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REAUTHORIZATION OF THE SBA'S INNOVATION PROGRAMS

HEARING

BEFORE THE

COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

MAY 15, 2019

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REAUTHORIZATION OF THE SBA'S INNOVATION PROGRAMS

WEDNESDAY, MAY 15, 2019

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

The Committee met, pursuant to notice, at 2:30 p.m., in Room 428A, Russell Senate Office Building, Hon. Marco Rubio, Chairman of the Committee, presiding.

Present: Senators Rubio, Scott, Ernst, Kennedy, Hawley, Cardin, Cantwell, Shaheen, Markey, Coons, and Rosen.

OPENING STATEMENT OF HON. MARCO RUBIO, CHAIRMAN, A U.S. SENATOR FROM FLORIDA

Chairman Rubio. The hearing of the Senate Committee on Small Business and Entrepreneurship will come to order.

I want to thank you all for being here. I want to extend a welcome to our witnesses. The hearing today is titled "Reauthorization of SBA's Innovation Programs," to delve into the programs that provide needed investment in America's most innovative small businesses.

Today we are going to continue our work to reauthorize the Small Business Act by focusing the discussion on the dynamic sector of those firms with high-growth potential participating in the Small Business Innovation Research and Small Business Technology Transfer programs at the SBA.

To frame this discussion, I would like to first start by addressing the landscape that I believe we find ourselves in today when it comes to competitiveness. We are currently facing the most significant global competition this Nation has ever confronted. Other countries have taken note of our past investments and the resulting successes and are investing in research and development at far higher rates than the U.S. currently is.

According to the Information Technology and Innovation Foundation, U.S. productivity growth over the last decade is the lowest since the government started recording this data in the 1940s.

Meanwhile, our global competitors are investing in research and development and increasing their technological sophistication, pulling ahead in key areas such as life sciences, flexible electronics, advanced manufacturing.

As a Nation, we must decide where our priorities lie. If we want to remain competitive leaders in the world, we have to make investments and prioritize programs that achieve those results. Today I released a report that explores the nature of investment in the United States and details what the decline of business investment in the private sector has wrought for our long-term productive capacity. The report finds that while investing in productive, long-life capital assets and industries may be more challenging than capturing quick profits from financial maneuvers, it is required for a successful economy that produces dignified work for our people and secures our national strength and prosperity.

Investing in productive industrial capacity is in our vital national interest. In other words, we need to understand the need to invest in ourselves and what investing in ourselves requires. This includes investing in the technological innovation that will allow us

to maintain our competitive edge across industries.

There is a correlation between these national competitiveness

concerns and the SBA programs we are discussing today.

The SBIR and STTR programs are highly competitive programs that marry basic research and development with funding to meet a government need with the goal of moving basic research through developmental phases to commercialization.

Authorized in 1982 and 1992, respectively, the basic tenets of the programs require any agency with \$100 million in extramural research and development funding to use 3.2 percent of those funds

for an SBIR program.

If the agency has more than \$1 billion budgeted for extramural research and development, they must use 45 percent of those funds

for an STTR program.

There are currently 11 agencies participating in the SBIR program and 5 agencies participating in the STTR program. Each program consists of three phases, moving from a Phase I award of up to \$150,000 for basic research and development to a Phase II award that provides up to \$1 million for further development of the technology and moving the small business toward commercialization. Phase III of the programs does not include funding from the SBIR and STTR programs but is intended to act as a facilitator for commercialization. Phase III funding is expected to be generated by the private sector or through working with agencies through additional contracts, including sole-source awards.

These programs have proven to be impressive examples of what investment in research and development can achieve and how par-

ticipating small businesses can grow and scale.

Some examples of the recipients of SBIR that have had immense success scaling are names that sound familiar: Qualcomm, iRobot, Symantec, Amgen, 23andMe, and others. One of the companies NASA just funded could very well join these well-known companies.

The agency just announced it has selected 142 Phase II proposals from 28 States and awarded them \$106 million to develop technologies ranging from managing pilotless aircraft to developing solar panels that can help humans live on the Moon and Mars, to sensor technology for autonomous entry, descent, and precision landing on planetary surfaces.

These awards are exciting because they forecast both advancements for NASA, the country and are opportunities for businesses to become the next big SBIR success story and contribute to the

overall national impact of the programs.

The success of the SBIR and STTR programs has been studied by a number of different entities, and several agencies have commissioned studies on the commercialization and economic impact of the programs.

The Navy commissioned a study of their programs for fiscal year 2000 to 2013 and found that of a \$2.3 billion investment, the pro-

grams provided an economic output of \$44.3 billion.

The economic impact also included the creation of nearly 200,000 jobs with an average wage of approximately \$69,000, which is 42

percent higher than the average U.S. wage.

The programs are not only successful at the Department of Defense. A 2018 National Cancer Institute study of its SBIR and STTR programs showed that NCI's investment of \$787 million from fiscal year 1998 to 2010 resulted in \$9.1 billion in sales of products and services, \$8.1 billion in labor income, \$13.4 billion in value-added wealth to the economy, and \$26 billion in total economic output.

The programs also created more than 107,000 jobs with an aver-

age wage of approximately \$75,000.

The National Science Foundation, which focuses largely on basic research, also reports that they fund roughly 400 companies per year, and since 2012, the agency has made nearly 3,000 awards to

startups and small businesses.

Since 2014, the NSF's awardees have received \$6.5 billion in private investment in a wide range of industries from advanced manufacturing to artificial intelligence, robotics, semiconductors, biomedical technologies and more. These proven programs are examples of the types of public investment our country should be making. In fact, it is the type of investment we should be making more of.

My home State of Florida has had a very successful relationship with the programs, with more than 4,000 total awards since 2010. I would like every State to be successful in using the program, and the barriers to success in States across the country should be part of this conversation.

I look forward to having a robust discussion and identify ways we can increase the number of firms with opportunities for SBIR

and STTR awards.

It is important to make these programs more efficient and better provide small businesses nationwide with the tools they need to commercialize and scale, including through additional private-sector venture capital investments.

With that, I turn it over to the Ranking Member.

OPENING STATEMENT OF HON. BENJAMIN L. CARDIN, RANKING MEMBER, A U.S. SENATOR FROM MARYLAND

Senator Cardin. Well, Chairman Rubio, thank you very much for calling this hearing. This is one in a series of hearings that our committee is holding on looking at the reauthorization of the programs under the Small Business Administration. This one is an extremely important hearing dealing with the SBIR and STTR program.

I think the Chairman outlined rather effectively how these programs work and how critically important they are to our economy.

We talk frequently about America's economy dependent upon small businesses. Small businesses is where the growth engine of America is for creation of jobs and innovation. When we talk about that, the statistics are very clear that we create more innovation through small companies, per employee for sure, than larger companies. So encouraging innovation in small businesses is critically important to success of our economy, and the SBIR program and STTR program do that. End result, a lot of high-paying jobs are created here in America.

In meeting the growing challenge from foreign competition, we had a hearing not too long ago on China, "Made in China 2025." Well, if we are looking at ways that we can globally compete against the competition we have today, let us invest in programs such as the SBIR and STTR programs. To me, it is more effective, quite frankly, than looking at tariffs. So I would hope that we will continue to invest in innovation and small companies.

We have been successful. We can talk about some of the examples. The Chairman mentioned some of the fields from public health to national security, companies such as Sonicare Electric Toothbrush—this tool helped develop that—iRobot, LASIK eye surgery so we all can see better, Qualcomm. These are just some examples of where we have been able to use the small business tools to help new companies that have made a major impact on innovation in our economy as leaders and new ways of doing things that are now very much helping America's competitiveness.

As we look at the reauthorization, I want to acknowledge the work of Senator Shaheen in extending these programs through September 30, 2022. That is a major step forward.

Mr. Chairman, I would urge us all as we look at the reauthorizations. Yes, there are ways that we can improve both of these programs, and let us look at ways that we can improve both of these programs. But I hope we all would agree we should make them permanent.

If you are an investor, you need certainty. Congress is notorious for missing deadlines, and it would be good if we could take this one off the table so we do not have to worry about the next deadline and our companies can look for partners and investors, knowing full well that these tools will be available to help them in the growth of their innovation.

I want to welcome all of our witnesses that are here today, our governmental witnesses—thank you—on the first panel and our private-sector witnesses. I want to acknowledge Dr. Stephen Hoffman and the work that he is doing—to me, it is critically important—in Sanaria. It is a company developing a vaccine for malaria. The company has grown to 80 employees. That is quite an accomplishment. They are partnering with the National Institutes of Health. A vaccine for malaria will save hundreds of thousands of lives. It is certainly high risk to be able to develop this, but the rewards are great. And that is exactly why we have the partnerships with the Federal Government, and I look forward to hearing from Dr. Hoffman.

I am very proud of the role that the State of Maryland has

played in innovation.

Senator Shaheen, I just mentioned your good work on the SBIR program, STTR program, and extending it through your service on the Armed Services Committee. We appreciate very much your work on that.

Maryland is a national leader in research and development. We have the National Institutes of Health, the National Institute of Standards and Technology, Johns Hopkins University, University of Maryland. These are all partners that we have on research.

Recently there was a tech transfer summit held at NIST sponsored by the State of Maryland. One of our witnesses, Jere Glover, was there, participated in that. He is the executive director of the

Small Business Tech Council.

We talked about commercialization because that is what this is about. It is about innovation being pursued but leading toward commercialization, and this summit helped us develop ways that we can work with our Federal and university labs to develop more commercialization with the help of the SBIR program and the STTR program.

Shortly, the Maryland Department of Commerce will be releasing its actionable strategies to advance the commercialization of technology. So we are moving forward, thanks to the partnership with

these SBA tools.

I look forward to hearing from all of our witnesses today so that we can strengthen and make more predictable the role that we play in advancing innovation and small businesses.

Chairman Rubio. All right. Let us get right to it.

Joseph Shepard is the Associate Administrator of the Office of Investment and Innovation at the Small Business Administration. In his role, he manages the SBIC program, the SBIR program, and the STTR program.

John Williams is the Director of Innovation and Technology for the Office of Investment and Innovation, where he oversees policy implementation and conducts programmatic oversight of the SBIR and STTR programs and their administration at participating agencies.

So we will begin with you, Mr. Shepard.

STATEMENT OF JOSEPH SHEPARD, ASSOCIATE ADMINISTRATOR, OFFICE OF INVESTMENT AND INNOVATION, U.S. SMALL BUSINESS ADMINISTRATION, WASHINGTON, DC

Mr. Shepard. Very good. Chairman, thank you. Thank you, Chairman Rubio and Ranking Member Cardin and members of the committee. Thank you. It is good to be here today and appreciate the invitation to come here and discuss the United States Small Business Administration, or SBA, Innovation Programs, which as we have been talking about include SBIR, the Small Business Innovation Research, created, Chairman, as you said, in 1982, also the Small Business Technology Transfer, STTR, program created in 1992.

Since their beginning, these programs have encouraged innovation and entrepreneurial activity in our Nation. Today small businesses continue to be encouraged to develop and commercialize

their innovative products through these programs.

I also wanted to mention that as a father of a 13-year-old son with an interest and aptitude in science, technology, engineering, and math, I am keenly aware of the importance of these programs for the next generation of American entrepreneurs, small business owners, and university researchers who will seek to make meaningful contributions that will help our economy grow and strengthen in the future.

SBA is responsible for the oversight of these programs in areas that involve policy, reporting to Congress, data collection, and data maintenance.

In regards to policy, SBA's new SBIR/STTR Policy Directive has been published and became effective on May 2nd, 2019. The Policy Directive provides updated guidance to the 11 Federal agencies that participate in these programs and replaces the previous 5-year-old 2014 version.

Additionally, the new Policy Directive increases the data protection period for small businesses from 4 years to a minimum of 20

years.

SBA has improved its reporting frequency to Congress. During the past 21 months, SBA has delivered both the Fiscal Year 2014 and 2015 annual SBIR/STTR reports. The Fiscal Year 2016 report was delivered last month, and the Fiscal Year 2017 report will be delivered this summer.

Concerning SBA data collection and maintenance, SBA's SBIR.gov Business Intelligence Platform currently contains award data for more than 170,000 awards and 26,000 companies. Each year, SBA collects and analyzes additional program data provided by the 11 participating Federal agencies to evaluate agency and SBIR/STTR program performance.

A main goal at SBA has been to modernize and streamline all SBA programs using improved technology to create a better user

experience.

As SBA's Chief Information Officer Maria Roat discussed in her March 13, 2019, hearing before this committee, the SBA is engaged in numerous enterprise-wide modernization initiatives, including hardware, software, and application standardization, as well as infrastructure upgrades. Improving the SBIR.gov platform is an area where SBA continues to focus as we seek better ways to collect, maintain, analyze, and publish SBIR/STTR data.

During the past 2 years, we have worked to implement data quality control tools and modernize the platform. Last year, the platform was moved to the cloud to improve reliability and secu-

rity.

For the majority of the activities I have discussed, the 3 percent administrative funding pilot introduced in 2011 and reauthorized through 2022 will continue to be beneficial to the SBA in regards

to SBA's oversight responsibilities for these programs.

The pilot provides authority for participating agencies to utilize 3 percent of the SBIR program for costs related to SBIR oversight. However, the SBA is dependent on the agencies to provide these funds to SBA. Once provided, funding associated with the pilot en-

ables SBA to make improvements in oversight areas related to policy, reporting, and data, as well as outreach.

In regards to all of these activities, SBA remains committed to improving the effectiveness, efficiency, and accountability of the

SBIR/STTR programs.

