate of employment growth among, for example, NIH-funded companies has been about 11 percent per year. And this estimate does not take into account employment growth associated with those companies that purchase innovations created by the funded companies.

Also, across agencies employment growth has increased by about 30 persons per million dollars of SBIR funding. Employment

growth varies among companies, and it is greatest among those that have patented their intellectual property and have acquired Phase III funding. Controlling for these effects, there do not appear to be differences in employment growth among companies that are owned by women and/or minorities compared to other companies. But women and/or minority companies tend to patent their intellectual property less often.

Commercializing new technology funded by SBIR is an explicit objective of the program, and about 50 percent of the funded projects reach the commercialization stage. The probability of commercializing a new technology also varies among companies and it is greatest among those that have acquired Phase III funding and who have partnered with the university. And I suspect that partnering with a national laboratory would bring about the same result.

And controlling for these effects on the likelihood of commercialization, again, there do not appear to be differences among women and minority-owned companies compared to other companies.

The magnitude of the effect of Phase III funding on the probability of commercializing a new technology is noteworthy. Again, if I may draw from NIH as an example, the probability of commercialization nearly doubles when Phase III funding is available. Phase III funding thus has an economic importance to SBIR-funded companies. It is correlated with employment growth and commercialization, and the two are related.

In conclusion, thank you again, Chairwoman Ellmers, Ranking Member Richmond, and members of the Committee for the opportunity to offer these observations on the overall economic importance of the program. I strongly encourage the Committee to move toward a reauthorization of the program and to include in that reauthorization continued evaluation studies of the program within an emphasis on any economic consequences associated with changes in the economic environment or in the composition of applicant and recipient companies. Thank you.

[The statement of Albert Link follows:]

SMALL BUSINESS INNOVATION RESEARCH PROGRAM

Testimony of

Albert N. Link

Professor of Economics
University of North Carolina at Greensboro

before the

Committee on Small Business
Subcommittee on Healthcare and Technology
The Creating Jobs Through Small Business Innovation Act of 2011
United States House of Representatives

April 7, 2011

Good morning Chairwoman Ellmers, Ranking Member Richmond, and members of the Subcommittee on Healthcare and Technology.

My name is Albert Link and I am a Professor of Economics at the University of North Carolina at Greensboro. It is an honor and a privilege to be here today and to offer observations about the overall economic importance of the Small Business Innovation Research (SBIR) program and, in particular, the role of venture capital in the performance of funded projects and companies.

My areas of research include the economics of innovation, technology-based entrepreneurship, and public sector program evaluation. I have been associated with the Board on Science, Technology, and Economic Policy within the National Research Council (NRC) since the late 1990s, initially as a member of the research team involved with the first assessment of the Department of Defense's (DoD's) Fast Track Initiative,¹ then as a member of the research team involved with the initial assessment of the SBIR program, and most recently through its study of science and technology parks.²

The observations that I offer below are based on my general understanding of the SBIR program and on my detailed statistical analyses of data collected through the NRC's assessment of the SBIR program.³

Background on the SBIR Program

The SBIR program is a public/private partnership that provides grants to fund private-sector R&D projects. It aims to help fulfill the government's mission to enhance private-sector R&D and to commercialize the results of federal research.

A prototype of the SBIR program began at NSF in 1977. At that time, the goal of the program was to encourage small businesses—increasingly recognized by the policy community to be a source of innovation and employment in the U.S. economy—to participate in NSF-sponsored research, especially research with commercial potential. Because of the early success of the program at NSF, Congress passed the Small Business Innovation Development Act of 1982 (P.L. 97-219).

The 1982 Act required all government departments and agencies with external research programs of greater than \$100 million to establish their own SBIR program and to set aside funds equal to 0.20 percent of the external research budget.⁴ As part of the 1982 Act, SBIR awards were structured and defined by three phases.⁵

The 1982 Act stated that the objectives of the program are:

- (1) to stimulate technological innovation,
- (2) to use small business to meet Federal research and development needs,
- (3) to foster and encourage participation by minority and disadvantaged persons in technological innovation,⁶ and
- (4) to increase private sector commercialization of innovations derived from Federal research and development.

Eleven agencies currently participate in the SBIR program, with an annual award amount of approximately \$2.5 billion.

Employment Growth from SBIR-Funded Research

Employment growth—jobs—is of great importance in our current economic environment.⁷ The average annual rate of employment growth in SBIR-funded companies has grown much faster than the growth rate of the economy as a whole.

Employment growth occurs in funded companies in areas beyond those directly associated with the funded project. In other words, a SBIR-funded project leverages a number of activities of the company allowing it to grow through hiring new employees in areas related to but broader than the specific project.⁸

The average annual rate of employment growth varies among companies and across funding agencies. Generally, those businesses with higher growth rates have:⁹

- patented their intellectual property, and
- acquired Phase III funding.¹⁰

And, there are no differences in the average rate of employment growth among companies that are owned by women and/or minorities than are owned by men and/or non-minorities.¹¹

Commercializing New Technology from SBIR-Funded Research

Commercializing new technology funded by SBIR is an explicit objective of the program, and about 50 percent of funded projects have resulted in new technologies being brought to market, and this percentage is about the same across the five funding agencies studied by the NRC.¹²

The probability of commercializing a new technology varies among companies and across funding agencies. Generally, those businesses that have been successful in commercializing their technology have:¹³

- acquired Phase III funding, U.S. venture capital among DoD- and NIH-funded companies in particular,¹⁴
- partnered with a university,¹⁵

And, there are no differences in the average rate of commercialization among companies that are owned by women and/or minorities than are owned by men and/or non-minorities.¹⁶

The magnitude of the effect of Phase III funding on the probability of commercializing a new technology is noteworthy. For example, among NIH-funded companies the probability of commercializing a new technology nearly doubles when venture capital research funding is available.¹⁷

Venture Capital Support among SBIR-Funded Projects

A woman and/or a minority owned business that receives SBIR awards does not appear to be disadvantaged in receiving Phase III venture capital investments.¹⁸

Larger companies do not appear to have an advantage in accessing Phase III venture capital investments.¹⁹

Need for Continued Evaluation Studies of the SBIR Program

I would again like to thank the Committee on Small Business for allowing me to offer my observations on the overall economic importance of the SBIR program and, in particular, the role of venture capital in the performance of funded projects. I encourage the Committee to move toward a reauthorization of the program and to include in that reauthorization continued evaluation studies of the program with an emphasis on any economic consequences associated with changes in the economic environment or in the composition of applicant or recipient companies.²⁰

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Notes

¹ See, Link (2000); Link and Scott (2000); and Audretsch, Link, and Scott (2002).

² See, Link (2009).

³ The Small Business Reauthorization Act of 2000 mandated that, among other things, the NRC conduct “an evaluation of the economic benefits achieved by the SBIR program” and make recommendations to Congress for “improvements to the SBIR program.” In its evaluation of the SBIR program, the NRC steering committee charged with the study took several approaches to the evaluation. These approaches included multiple surveys, interviews, and over 100 case studies. The NRC conducted an extensive and balanced survey in 2005 based on a population of 11,214 projects completed from Phase II awards made between 1992 and 2001 by five agencies: Department of Defense (DoD), National Institutes of Health (NIH) within Health and Human Services, National Aeronautics and Space Administration (NASA), Department of Energy (DOE), and the National Science Foundation (NSF). In 2005, these five agencies accounted for 94% of the 1,842 Phase II awards and 98% of the \$1.4 billion awarded. Data were obtained from a final sample of 1,878 randomly chosen projects. Much of my analysis of the NRC database was done jointly with my research colleague John Scott, from the Department of Economics at Dartmouth College.

⁴ In 1983, the set aside totaled \$45 million.

⁵ The objective of Phase I is to determine the scientific or technical feasibility and commercial merit of the proposed research or R&D efforts and the quality of performance of the small business concern, prior to providing further Federal support in Phase II. The objective of Phase II is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II proposal. The objective of Phase III, where appropriate, is for the small business concern to pursue with non-SBIR funds the commercialization objectives resulting from the outcomes of the research or R&D funded in Phases I and II.

⁶ The 1992 reauthorization of the Act broadened objective (3) to focus also on women: “to provide for enhanced outreach efforts to increase the participation of ... small businesses that are 51 percent owned and controlled by women.”

⁷ Recent legislation, as well as a number of recent reports, emphasizes the relationship between job growth and public investments in innovation. See for example the America COMPETES Reauthorization Act of 2010 as well as the National Economic Council, the Council of Economic Advisers, and the Office of Science and Technology Policy’s February 2011 report, *A Strategy for American Innovation: Securing Our Economic Growth and Prosperity*.