Again, I want to thank you for the invitation to be here today and also thank you for your support of SBA. We look forward to continuing our work to better assist America's small businesses.

Director John Williams will now highlight a few areas SBA is fo-

cusing on as well as some other program areas.

So thank you.

Chairman Rubio. Thank you.

Mr. Williams.

STATEMENT OF JOHN WILLIAMS, DIRECTOR, INNOVATION AND TECHNOLOGY, OFFICE OF INVESTMENT AND INNOVATION, U.S. SMALL BUSINESS ADMINISTRATION, WASHINGTON, DC

Mr. WILLIAMS. Thank you.

Chairman Rubio, Ranking Member Cardin, and members of the committee, it is truly an honor to be here and specifically to discuss programs of SBA's Innovation Program and how they relate to SBIR and STTR.

I have dedicated the last 25 years of my career focused on these programs, most of it at Navy and then 4 years ago here at SBA.

Today you will hear from others that talk about the program, and we all know the program works. We believe there is no better Federal program when it comes to commercializing basic research and creating high-growth, high-generation, next-generation companies.

I want to start by highlighting a few areas that SBA has been focused on over the last couple years that is improving data quality that comes to us from the agencies and that we then report to Congress: increasing the participation from new applicants, especially those from underrepresented States, women, and minorities; reducing the barriers to entry and workload on all sides; and improving the tools and resources that increase commercialization success.

SBA is focused on reducing geographic inequalities, and increased SBIR funding to rural States will help to establish highgrowth companies in those areas which in turn will fuel economic growth in that region.

SBA is leading efforts to increase proposals for woman- and minority-owned firms, groups that continue to receive too small a percent of the Federal R&D funding.

Events like our SBIR road tour, which is now in its fifth year—and we will have hit all 50 years at the end of the year, including Puerto Rico—our 60 training modules that are on our SBIR.gov website, and our Train the Trainer Program have all helped to support the ecosystem partners and those that work directly with the entrepreneur.

The Chairman's Made in China 2025 report discusses creating new ecosystems of innovators and how SBA is uniquely positioned to service new and small businesses. I could not agree more and believe that SBIR and STTR funding and our efforts to strengthen the innovation ecosystems are key pieces in helping the Federal Government's strategic long-term approach to address that challenge.

The Office of Innovation and Technology is uniquely positioned to support the ecosystem of innovators, and through our established networks and our coordinated activities across SBA and the

agencies, we are in a good position to support that goal.

As Congress considers the next reauthorization, I think it is important to evaluate the duties and authorities for SBA and the participating agencies, build on best practices, and ensure statute provides resources for the agencies and tools for the businesses to commercialize.

Other areas to be considered and looked at would be to continue to focus on Senator Cardin, what he started, with the recent legislation focused on reducing the burden for submitting proposals, getting between Phase I and Phase II of the GAO study, all those things that are part of the problem with the SBIR and make it not as attractive to new small companies coming in that have not been

part of the program.

Looking and evaluating ways to encourage new companies to participate; review the maximum size, which is currently 500 people, and the number of Phase IIs any one company gets; assess our current commercialization programs and pilots. We have multiple programs geared toward commercialization, and we have really never assessed them and looked at how they work at different agencies. Ensure continued improvement of our data collection system while maintaining quality, transparency, and improve the ability to assess that data from the public and Congress, and keeping the program flexible so that it addresses the mission of each agency while allowing experimentation.

With that, I want to thank you for the opportunity to be here,

and I am looking forward to questions. Thank you.

[The prepared statement of Mr. Shepard and Mr. Williams follows:]



Statement of Joseph Shepard
Associate Administrator
Office of Investment and Innovation
U.S. Small Business Administration

John Williams
Director of Innovation and Technology
U.S. Small Business Administration

before the Senate Committee on Small Business and Entrepreneurship

Hearing on Reauthorization of the SBA's Innovation Programs

May 15, 2019

Joint statement of Joseph Shepard & John Williams Office of Investment and Innovation U.S. Small Business Administration

Chairman Rubio, Ranking Member Cardin, and members of the committee, thank you for the invitation to discuss the U.S. Small Business Administration (SBA) Innovation Programs, which include SBA's oversight of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Joseph Shepard is the SBA Associate Administrator for the Office of Investment and Innovation. Prior to the SBA, his business career included participating as an investor and intermediary in venture capital and early stage financings as well as leadership positions in consulting, investment banking, private equity, and investment fund management for such organizations as KPMG, Texas Pacific Capital, Principal Financial Securities, Banc One Capital Markets, as well as a previous tenure in public service at the SBA.

John Williams is the SBA Director of Innovation and Technology and has focused the last 25 years of public service on the SBIR and STTR programs. John began his career at the Department of Navy, where he started by managing individual SBIR projects and eventually worked his way up to managing the Navy's SBIR/STTR and Technology Transfer program offices. His focus was on helping small firms transition their technology into Navy systems and platforms. Accomplishing this mission required him to develop special programs that provided awardees with business and commercialization assistance. Through these efforts, the Navy obtained the highest SBIR/STTR commercialization rate across all the federal agencies. In 2014, the opportunity arose to join the SBA and impact the policy and serve in a lead role for the SBIR/STTR programs.

As defined in the Small Business Act, SBA assists small businesses in obtaining federal research and development (R&D) awards and to ensure that small businesses are afforded the opportunity to receive the benefits of the work associated with that funding. SBA's responsibilities related to the SBIR/STTR programs include establishing policy through program Policy Directives; conducting outreach to small businesses; collecting, maintaining, and publishing data; monitoring program implementation, and reporting to Congress; and providing suggestions to improve participating agency SBIR/STTR programs. SBA is uniquely positioned to support small businesses and innovation through our services and programs. While participating agencies unilaterally control decisions and issue awards, SBA is actively involved in ensuring companies, service providers, and agencies are aware of the guidance in the Policy

In 2015, SBA launched the SBIR Road Tour, a national outreach effort to increase program access and awareness. SBA has also focused on strengthening local innovation ecosystems through targeted outreach and training. These efforts engage local SBIR/STTR service providers to increase the number of SBIR/STTR proposals, awards, and commercialization success of companies from their state. These efforts are critical to assisting small businesses and entrepreneurs with access to the information and resources they need to help make their companies successful through the SBIR/STTR program.

The SBIR/STTR program provides approximately \$3.5 billion per year in funding to small businesses, making it the largest single source of non-dilutive, early-stage, high-risk funding. Since 1983, participating agencies have obligated over \$50 billion in total funding across more than 170,000 awards and 26,000 firms. SBIR/STTR awards are not loans and the firms maintain ownership of the intellectual property. The protection period for SBIR/STTR Data was recently increased from a minimum of four years to a minimum of 20 years as part of the SBA's revised SBIR/STTR Policy Directive that was published in the Federal Register on April 2, 2019.

A good way to illustrate how the SBIR/STTR program operates and scales early stage, high risk research into products and services is through examples. Illumina, a 2016 SBIR Hall of Fame inducte, received its first SBIR award 20 years ago. It currently has a market capitalization of approximately \$46.6 billion, annual revenues of \$3.33 billion, 7,300 employees, and is a leader in the global DNA gene sequencing market.

Illumina is also an example of how SBIR can commercialize university-based research. In 1998, Illumina was founded by five individuals based on technology they obtained in an exclusive license from Tufts University, where a federally-funded inventor and co-founder was faculty. From 1999 to 2006, the company received \$9 million through 27 SBIR awards from the National Institutes of Health (NIH). Illumina underwent rapid growth and attracted venture capital funding. The SBIR/STTR program is a valuable tool for demonstrating proof of concept. In this case, Illumina leveraged their SBIR funding to focus on research that was higher risk than their venture capital funding would support.

There are thousands of SBIR/STTR success stories throughout the country and life of the program. Some of those companies became industry leaders, but all of them turned an idea into a solution for a need advancing the missions of the federal government. SBA collects and analyzes program data provided by the eleven participating agencies to evaluate performance by individual agencies and across the SBIR/STTR program. In addition, SBA works with the agencies to review and improve the data fields captured in the SBIR and STTR Annual Report. However, capturing the entire picture of commercialization data remains a challenge. SBIR.gov contains award data for more than 170,000 awards and 26,000 companies. Furthermore, companies are not required to update their company commercialization report information unless they are applying for another award in the program.

In Chairman Rubio's "Made in China 2025 and the Future of American Industry" report, one of the key highlights is "Creating new ecosystems of innovators and promoting the dynamism of new businesses entails one of rejuvenation. Uniquely positioned among government agencies in this regard is the U.S. Small Business Administration, which operates a number of programs to service new and small businesses." The SBIR/STTR program is a fantastic resource to help companies and communities leverage their expertise and capabilities to create game changing innovation. This includes leveraging existing networks and infrastructure (such as universities, incubators, accelerators), and encouraging public-private partnerships. These types of collaborative programs can be catalysts for innovation. This is particularly important in rural states, many of which have components needed for a successful innovation ecosystem and are building their capacity to support innovators. SBA is encouraged by the advancements in this area and looks forward to discussing this further with the committee.

Lastly, let us share some of the SBA's accomplishments during the past year involving SBA's Innovation Programs. They include:

- Publishing a revised SBIR/STTR Policy Directive.
- Publishing the fiscal year (FY)15 and FY16 SBIR/STTR Annual Reports, which
 greatly expanded detail into the statutorily required measurements and agency
 compliance. (SBA plans to submit the FY17 Annual Report to Congress this
 summer.)
- Increased collaboration with the other federal agencies, including direct participation in the President's Lab to Market cross agency priority goal working group, to improve technology transfer from labs to small businesses.
- SBA has focused extensively on data quality. This includes improvements in automating the data upload process, increasing the accuracy of the data submission, adding new data quality checks, and working with the agencies on data definitions.
- Expanded our leadership role with the innovation ecosystems across the country.
 SBA currently leads a monthly call with 400 ecosystem partners throughout the country, provides online and in-person training, and participates in outreach events at the local, regional, and national level.
- SBA led 18 Road Tours in 2018, with another 16 planned for 2019. By the end of this
 year, SBA will have held a Road Tour or Conference in all 50 states and Puerto Rico.
 This included additional collaboration with the Federal Laboratory Consortium, U.S.
 Patent and Trademark Office, and the Minority Business Development Agency.

As the coordinating agency for the SBIR/STTR programs, there are several areas of focus and discussion that we will continue to review, among them:

- Helping underrepresented states, as well as woman- and minority-owned firms, submit more competitive proposals and win more awards.
- Building public-private partnerships focused on supporting R&D focused startups.
- Reducing the time from proposal submission to award, especially the time between Phase I and Phase II.
- Reducing the level of effort placed on small businesses to submit proposals.
- Working with the participating agencies to simplify the contracting process.
- Allowing more of the SBIR/STTR funding that firms receive to be used for activities associated with the commercialization process.
- Improving and streamlining data collection from the agencies and firms, while
 improving the ability to review the data and trends through enhanced Business
 Intelligence tools. This is a continuous effort of SBA and the eleven participating
 agencies.
- Encouraging agencies to look for ways to improve its programs and adapt the way
 they execute. SBA will continue to offer opportunities for the agencies to discuss
 ideas and share best practices.
- Improving SBA's understanding of the economic impact of the SBIR/STTR program
 and how it feeds into addressing many of the concerns raised in the "Made in China
 2025 and the Future of the American Industry" report.

In conclusion, thank you for your support of the SBA. SBA looks forward to continuing our work to better assist America's small businesses.

Chairman Rubio. I will defer my questions.

Ranking Member.

Senator CARDIN. Well, let me thank both of you for that outline. Mr. Williams, I particularly appreciate the specific suggestions that you are making. I am going to make sure that our staff drills down on each one of those and see what we can do.

So let me start on the one you mentioned on the challenges, on

the time problems between Phase I and II grants.

According to the Small Business Administration, the Defense Department took nearly 500 days in 2015 to enter into contracts with the SBIR/STTR firms between Phase I awards and Phase II awards. As a result of that, I worked on a provision that was included in the 2019 National Defense Authorization Act that sets up a pilot program to look at accelerating that time. Our goal was to get to 90 days. To do that, we need to streamline the process within DoD once these awards are made and to make it a little bit easier for companies to be able to figure out what needs to be followed in order to get these awards actually made.

Can you share with us conversations you are having with DoD

on implementing this pilot program?

Mr. WILLIAMS. So we have monthly—every other month program manager meetings, and then I actually attended the Air Force's pilot programs that they are working, where they are doing Pitch

Day competitions.

The two groups that I think stand out are the Department of Navy, where they have really established contracting centers that are just focused on SBIR—one of the challenges has always been when SBIR is merged with other work for large companies and universities and it does not take precedent, and maybe they do not understand how to write those contracts. So a standalone contracting shop has seemed to work well for the Navy to reduce the time gap and actually accelerate and actually provide better contracts.

I certainly think—and what I was most impressed with was the Air Force being able to come with literally a one-page contract that they awarded to companies, and I sat there and watched the individuals come out of a room, be selected for award, sit down at a table. They had three tables with different contracting shops, and between 3 and 15 minutes, they had a contract. And they had half the money on a credit card that they could then start to bill against

against.

What was most impressive about that was that did not require any change to DFAR, any change to any policies. They used existing programs. It requires a program office and a contracting officer to take risk and to believe in small businesses, and that has always been the challenge. We have kind of sometimes moved toward we need more regulation and more protection in case there's fraud and waste, and we need to add more layers and cost accounting things.