⁸ Over the time period of the data collected from a random sample of projects by the NRC, DoD-funded companies have enjoyed an approximated average annual rate of employment growth of 6%; it was 11% per year among NIH-funded companies, and it was 5% per year among DOE-funded companies. See, Link and Scott (forthcoming a, forthcoming b). Generalizing to the cumulative number of new jobs created through the SBIR program is ambitious because the data available are averages and the life of funded company is unknown. However, one can conservatively extrapolate from the random sample of projects in the NRC database to conclude that, on average, employment in funded companies has increased by 30 persons per \$1 million of SBIR funding over a 10 year period (taking into account projects that were funded but did not succeed on a scientific or technical basis).

⁹ There are other agency-specific correlates with the average annual rate of employment growth. For example, growth rates are greater among a random sample of DoD-funded companies that have a university as a research partner and that have previously been granted a Phase II award in a related technology area; they are greater among a random sample of NIH-funded companies in which the SBIR award is a larger percent of their overall R&D budget and that have received U.S. venture capital funding; and among a random sample of DOE-funded companies that have entered into R&D agreements with other companies.

¹⁰ Outside funding includes investments from private investors and inside funding includes own-company funding.

¹¹ Female owned companies are less likely to patent intellectual property resulting from an SBIR-funded project than are non-white owned companies. See, Link and Ruhm (2011).

¹² See, Link and Ruhm (2009) and Link and Scott (2009, 2010).

¹³ The following two generalizations are based on a statistical analysis of the random sample of projects in the NRC database. Those data were collected in 2005 based on Phase II awards between 1992 and 2001. The probability of having commercialized from a funded project by 2005 is greater the older the funded project.

¹⁴ Link and Scott (2009, 2010) emphasize that the presence of outside funding should be positively correlated with commercialization success for at least three reasons. One reason is that outside private investors have useful information about the commercial prospects of the output of a Phase II project and they signal that information by investing in the project that are likely to be most successful. Relatedly, Link and Ruhm (2009) make the point that when outside investors do invest at least two hurdles have been cleared. One hurdle is that the company's project was selected by the investor among all projects to be scrutinized, and the second hurdle is that the project was selected among all those scrutinized. A second reason is that the presence of outside investors provides useful business and management guidance to small, and often newly formed companies. And the third reason is that companies that have taken an internal assessment of a project's commercial potential, and thus believe that their project will be successful, may be able to identify private outside private investors more easily.

¹⁵ Link and Ruhm (2009) have only studied the university effect for NIH-funded companies.

¹⁶ Link and Ruhm (2009) have only studied the gender/race effect for NIH-funded companies.

¹⁷ Link and Ruhm (2009) estimated that the probability of commercializing a new technology from a random sample of NIH-funded project with \$0 of additional funding is about 25 percent. Venture capital support increases the probability of commercialization by about 26 percentage points. And, university involvement increases the base probability by about 12 percentage points.

¹⁸ For example, among the random sample of DoD-funded projects: 3.6% of a woman-owned businesses received Phase III venture capital support, 2.2% of a minority-owned businesses received Phase III venture capital support, 0% of businesses owned by a minority woman received Phase III venture capital support, and 3.3% of other businesses received Phase III venture capital support. Among the random sample of NIH-funded projects: 0% of a woman-owned businesses received Phase III venture capital support, 7.7% of a minority-owned businesses received Phase III venture capital support, 0% of businesses owned by a minority woman received Phase III venture capital support, and 3.5% of other businesses received Phase III venture capital support.

¹⁹ For example, among the random sample of DoD-funded projects 1.5% of companies with less than 8 employees (mean 3.8 employees) received Phase III venture capital, 6.9% of companies with between 8 and 22 employees (mean 13.6 employees) received Phase III venture capital, 2.5% of companies with between 22 and 64 employees (mean 38.9 employees), and 2.6% of companies with greater than 64 employees (mean 183.8 employees) received Phase III venture capital.

²⁰ See Link and Link (2009) and Link and Scott (2011) for a discussion of the economic as well as managerial importance of program evaluation.

Chairwoman ELLMERS. Thank you, Dr. Link, for your testimony.

Our last distinguished panel member is Dr. Scott Koenig, who is the chairman of the Board of Directors at Applied Genetic Therapy Corporation, a private biotechnology company. Dr. Koenig is a board member of the Biotechnology Industry Association, as well as a member of its emerging company section. Dr. Koenig is also a board member of the Children's Research Institute at the Children's National Medical Center. He received his A.B. and Ph.D. from Cornell University and his M.D. from University of Texas, Health Science Center in Houston. He completed his residency in international medicine at the Hospital of the University of Pennsylvania and is board certified in internal medicine and allergy and immunology.

Dr. Link, you could probably discuss this with Dr. Koenig to suffer as a fellow North Carolinian.

Welcome to the Subcommittee, Dr. Koenig.

STATEMENT OF SCOTT KOENIG

Mr. KOENIG. Thank you very much. Good morning, Chairwoman Ellmers, Ranking Member Richmond, members of the Committee, ladies and gentlemen. I am president and CEO of MacroGenics and chairman of the board of Applied Genetics Technology Corporation. I am appearing before the Committee on behalf of the Biotechnology Industry Organization, which 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 I have worked at the NIH and in the biotechnology industry for the past 27 years. During my career I have held positions, including senior vice president of research at MedImmune, cofounder and CEO of MacroGenics, and board director of AGTC.

During this time, I have been involved in the development of multiple biological product, such as a therapy to prevent a fatal viral illness in premature infants, a vaccine to prevent cervical cancer, and a number of other promising therapeutics still in development to treat juvenile diabetes, West Nile virus infections, and many types of cancers.

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

Let me illustrate examples of each with two quite different outcomes for treatments for children. In the 1990s, MedImmune was a small, biotechnology company in Gaithersburg, Maryland, funded by venture capitalists and became a publicly traded company in 1991. At that time, one of the lead programs was a monoclonal antibody to prevent respiratory syncytial virus infection in neonates. The research and development of this program was funded by SBIR Phase I and II grants. Today this product is called Synagis, the first and only FDA-approved product to prevent an infectious disease and has been used now in over 600,000 children. MedImmune employs thousands of highly skilled professionals. If

current SBIR rules prevailed at the time when MedImmune scientists first were working on and applied for these grants, MedImmune would have been illegible to receive those SBIR funds and it would have significantly impacted the development of the program and the company.

Contrast this with the outcome at AGTC. Today AGTC is a small, private, biotechnology company in Alachua, Florida. It is developing cutting edge product candidates to treat and cure different generic diseases using adeno-associated viral vectors produced by their proprietary manufacturing process. The company by all parameters is a small company. They have seven employees, no product revenues, and large capital requirements to advance their programs through early stage pre-clinical and clinical development. Currently, all their venture capital money is being used to fund two early clinical trials and they have no other capital support to support other avenues of research.

Prior to 2003, AGTC received several SBIR grants for three different projects to advance treatments of rare diseases, but in 2003 the company applied for a Phase I and II grant and was initially awarded the grant but the application had to be withdrawn due to the circumstances of VC ownership. This grant would have advanced the treatment for Pompe disease, a fatal genetic disorder which results in the death of many infants by one year of age. No investors were willing to fund this early stage work for Pompe and no further work has been done in the last eight years.

Currently, the company is working on one of the most promising programs to treat blindness in children caused by genetic disorders. An initial clinical study using their technology to treat Leber's congenital amaurosis (LCA), a rare retinal disease affecting a few thousand patients in the U.S., resulted in the first restoration of partial sight in legally blind patients with this inherited, defective gene. The company desires to use their technology to treat three other genetic eye diseases but is unable to do so because they have no resources available and they cannot participate in the SBIR funding. In fact, AGTC did apply for a grant for one of these eye diseases called achromatopsia in anticipation of congressional resolution of matters of SBIR funding related to VC ownership. The grant was scored and awarded, but AGTC is unable to accept the funds due to the prevailing rules.

As developers of the next generation of treatments for diseases that would have been unapproachable just a decade ago, we need to find ways to support these risky transformational therapies that could improve the lives of children and adults suffering from genetic disorders, infectious diseases, cancer and autoimmune diseases among others. This has personal and economic benefits to the individuals affected, the organizations and companies working on these initiatives and society in general. We should update the SBIR program to reflect today's realities and this has never been more important. The impact of the economic downturn is still being felt by the industry. The amount of venture capital dollars decreased by 27 percent between 2009 and 2010 and finding funding for promising early stage projects is still difficult as it has ever been.