They moved away and they were willing to take risk because their belief was the risk of not getting technology quick to their warfighter is the big risk, and they need to get that technology. What they did not just in awarding Phase Is, but they also had this practice between Phase Is and Phase IIs. So I would like to see that modeled across the DoD. Senator CARDIN. Do you think the policy document that we are supposed to be receiving, I think, in July from DoD will include those types of recommendations?

Mr. WILLIAMS. I hope so, and the GAO studies should look into

that.

I am glad that the GAO study is multiple years because sometimes it takes a while to gather the data and start to dig in, and then the DoD is also supposed to report on those things.

Senator CARDIN. And I hope we can hit a 90-day threshold.

Mr. WILLIAMS. That would be wonderful.

Senator CARDIN. It seems like they have been able to even do it

faster. It would be great.

You lived through the uncertainty of the extensions of these programs with DoD. They had 14 temporary extensions. Can you just explain to us how important it is to have the predictability of these programs? I mentioned in my opening statement I would like to see them made permanent. I really congratulate Senator Shaheen for her ability to get this extended through 2022, but to make these permanent so we do not miss extensions in the future. How important is that for the success of the program?

Mr. WILLIAMS. From an agency standpoint, it certainly helps in

planning.

I think—and maybe this was misguided—that there is strong support for the program, and so many of us believed it would get extended. But we spent an awful lot of effort dealing with—as did Congress with those multiple extensions, where that work could have been in better places.

Now, I think it is really the hardest on the small businesses because they do not know and should they propose to a program in a Phase I that may not be there and a Phase II when they are new

to the program.

So I think having structure and even in the pilot programs, not knowing how long those will continue is a challenge for both, but mainly the small businesses.

Senator CARDIN. I appreciate that.

You mentioned in your opening statement your commitment to improve diversity in these programs—

Mr. WILLIAMS. Yes, sir.

Senator CARDIN [continuing]. Particularly among minorities, women, and veterans. Can you give us a little more detail on how you tried to implement that?

Mr. WILLIAMS. So one of the best examples I can give is currently we have programs that we use with FAST, where we actually give

money to local States and then let them try things.

So we do a road tour, and that is great because we get out there and we get the awareness. But the government individuals, we cannot help them with grants.gov. We cannot write their proposals for them. We cannot hand-hold them through a lot of these things.

So what we found is paying for boots on the ground and working with local areas that already are helping high-tech companies but then focus them on training has been really successful, and a lot of these have done these kind of pilots where they will bring through 10 people that are from rural areas or they will bring through 10 minorities or 10 women.

New Mexico has a great program. Maryland has a fantastic program out of University of Maryland where 90 percent of the women are the 22 companies that went through this kind of boot camp that runs for 10 weeks, and at the end of it, you submit a proposal.

But 90 percent of those were women and minorities.

So we are seeing programs like that where we are saying we are going to give you money to help SBIR, but we want to see you targeted toward either a rural area or a minority or woman and help them write proposals, because what we find is the winning percentage is the same, whether you are a woman, minority, or underrepresented State. The issue is getting proposals from those organizations.

Senator CARDIN. Thank you. I thank you for those answers.

Thank you, Mr. Chairman.

Chairman Rubio. All right. Thank you.

Senator Hawley.

Senator HAWLEY. Thank you, Mr. Chairman.

Mr. Shepard, my question is for you. According to the 2016 annual report of the SBA, there is a dramatic difference in the amount of funding being awarded between States. For example, Missouri received 40 awards last year that totaled \$17.5 million, if we have got our stats right, while California received a little more than 1,000 awards totaling \$550 million. Now, that is more than 30 times the award amount, even though California's population is just six times larger.

Can you tell me why the discrepancy exists?

Mr. Shepard. Well, good question, Senator, and I think as you look at the data from year to year historical and as we go forward in your tenure as a Senator, you will see variability from State to State

The SBA, of course, oversees and reports that information. The 11 participating agencies are the ones that actually make the awards. They are the ones that are engaging with the small businesses, and so you are going to have years that are up and down, really depending on the applications that come in, the activity from those small businesses, and so that variability is there and will continue to be there. So, again, we are somewhat dependent on those small businesses to apply, and then the subsequent awards follow.

Senator HAWLEY. That leads me to my second question. What is it that I need to do and we need to do to ensure that there is sufficient outreach to small business owners and entrepreneurs in rural States so that they have the knowledge of these programs and the opportunities to benefit from them?

Mr. Shepard. Well, that really hits on the question. Certainly, if you look at that data for the 50 States and the Territories, you

are going to have some areas.

I was with Senator Risch in Idaho 2 weeks ago where you have some years where you might have two awards and that is it, and so continuous outreach, education, awareness, certainly in some of these geographic areas that we will speak about today and that we have already touched on in terms of rural, geographic areas where people may not know about the program, certainly the small businesses. So that is really key is awareness, outreach.

I know John is going to speak more about some of those activities today specific to the SBIR Road Tour, which is intended to do that.

From our view, it is really about education.

Senator HAWLEY. Mr. Williams, let me just give you a chance to do that now, if you would like, to address some of these outreach efforts.

Mr. WILLIAMS. Yeah. Again, I think the thing that we have seen works the best, we have growth accelerators in FAST, putting and

building that innovation ecosystem.

Typically right now, Austin, San Francisco, Boston have strong innovation ecosystems. They have the schools and things like that, but we still believe—and so that is where the money is, and those programs are established. And that has helped these individuals write proposals because they are around others that have won.

I think we have to make an effort to increase that type of assistance, ecosystem building. We cannot train individual companies, but we can train people that will help SBIR awardees write proposals because it is a long process. It is not just coming there on a road tour and saying, "Hey, are you aware of the program?" and then going away. It is how do you build an ecosystem that really focuses on getting some of that \$2.5 billion to that area, and that is where I said I think that in turn helps other Main Street companies because you are getting high-growth, high-paying companies to come in using government dollars to get started, so that seeds them for 2 years with a couple million dollars. And then, hopefully, that helps.

Senator HAWLEY. Very good. Thank you.

In the brief time I have remaining, let me shift gears and ask

a question, if I could, about China.

The Chairman has released a very important report today—thank you, Mr. Chairman, for your work on this—about investment, capital investment in China.

But let me just ask you. The next panel is going to talk some about this. There is testimony that shows a dramatic decrease in America's share of global venture capital investment from almost 100 percent in 1992 to just 50 percent today, most of that difference going to China.

There have been a number of recommendations for the SBIR program, including enacting strict guidelines on intellectual property generated from these projects to ensure that Federal investment that does exist is not subsidizing technology used and produced in

other countries.

Knowing that China is the world's worst perpetrator of IP theft, what can be done to leverage these investment programs to counteract China?

I will pose that to either of you. Would either of you like to comment?

Mr. Shepard. John, I know your team has gone somewhat deep

Mr. WILLIAMS. Sure. And I think one of the challenges is privatesector investment is looking for short-term returns. SBIR and Federal investments are really geared—A, they must say in the U.S., and they must be for U.S. companies, and they are geared for that longer-term play. And so we are not looking at a return on investment, and I think just that mentality addresses some of what the Senator is talking about that we really do need to take that strategic longer term and maybe even pick certain technology areas where we want to put more emphasis, but then use SBIR to seed those companies and develop those ideas, but still then try to bring back some of that investment.

Mr. Shepard. And emphasizing the wonderful thing about this program, that it is non-dilutive. So the government, the Federal participating agencies are not taking an equity positions at these early phases. That is a fantastic thing. The venture capital community obviously is going to. So emphasizing that in these investment structures is important for us to do.

Senator HAWLEY. Very good. Thank you, Mr. Chairman.

Chairman Rubio. Senator Rosen.

Senator ROSEN. Thank you, Chairman Rubio and Ranking Member Cardin, for holding this important hearing.

Thank you to the witnesses for the work and investment that

you have done.

Nevada is home to more than 270,000 small businesses. We only have 3 million people in our State, so it is pretty good, including approximately 72,000 minority-owned businesses and 83,000 woman-owned businesses. Additionally, Nevada is leading the way in the Nation for woman-owned businesses over the past decade. So these numbers, of course, they illustrate the large footprint that small businesses have in my State and why your departments, of course, as so important, and the key goals for you to provide the grants, contracting opportunities for minority, disadvantaged, small business owners.

So from 2016 to 2018, Nevada small businesses won 31 grants totaling more than \$15 million through your programs, and awareness of these programs is key. You talk about your Road Tour. Are you planning to make a stop in Nevada anytime soon or in some of the States with the smaller population as opposed to some of the big centers that you are talking about?

Mr. WILLIAMS. Actually, we do concentrate on the smaller States. We did go to Nevada in 2017. Typically, we have been trying to get around every 3 years or so to the States. So we did want to get to every State, but we have probably been to the smaller or the

lower-population States more often than the large States.

Senator ROSEN. So when you are doing the Road Tours and you are getting these key takeaways for our businesses, how are you dispersing that to either our offices perhaps, congressional offices, and so we can work with our stakeholders like Chamber of Commerce, Urban Chamber or Latin Chambers or community colleges, whatever they may be? How are we getting this information so we can be helpful?

Mr. WILLIAMS. So every Road Tour—we start the next Road Tour next week. Probably 2 months earlier, we sent letters to all our congressional members, so both Senators and the congressional members, letting them know about it. We work with the State economic development groups, and we will usually have some type of group on the ground that usually has relationships. But we certainly will send letters directly to the congressional members two months prior to going on a Road Tour.

Senator ROSEN. And will those give some hands-on tips?

Mr. WILLIAMS. Absolutely.

Senator ROSEN. Because the other thing that I hear most often from women, minority-owned businesses, or smaller companies who want to get started is that they just do not have the manpower, the talent to hire a grant writer, or they do not have this expertise in-house. They know that they can get it, but they just do not have the skills.

So are you able to give—or where can we be sure that we are dispersing hands-on information for people on the ground so we can

add more people to these roles?

Mr. WILLIAMS. Right. So we do it a couple different ways. On our Road Tour events, the morning will be the Federal managers explaining what the program is. In the afternoon will be the local providers because, again, really you need someone that can stay with the company and work with them over months to identify.

And as I have talked about, some of these pilots that work really well, they say, "Okay. A defense solicitation is coming out. Let us have a group that starts 2 weeks before that and work through the

solicitation and write proposals."

So there is information on our website on how to train and find the right agencies, how to write proposals, all the instructions. So on SBIR.gov, we have about 50 modules on training, and then again, we spend a lot of time training those in the State to know what SBIR is. And so they can provide them materials so that they can go out and train, and we would be glad to work with your State on that.

Senator Rosen. Perfect.

My last question really is, from our committee, what can we do? These are terrific programs. You see the number of small businesses in my State and, of course, across the country. What can we do here to help strengthen these programs? What would you need from us?

Mr. Shepard. I did want to just make one quick comment, Senator Rosen. Utilizing the field offices with SBA, the small business development centers as well, that is always a resource for the small businesses in those communities, and we do have engagement, interaction so that they are not just having to always call into Washington, D.C., and headquarters. So that is all across the Nation, of course, 65 offices. So that is something that should not go overlooked.

John, please speak to-

Mr. WILLIAMS. And so I think it is always a balance. The SBIR is about \$3.5 billion. That is for the agencies. So the 3 percent admin was a big plus to give the agencies some resources to actually help run programs, develop websites, develop training materials and all those things that are outside, because the \$3.5 billion has to go to the small businesses.

SBA is a little challenged because we do not have an SBIR program, and so we have to get those fundings from the charities of

others, those that might give us 3 percent.

So resources are usually what limits our ability to do as much training, but I think we are pretty effective with what we have, and some of the programs that you have appropriated with FAST and growth accelerator and the 3 percent have helped us to do—

provide that training.

Senator ROSEN. But being sure that we have a central—maybe whether it is on your website or field offices so all of our constituent services can have a central place to talk to people to help our businesses within our communities be sure we have a certain amount for admin is a good thing.

Mr. WILLIAMS. Right. And if you have contacts, we will be glad we have a call with 400 service providers once a month. So we try to get them to talk to each other. So we would be glad—any people you know would like to be part of that, we will add that.

Senator ROSEN. Perfect. Thank you so much.

Mr. Shepard. And I think another thing to consider as well for the committee, to get to your question, is thinking about looking at the SBIR/STTR legislation and knowing what SBA's oversight role is and the fact that we do not provide the funding—and John mentioned what we can do if we get money from the 3 percent, which allows us to do more in terms of outreach.

But what should our role be, and should our role expand? And can SBA do more than what is currently—and can currently do under the current statute? And so that is something to consider as well. As you ponder with reauthorization issues and we engage with the staff and we start to have some meetings after this committee, really having some healthy discussions about how our role might change. Again, SBIR has been around since 1982. So maybe it is time to look in this free enterprise system with technology and the advancements that have been made. Maybe it is time to look at that with different eyes and thoughts and maybe do some things differently and think about what SBA's role is. So we are up to having that conversation as well.

Thank vou.

Senator ROSEN. Thank you. My time is up.

Chairman Rubio. Thank you.

Senator Coons.

Senator Coons. Thank you, Chairman Rubio, Ranking Member Cardin, for holding the hearing and to our witnesses, Mr. Shepard,

Mr. Williams, for your great work.

As you know, I am a big believer in SBIR and STTR programs. They are vital to transitioning compelling new technologies from lab bench to marketplace, which is at times a perilous and challenging journey, and if we are going to accelerate, commercialize, and manufacture in the United States the next generation of competitive technologies, we need to do everything we can to take advantage of cutting-edge research, particularly that that is federally funding and defense-aligned.