There is an opportunity to strengthen and restore the SBIR program. First, allow small U.S. biotechnology companies that are ma-

jority owned by venture capitalists to once again compete for the SBIR awards based on scientific merit. This will ensure that the most competitive pool of applicants and grants will be awarded for projects that show the most promise in bringing breakthrough therapies to the public. Second, clarify SBIR eligibility rules to make the application process more straightforward and user friendly. It is equally important that the reauthorization clarifies SBIR affiliation regulations.

[The statement of Scott Koenig follows:]



HEARING TESTIMONY

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

CHAIRMAN OF THE BOARD, APPLIED GENETIC TECHNOLOGIES CORPORATION

ON BEHALF OF THE

BIOTECHNOLOGY INDUSTRY ORGANIZATION

BEFORE THE HOUSE OF REPRESENTATIVES SMALL BUSINESS HEALTHCARE &
TECHNOLOGY SUBCOMMITTEE

April 7th, 2011

Good morning Chairwoman Ellmers, Ranking Member Richmond, Members of the Committee, ladies and gentleman. I am 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-seven 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, as a result of a 2003 Office of Hearings and Appeals ruling, 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 NASDAQ 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 and is still MedImmune's most significant product. MedImmune was acquired by AstraZeneca in 2007, one of the largest acquisitions of a biotechnology company by a pharmaceutical company. MedImmune now employs 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 proprietary manufacturing process. The company, by all parameters, is small. They have seven employees rent space in a university 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 \$45M 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 and 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's 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's and no further work has been done on this program in the past eight years.

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 in *Human Gene Therapy* and the *New England Journal of Medicine* (2009). 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 three 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 receive SBIR funds for the high risk, but likely rewarding approach to treating these debilitating eye disorders. In fact, AGTC applied for an SBIR grant in 2010 to develop a treatment for one of these genetic eye diseases called achromatopsia in anticipation of congressional resolution of matters of SBIR funding related to VC ownership. The grant was scored and awarded, but AGTC is unable to accept the funds due to the prevailing rules.

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 recommended that the SBA

ruling be repealed or modified so that majority-venture funded companies with significant commercial potential can compete for SBIR funding.

The ability of the SBIR program to provide critical funding for projects with the most potential to benefit the public, will remain hampered, unless SBIR reauthorization updates the program to address the current realities facing small, innovative American companies. Impacts of the economic downturn are still being felt by the industry. The amount of venture capital dollars decreased by 27% between 2009 and 2010 (BioWorld Today; January, 2011) and finding funding for promising early-stage projects is as difficult as it has ever been. This an industry that provides high-paying jobs to millions of individuals. This is a 21st century industry whose potential both as an economic driver and in delivering solutions to our nation's most critical public health needs has not yet been maximized. SBIR could play a critical role in helping achieve those goals.

OPPORTUNITY TO STRENGTHEN/RESTORE SBIR PROGRAM

Increase Science-Based Competition

Allowing small, U.S. biotechnology companies that are majority owned by venture capital companies to once again compete for SBIR awards based on scientific merit 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. 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 an SBIR reauthorization legislation that creates a more rational and effective affiliation process regarding determinations about an SBIR applicant's investors' portfolio companies supported by its investor. This is common-sense and would provide clarity and peace of mind for small business entrepreneurs looking to participate in 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. This is an industry full of potential to create high-paying jobs and to provide solutions to our nation's most critical public health needs. BIO believes that the modernizations to the SBIR program being considered by the committee will help to accomplish this important objective.

Chairwoman ELLMERS. Thank you for your testimony, Dr. Koenig.

I would like to begin questioning with Mr. Norem. Technologies such as yours, and really technologies in general, tend to advance exponentially. Where could you see your technology going? Where else could it be adapted?

Mr. NOREM. Thank you for the question, Chairwoman Ellmers.

We believe, and our investors believe, that we have a very rare opportunity to expand the physical security levels of our nation, not only at the Department of Defense military bases, the State Department and embassies worldwide, both here and abroad, but also for our communities as they want to deploy this in universities for increased security on campuses, hospitals and local jurisdictions, police departments, K-12 education. So it is a very open market at both state, local, and federal here in the United States, not to mention the growth of the surveillance and sensor grid arrays that are being built in Europe and other places in the world.

Chairwoman ELLMERS. Thank you.

To Dr. Brewer, we have been really focusing on job creation. That is the main focus of the 112th Congress. Could you put your SBIR award into jobs? Upon receipt of a Phase I or a Phase II, does that directly impact your hiring practices?

Dr. BREWER. Of course we can put SBIR directly into jobs. We have. And yes, the Phase I and Phase II awards do affect our hiring practices and make a major contribution to just how far we can extend our own technology. So very significant to that, and very significant to job creation.

Chairwoman ELLMERS. Great. Thank you.

And Dr. Link, agency flexibility is often cited as a value to the SBIR program. Can you explain how this flexibility is beneficial to the program across agencies?

Mr. LINK. If one talked to a group of entrepreneurs, each would probably have a different definition of what an entrepreneur is. The same if you talk to those in the academic community who study it. The common thread among those definitions would be the ability to be creative and the ability to bring that creativity into action. In this case the marketplace. And I think the flexibility of the SBIR program embraces both of those. It embraces both creativity and embraces both action. It allows for two phases. It allows for firms to attempt to try out new ideas, and if successful then follow them forward into a Phase II. It also allows for other support, whether it be federal or federal non-SBIR money or other forms of private investment. And there is not a formula that is presupposed on how those other forms of financing will have an effect. The market is playing itself out, as it should, and the success, I think, has been well documented by the members of this Committee.

Chairwoman ELLMERS. Thank you, Dr. Link.

And lastly, Dr. Koenig, have you seen businesses increasingly seeking out more opportunities in the SBIR program because of the general lack of availability of capital nationwide at this time?

Mr. KOENIG. I think the effect of the economic downturn has had a dramatic effect on the biotechnology industry. The lack of funds available from other sources, particularly venture capitalists, has ended up forcing the companies to seek other ways to obtain new

sources of capital. I have seen a lot of effort in trying to get SBIR funding, but because of the current rules, and since most of the companies within the Bio organization are majority owned by venture capitalists, they have been prohibited from participating. That has been a great frustration, as you can imagine, for the member companies. And I think that in the interest of both the companies creating new jobs and getting the most innovative technologies developed, if the rules can be changed to allow the majority funded VC companies to participate, it will have a huge impact on our country and the public.

Chairwoman ELLMERS. Thank you, Dr. Koenig.

I now yield to Ranking Member Richmond for his questions.

Mr. RICHMOND. Madam Chairwoman, if I could, I yield to Congressman Peters to do his before me.

Mr. PETERS. Thank you, Ranking Member Richmond. I appreciate that. Thank you, panelists, for your comments here.

Dr. Link, I just want to flush out some of the things that you had mentioned in your analysis of the SBIR program. One, you talked about how the average annual rate of employment growth varies across funding agencies, and I think you quoted the NIH as about 11 percent growth. I do not know if that correlated to jobs. What sort of variation do you see in these agencies? Is there a wide variation?

Mr. LINK. The NIH was the largest and that is the agency I studied the most. The Defense Department is about five percent and the Department of Energy is about six percent. NASA and the National Science Foundation are in between.

Mr. PETERS. And what do you account for that difference? Anything in particular?

Mr. LINK. First of all, NIH and Department of Defense are the two—projects funded from those two agencies have received the most amount of Phase III money, and I think that has a dramatic effect on the probability of commercialization.

When one talks about commercialization, it is not a dichotomous event. You either commercialize or do not commercialize. If you do commercialize, how successful are you in reaching the market? And in those two agencies, which, of course, are the largest in terms of allocations, they have been most successful in terms of the magnitude of sales. And I attribute that primarily to Phase III funding in those two agencies more so than in the others.

Mr. PETERS. And to pick up on that, you quoted about per one million dollars of investment is 30 jobs. Now, is that folks that are just getting Phase I and II or is that looking at Phase III as well? Does that skew the job number because the Phase III funding is really, and in some respects, most important when it comes to job creation?

Mr. LINK. Those numbers take into account Phase III money. And I do not think it skews the numbers because I am talking first about an average and the variance around that 30 is relatively small. It is a point estimate but I think it is a very good approximation across funding agencies. And we have looked at the data from the early 1990s to the present, and so I feel very comfortable with that as a sound bite.

Mr. PETERS. Right. Yeah. But the Phase III, obviously, is critical, not being done by all agencies. Are there recommendations that you have to this Committee as to maybe looking at structuring it to ensure that other agencies are engaged in Phase III funding?

And I will open this up to all the panelists, too, because commercialization is the key thing when it comes to jobs. And the bottom line, we want to create jobs and small businesses are the engine of growth. I serve on the Financial Services Committee and deal with financing issues all the time, which is very difficult right now if you are a small business person to get the loans you need. Do we need to have a focus on Phase III to get our best bang for our dollar? And how do we do it? And just some ideas that any of the panelists have would be appreciated.

Mr. LINK. Let me just finish. I think it is open across agencies. We just do not see much venture capital among DOD and NASA projects compared to the others. An issue tied to Phase III is trying to shorten the time period between Phase I and Phase II. Shortening that time period helps companies retain employees, and I think that is very important.

Another issue associated with Phase III funding across all agencies is consistency in the funding of the SBIR program, not going through the temporary period from 2008 to the present time. And the reason for that is venture capital firms, as well as other private equity and investment firms, they span companies that have received SBIR awards. The SBIR award is in a sense a seal of Good Housekeeping approval. It does send a positive signal to the marketplace, and companies are willing to—I am sorry, venture capital companies in particular are willing to invest in the time and effort to study those projects that have been funded and to approach those that appear to be the most successful.

Mr. KOENIG. So I have a sort of mixed view with regard to the requirements for SBIR Phase III funding, per se. I have found historically, and in my own experiences with getting funds for SBIR one and two, that this has a huge impact. I think the validation is very important to the VC community, but beyond that, it is the ability to have these funds to fund very early stage programs and move them far enough along that you can actually have results that can be endorsed. They become attractive not only to the venture capitalists, but to other, larger biotechnology companies or pharmaceutical companies that will engage these companies.

There is an amplifying effect that once you have actually conducted the research that has been funded by Phase I and II, it helps to mature the early stage work to a point where it has some validation to be more attractive to larger sources of capital, both in the venture community, as well as the biotech and pharmaceutical industries.

Mr. PETERS. Good. Thank you.

Chairwoman ELLMERS. Thank you. That was very good.

I now recognize Mr. Mulvaney.

Mr. MULVANEY. Thank you, Mrs. Chairwoman.

Gentlemen, before I come back to the venture capital question that I want to follow up on, I want to ask a general question. I am a small businessman. I participated in a SBA program before. It is not the one we are talking about here today. And I would classify

my experience as fair. It could have been better. I have heard some really good stories about some things the SBA does well. I have heard some stories about things that are not administered as well as they might, could be. Tell me, how hard is it to use this program? Is this a relatively easy program to use? I mean, you all are in small business. Does it make sense to you or is it one of those things you have got to fill out 15 different forms and it is a complete disaster? Tell me about the experience of actually using the SBIR process and whether or not we can improve it. Anybody. Dr. Koenig.

Mr. KOENIG. I have to say I have been involved with SBIR funding since the early 1990s so I have a very long view of this. I remember telling one of my colleagues back in 1994 musing that this was the jewel of the government. There is always criticism about government-supported programs, but when I saw the impact of that program and the ease in terms of applications and getting the funding, it made this a wonderful resource.

Move forward to 2003 when the rules changed and I was actually very depressed about it because I saw tinkering in a program that was so successful. The actual application process is quite easy. I mean, we mostly dealt with the SBIRs through the NIH and this is not any more difficult, and in fact, less difficult than most grant submissions. The actual administration of that funding, getting the awards, has been quite easy. So I have not heard any issues in regards to the administrative aspects of the granting process.

Mr. MULVANEY. Gentlemen? Yes, sir.

Mr. NOREM. We work primarily with the Department of Defense and I have to say, and I would speak for my colleague, that it has been a great agency to work with. Sometimes they are short of administrative help themselves, but for the recipient it is a very helpful process, very encouraging with their support, and it has been, I think, a very solid program for our company.

Mr. MULVANEY. Dr. Brewer, do you want to check in on this, or is it pretty much the same?

Dr. BREWER. Yes, I want to echo pretty much the same. We have worked with a broad range of agencies, and have also found that kind of experience across the board. We also do non-SBIR government contracts and if you compare the two I would say SBIR is certainly a jewel in the crown I think. It is very good.

Mr. MULVANEY. That is good to know then. Let us come to the issue that Dr. Koenig has talked about at length and I know each of you touched on it a little bit. If we wanted to fix it, do you just get rid of section 107? Do you get rid of the 34, 35 percent caps or, is there another way? Do you throw all the 200 rule changes out and go back to the way it was before? I mean, if we decide that we would like to try and take this up, what are your recommendations about the best, most efficient way to proceed?

Mr. KOENIG. Well, I would personally love to throw the rules back and go pre-2003. Obviously, I know that this has been a very difficult process to change. I mean, we have been discussing this since 2003. I have actually appeared before the Committee several years ago and we are now eight years beyond and have not resolved the issue. What I believe and what Bio believes is let us find a pathway forward that allows as much participation as we can for

majority VC-owned companies. If the Senate and the House could come to a solution that removes the caps, of course, we would endorse it, but any ability to have VC majority owned companies participate at this point would be very favorable.

Mr. MULVANEY. And I have got only about half a minute left so let me ask this. Are there any other changes to the 2003 rules that we should be looking at primarily or is this VC rule the one that seems to be the sticking point for most folks in your industry? Mr. Norem.

Mr. NOREM. I would encourage you to look at the definition of venture capital firms themselves. When we call on family offices, wealthy individuals who have a propensity to do this and angel capital, they form LLCs to protect themselves legally. They hire professional managers. They make more than one investment and so many of the angel capital investors are now deemed venture capital. So it is just another barrier for us to raise capital and participate in the SBIR program if that definition is too loosely interpreted.

Mr. MULVANEY. Dr. Brewer, I am out of time so I am going to let the Chairwoman take it from here. So.

Chairwoman ELLMERS. I am going to yield some time to Mr. Richmond for some questions that he has as well.

Mr. RICHMOND. I guess I would start with have you all had a chance to review the draft legislation that would come out of this Committee? And in that legislation, if you have some ideas of changes, please go ahead and offer it.

But one of the things that I notice that is different in this legislation than the previous legislation was a 90-day window that they would have to respond. Do you think that will expedite things or do you think that could have some potential negatives to it? Dr. Brewer.

Dr. BREWER. Yes. I think it is a good idea. Shortening the time of response will be a real advantage.

Mr. RICHMOND. And Dr. Link, I think, oh, did you want to respond, Dr. Koenig?

Mr. KOENIG. I have nothing to respond to the 90 but you asked about other changes.

Mr. RICHMOND. Yes.

Mr. KOENIG. This is actually not an opinion endorsed by BIO, but is my personal opinion. I remember in the mark-up of last year's legislation there was a limitation of VC companies that were affiliated with large corporations and there had to be less than a 20 percent ownership of the small companies by these large affiliated VCs. I think this is just a very arbitrary rule and my personal opinion, it should be excluded. In fact, AGTC, which I described before, would not be able to now participate because there is one VC, a large corporation associated entity, that owns a little more than 20 percent. And so again, the arbitrary nature of this does not seem very useful for such companies.

Mr. RICHMOND. The other thing that I noticed in the bill, and I would assume you all are going to say it is a very good thing but I want to make sure, is the increase in the Phase I and Phase II grant amounts, do you think it is a sufficient increase? Do you think it was a necessary increase?

Mr. KOENIG. The costs of doing research have escalated and I think, I wholly endorse the amounts here. Knowing where we are in terms of the economy and issues with regards to funding new programs, I think there will be limitations and pushbacks. So any additional funding is well deserved in supporting this program, but obviously you have to deal with the realities of funding such programs.

Mr. RICHMOND. Go ahead, Dr. Link.

Mr. LINK. Yes, I agree with the increase in the limits. I also agree with the inflation escalation that is suggested for funding.

If I may have a little breadth in my answer here. There is another part of the proposed bill that gives directors discretion for a 50 percent increase in those amounts. I did not see in the bill, perhaps it is there, information with regard to oversight on how that 50 percent may be monitored, what kind of accountability may take place there. An alternative idea may be in the spirit of accountability to allow those companies that are invited for Phase II awards that look very promising and perhaps in the spirit of the purpose of the agency need additional funding, be invited to propose two Phase II awards, one for the maximum amount and one for 50 percent greater than the maximum amount, and then have both of them scored rather than have the discretion for the agency to go above the amount without any oversight associated with that.

Mr. RICHMOND. Thank you for that.

Mr. Norem.