Delaware over the last 3 years has benefited from about \$54 million in SBIR funding, fully two-thirds of which was paired with

coaching by our SBDC

One of my favorites is Phase Sensitive Innovations in Newark that grew out of DoD-funded SBIR funding and is now developing really compelling, both national security-related and commercially relevant imaging technology that would allow a helicopter landing in a cloud of dust to see exactly where it is going and other applications.

I am glad your new Policy Directive for SBIR/STTR includes a focus on manufacturing. Chairman Rubio and I introduced, I think, last week, the Global Leadership and Advanced Manufacturing bill, which is bipartisan, which would reauthorize and expand the Manufacturing USA strategy.

I am also interested in two other areas, if I could, that I would

like to talk about briefly.

Last year, my Support Startup Businesses Act became law through the NDAA. It fills what I think was a critical gap in terms of allowing startups to use up to \$50,000 in funds for commercialization, IP protection, market research validation.

What is the SBA doing or planning to do to make use of this and to encourage SBIR recipients to use this new opportunity to commercialize, if I could, Mr. Williams? And then I have got a question

for you, Mr. Shepard.

Mr. WILLIAMS. Sure. So I think we are going to look back, and that is going to be one of the strongest changes that has been made in the SBIR program. Always that challenge has been, well, you cannot use R&D dollars for that business side.

Senator Coons. Right.

Mr. WILLIAMS. And so it is adding—because, again, it was technical assistance which small businesses did need. They needed business assistance, protection on patenting, charges they were not allowed to bill.

So the challenge we are having right now is we are establishing the guidelines, and actually, we probably need to sit down with some of your staff to really determine what was meant by some of the language because there was pushback by some of—

Senator COONS. I am happy to answer your question.

Mr. WILLIAMS. Do I have to dissolve—do all agencies actually have to allow a company to come in with a proposal? There are words of "may" in there. They are saying, "Well, we do not have to have a program. We may," and so our interpretation was, yes, all agencies would have to allow a company to submit in their application or be able to submit in an application support and using business assistance.

What is interesting also, it talks about all that money has to be spent and contracted out, so none of it can be spent in the small business, but they would have to find contractors. And I am not sure that was the original intent also.

So we want to work, because we are in that early policy stage, developing those guidance. We have come out with it. We have gotten some—

Senator Coons. Feedback.

Mr. WILLIAMS [continuing]. Feedback from other agencies, and I think now is the perfect time for us to feel comfortable to say, "No. This was the intent."

So that said, the challenge of the program that you gave us was you said implement it right away, and it is one of the more complex programs that I have dealt with.

So the challenges going downstream are you are now allowing a company to build things that would not normally be billable on any other contract. So their DCA, auditor, or whatever are going to

come in and say, "No, no, no." How do you deal with that? So training to the contracting shots, training to the auditors—

Senator Coons. Yep.

Mr. WILLIAMS [continuing]. For a relatively small program. So we are going to have to work those issues out and then really defining its IP protection, is that what, what level and things like that.

Companies have needed this. This was an area I was very focused on as important, and so kind of working that out and figuring out what those details are is where we are at. That is the stage we are at right now.

But that said, some companies, some agencies are already allow-

ing it.

Senator COONS. To the extent my input would be in any way relevant or helpful, I would certainly be happy to offer it.

Mr. WILLIAMS. Thank you, sir.

Senator COONS. I am certain that other members of the committee who were cosponsors as well—I see a gentle head nod from the Chairman—would also be interested in offering some input on that.

If I could, Mr. Shepard, your office manages the Small Business Investment Company, the sort of, if I might, venture capital arm of SBA. Over a quarter of all SBIC investment is in small manufacturers.

I had a bill in the last Congress to strengthen access to 7(a) loans for small manufacturers. I am retooling it to look at 7(a) and SBIC. I would be interested in your input on how to enable that particular program, SBIC, to reach more small manufacturers.

Mr. Shepard. We would look forward to having continuing dis-

cussions in that area.

Of course, the legislation was written to supplement the private equity capital, long-term loan funds to small business concerns. So the SBA does that through the formation, the conduit, if you will, of the small business investment companies.

Those companies actually direct the funding and where the funding goes. So SBA does not participate in those funding decisions

that are made by the SBICs.

So what we would have to do is have discussions and look for ways if more direction should be given or could be given in the licensing process in terms of what types of SBICs are being licensed and then specific to manufacturing, but currently, that is not the way the program is set up.

Senator COONS. Well, I would welcome any input on what you think would be welcome and appropriate in terms of scope—

Mr. Shepard. Yes.

Senator Coons [continuing]. And encouragement or incentives.

Let me just last speak briefly to the SBIR Road Show. There was one in Delaware. You said you have been in every State. The one in Delaware, I thought, was spectacularly successful. There were long lines at each of the Federal agency tables, folks trying to understand how to commercialize, how to connect. It is clear to me that the appetite for outreach programs like the Road Show is large, and so I think it is a valuable thing for us to continue to support and invest in.

And I could not agree more with the point made by the Ranking Member at the outset about permanency. I do not think there should be any question about the permanent value to the United States of SBIR and STTR.

Thanks for the great work you do.

Thanks for letting me go over, Mr. Chairman. This has been a great conversation so far. Thank you.

Chairman Rubio. The Ranking Member had a follow-up.

Senator CARDIN. One question. Do you have any specific recommendations for statutory change in regards to the 3 percent on administrative?

Mr. SHEPARD. Other than making it permanent? Senator CARDIN. Other than making it permanent.

Mr. Shepard. We really have been, Senator, dependent on the committee to give SBA feedback in terms of what it would like to do, but I think we can all look at the benefits of permanency with that funding and——

Senator CARDIN. So you are satisfied to negotiate with the agencies as to how you can help finance some of these issues? Right

now, they control the dollars, as I understand.

Mr. Shepard. They do, indeed, yes, and we are dependent on them to provide to. So anything statutorily that we could talk about with the committee to improve SBA's ability to get funding for those oversight areas, those outreach areas would be very helpful. One of the ways to do that is—

Senator CARDIN. We are your friends. We are your advocates. So give us some ideas. We understand there may be a hurdle to try to get those done. We recognize there are other interests, but it would be nice to know if it is working well, let me be. But if you

need help, let us know.

Mr. WILLIAMS. So a thing to consider is the FLC program does an assessment tax that generates money that goes to NIST that is a tax on all the RDT&E money. It is rolled into a bucket and then provided to NIST to manage the FLC program. So those are ideas that could potentially—maybe my agency friends would not like that idea, but that is an idea. I have seen that work.

Senator CARDIN. Thank you.

Senator CANTWELL. Thank you, Mr. Chairman.

Chairman Rubio. Senator Cantwell. She does not even put—she is ready to go. Look at that.

Senator CARDIN. Right.

Chairman Rubio. It would take me at least 5 minutes to realize

I am not in foreign relations—

Senator Cantwell. Well, thank you. I so appreciate you having this hearing and the reauthorization of the SBA's innovation program. Innovation is very important to the State of Washington and continuing to make the right decisions and helping to stop the decline of American startups.

I have a question for you, Mr. Shepard. The rate of startup creation in the United States has been decreasing for several years, and while there are many reasons why you might say that is—and certainly, we have seen a rise in China's startup level, again, very different structure. But if we want to continue to build and maintain a 21st century economy, I have always believed that we live

in an information age, and the amount that innovation that can happen because of the information age is just unlimited. But guess what you have to have to make that idea a reality? Access to capital.

So the SBA's Growth Accelerator Fund provides early staged companies with vital mentorship and financing. In our State, the SBA supported accelerators like the Washington Innovation Network; Life Sciences Startup Accelerator Program in Seattle; Ignite Northwest, a technology-focused business accelerator in Spokane. And I am concerned about the President's budget trying to eliminate that.

So what is the SBA doing to try to writ large reverse the trend that we are seeing stagnant on startups, and what can we do to get the Trump Administration to change its mind on trying to zero out this program?

Mr. Shepard. Thank you, Senator, for your question.

Certainly, in my opinion comments, not only historically has this program, SBIR/STTR, been beneficial to the businesses, small businesses have had an opportunity to take advantage of it from 1982 forward. In the case of SBIR, we can look at today's results, but then we have to think about our next generation of young people and certainly our competition against other global leaders, so certainly agree.

When I came into the SBA 2 years ago, these programs with the Growth Accelerator Fund Competition have been unauthorized programs. So they have not been presented in SBA's budget proposal.

We have received the funding, and obviously, we will support that funding when it is received. And if Congress authorizes that, then we are going to continue to implement those programs and work toward implementation of any of those activities that we are directed to do by Congress.

Senator CANTWELL. Do you question any of the methodology or the focus that they are being able to give to communities?

Mr. Shepard. No. There have been varying reports on both sides. I think none of this question about startups and the importance to our economy and small businesses and the need to support them in the large mandate of SBA in terms of the free enterprise system and how it works with—does it do a good job with the accelerator community already? Is it necessary to be federally supported? Those are certainly questions that loom that we do not necessarily

have the answers to.

Senator Cantwell. To me, the phenomenal amount of innovation that is happening—I ran into some kids at the—actually at Western University. So they had established in a consortium of just working together a technology to take a windowpane and generate electricity from that windowpane.

But the fact that they could get some money, I think in this case, they had a small grant from EPA but then got backed by a smaller funding source in the community. But that research now is being put into a startup, and it is well on its way to commercialization.

So that is the thousand flowers that we want to bloom, and I appreciate you taking a look at this program and giving us some more ammunition on how we can make sure we secure funding for it.

Thank you, Mr. Chairman.

Mr. Shepard. Very good. Thank you. Thank you very much.

Chairman Rubio. Senator Markey, are you ready? Senator Markey. Yes. Thank you, Mr. Chairman.

SBIR/STTR programs absolutely essential to the competitiveness of our country, the competitiveness of Massachusetts for sure. The numbers in Massachusetts are staggering.

Since the programs were created, 22,500 of these grants went to Massachusetts, which is amazing. Think of that many companies

in one State.

And last year alone, Massachusetts businesses received 593 awards valued at over \$350 million worth of investment. That is like a job creation engine that is out there and working for the smallest companies that otherwise would have a harder time gaining access to capital which they need.

We actually rank—even though we are only 2 percent of America's population, we rank second only to California in terms of total funding from these programs, and a lot of that success is because

of this ecosystem of innovation that we have in the State.

So I just want to echo what Senator Cardin said about permanent authorization for this program. I just think it should be out there, and small businesses should know that they are going to have a program 2, 3, 4, 5 years from now. If they start right now with their little idea, that there will be something there that they can gain access to.

In Massachusetts, while our businesses are successful at receiving a large number of awards, it is important to remember that they receive these awards from a very diverse set of agencies. For example, Massachusetts small businesses receive \$11 million from NIH, \$48.5 million to work with the U.S. Navy. Those agencies have very different missions with very different needs.

Mr. Williams, I imagine that your needs running the program at Navy to deliver for the warfighter were quite different from what NIH may be trying to accomplish. You probably had different cri-

teria, requirements from other agencies.

For example, the peer review process at NIH's SBIR program is critical to what they do but may not be applicable to the Navy. The USDA program has to follow crop cycles, so timeliness for other agencies probably does not always make sense for them.

So, Mr. Williams, I would be very interested to hear how you think we should be balancing the issues of ensuring overall success for the program but at the same time making sure we allow for flexibility at each of the individual agencies to carry out their missions.

Mr. WILLIAMS. I guess I would answer that I think we are doing a pretty good job with that, and so I think when we look at reauthorization, that is one of the beauties of the program is it does allow flexibility.

There are certain programs that more recently have come on which require agencies to attempt, and some of the smaller agencies have a harder time adapting to some of these programs.

So, at the same time, I still think that the gap and the time it takes to do a review process or the peer review process is a very

long process, but DOE was able to figure out a way to get an early

letter. And it actually reduced the typical peer review.

I still think there are some things that we can do to improve without changing an agency's policies on how they manage programs but yet continue to leverage the program the way it is meant to be.

Senator Markey. And I do think it is important for us to understand that SBIR is actually 11 different programs——

Mr. WILLIAMS. Correct.

Senator Markey [continuing]. Eleven different criteria.

Mr. WILLIAMS. Yes.

Senator Markey. There is not one size that fits all.

When Congress created SBIR in 1982, we specifically exempted two groups of agencies from participation in the program—the intelligence community and the National Nuclear Security Administration at the Department of Energy. So while these agencies do not have a formal SBIR program, it seems obvious that small businesses would have a huge amount to contribute to their missions in fields like cybersecurity, sensors, nuclear security.

For either of our witnesses, from your perspective at the SBA, what would you see as some of the potential upsides and downsides of including the intelligence community or NNSA in the SBIR pro-

gram?

Mr. Shepard. Senator, I will answer first and just say there is no question about the boundless opportunity that small businesses can provide to the economy in any industry sector, so you are spot on with the observation.

I am not familiar with the exclusion as the legislation was first written in the 1982 time period or even subsequent in 1992.

John, do you have thoughts on that?

Mr. WILLIAMS. Yeah, two quick thoughts.

Absolutely, intelligence is a great place for SBIR companies. We would have to work security issues, but again, those are all workable.

Exemptions do make it challenging for SBA to determine whether the right amount of money is set aside since we do not usually have insight into those classified lines. So if I look at a bottom line, then they say these things are removed, and I cannot validate that.

But, also, I think you should be aware that other bills like the Department of Transportation has actually allowed FHA and the Highway to not have an SBIR program. So these are outside of the SBIR legislation, but yet other agencies and I would certainly think FAA could use SBIR technology. So it is a worthwhile question to ask

Senator Markey. Thank you. Thank you both for your great work.