Mr. NOREM. If I could respond to that. I think, and speaking for the DOD programs and SBIR, the administrators themselves have oversight, and as long as they have the discretion on the size of award, they do a very good job, we find, at managing the amount, an appropriate amount of money that gets assigned to each program. So the discretion of the administrator would be my recommendation.

Mr. RICHMOND. The last question I will ask. Because we keep talking about venture capital a lot and it is very clear that VCs play an important role in helping these companies start up. One of the other shining stars, at least in my experience through federal programs, is the New Market Tax Credit. And I was wondering how large of a role New Market Tax Credit allocations play in this area.

And two, and you do not necessarily have to answer this now, but do you see a way in the future we could link or make some provisions in New Market Tax Credit allocations for this area of technology or in this area? Because I think that when you talk about job growth and benefit to the country, this is very significant. The rules on New Market are very open in what you can invest in is a large area. Would it make sense to direct or incentivize New Market Tax Credit companies to look at this area. And just, Dr. Koenig.

Mr. KOENIG. I think that tax credits are a great incentive in general but in the context of the companies we are talking about, they cannot get to use these tax credits because it takes over a decade for most of these companies to actually realize any revenue if they are successful. So unless there is an ability to take those tax credits and assign them or sell them or some way of actually helping

the company indirectly to bring in more resources, I do not see an immediate impact on the company.

Mr. RICHMOND. No, what the New Market program does is allow venture capital companies to raise——

Mr. KOENIG. Oh, I see. Yes.

Mr. RICHMOND. So the VCs raise money through New Market but those VCs are allowed to invest that capital that they raise in a number of things, from housing to loans to clothing stores. And I guess I am asking if this is such a jewel should we try to find a way to incentivize those VCs to look in this area in terms of investing their money? And after you all answer the question, Madam Chair, I will now yield back.

Mr. NOREM. Ranking Member Richmond, I can only comment that as an entrepreneur and living in the state of Texas, we have got a lot of state programs that encourage and foster innovation and encourage entrepreneurs like ourselves in Texas. We have found that encouraging and linking those programs, providing additional access to capital for the entrepreneurs had been very helpful across the board and we are in a very severe time to raise—it is very tough to raise capital today in this economy. And I think all of those programs help a great deal.

Chairwoman ELLMERS. Thank you. Thank you. I have one follow up question for Dr. Brewer.

In regard to commercialization there has been a lot of debate about so-called SBIR mills, companies that simply win multiple Phase I awards, very few Phase II awards, but do not commercialize much. I have heard both sides of this argument, but as a participant in the SBIR program do you view this as a problem?

Dr. BREWER. Thank you. It is a good question. Yes, we recognize the problem exists, but I think it is a very poor business model, so I believe the mills will not be around for long anyway. The mills are there, but I do not see this as a significant problem. However, additional metrics will help us better determine the severity of the problem and whether or not a more comprehensive solution is warranted in the future.

Chairwoman ELLMERS. Okay. Thank you. I appreciate that.

Well, in conclusion, I thank all of you for participating today. The SBIR and STTR programs are widely supported and recognized as one of the country's most important engines of innovation. Today was the second step in our Committee's effort to fully reauthorize these important initiatives. As Chairman Graves said at our previous hearing, we plan to work quickly, yet thoroughly, over the next several weeks to get this legislation on the House floor in May, and ultimately to get a bill to the President's desk as soon as possible.

Thank you all again, and I ask unanimous consent that the members have five legislative days to submit statements and supporting materials for the record.

Without objection, so ordered. This hearing is now adjourned.

[Whereupon, at 11:08 a.m., the hearing was adjourned.]



**AN OPEN LETTER FROM EXECUTIVES OF U.S. SMALL BIOTECHNOLOGY
& MEDICAL DEVICE COMPANIES REGARDING SBIR REAUTHORIZATION
& INCREASING THE NIH SBIR INTERNAL ALLOCATION**

March 18, 2011

Chairman Graves & Ranking Member Velazquez
House Committee on Small Business;

Chairwoman Landrieu & Ranking Member Snowe
Senate Small Business Committee;

Chairman Hall & Ranking Member Johnson
House Committee on Science, Space, & Technology;

Chairman Quayle & Ranking Member Wu
House Subcommittee on Technology & Innovation;

Dear Honorable Chairpersons & Ranking Members,

We, the undersigned leaders of small U.S. biotechnology and medical device firms write in strong support of the SBIR/STTR Reauthorization Act of 2011 (S. 493).

Today there is limited access to capital for companies developing cutting edge, early stage technologies that can cure or ameliorate disease while creating substantial numbers of new high wage jobs. The SBIR/STTR program has therefore become a primary and essential funding source for most small biotech and medical device companies throughout the country. Many important medical products now on the market were developed with funds from the SBIR/STTR program.

While we fully support this legislation we respectfully urge that the SBIR/STTR allocation at the National Institutes of Health (NIH) be increased by at least one percent for each of the next three years.

In considering our request please consider the following facts.

- For more than a decade, small business has created more than 2/3 of all new science & engineering jobs in this country and continues to sustain 38% of all science & engineering jobs nationwide. These high-paying jobs knowledge industry jobs often average \$60,000+ per year.
- Small businesses receive only about 2.8% of NIH funding (4.3% of all federal R & D funding). Academic institutions are awarded over 97% of NIH's funding, and as much as 32% of all Federal R & D.
- The number of SBIR/STTR grant applications at the NIH is at an all time high while the percentage receiving funding are at an all time low. 2010 applications increased by 40% from the prior year while the number of applications that received funding plummeted to 17.0% from 24.5% in 2009.
- Small businesses apply for 38% of new patents, 12 times more than the number of applications filed by academic institutions, and at 1/35 the cost.
- Firms receiving SBIR grants now account for nearly a quarter of *R&D 100 Awards*
- The Biomedical Research Authority of the European Union awards about 15% of their research funds to small businesses, and other countries are following suit.
- The SBIR/STTR allocation was removed from the NIH stimulus funding on the eve of passage due to behind-the-scenes lobbying by the academic community.
- Small technology companies lead translational science, transferring the majority of technology breakthroughs to the public. This translates to better medicines and better diagnostic devices that lead to a healthier society.
- The SBIR/STTR program represents a path to translate discoveries made by academic, government and non-profit institutions, funded by NIH, into valuable products and new jobs, leveraging the enormous investment in basic research.

Many of us have advanced scientific degrees and have extensive experience in working in or with nonprofit biomedical research institutions. We understand both the value

and limitations of academic research with respect to developing and commercializing innovative technologies. While academic research often serves as a foundation for our work, the true costs and risks of bringing biomedical products to market are overwhelmingly borne by companies. This reality is not reflected in the current NIH funding paradigm which provides disproportionate funding to academia.

The gross funding imbalance at the NIH—a result of persistent lobbying by the university community – hinders the ability of small companies to deliver lifesaving drugs, diagnostics and devices to patients as quickly as can be done with critical, early stage government funding. Timely delivery to the market of new products by innovative companies creates job growth in fields as diverse as manufacturing and marketing. In contrast, research projects by academia are often sustained solely with perpetual government funding

We recall that the academic lobby vigorously fought the creation of the SBIR program when it originated in the early 1980s. They argued then that the NIH in particular should devote 100% of its external funds to university based research. Over the past 30 years, SBIR funded companies have delivered hundreds of successful products to market and each year are responsible for nearly one quarter of *R&D Magazine's* list of 100 top innovations. Numerous studies by the National Academies of Sciences and others have documented the enormous success and productivity of the SBIR program which has become a global model duplicated in several other nations.

Expansion of the allocation at the NIH specifically is warranted because other agencies like DOD have an array of contract and grant programs for which companies can fairly compete. At the NIH, where funding priorities and review criteria are established by academia, companies win less than 0.1% of funds outside of the SBIR/STTR programs.

Importantly, the proposed modest increases in the SBIR/STTR allocations do not increase the Federal deficit and could be implemented without any reduction in government supported research by nonprofit entities. A mere 1% decrease in the overhead rates to all NIH grantees should permit at least a doubling of the current SBIR/STTR allocation.

In conclusion, we respectfully urge prompt reauthorization of the SBIR/STTR program with an increase in the allocation at the NIH to help us launch products that cure disease, promote human health, and create sustainable new jobs.