Thank you, Mr. Chairman. Chairman Rubio. Thank you.

I just have a couple quick questions. So much has already been covered.

Mr. Shepard, how many vacancies are there on the team managing SBIR and STTR programs?

Mr. Shepard. Yes, Senator. We have six FTEs in the office. We have one vacancy that we are in the process of hiring, and we have

another one that is detailed out to the White House, so one if you do not count the detail.

Chairman RUBIO. How long has that one been open?

Mr. Shepard. It is a backfill. So it is a position that has been out, but it has been about 12 months on that position.

Chairman Rubio. What are the efforts to fill the position?

Mr. SHEPARD. We have filled it, filling it again. We are working on it right now, very important with the team and its size to get that taken care of, obviously.

Chairman Rubio. Mr. Williams, one of the goals of these programs is to make sure the small businesses with these technologies are able to pursue commercialization of these innovative ideas.

We hear all the time about what they call the "valleys of death" and the difficulties that entrepreneurs face in the process of moving from basic research to commercialization.

What changes do you believe should be made to improve the commercialization metrics for small firms?

Mr. WILLIAMS. So the challenge with metrics in an area like this, there is no one path to commercialization. There are variations in technology. Software is very quick; medicine is very slow. DoD goes to a private sector. So we have been challenged by defining a standard metric of you have a Phase I. We give you a million dollars at Phase II. We would except X amount of Phase III dollars by a certain time frame.

So what we have done is we have created the databases and the tools to measure those things, but developing a metric on what is good and what is bad has been challenging.

What we do and are impressed with—and you will hear about it later—some of these economic studies that have done deep dives like the NCI, the Navy study, to really understand there is an economic benefit.

I think then, separately, as a company proposes, it would be up to the evaluator to evaluate whether they are commercializing at a good rate.

Chairman Rubio. All right. Well, you have given us a good solid hour and many great questions, and I want to thank both of you for being here. We really appreciate your testimony. It is very helpful. I think the numbers on these—there are always ways to improve these programs, and you obviously heard the talk about making them permanent. However, I think just the numbers alone testify to the importance of this, especially at a time in which our Nation is already not from the private-sector side investing enough in the long term and for our future. This sort of government role is essential.

So thank you both for giving us that time.

I am going to go ahead and call up the second panel, and while we transition over, I will introduce them. Stephen Ezell is the vice president of Global Innovation at the Information Technology and Innovation Foundation, where he focuses on science, technology, innovation policy, as well as international competitiveness, trade, and manufacturing policy issues.

Jere Glover is the executive director of the Small Business Technology Council, the trade association representing SBIR firms.

Dr. Sridhar Kota is a professor of engineering at the University of Michigan, the executive director of Alliance for Manufacturing Foresight, and founder of FlexSys, a company that has received SBIR awards from the Air Force, the Army, the National Science Foundation and NASA.

Dr. Stephen Hoffman is the founder, CEO, and chief scientific officer—founder, CEO, and chief scientific officer, that is like three jobs—of Sanaria, Inc., which is located in Rockville, Maryland. It is a biotechnology company developing vaccines to protect against malaria. We heard about that a moment ago from the Ranking Member.

We thank all four of you for being here. We will begin with you, Mr. Ezell. Or is it "Ezell"? How do I pronounce? What is the perfect way to pronounce it?

Mr. Ezell. Mr. Ezell.

Chairman Rubio. Ezell. Got it.

Mr. Ezell. Thank you.

Chairman RUBIO. Thank you for being here.

STATEMENT OF STEPHEN EZELL, VICE PRESIDENT, GLOBAL INNOVATION POLICY, INNOVATION TECHNOLOGY AND INNOVATION FOUNDATION, WASHINGTON, DC

Mr. EZELL. Well, good afternoon, Senator Rubio, Ranking Member Cardin, and members of the committee. I am Stephen Ezell, vice president of Global Innovation Policy at the Information Technology and Innovation Foundation, ITIF. We are a nonprofit, nonpartisan science and technology policy think tank based in Washington, D.C.

I appreciate the opportunity to testify before you today regarding the reauthorization of the SBA's principal innovation support pro-

grams.

As my fellow panelists have attested, SBIR and STTR are truly some of the most effective programs in the Federal arsenal as stimulating private-sector commercialization of innovations derived from Federal R&D and helping promising young high-tech startups launch and scale.

We have heard the stories about the launch companies like 23andMe, Apple, Amgen, and Qualcomm. ITIF has found that SBIR-nurtured firms consistently account for about one-quarter of all U.S. R&D 100 Innovation Award winners from R&A magazine, showing that they are producing some of the highest breakthrough innovations in the country.

SBIR also leads to additionally, projects that would not have otherwise happened. For instance, a study of NSF SBIR Phase II awards finds that 75 percent of the development projects would likely not have advanced without SBIR funding.

As we have heard, more recent agency-level studies from the Navy, Air Force, and the National Cancer Institute attest to the SBIR successful impact. For instance, the Air Force and Navy have found that each \$1 of SBIR investment generates an ROI of \$12 and \$19.50, respectively.

The SBIR program has been copied by 17 countries around the world; it is so successful.

In short, the SBIR and STTR programs deserve Congress' continued and enthusiastic support; however, there remains opportunity to refine the structure and administration of the programs to fur-

ther enhance their commercialization potential.

The previous panel discussed the NDA from 2018 making \$50,000 of Phase II awards available for commercialization-oriented activities like market validation, IP protection, and market research. Congress should clarify, however, that all participating Federal agencies are expected to offer this option to awardees at amounts of up to \$50,000 per award, include provisions that awardees can use these funds on internal personnel and expenditures instead of being required to use third-party services for the third-party service providers and also clarify that this includes customer discovery programs, including but not limited to I–Corps.

SBIR is at its most successful when it is empowering early stage, high-potential entrepreneurs with resources supporting their development and commercialization. Such firms wish to leverage an SBIR award to scale a high-tech business, not as viewing SBIR

awards as a component of their business model.

Accordingly, Congress should encourage Federal agencies to implement a prioritization system in the award process that gives a degree of preference to applications who have received fewer grants over time. Here, Congress could also direct the SBA to explore streamlining and accelerating the application process, as sometimes the initial requirements may be sufficiently onerous to prevent promising potential candidates from applying.

The SBIR program would certainly benefit from additional resources, but leaving the SBIR set-aside level issue aside, the best way for Congress to increase SBIR funding would be to restore a lagging investment in Federal R&D, which in 2017 fell to its lowest

level as a share of GDP since 1995.

In fact, to match the average level of Federal R&D investment over each year of the decade of the 1990s, Federal-funding R&D levels in 2017 would have needed to be about 80 percent higher

than they were.

To maintain America's international competitiveness, technical advantage, and securing the pipeline, enabling more entrepreneurs to leverage SBIR to launch breakthrough businesses, ITIF calls upon Congress to increase Federal R&D funding by at least \$40 billion over the next 5 years. That is the best way to get more resources to SBIR.

SBIR operates important programs like the Federal and State Technology Partnership program, which engages accelerators, incubators, and maker spaces, and the growth accelerator fund program. We think these programs, including FAST and the growth accelerator, should be made permanent.

Further, to assist SBA and having greater predictability in managing its programs, Congress should make permanent the authorization of the 3 percent administrative funding that has made the

SBIR, I-Corps, and other pilot programs possible.

Lastly, despite SBIR's great success, America's broader system for funding research still pays too little attention to technology commercialization. SBIR and STTR are still fundamentally associated with the level of 11 Federal funding agencies. So ITIF has pro-

posed that Congress allocate a modest share of .15 percent of agency research budgets or about \$125 million per year to create spurring commercialization of our Nation's research program that would enhance commercialization activities at universities and at the State level.

In conclusion, SBIR and STTR programs demonstrate that public-private partnerships played an important role in driving America's innovation economy forward. The programs are working well. The question is only about how to refine and improve them.

Thank you.

[The prepared statement of Mr. Ezell follows:]



Testimony of

Stephen J. Ezell

Vice President, Global Innovation Policy
Information Technology and Innovation Foundation

Before the

Senate Committee on Small Business and Entrepreneurship

Hearing on

"Reauthorization of the SBA's Innovation Programs"

May 15, 2019 Senate Russell 428A Washington, DC Good afternoon Chairman Rubio, Ranking Member Cardin, and members of the Committee; thank you for inviting me to share the views of the Information Technology and Innovation Foundation (ITIF) on the issue of reauthorization of the Small Business Administration's (SBA's) innovation programs, including the Small Business Innovation Research Program (SBIR) and Small Business Technology Transfer Research (STTR) programs.

The Information Technology and Innovation Foundation is a non-partisan think tank whose mission is to formulate and promote public policies to advance technological innovation and productivity internationally, in Washington, DC, and in the states. Recognizing the vital role of technology in ensuring prosperity, ITIF focuses on innovation, productivity, and digital economy issues.

THE SUCCESSFUL IMPACT OF THE SBIR/STTR PROGRAMS

The SBIR and STTR programs (enacted in 1982 and 1992, respectively) have grown to become the federal government's most impactful programs and largest sources of early-stage capital for technology commercialization, allowing U.S.-owned and operated small businesses to engage in research and development (R&D) activity that has a strong potential for commercialization. SBIR and STTR help promising new high-tech start-ups to grow and scale to become important economic and employment contributors to the U.S. economy.

SBIR is a set-aside program in which 11 federal agencies (all those with R&D budgets greater than \$100 million annually) participate, designed for small businesses to engage in federal R&D with robust potential for commercialization. In 2017, 3.2 percent of these agencies' budgets were allocated to the SBIR program. In 2017, 0.45 percent of the research budgets of federal agencies with greater than \$1 billion annually went to STTR, a sister set-aside program designed to facilitate cooperative R&D between small business concerns and U.S. research institutions with potential for commercialization.' In establishing the SBIR/STTR programs, Congress articulated several objectives, including: 1) to stimulate technological innovation; 2) to leverage small businesses to address federal R&D needs; and 3) to increase the extent of private-sector commercialization of innovations derived from federal R&D.

SBIR and STTR provide over \$2.5 billion annually to support small businesses engaging in R&D with commercialization potential. Since its inception, SBIR has granted over 160,000 awards, with total grants awarded to research-intensive small American businesses now exceeding \$43 billion. On average, SBIR-supported companies receive 10 patents each day, testament to the innovative prowess of the more than 450,000 engineers and scientists working in companies that have been SBIR-supported.³ Over the first 30 years of the program (according to data provided in 2013), SBIR grants engendered 70,000 issued patents and supported the launch of almost 700 public companies, with those companies attracting approximately \$41 billion in subsequent venture capital investment.⁴ Companies launched in part with SBIR support feature a "who's who" of some of America's most successful innovators, including 23andMe, Amgen, Apple, Biogen, Jarvik Heart, LIFT Labs, Millennium Pharma, Qualcomm, Symantec, iRobot, and countless others. The SBIR program has been so successful it's been copied by 17 countries. Moreover, a number of U.S. states have implemented state-level matching programs to empower their innovators to take advantage of, and extend, federal SBIR funding. For instance, Kentucky matches, on a competitive basis, Phase 1 and Phase II federal awards received by Kentucky high-tech small businesses, with the initiative attracting almost \$50 million in federal grants and leveraging \$1.84 in federal awards for every \$1 awarded in state matching funds.³ On May 13, 2019, Tennessee announced it would increase the size of its SBIR/STTR matching program to \$3 million.

SBIR accounts for only about 3 percent of federal extramural research funding, yet numerous studies have documented the SBIR/STTR programs' tremendous contributions to the U.S. innovation economy. For instance, a 2008 ITIF study of the U.S. national innovation system from 1970 to 2006 found that SBIR-nurtured firms consistently accounted for about one-quarter of all U.S. R&D 100 Award winners, signaling that SBIR-supported firms were regularly contributing some of the most important, breakthrough innovations to the U.S. economy.⁶ A 2016 ITIF report, "The Demographics of Innovation in the United States," surveyed 900 individuals who have made meaningful, marketable contributions to technology-intensive industries as award-winning innovators and international patent applicants. It found that among private firms with fewer than 25 employees which produced groundbreaking innovations, over half received assistance from public sources, including grants from the SBIR program.⁷ Of private firms with between 25 and 100 employees in ITIF's study, 17.1 percent received SBIR grants, and 34.2 percent received some form of federal grant.⁸ Similarly, a 2016 Bay Area Council Economic Institute study found that 1,267 companies were generated by the University of California from 1968 to 2015; and that of the 622 still active as of 2015, 189 of them, or 30 percent, received SBIR or STTR grants.⁹

More-recent studies of the impact of SBIR at specific federal agencies have found similarly powerful effects. A 2017 study of SBIR at the Navy and Air Force found that a total investment in SBIR/STTR of \$6.25 billion generated \$92.1 billion in total output, supported 30,000 jobs annually on average, and delivered a return on \$1 of federal investment of \$12 for the Air Force and \$19.5 for the Navy. A 2018 study of the National Cancer Institute's (NCI) SBIR/STTR program found that 690 awards issued as part of NCI SBIR/STTR Phase II grants from 1998 to 2010 supported companies that had generated \$9.1 billion in total sales, delivered \$26.1 billion in economic output, and supported almost 108,000 new jobs. The study further found that 65 percent of the awards funded the development of a new treatment for patients who previously lacked a treatment option and that 89 percent of the grantees reported the NCI SBIR/STTR program provided funding at a pivotal moment for the business. Of the 690 awards, the study found that 247 NIC SBIR-funded products were commercialized and that 110 were still under development. The NCI SBIR program has clearly had a powerful impact in promoting the development of technologies and products that have improved the lives of cancer patients worldwide.