Sincerely,

Arthur DeCarlo
President and CEO
Agenta Biotechnologies, Inc.
1500 1st Ave. N., Unit 31
Birmingham, AL 35203

Ambuj Singh
President
Acelot, Inc.
5385 Hollister Avenue
Santa Barbara, CA 93111

Hans Schantz
CTO
Q-Track Corporation
3414 Governors Drive SW, Suite Q
Huntsville, AL 35805

Douglas Lappi
President/Chief Scientific Officer
Advanced Targeting Systems
10451 Roselle St, #300
San Diego, CA 92014

Dean Roberts
Research Scientist
Acetaminophen Toxicity Diagnostics, LLC
3 Childrens Way, Mail Slot 512-23
Little Rock, AR 72210

John Howard
President
Applied Biotechnology Institute
Bldg 83 1D, Cal Poly Tech Park
San Luis Obispo, CA 93407

Laura James
Chief Medical Officer
ATD, LLC
3 Children's Way
Little Rock, AR 72202

Vu Truong
Chief Scientific Officer
Aridis Pharmaceuticals
5941 Optical Ct
San Jose, CA 95138

Steve Green
President
Green Technologies, Inc.
13387 Green Road
West Fork, AR 72774

Eric Patzer
President
Aridis Pharmaceuticals
5941 Optical Court
San Jose, CA 95138

Peter Wiktor
Principle Investigator
Engineering Arts LLC
2640 Medtronic Way
Tempe, AZ 85281

Thomas Smith
CEO
Auritec Pharmaceuticals
1434 6th St, Suite 3
Santa Monica, CA 90401

Michael Hogan
Chief Scientific Officer & Founder
GMS Biotech
3450 S Broadmont Dr Suite 104
Tucson, AZ 85719

Xiaomin Fan
President
AvantGen
9924 Mesa Rim Rd.,
San Diego, CA 92121

Stephen Bartelmez
President and Founder
BetaStem Therapeutics
300 Brannan Street, Suite 407
San Francisco, CA 94107

Pamela Nuccitelli,
President
BioElectroMed Corp.
849 Mitten Road Suite 105
Burlingame, CA 94010

Philip Lee
Director of R&D
CellASIC Corp.
2544 Barrington Ct.
Hayward, CA 94545

Robert Balint, CEO
CytoDesign, Inc
4003 Scripps Avenue
Palo Alto, CA 94306

Nicolas L'Heureux
C.S.O.
Cytograft Tissue Engineering, Inc.
3 Hamilton Landing, Suite 220
Novato, CA 94949

Robert Bilhorn
President
Direct Electron, LP
13240 Evening Creek Dr. S., Suite 311
San Diego, CA 92128

Nima Shiva, CEO
Encode Bio, Inc.
1 W. Mtn. St, #10
Pasadena, CA 91103

Iman Famili
Sr. Director, R&D
GT Life Sciences, Inc.
10520 Wateridge Circle
San Diego, CA 92121

Thomas Reed
President & CFO
GT Life Sciences, Inc.
10520 Wateridge Circle
San Diego, CA 92121

Ilse Ortabasi
Owner
Kinder Magic Software
1680 Meadowglen Lane
Encinitas, CA 92024

Michelle Call, CEO
Lypro Biosciences, Inc.
1700 4th Street, Byers Hall, BH 218B
San Francisco, CA 94158

William MacConnell
President/CEO
MacConnell Research Corp
9550 Waples Street, Suite 120
San Diego, CA 92121

Mark Dilorio
President & CEO
MagneSensors, Inc.
9717-A Pacific Heights Blvd.
San Diego, CA 92121

Larry Zeitlin, President
Mapp Biopharmaceutical
6160 Lusk Blvd #C105
San Diego, CA 92121

Kevin Whaley, CEO
Mapp Biopharmaceutical
6160 Lusk Blvd., Suite C105
San Diego, CA 92121

Richard Tamaki
Secretary and COO
Molecular GPS Technologies
2011 University Drive
Rancho Dominguez, CA 90220

David Hosfield
Owner and CSO
Molecular Tagging Systems
1425 Russ Blvd, T112C
San Diego, CA 92101

Eugene Levin
President
Motility Incorporated
3883 Caminnito Litoral 2226
San Diego, CA 92107

Armin Reitmair, CEO
Nesher Technologies, Inc.
2100 W. 3rd St.
Los Angeles, CA 90057

Kumar Subramanian, CEO
Phoenix Biosystem, Inc.
1061 Serpentine Lane, Suite A-1
Pleasanton, CA 94566

Bruno Kajiyama, CEO
Photozig, Inc.
NASA Research Park, PO Box 128
Moffett Field, CA 94035

James Maclean
Senior Scientist
Planet Biotechnology
25571 Clawiter Road
Hayward, CA 94545

Keith Wycoff
Research Director
Planet Biotechnology
25571 Clawiter Rd
Hayward, CA 94545

Ariane van der Straten
Senior Research Scientist
RTI International
114 Sansome Street, suite 500
San Francisco, CA 94104

Daniel Resnic
CEO/ Inventor
Strata Various Product Design
4445 Overland Ave
Culver City, CA 90230

Ray Chavez
Project Coordinator
Strata Various Product Design
4445 Overland Ave
Culver City, CA 90230

Shenda Baker
President
Synedgen Inc
1420 N Claremont Blvd, Suite 105D
Claremont, CA 91711

Sunil Bhonsle
President
Titan Pharmaceuticals, Inc.
400 Oyster Point Blvd, Ste 505
South San Francisco, CA 94080

Roger Kaspar, CEO
TransDerm
2161 Delaware Ave., Suite D
Santa Cruz, CA 95060

Victor Bronshtein
President & CSO
Universal Stabilization Technologies, Inc.
4050 Sorrento Valley Blvd., Ste. L
San Diego, CA 92121

Paul Davoust
President
CaringFamily LLC
1003 Turnberry Circle
Louisville, CO 80027

Bo Chen
Technical Fellow
Covidien
6135 Gunbarrel Ave
Boulder, CO 80301

Robert Wagner
President & CEO
Gene Check, Inc
1175 58th Ave, Suite 100
Greeley, CO 80634

Dan Stinchcomb, CEO
Inviragen, Inc.
1613 Prospect Parkway, Suite 100
Fort Collins, CO 80525

Christopher Myatt
Founder and CEO
MBio Diagnostics, Inc.
3122 Sterling Circle, Suite 100
Boulder, CO 80301

Jon VonOhlsen, CTO
Quest Product Development
6833 Joyce Street
Arvada, CO 80007

Ruth Shrairman
President and Chief Scientific Officer
VeriFax Corporation
7783 Cornwall Circle
Boulder, CO 80301

Rosalyn Liss, Partner
Applied Behavioral Research
59 Elm St Suite 200
New Haven, CT 06510

Joseph Backer, CEO
SibTech, Inc.
115A Commerce Drive
Brookfield, CT 06804

Nicole Kuzmin-Nichols
President & COO
SANERON CCEL THERAPEUTICS, INC
3802 Spectrum Blvd, Suite 147
Tampa, FL 33612

Charles Rigby
CEO/President
Self-Determined Health, Inc.
814 Deer Woods Road
Celebration, FL 34747

Kristen Holtz
president
KDH Research & Communication
730 Peachtree Street NE, Suite 820
Atlanta, GA 30308

Meera Saxena
President
Luminomics Inc
1120 15th Street, CA-2105
Augusta, GA 30912

Jeffrey Neighbors
Senior Scientist and Founder
Terpenoid Therapeutics Inc.
2500 Crosspark Road, Suite E132
Coralville, IA 52241

Hansen Mansy
VP for R&D
BARC
3847 Mandeville Lane
Naperville, IL 60564

Morteza Janghorbani
President
BioChemAnalysis Corp.
2201 W Campbell Park Dr STE 28
Chicago, IL 60612

Roy Wesley, CFO
Fermalogic
2201 W. Campbell Park Dr.
Chicago, IL 60657

Benjamin Glick
President and Chief Scientist
GSL Biotech LLC
5211 S. Kenwood Ave.
Chicago, IL 60615

Miles Wernick
President
Predictek, Inc.
10 W 35th St, Suite 10F4-2
Chicago, IL 60616

Miles Wernick
President
Predictek, Inc.
10 W. 35th St., Suite 10F4-2
Chicago, IL 60616

Thomas Myers
VP, Business Development
WisdomTools Enterprises, Inc.
501 N Morton St, Ste 206
Bloomington, IN 47404

Donna Johnson, CEO
Pinnacle Technology Inc.
2721 Oregon Street
Lawrence, KS 66046

Kathryn MacLeod
Vice President of Research & Development
ApoImmune, Inc.
1044 East Chestnut Street
Louisville, KY 40204

Bruce Webb
President
ParaTechs Corp
1122 Oak Hill Drive
Lexington, KY 40505

Stephen Carithers
Vice-President/Principal Investigator
Sequela, Inc.
1002 Buckner Centre Drive, Suite 3
LaGrange, KY 40031