Looking across all federal agencies, various National Academies studies have found that commercialization rates from SBIR/STTR Phase II awards range from 40 to 70 percent, varying by federal agency.¹³ Those studies have also found that SBIR plays a major role in making projects that would not happen otherwise possible.¹⁴ For instance, a study of NSF SBIR Phase II recipients found that 75 percent thought their project probably or definitely would not have proceeded absent program funding: 34 percent were definite and 41 percent thought it rather unlikely.¹⁵ SBIR funding also leads to more impactful innovations. A 2018 study by Albert Link and John Scott, "Toward an Assessment of the U.S. Small Business Innovation Research Program at the National Institutes of Health," indicates that SBIR awards are not only largely successful in helping companies to convert promising innovations into new products or services, but that the program encourages companies to develop higher-risk technologies than would be developed without the award.¹⁶ The authors found that projects that were expected to go forward without SBIR awards achieved sales about 23 percent more often than projects that did need the awards to advance (88 percent versus 71 percent); the authors attribute this slightly lower rate of commercialization as an indicator that many Phase II awardees are developing higher-risk technologies than would otherwise be advanced.

Finally, for many emerging start-ups, not only does SBIR funding assist their development of a process or technology up to the point of market commercialization, it also provides a "good housekeeping seal of approval" validation that is attractive to potential innovators, including venture capitalists, as a company seeks further financial resources to commercialize and grow their businesses.

FURTHER ENCHANCING THE IMPACT OF THE SBIR/STTR PROGRAMS

The SBIR/STTR programs have been tremendously successful, however there remains opportunity to further refine the structure and administration of the programs to further enhance their potential to facilitate the commercialization of technology and seed the development of innovative new businesses. Ideally, SBIR awards go to enterprises demonstrating the greatest potential for commercializing technologies and scaling into mature enterprises that contribute innovative products and services, support high-wage employment, and contribute to U.S. economic growth. According to SBIR data, 36 percent of SBIR-receiving firms have received from 1 to 10 SBIR grants (21,951 firms receiving 56,626 awards) and 30 percent of firms have received from 11 to 50 SBIR grants (2,295 firms receiving 47,343 grants). However, 159 companies have gotten more than 100 awards, with these companies receiving a total of 36,533 awards (23 percent of all awards), while another 273 companies received from 51 to 100 awards (with these companies receiving 12 percent of total awards).

A company receiving multiple SBIR grants is not necessarily a concern; indeed, in many cases, firms with multiple SBIR awards usefully meet the mission needs of an agency. Yet, ideally, recipients eventually largely graduate from SBIR and grow into high-tech enterprises that scale and create well-paying jobs in communities throughout the United States. This raises a concern because Link and Scott have found that companies repetitively seeking SBIR contracts are less likely to commercialize their projects.¹⁹ Further, in a February 2019 study, "Analysis of the U.S. Department of Energy's Energy Efficiency & Renewable Energy and Fossil Energy SBIR Programs," Howell similarly finds evidence of decreasing returns from previous non-DOE SBIR awards. Specifically, Howell finds that among firms with no previous SBIR awards, an award increases a firm's probability of subsequent venture capital investment by 14.8 percentage points. For firms with at least one previous SBIR, the effect is halved to 7.5 percentage points.20 Howell concludes that additional SBIR awards may produce valuable prototyping, but that a significant portion of firms with previous SBIRs are firms that may view SBIR awards as a core part of their buinses model, rather than a leg up to commercial success. Howell notes that her findings concord with Lerner's that "multiple awards are not associated with increased performance for SBIR awardees." 21 Accordingly, Congress should encourage federal agencies to implement a prioritization system in the award process that—presuming the technical aspects and commercialization potential of a given application are ceteris paribus—gives preference to applicants who have received fewer grants over time from the SBIR program.

As noted, an important Congressional objective of the SBIR/STTR program is to promote private-sector commercialization of innovations derived from federal R&D. However, as ITIF and Brookings wrote in their 2016 report, "Localizing the Economic Impact of Research and Development: Policy Proposals for the Trump Administration and Congress," SBIR's impact could be strengthened if some facets of the program were geared slightly more strongly toward commercialization.²² Heeding that proposal, in 2018, Senators Chris Coons (D-DE) and Cory Gardner (R-CO) advanced the Startup Businesses Act, which proposed permitting SBIR and STTR grant awardees to allocate up to \$50,000 of their awards for activities critical to building their businesses, including services such as market validation, intellectual property protection, market research, and business model development.²³ That

bill was incorporated into the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which permits SBIR Phase II awardees to enter into agreements with one or more vendors to provide technical and business assistance (TABA).24 TABA allows up to \$6,500 for a Phase I award and up to \$50,000 of a Phase II award to be directed toward activities focused on improving the commercialization success of SBIR awardees. The legislation marked a welcome step to allow a greater portion of SBIR R&D funds to go toward commercialization-oriented activities, in order to improve the commercialization success of small businesses. Specifically, TABA empowers federal agencies to enter into an agreement with one or more vendors to provide small business concerns engaged in SBIR or STTR projects with technical and business assistance services, such as access to a network of scientists and engineers engaged in a wide range of technologies, assistance with product sales, intellectual property protections, market research, market validation, and development of regulatory and manufacturing plans. All SBIR-active federal agencies should permit SBIR awardees to leverage up to \$50,000 of their grant funding for technical and business assistance activities. However, one aspect of the TABA funds is that they must be contracted to a third-party service-provider, as TABA funds cannot be allocated to company staff. While small businesses will often find this a preferable option, tapping into the extensive expertise, experience, and knowledge base of external experts and specialists on commercialization-oriented activities, Congress should consider permitting SBIR recipients to use a share of TABA funds on internal personnel (e.g., a full-time internal asset focused on commercialization).

The National Science Foundation's I-Corps program has successfully helped scientists and researchers translate federally funded technologies into marketable products and services. ²⁵ ITIF has called for increasing the scale of the I-Corps program across the federal government so that it can be made available to scientists and engineers at all federal agencies. In this regard, ITIF endorses the Innovators to Entrepreneurs Act of 2019, so-sponsored by Senators Chris Coons (D-DE) and Scott Todd Young (R-IN), which would expand application eligibility to anyone who receives a Small Business Innovation Research or a Small Business Technology Transfer award from any federal agency and allow them to use their grant funds to cover expenses of the I-Corps program. ²⁶

The amount provided to successful applicants in Phase I and Phase II of the SBIR program is appropriate, but one adjustment could be to index SBIR awards to inflation with an automatic adjustment made every five years, so that the relative value of awards keep pace with the rate of inflation growth over time.

As recommended by NACIE, the National Advisory Council on Innovation and Entrepreneurship (an initiative of the U.S. Department of Commerce), another step that could be taken to promote SBIR's commercialization potential would be to modify the criteria and composition of SBIR review panels to make commercialization potential a more prominent factor in funding decisions. All participating SBIR agencies consider commercialization potential and plans in their grant funding decisions; however, agencies differ in the weight or emphasis they place on commercialization.²⁷ In particular, some agencies, such as NASA and the Department of Defense (DoD), more regularly intend to use the commercial products that flow from their R&D investments. In agencies where the intended customers are external, a greater portion of the merit review evaluation criteria and scoring should include commercialization factors, such as the company's understanding of market opportunity, product development timelines, and needed resources.²⁸ Further, to evaluate these important criteria, the composition of SBIR/STIR review panels at these agencies should include industry experts, investors with relevant industry or technology expertise, and/or representatives from commercialization intermediary organizations or venture development organizations.

Since 2010, SBIR/STTR has operated the Federal and State Technology (FAST) Partnership Program, which provides one-year funding to organizations to execute state/regional programs that increase the number of SBIR/STTR proposals (through outreach and financial support), to increase the number of SBIR/STTR awards (through technical assistance and mentoring), and to better prepare SBIR/STTR awardees for commercialization success (through technical assistance and mentoring).²⁰ FAST provides \$3 million in total funding (up to \$125,000 per applicant) for outreach, financial support, and technical assistance to next-generation, R&D- focused small businesses, with eligible applicants for FAST funding including state and local economic development agencies, Small Business Development Centers (SBDCs), accelerators, incubators, Women's Business Centers, Procurement Technical Assistance Centers (PTACs), colleges, universities, and other entities.²⁰ The FAST program fulfills an important function and it should be formally authorized by Congress and the Trump Administration.

As noted, the SBIR and STTR programs are effective, yet they do set a high bar for extremely early-stage enterprises. There is often insufficient funding available at universities (or from other sources) to push nascent technologies to the point where these companies are positioned to receive an SBIR or STTR grant. The problem is essentially that researchers and universities do not have the resources available to support the proof-of-concept work, market analysis, and mentoring needed to translate ideas and nascent technologies from the university laboratory into a commercial product. Furthermore, SBIR awardees tend to be more successful when commercialization potential is considered before the application process begins.

A national "Phase Zero" proof-of-concept program would not only help more projects cross the "valley of death," but would also help enhance the infrastructure (e.g., expertise, personnel, support, small business, and venture capital engagement) and facilitate the cultural change necessary for universities, federal laboratories, and other non-profit research organizations to better support commercialization activities.³¹

America's competitors have recognized the need for such an instrument. For instance, the European Research Council (ERC) has announced a new proof-of-concept funding initiative to help bridge the gap between ERC-funded research and the earliest stage of marketable innovations. These awards can be as high as \$215,000 for individual researchers, in total, equivalent to about 1 percent of ERC's budget. Here in the United States, the Wallace H. Coulter Foundation has established Translational Research (for individual researchers) and Translational Partnership (for institutions) Awards for proof-of-concept research in biomedical engineering. The Translational Research Awards are made in amounts of approximately \$100,000 per year, while the university grants have a duration of five years at over \$500,000 per year. The Coulter Translational Research Partnership Award in Biomedical Engineering award provides \$1 million each year for a period of five years.

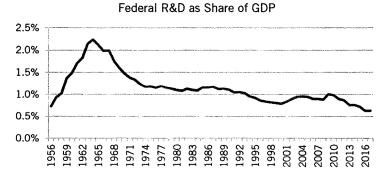
Similarly, NIH's Research Evaluation and Commercialization Hub (REACH) program fosters the development of therapeutics, preventatives, diagnostics, devices, and tools that address diseases within NIH's mission in a manner consistent with business case development. The work supported by the REACH program may include technical validation, market research, clarification of intellectual property position and strategy, and investigation of commercial or business opportunities.³⁶ Finally, a number of states, such as Colorado, Louisiana, and Tennessee, have

developed Phase Zero grants to help firms apply for SBIR grants and support early proof-of-concept research. For instance, Colorado's Bioscience Discovery Evaluation Grant program provided 163 proof-of-concept grants from 2007 to 2013 with \$10 million, launching 38 companies. However, while a step forward, collectively these foundation and government programs are still modest in size. As such, Congress should implement a proof-of-concept-program, perhaps through a grant program for states that agree to match the funds on a dollar-for-dollar basis. (Such an initiative could be rolled into the SCNR program recommended subsequently).

In addition, federal agencies with SBIR/STTR programs should standardize their commercialization data-collection practices. The data are now collected individually by each agency in their own form and with different requirements, which both makes it more difficult for small businesses to comply or for useful insights to be gleaned from the data.

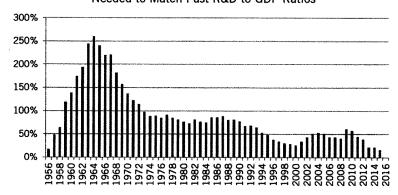
Finally, the United States would benefit from increasing SBIR funding. For instance, the FY 2016 National Defense Authorization Act commissioned the "Section 809 Panel," a small advisory group tasked with identifying and recommending ways to streamline and improve the federal defense acquisition process. The panel's final report found that SBIR had "effectively leveraged small businesses to further DoD's mission-related capabilities" and called for increasing the Department of Defense's percentage allocation of extramural R&D funds allocated to SBIR from 3.2 to 7 percent, phased in over a five-year period.³⁷

However (leaving the SBIR percentage set-aside level issue aside), the most important way for the federal government to increase its levels of SBIR funding would be to increase its investment in R&D, which is woefully lagging compared to historical norms (and relative levels invested by peer nations). For instance, in 2017, federal R&D investment as a share of GDP fell to 0.62 percent, the lowest level since 1995, as the chart below shows.³⁸



To understand just how far off the historical pace federal funding for research has fallen, the graph below shows how much 2017 R&D funding levels would need to increase in order to match past R&D-to-GDP ratios. For example, to match levels from the 1980s, federal R&D funding levels in 2017 would have needed to be about 80 percent higher than they were.

Increase in 2017 Federal R&D Spending That Would Be Needed to Match Past R&D-to-GDP Ratios



Public R&D is crucial for the United States' position in the global economy because many of the benefits of innovation are concentrated domestically. Thanks in part to programs like SBIR and STTR, federal R&D funding makes it more likely that U.S. firms are the first to leverage new discoveries, giving them advantages over international competitors. Thus, anemic government R&D spending is particularly concerning in the light of increases by other nations around the world, especially adversaries.³⁹

FURTHER STIMULATING U.S. TECHNOLOGY TRANSFER AND COMMERCIALIZATION ACTIVITY

While SBIR and STTR represent effective programs for tapping into the potential of small businesses to meet federal agencies' R&D needs and to promote the commercialization of technologies stemming from federal R&D activity, America's current system for funding research still pays too little attention to the commercialization of technology, and is still based on the linear model of research that assumes that basic research gets easily translated into commercial activity. ⁴⁰ The innovation process remains choked with a variety of barriers, including institutional inertia, coordination and communication challenges, and lack of funding for proof of concept research and other "valley of death" activities. Accordingly, it's time for federal policy to explicitly address this challenge and to allocate more resources to commercialization activities. ITIF proposes that Congress allocate a modest share of 0.15 percent of agency research budgets (about \$125 million per year) to create a Spurring Commercialization of our Nation's Research (SCNR) program that would fund university, federal laboratory, and state government technology commercialization and innovation efforts. ⁴¹ Ideally, the SCNR funding would be added to the current SBIR percentage allocation.

Half of the SCNR funds would go to universities and federal laboratories, which could use the funds to create a variety of different initiatives, including mentoring programs for researcher entrepreneurs, student entrepreneurship clubs and entrepreneurship curriculum, industry outreach programs, seed grants for researchers to develop commercialization plans, etc. For instance, the funds could be applied to "commercialization capacity building grants" to institutes of higher education pursuing specific innovative initiatives to improve an institution's capacity to commercialize faculty research or to "commercialization accelerator grants" to support institutions of higher education pursuing initiatives that allow faculty to directly commercialize research in an effort to accelerate research breakthroughs. The intent would be to use the funds to continue to turn America's federal laboratories and universities into engines of innovation, broadening the capacity of both students and faculty in the latter to successfully innovate. This matters because universities play an increasingly important role in the U.S. innovation system. For instance, from 1996 to 2015, academic technology transfer contributed to 380,000 invention disclosures, 80,000 U.S. patents issued, and 11,000 start-up companies formed. 42 And according to a report prepared for AUTM and the Biotechnology Industry Organization (BIO), from 1996 to 2015, academic patents and their subsequent licensing to industry—substantially stimulated by the Bayh-Dole Act—bolstered U.S. GDP by up to \$591 billion, contributed to \$1.3 trillion in gross U.S. industrial output, and supported 4,272,000 person years of employment.⁴³ SCNR would be a mechanism enabling the federal government to bolster the innovation capacity of U.S. universities which are contributing tremendously to the U.S. economy.

The other half of SCNR funds would go to match state technology-based economic development (TBED) programs. State TBED programs spur the development of cutting-edge, science-based industries by boosting research funding. For example, Oregon's Nanoscience and Microtechnologies Institute serves as a forum for R&D synergy among Oregon's three public research universities, the Pacific Northwest National Laboratory, the state, and the "Silicon Forest" high technology industry cluster. States also try to ensure that research is commercialized and good jobs are created in both cutting-edge, science-based industries and industries engaging in related diversification. For example, the Georgia Advanced Technology Development Center at Georgia Tech is a technology incubator that offers services including consulting, connections to university researchers, and networking with other entrepreneurs and service providers. States have also established programs to help small and mid-sized firms support collaborative research at universities. For example, Maryland's Industrial Partnerships program provides funding, matched by participating companies, for university-based research projects that help companies develop new products or solve technical challenges.44 Finally, states have established initiatives to help firms commercialize research into new business opportunities. For example, Oklahoma's nonprofit i2E organization helps Oklahoma companies with strategic planning assistance, networking opportunities, and access to capital. i2E's Oklahoma Technology Commercialization Center assists researchers, inventors, entrepreneurs, and companies in turning advanced technologies and high-tech startup companies into growing companies.⁴⁵ But without assistance from the federal government, states will invest less in TBED activities than is in the national interest. A performance-based allocation to help fund state TBED efforts would help correct this limitation.

The portion of SCNR funds supporting state TBED activities could also be structured in a way to match states' investments in their technology commercialization programs. Matching federal funds would be available concomitant with a state's level of investment (prorated against state population with a maximum cap) in its technology commercialization programs. States would use the money for direct, merit-based project grants to existing SMEs or to startup companies looking to commercialize new products or technologies.

One issue an SCNR program could help address is Congressional concern regarding a lack of regional balance in allocation of federal technology transfer and commercialization support funding. SCNR could help a more-diverse set of universities and research institutions bolster their innovation capacity, thus bringing more opportunity to more regions of the country, not just predominantly leading high-tech hubs. Another challenge is increasing the amount of SBIR/STTR applications coming from minority- and female-led applicant teams; such individuals tend to experience similar SBIR application success rates, but there tend to be far-fewer applicants, so there overall numbers are lesser.

The U.S. Small Business Administration's Office of Investment and Innovation (OII) operates the Growth Accelerator Fund Competition (GAFC) program, which the SBA instituted to "support the development of accelerators and their support of startups in parts of the country where there are fewer conventional sources of access to capital."46 The program seeks to stimulate economic development and innovation via the award of several nominal (\$50,000), flexible, non-repayable prizes that support organizations such as accelerators, incubators, maker spaces, and various hybrid forms of them. It awarded 223 awards to 187 distinct organizations from 2014 through 2016 (with funding levels of \$2.5 million in 2014 and 2015 and \$3.4 million in 2016, though just \$1 million in 2017). In 2018, the Library of Congress evaluated the first years of the program (2014 to 2016).47 The Library of Congress's analysis included a variety of interviews and surveys, but concluded by noting that the preponderance of respondents found the program to be "a relatively low-cost, small, impactful government program, unique in structure and target, which supports the infrastructure needed to successfully launch startups" and which "should continue to be funded" although ideally with a higher prize level (up to \$100,000) and a larger staff to handle program management and metrics development. 48 The GAFC uniquely provides seed resources to a broad range of accelerator models and programs across a diverse footprint of geographies and sectors across the United States. The Growth Accelerator Fund fulfills an important function, and Congress and the administration should continue to authorize it, and support it with an annual program budget of at least \$10 to \$20 million. The Growth Accelerator Fund Competition could fit within an umbrella of programs under a SCNR if Congress were to introduce such an instrument.

Access to risk capital is not evenly distributed throughout the United States. In 1995, Silicon Valley accounted for 22.6 percent of U.S. venture capital, Los Angeles/Orange County 12.5 percent, Boston 9.9 percent, New York 6.4 percent, and all other areas of the United States 48.6 percent. Twenty years later, in 2015, Silicon Valley had more than doubled its share, to 46.4 percent, New York's share rose to 12.4 percent, Boston moved to 10.2 percent, and Los Angeles to 8.7 percent, while the share for the rest of the United States fell to 22.2 percent. In other words, today just four regions of the United States account for 78 percent of all U.S. venture capital investment, while the remainder of the country contests for the remaining one-fifth. Accordingly, a substantial number of promising young businesses scattered throughout all regions of the United States likely have difficulty securing capital.

The Small Business Jobs Act of 2010 helped to address this problem by creating the State Small Business Credit Initiative (SSBCI), a \$1.5 billion fund, administered by the U.S. Department of the Treasury, designed to strengthen state programs that support lending to small businesses and small manufacturers. The SSBCI gave states significant flexibility to design programs to meet local market conditions, with SSBCI supporting 152 small business programs from 2011 to 2015. Approximately 69 percent of the funding supported lending or credit support programs and 31 percent supported venture capital programs. From 2011 to 2015, SSBCI programs supported nearly \$8.4 billion in new capital in small business loans and investments. In effect, SSBCI provides an opportunity for states to

supplement existing venture capital programs, revitalize programs lacking sufficient state support, and create new programs where state managers perceive unmet needs in evolving entrepreneurial ecosystems. The SSBCI has made a positive impact in expanding high-potential businesses' access to credit, and therefore Congress should reauthorize it and double its funding, although Congress should indicate that its preference would be for SSBCI funds to go primarily to traded-sector enterprises (i.e., those competing in international markets).

Congress could take further steps to help new and small business, particularly in globally traded sectors. One step would to be encourage the Small Business Administration to focus more resources on firms in traded sectors, like agriculture, manufacturing, and software, content and internet services. ³² Currently the SBA treats all industries alike in its funding priorities, but industries serving local markets (e.g., liquor stores) play little role in supporting local or national economic competitiveness, and by and large providing funding the them simply shifts activity from one firm to another. Neither of these things is true for firms in industries that are globally traded, yet only 7.5 percent of loans under the SBA's primary program for assisting small businesses (7A loan program) go to manufacturers. Congress should require the SBA to develop a plan to significantly increase the share of support going to traded-sector firms. ³³

CONCLUSION

The success of the SBIR and STTR programs show that effective public-private partnerships can play an important role in stimulating America's innovation economy. In general, the SBIR and STTR programs have been highly successful and deserve Congress's continued and enthusiastic support. In fact, cutting back SBIR/STTR funding, or eliminating entire SBIR programs, such as at the Department of Energy, as the Heritage Foundation proposed in its Blueprint for Balance, would weaken the United States' capacity for private-sector innovation.⁵⁴

Yet despite the success of the SBIR/STTR programs, innovation never ceases, nor does global competition for innovation advantage, and efforts to continue to enhance the programs' potential to contribute to greater levels of technology transfer and commercialization are warranted, with a good example of "institutional innovation" in the programs being Congress's recent authorization that a modest share (up to 5 percent) of SBIR Phase II funds could be applied to commercialization-oriented activities. Expanding resources available for "Phase Zero" or related proof of concept activities could also help enhance the impact of SBIR applications.

While eleven federal agencies participate in SBIR—and, as this testimony has contended, generally effectively so—federal policy can and should still do much more to promote technology transfer and commercialization from U.S. universities, federal laboratories, and other research institutions. A broader initiative is needed. Accordingly, a Spurring Commercialization of our Nation's Research program would build institutional capacity for innovation at U.S. universities and federal laboratories and provide additional resources to help U.S. states stimulate technology transfer and commercialization activity, such as by supporting state TBED programs or by providing a pool of funds that could be used to provide matching funds for initiatives such as states' Phase Zero proof of concept programs. In conclusion, the SBIR/STTR programs are some of the most effective in America's arsenal of programs to stimulate innovation, though efforts toward continued refinement and improvement are warranted.

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Chairman RUBIO. Thank you. Mr. Glover.

STATEMENT OF JERE W. GLOVER, EXECUTIVE DIRECTOR, SMALL BUSINESS TECHNOLOGY COUNCIL, ANNAPOLIS, MD

Mr. GLOVER. Chairman Rubio, members of the committee, I am Jere Glover, executive director of the Small Business Technology Council.

Thirty-seven years ago, I had the privilege of testifying in support of the original SBIR legislation. Then the United States was the undisputed worldwide leader in innovation. It dominated with virtually 100 percent of venture capital. We had the best education system in the world and the strongest patent protection in the world.

America's small businesses were the most innovative sector of the economy and the wellspring of entrepreneurial energy but received only 5 percent of the R&D dollars.

Today about half of the venture capital investments are outside the United States. Our patent system is severely weakened. We now publish patent applications shortly after they are filed telling the rest of the world what our technology is and how to make it.

Small business still only receives about Federal 5 percent of the extramural R&D funding, but we are still the most innovative and productive sector of the U.S. economy.

Just candidly, China has been eating our lunch, and when we look at things like the European Union spends four times more money on small business R&D than America does, they spend 20 percent; we are basically at 5. Even France spends \$13 billion to fund disruptive technologies.

But the one thing that we have going for us in America is the SBIR program. Seventeen National Academy studies, four economic impact studies clearly show the program is the economic engine that drives innovation in America.

The return on investment for the SBIR program at the National Cancer Institute is 33 percent. For every dollar invested in the economic impact results in \$3 in Federal tax, local taxes, and State taxes coming back.

If you look at the chart, the companies that were acquired, just those that were acquired in the National Cancer Institute, funding rose \$21 billion, 27 times the SBIR total investment at the National Cancer Institute.

The DoD industrywide study, which has been partially released, has similar results. I guarantee you that you are using SBIR technology on a daily basis. Two actual items, one is GPS on a chip, which allows you to know where you are on your phone and throughout your GPS, and CMOS, which is cameras making digital cameras work better on your phones right now—are SBIR-funded technologies. You have a brief description there.

Let me just say this. The market loves the SBIR program. As mentioned earlier, 17 countries have copied it. Ten percent of all venture capital investment goes to SBIR-related firms. Nineteen percent of In-Q-Tel's investments go to SBIR-related firms. Eight hundred twenty-nine SBIR firms have gone public. One thousand

three hundred have been acquired, with an average purchase price of \$42 million.

One of the things that is surprising—and we need to understand—the only source of money for most small businesses in the innovation area is SBIR. When we look at venture capital, for example, we see that 80 percent of all venture capital is in three industries: software, telecom, and the internet. And for those in the Defense Department who think venture capital is going to help them out, what you see, 20 percent of VC money is all we have to share in every industry except those three.

In defense, what we see in the defense area is—next chart, please—on average, the entire venture capital investment portfolio at every stage funds six defense-related technologies a year, to the tune of \$73 million. That is all they do.

So when we see folks talking about that is going to save the defense industry, that is going to speed up things, it certainly has not to date.

Now, what is working is the Air Force one-page contract and upfront payments, GSA doing Phase IIIs, and SBA's new Policy Directives.

One of the questions that I ask for everybody involved in the innovation world is tell me what works better than SBIR, and if you can tell us that, fund it.

What we need to do is increase Federal spending and make spending more productive, make sure we use SBIR, double it. The 809 Panel report says separate funding for Phase III should be added to the SBIR program, and we want 30 percent of the administrative 3 percent money to be spent on the educating and outreach and contracting to make the process work faster.

Thank you very much for your time.