Jong Rim
Senior Scientist
NuPotential, Inc.
Louisiana Emerging Technology Center, LSU
Bldg #340, East Parker Blvd.
Baton Rouge, LA 70803

Barbara Fox
CEO
Avaxia Biologics, Inc.
26 Pemberton Rd.
Wayland, MA 01778

Bertrand Lemieux
S. Director for Technology Development
BioHelix
500 Cummings Center, suite 5550
Beverly, MA 01915

Matthew Phaneuf
President and CTO
BioSurfaces, Inc.
200 Homer Avenue, Unit 1P
Ashland, MA 01721

Jose Bohorquez
President and CEO
Convergence Medical Devices
400 TradeCenter, Suite 5900
Woburn, MA 01801

Paul Stroobant
Founder, VP and Chief Scientific Officer
Differential Proteomics, Inc.
Venture Development Center, Wheatley Hall,
100 Morrissey Blvd.
Boston, MA 02125

Anthony LaConti
Chief Executive Officer
GINER, INC.
89 Rumford Avenue
Newton, MA 02466

Thomas Pistone
Business Development Manager
Jameson & Company
251 Swanton Street
Winchester, MA 01890

Edward Jameson
CEO
Jameson & Company, LLC
394 Lowell Street, Suite 8
Lexington, MA 02420

Andrew Worth
President & C.T.O.
Neuromorphometrics, Inc.
22 Westminster St.
Somerville, MA 02144

Aram Salzman, CEO
NovoBiotic Pharmaceuticals
767C Concord Ave
Cambridge, MA 02478

Anthony Ferrante
Principal Research Scientist
Physical Sciences Inc
20 New England Business Center
Andover, MA 01810

Radhakrishnan Iyer
Chief Scientific Officer
Spring Bank Pharmaceuticals, Inc
113 Cedar street
Milford, MA 01757

Jonathan Cohen
President and CEO
20/20 GeneSystems, Inc.
9430 Key West Ave., Suite 100
Rockville, MD 20850

Ozge Alper, CEO
Alper Biotech
9700 Great Seneca Highway, Suite #188
Rockville, MD 20850

Martin Woodle
Chief Executive and Scientific Officer
AparnaBio
12111 Parklawn Drive, Suite 125
Rockville, MD 20852

Aprile Pilon
President
APC Biotechnology Services, Inc.
9700 Great Seneca Highway
Rockville, MD 20850

Ilya Mazo, CEO
Ariadne Genomics Inc
9430 Key West ave
Rockville, MD 20850

Darryl Sampey
President and CEO
BioFactura, Inc.
9430 Key West Avenue, Suite 125
Rockville, MD 20850

Gregory Tobin
Chief Scientific Officer
Biological Mimetics, Inc.
124 Byte Drive
Frederick, MD 21702

Martha Knight
Director
CC Biotech LLC
9700 Great Seneca Highway, #163
Rockville, MD 20850

Aprile Pilon, CEO
Clarassance, Inc.
9700 Great Seneca Highway
Rockville, MD 20850

Cha-Mei Tang
President
Creatv MicroTech, Inc.
11609 Lake Potomac Dr.
Potomac, MD 20854

Richard Huguen
Vice President
CSA Medical
1101 E. 33rd Street, Suite E302
Baltimore, MD 21218

Steven Schaefer, CFO
CSA Medical, Inc.
1101 E. 33rd Street, Suite E- 305
Baltimore, MD 21218

Andrew LEES
Scientific Director
Fina BioSolutions LLC
9610 Medical Center Dr., Suite 200
Rockville, MD 20850

Steingrímur Stefánsson
Director
Fuzbien Technology Institute
9700 Great Seneca Hwy, Suite 302
Rockville, MD 20850

Xinli Lin
Vice President R&D
GeneCopia, Inc.
9620 Medical Center Dr., #101
Rockville, MD 20850

Allen Tien
President and Director of Applied Research
Medical Decision Logic, Inc.
1216 E. Baltimore St
Baltimore, MD 21202

Marco Chacon
President & CEO
Paragon Bioservices, Inc.
801 W. Baltimore St., STE 401
Baltimore, MD 21201

Yvonne Rosenberg, CEO
PlantVax Inc
9430 Key West Ave, Suite 120
Rockville, MD 20850

Antony Dimitrov
Senior Staff Scientist
Profectus BioSciences, Inc.
6411 Beckley Str.
Baltimore, MD 21224

Kim Lee Sim, President
Protein Potential LLC
9800 Medical Center Dr., ste A209
Rockville, MD 20850

Robert Thompson
Vice President
Sanaria Inc.
9800 Medical Center Dr, a209
Rockville, MD 20850

Stephen Hoffman, CEO
Sanaria Inc.
9800 Medical Center Dr, A209
Rockville, MD 20850

Patrick Lu, CEO
Sirnaomics, Inc.
401 Professional Drive, Suite 130
Gaithersburg, MD 20879

Raghu Raghavan
President
Therataxis, LLC
1101 East 33rd Street, Suite B305
Baltimore, MD 21218

Irving Weinberg
President
Weinberg Medical Physics LLC
5611 Roosevelt Street
Bethesda, MD 20817

Kenneth Carr, CEO
Meridian Medical Systems
77 Goose Cove Lane
Woolrich, ME 04579

Xincheng Zheng
Chief Operating Officer
OncoImmune Inc.
333 Parkland Plaza, Suite 1000
Ann Arbor, MI 48103

Maria Ines Morano
Chief Scientific Officer
Originus, Incorporated
3985 Research Park Dr., Suite 200
Ann Arbor, MI 48108

John Hilfinger
President
TSRL, Inc.
540 Avis Drive, Suite A
Ann Arbor, MI 48108

Anja Metzger
VP R&D and Grant Affairs
Advanced Circulatory Systems, Inc.
1905 Cty Rd C West
Roseville, MN 55113

Patrick Guire
President
Innovative Surface Technologies, Inc.
1000 Westgate Drive, #115
Saint Paul, MN 55114

Jim Stice
President
Twin Star Medical
700 S 10th Avenue
Minneapolis, MN 55415

Shuan Huang
President & Research Director
Auxagen, Inc.
Center for Emerging Technologies, 4041 Forest
Park Ave
St. Louis, MO 63108

Mark (Meng) Chen
Vice President
Nanova, Inc.
1005 Brook Trout Ct.
Columbia, MO 65203

Mary Metcalf
Vice President
Clinical Tools, Inc.
1506 E Franklin Street, #200
Chapel Hill, NC 27514

Feng-Qiao Li
Principal Scientist
Cognosci, Inc.
79 TW Alexander Drive
4401 Research Commons, Suite 200A
Research Triangle Park, NC 27709

William Griffin, CEO
ILR, Inc.
411 Andrews Road, Suite 140
Durham, NC 27705

Luke Burnett
Senior Scientist, Director of Product
Development and Research
KeraNetics LLC
Richard Dean Research Building, Suite 168
391 Technology Way
Winston-Salem, NC 27101

Harry Burrell
Vice President (ret.)
Lucigen Corp.
6284 Cattail Ct.
Southport, NC 28461

Helmut Eckhardt
President & CEO
Premitec, Inc.
1021 Main Campus Drive, Suite 300
Raleigh, NC 27606

Benjamin Brodey, MD, MPH
CEO and Director of Research
TeleSage, Inc.
157 E. Franklin St. #1
Chapel Hill, NC 27514

Patrick Flood
Chief Operations Officer
Theralogics, Inc.
600 Franklin Square, 1829 E. Franklin St.
Chapel Hill, NC 27514

Philip Schaefer, President
Vortant Technologies, LLC
88 High Country Road
Weaverville, NC 28787

Ben Buehrer
Vice President
Zen-Bio, Inc.
3200 Chapel Hill-Nelson Blvd., Suite 104
RTP, NC 27514

David Vilkomerson
President
DVX, llc
31 Airpark Road
Princeton, NJ 08540

Richard Russo
President
Endomedix, Inc.
211 Warren Street
Newark, NJ 07103

Joseph Huang, President
MicroDysis, Inc.
1200 Florence-Columbus Road
Bordentown, NJ 08505

Nikolaos Tezapsidis, CEO
President & CEO
Neurotez, Inc.
991 Highway 22, Suite 200A
Bridgewater, NJ 08807

Rick Weiss
President
Viocare, Inc.
145 Witherspoon Street
Princeton, NJ 08542

Reid Hester, Ph.D.
Director, Research Division
Behavior Therapy Associates, LLP
9426 Indian School Rd NE Ste 1
Albuquerque, NM 87112

Michael Zwick, CEO
AndroBioSys, Inc.
Elm and Carlton Streets
Buffalo, NY 14263

Mark McPike, CSO
AptaMatrix
100 Intrepid Ln, Suite 1
Syracuse, NY 13205

Barbara Soltz, CEO
Conversion Energy Enterprises
81 Pinebrook Rd.
Spring Valley, NY 10977

Jonathan Kaufman
President & CEO
Cyberlogic, Inc.
611 Broadway, Suite 707
New York, NY 10012

James T Woo
President
InterScience, Inc.
105 Jordan Road
Troy, NY 12180

Allen Barnett
CEO
Kinex Pharmaceuticals
701 Ellicott St.
Buffalo, NY 14203

Anthony Sterns
Vice President of Research
Creative Action LLC
395 Merriman Rd.
Akron, OH 44303

Robert Buck, CSO
Gauge Scientific
5920 NE 112th Ave
Portland, OR 97220

Stanley Patton
Proj Director/PrinInvestigator/President/Chair
Health Education Research Systems, llc
1704 NE Cliff Drive
Bend, OR 97701

Douglas Brenneman
Chief Scientific Officer
Advanced Neural Dynamics, Inc
PA Biotechnology Center
3805 Old Easton Road
Doylestown, PA 18902

Jason Smith
Manager of R&D
Carmell Therapeutics
320 E. North Ave., 10 S. Tower
Pittsburgh, PA 15212

Matt Bootman, CEO
Crystalplex Corp.
2403 Sidney St, Ste 271
Pittsburgh, PA 15203

Michael Bozik, CEO
Knopp Neurosciences
2100 Wharton St
Pittsburgh, PA 15203

Tom Petzinger, CEO
Launchcyte LLC
2403 Sidney St, Ste 271
Pittsburgh, PA 15203

Jonathan Kaufman, CEO
Lipella Pharmaceuticals Inc.
5414 guarino road
pittsburgh, PA 15217

Maureen Mulvihill
President
Piezo Resonance Innovations
310 Rolling Ridge Drive
Bellefonte, PA 16823

Jing Kong
CEO, Chief Scientist
Q-Chem, Inc.
5001 Baum Blvd, Suite 690
Pittsburgh, PA 15213

Matthew Oristano, CEO
Reaction Biology Corporation
1 Great Valley Parkway, Suite 2
Malvern, PA 19355

Sherin Abdel-Meguid
President
Shifa Biomedical Corporation
One Great Valley Parkway, Suite 8
Malvern, PA 19355

James D. Thacker, PhD
President & Chief Science Officer
TherimuneX Pharmaceuticals, Inc.
3805 Old Easton Road
Doylestown, PA 18902

Kelvin Brockbank
President
Cell & Tissue Systems
2231 Technical Parkway, Suite A
North Charleston, SC 29406

Craig Beeson
President
MitoHealth, Inc
645 Meeting St
Charleston, SC 29403

Professor Dukhee Lew
University of Tennessee
UTHSC 50 North Dunlap St. CFRC Rm401
Memphis, TN 38103

Gregg Siegel
President
Biomedical Development Corporation
500 Sandau #200
San Antonio, TX 78216

Bill Jackson
Senior Scientist
BioTex, Inc.
8058 El Rio St.
Houston, TX 77054

Christopher Frederickson, CEO
NeuroBioTex Inc & AndroDx Inc.
101 14th
Galveston, TX 77550

Harvey Wiggins
President
Plexon Inc
6500 Greenville Ave, Ste 700
Dallas, TX 75206

Fred Patterson
President
The SBIR Coach
1704 Newton Dr
Flower Mound, TX 75028

John Higuchi, CEO
Aciont Inc.
350 W. 800 N., #320
Salt Lake City, UT 84103

Chris Hopkins, CEO
KDT, LLC
2500 S State St
Salt Lake City, UT 84102

Danuta Petelenz
Manager
Nanomedic, Inc
615 Arapeen Dr
Salt LAke City, UT 84108

Jeremy Goeckeritz
Researcher
Sterling
28 S 400 E
Salt Lake City, UT 84111

Scott Sundberg
Postdoctoral Fellow
University of Utah
1795 E South Campus Dr Rm 5R441
SLC, UT 84112

Lauren Foley
Biomedical Research Technician
Luna Innovations
141 Brookwood Dr.
Charlottesville, VA 22902

Klaus Schafer
President & CEO
TessArae, LLC
46090 Lake Center Plaza, Suite 304, 46090 Lake
Center Plaza, Suite 304
Potomac Falls, VA 20165

Robert Davis, CEO
Stromatec, Inc
431 Pine St, Suite 214
Burlington, VT 05401

Peter Ariessohn
Vice President, R&D
Enertechnix, Inc.
P.O. Box 469
Maple Valley, WA 98038

David Vachon
Chief Executive Officer
Iasis Molecular Sciences
665 N Riverpoint Blvd, Suite 454
Spokane, WA 99202

Paul Slowey, CEO
Oasis Diagnostics Corporation
15720 NE 31st Avenue
Vancouver, WA 98686

John Zebala
President and CEO
Syntrix Biosystems, Inc.
215 Clay Street NW, Suite B5
Auburn, WA 98001

Todd Asmuth, CEO
AquaMost, Inc
100 S. Baldwin, Suite 101
Madison, WI 53703

James Tretheway
President and CEO
Bioionix, Inc.
4603 Triangle St
McFarland, WI 53558

Ward Tucker
Research Director
BioSentinel Pharmaceuticals Inc.
510 Charmany Drive
Madison, WI 53719

Dmitri Andreev
Sr. Scientist
Catalent Pharma Solutions - Middleton
8137 Forsythia Street
Middleton, WI 53562

Ken Kobak
Owner
Center for Psychological Consultation
22 North Harwood
Madison, WI 53717

James Prudent, CEO
CENTROSE
802 Deming Way
Madison, WI 53717

Fred Blattner
President
DNASTAR Inc/Scarab Geonomics, Inc.
3801 Regent Street
Madison, WI 53705

Mike Storck
Operations Manager
Functional Biosciences, Inc.
505 South Rosa Road, Suite 17
Madison, WI 53719

Alex Vodenlich
President & CEO
Gentel Biosciences, Inc.
5500 Nobel Drive
Madison, WI 53711

Ayla Annac, CEO
Invivosciences LLC
6102 canyon parkway
McFarland, WI 53558

Nancy Kendrick
President
Kendrick Labs Inc
1202 Ann St
Madison, WI 53713

David Mead, CEO
Lucigen
2120 W Greenview Dr
Middleton, WI 53562

Jeffrey Williams
President
Lucigen Corp.
2120 W. Greenview Dr.
Middleton, WI 53562

Thomas Hart
Research Scientist
Madison Biodiagnostics
1289 Deming Way
Madison, WI 53717

Mark T Nelson
President
Microscopy Innovations LLC
213 Air Park Rd Ste 101
Marshfield, WI 54449

Steven Goodman, CSO
Microscopy Innovations LLC
213 Air Park Road, Suite 101
Marshfield, WI 54449

John Verstegen
VP Research and Development
Minitube of America
419 Venture Ct.
Verona, WI 53593

Deven McGlenn, CEO
NeoClone, LLC
1202 Ann St.
Madison, WI 53713

Jediah White
VP of Business Development
Nerites Corporation
505 S Rosa Road, Suite 123
Madison, WI 53719

Jennifer Leny
Quality Manager
Pharming, N.V.
6938 Hickory Lane
DeForest, WI 53532

Earl Gibbs
 Director of Research
 PhysioGenix
 10437 Innovation Drive
 Milwaukee, WI 53226

Renee Herber
 Program Manager
 Platypus Technologies, LLC
 5520 Nobel Drive, Suite 100
 Madison, WI 53711

David Schlesinger
 Director of Research Genomics
 PreventionGenetics
 3700 Downwind Drive
 Marshfield, WI 54449

Ralph Kauten, CEO
 Quintessence Biosciences, Inc.
 505 South Rosa Road
 Madison, WI 53719

Benjamin Moga
 Vice President
 Ratio Inc.
 304 N Segoe Rd #102
 Madison, WI 53705

Katharine Muirhead, COO
 SciGro, Inc.
 510 Charmany Drive, Suite 175B
 Madison, WI 53719

Lisa Johnson
 Chief Business Officer
 Semba Biosciences, Inc.
 505 S. Rosa Road, Suite 106A
 Madison, WI 53589

Elizabeth Donley, CEO
 Stemina Biomarker Discovery
 504 S. Rosa Road, Suite 150
 Madison, WI 53719