[The prepared statement of Mr. Glover follows:]

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TESTIMONY BEFORE THE SENATE SMALL BUSINESS AND ENTREPRENEURSHIP COMMITTEE MAY 15, 2019

SMALL BUSINESS TECHNOLOGY COUNCIL (SBTC) JERE GLOVER, EXECUTIVE DIRECTOR

Robert N. Schmidt, Kevin Burns, & Alec Orban

Chairman Rubio, Ranking Member Cardin, members of the Committee, thank you for the opportunity to appear here today to discuss the importance of technological innovation to the United States, and the reauthorization of the SBIR and STTR Programs.

I am Jere W. Glover, Executive Director of the Small Business Technology Council (<u>SBTC</u>) of the National Small Business Association (<u>NSBA</u>), in Washington, DC. I have been involved in federal science and technology innovation programs since 1978, when I staffed joint Senate/House hearings and the resulting report that showed severe under-utilization of small business high-tech companies in the Federal R&D programs. The SBTC is an outgrowth of the White House Conference on Small Business in 1995, and is the nation's largest association of small, high-tech companies across diverse fields.

When Arthur Obermayer was inducted into SBIR Hall of Fame at the White House as one of the key founders of the SBIR Program, he stated that next to the GI Bill after WWII, SBIR was one of the most significant pieces of legislation ever passed by Congress. After considering his comments, I'm inclined to agree with him.

Executive Summary

Thirty-seven years ago, I had the privilege of testifying before Congress in support of passing the first SBIR legislation. A lot has changed since then, and a lot has remained the same.

In 1982, the U.S. was the undisputed worldwide leader in innovation. Then and now America's small businesses are the most innovative sector of the economy and the wellspring of entrepreneurial energy. Yet even though small business employs one third of our scientists and engineers, even though study after study has shown these small businesses produce the most new, good ideas, small businesses are only tapped to do about 5% of DOD's external R&D. We are underusing a primary resource for innovating America's future.

The U.S. was once the undisputed leader in developing technology and had clear technology advantage on the battlefield. The U.S. was where innovation happened. Today the rest of the world is catching up and passing us by. Thirty-seven years ago, America dominated venture capital, and we had the best education system, strong patents and private funding for



innovation. No other country was even close in these necessary elements. Today, about half the Venture Capital is being invested worldwide, our patent system is severely weakened, we now publish patent applications shortly after they are filed disclosing our technology to the rest of the world, and foreign governments have discovered the benefits of funding innovation

- As Chairman Rubio's report shows, China is rapidly challenging the U.S. in technology
 and innovation. Separate from trade practices and taking others' intellectual property,
 they are putting big money into developing their technology and small businesses.
- The European Union is investing 20% of its R&D in small businesses.² Even France is now putting \$13 Billion into "disruptive technologies".³

The US is continuing its decline in inventing and commercialization. America is now third in receiving Intellectual property payments, behind Ireland and The Netherlands.⁴ Even worse, on a per capita basis, the US is currently 11th, behind Switzerland, Sweden, the United Kingdom, Hungary, Australia, and Israel. This is in part due to our weakened patent system. Of most importance, America is number 8 in Bloomberg's Innovation Index (behind South Korea, and Finland).⁵

If we are going to change these disturbing trends and have America regain the world's leadership in technology and innovation, we need to take action. It is time to put our money where our innovation is, in small business.

The SBIR/STTR Program works. It works because it combines the entrepreneurial drive of America's small businesses with those business's scientists and engineers to create remarkable new innovations, which meet the mission requirements of Federal agencies and departments, and which the businesses use to create 21st century products and services and high value jobs. SBIR taps the potential for greatness in American small business, and is a key factor in driving our economy in competition with the rest of the world. After 17 National Academy studies and 4 detailed Economic Impact Studies, we can clearly state that the SBIR/STTR program is an economic engine that drives innovation in America. The return on investment for the SBIR/STTR program is between 22% and 33%, depending on the agency. For every dollar invested the economic impact results in three dollars in Federal state and local taxes. These studies show that, from an economic perspective, the best return on Federal R&D dollars flows from the SBIR program.

The just-finished SBIR/STTR economic impact study for the National Cancer Institute shows a return of \$3.68 in taxes for every dollar invested in SBIR R&D. In other words, SBIR at NCI not only paid for itself, it returned more than 2.6 times to the Government more than what was invested in SBIR. The NCI study looked at 12 years and 690 NCI Phase II SBIR/STTR awards totaling \$787 million dollars to develop new medical devices, drugs, research tools and in-vitro diagnostics for treating cancer. The results were \$9.1 billion in sales, \$2.9 billion in tax revenues, and 107,918 new jobs, as well as 45 spinouts, 103 licenses, \$4.26 billion in added outside investment, and 103 of the companies being sold for another \$21 billion to invigorate larger companies looking for new technologies. SBIR success stories were for Breast, Lung, Prostate and multiple other cancers.



SBIR provides new technologies for fighting cancer, good jobs from the new life-saving products and services, and we get back more in taxes than we invested – excellent returns on Federal R&D dollars. This is shown true throughout the SBIR program. SBIR is a GDP and jobs engine producing high leverage economic power. There are literally thousands of success stories here, and all of our lives are better for them.

Here are the results for just the National Cancer Institute's SBIR/STTR Program.

National Cancer Institute Economic Impact (1998-2010)

Return on Investment	33:1
Total Economic Output	\$26,100
Total Outside Investment Funding	\$4,260 (5.41 times SBIR investment)
Total Value of Acquired Firms	\$21,630 (27.48 times SBIR investment)
Follow-on R&D	\$957 (1.22 times SBIR investment)
Cumulative Sales	\$9,144 (11.62 times SBIR investment)
Rate of Commercialization	53%
Total SBIR/STTR Award Investment	\$787
Total Phase II Awards	690

^{*}dollar amounts in millions

The DOD-wide study that has only been partially released has similar results. I guarantee that you use at least two technologies funded by the SBIR/STTR Program on a daily basis and probably have products using these technologies in your pocket or purse right now. Dr. Reza Rofougaran developed GPS on a chip with SBIR, which is used in cell phones. And the fast CMOS camera technology was developed for military use but is now in most cell phones and digital cameras. One of the earliest DOD SBIR success stories is QUALCOMM, which was nurtured by the SBIR program and has maintained its leadership in cell phone chip technology, and now leads America's path to 5G networks. For a list of SBIR success stories by state, follow this link: https://sbtc.org/wp-content/uploads/2019/05/SBIR-Success-Stories-Book-2019.pdf



SBIR IS THE BEST R&D PROGRAM IN THE US

And has a great commercialization record

SBIR generates \$23 in economic returns for every \$1 invested.

Tor every 31 mivested.			
SBIR Investment	Sales	Value Acquired Firms	
\$15 B	\$135B 9:1	\$30B	
Outside	Economic	Percent	

Investment \$18B

Economic Output \$351B

Percent Commercialized 58%

This chart is a summary of 4 economic studies funded by the Air Force, Navy, DOD and National Cancer Institute. 5,000 SBIR and STTR firms were surveyed. Returns are reported as understated. The study was conducted by TechLink, a federally funded technology transfer center at Montana State University-Bozeman, in collaboration with the Business Research Division (BRD) of the Leeds School of Business at the University of Colorado Boulder.

No other program has such a remarkable record of commercialization success as that of the SBIR/STTR program.

^{*}DOD-wide numbers are from a preliminary report and are not official yet



We are at a crossroads with the world catching up. If we don't change, they will pass us by. Congress has the ability to take action to restore America to the leadership role in innovation.

SBTC believes America needs to:

- · invest more money on R&D funding,
- · encourage innovation by increasing and strengthing the SBIR program,
- encourage commercialization of new technologies by expanding the RIF program and funding Phase III SBIR projects.
- restore and strengthen the U.S. patent system.

What this committee can do is spend the federal R&D dollars more productively. Get the best possible return on investment on the Government's R&D dollar. As DOD's 809 committee has recommended, double the SBIR/STTR program and RIF funding, make SBIR/STTR permanent, streamline and simplify the Program and make the Government put the SBA Policy Directive and legislative changes to SBIR/STTR Program into the FAR and DFAR.

If you take these actions, you will unleash new technologies for America and for our warfighters while strengthening our economy and rejuvenating America's leadership in innovation.



SBIR/STTR Overview

The SBIR/STTR Programs together account for \$2.5-3 billion dollars, or about 3.5% of the Federal extramural R&D budget. SBIR/STTR represents less than 2% of the total Federal R&D budget. Each year 11 Federal agencies make almost 5,000 awards on a highly competitive merit basis (only 1 in 20 Phase I proposals advances to Phase II), with almost one half coming from the Department of Defense. For a description of how the program works see www.SBIR.gov.

It bears repeating that the National Academy of Sciences and its National Research Council's (NRC) 17 reports have shown that the SBIR/STTR Programs have met most of the Congressional objectives for the Program: (1) to stimulate technological innovation, (2) use small businesses to meet federal R&D needs, (3) foster and encourage the participation of socially and economically disadvantaged small businesses, and (4) increase the private sector commercialization of innovations derived from federal R&D. (While the NRC indicates that only number (3) has not been meet, NRC says it is not a SBIR/STTR problem, but a STEM problem). The SBIR and STTR firms also work closely with universities and their faculty. For example, the National Cancer Institute study showed 63% of awardees reporting being involved with universities. SBIR firms and small firms provide jobs to thousands of university graduates. Small and start-up firms license over 70% of all university licenses.

What is the critical role the SBIR/STTR program plays? Uniquely among Federal programs, and in fact in our overall economy, the SBIR program enlists America's small high tech firms to innovate on problems and opportunities for new technologies identified by the government agencies. We know that small businesses bring new innovations that transform our economy and prepare it for the future. The winning concept behind SBIR is that it creates new technologies needed by America and creates those technologies precisely within the small businesses that are already competitive and entrepreneurial in nature and well-suited to carry the new innovation into the economy.

The Federal government defines the problems to be solved, the small businesses compete to create the best solutions, with only the best surviving the screening to Phase II. The SBIR program pays for R&D, with the businesses responsible for subsequent commercialization. The small businesses bring their entrepreneurial drive and determination, and their flexibility and new perspectives, and use their innovative technical skills (employing approximately 1/3 of America's engineers and scientists) to create new, high value solutions. Venture capital rarely supports such early stage innovation, tending to invest much later in the new product development process, after products have been proven by prior R&D. Banks certainly do not lend for such early stage purposes. And small businesses do not have the internal capital to finance such R&D. By linking together these high performance drivers and enlisting small businesses to do R&D work, the SBIR program produces the very high innovation, government transition, and commercialization outcomes that multiple studies have now documented. The combination builds on uniquely American strengths and produces the remarkably large commercial outcomes. SBIR is a policy that works, and we should do more of it.



In addition to providing research meeting the Government's needs and leading to more tax revenues than had been invested through SBIR, SBIR also saves the Government money. In just one example from one program, the J-35, Joint Strikefighter, SBIR saved over \$500 million according the Lt. General Christopher Bogdan, PEO of the Joint Strikefighter program. From a Phase II NIH program to conduct sleep apnea tests at home, healthcare payers have saved over a quarter billion dollars using this home sleep apnea test.

The Market loves SBIR

The Federal government benefits tremendously from SBIR technology. But the market also appreciates SBIR technology. Some facts that show that SBIR makes a difference include:

- · 10% of all VC investments go to SBIR firms
- 19% of IN-Q-Tel investments are in SBIR companies (In-Q-Tel is the strategic investor for the U.S. intelligence and defense communities)
- 829 SBIR related firms have gone public
- 1300 or 9% of SBIR firms have been acquired
- L3 Com, GE, SAIC, BAE, Lockheed Martin, Raytheon, Gen Dynamics, Philips, Teledyne have each acquired 10 or more SBIR Firms
- The Section 809 Panel recommends doubling SBIR and RIF for DOD, and the Section 813
 Panel recommended the same SBIR data rights as those under private expense

SBIR success stories

SBIR has many, many success stories. In addition to the success stories mentioned above, the agencies publish their list of success stories. I would like to thank the Montana firm Techlink for their work on the agency Economic Impact Studies. Techlink took the National Academy Studies and using modern techniques and hard work were able to reach over 90% of SBIR Phase II winners and report on the award winners. Attached to my testimony is a chart showing the names and technologies of selected DOD success stories in states represented on this Committee. It is interesting to note that every state represented on the Committee had at least one success story. These success stories can be viewed in more detail at: https://sbtc.org/wp-content/uploads/2019/05/SBIR-Success-Stories-Book-2019.pdf

- SBIR Success Stories: https://www.sbir.gov/news/success-stories
- DOD: http://www.acq.osd.mil/osbp/sbir/about/success-stories.shtml
- NIH: https://sbir.nih.gov/statistics/success-stories
- DOE: http://science.energy.gov/sbir/highlights/
- NIST/DOC: http://www.nist.gov/tpo/sbir/sbir-success-stories.cfm
- USDA: http://nifa.usda.gov/impacts
- EPA: http://www.epa.gov/sbir/sbir-success-stories-and-highlights
 Tibbett's Award & SBIR Hall of Fame: https://www.sbir.gov/about-tibbetts-awards



Some Agencies are innovating to streamline and further improve effectiveness, speed, and transitions

A few examples:

- Air Force Pitch Day
 - o 51 Small Businesses competitively awarded simplified 1-page Phase I contracts
 - o \$8.75 million paid by government credit card over 2-day event
 - o SBTC letter to President Praising Sec Roper and AF Team
- GSA Phase III Assisted Acquisition
 - GSA pilot program provides contracting service to DOD SBIR offices who want to more rapidly award post-Phase II funding ("Phase IIIs")
- SBA Issued new SBIR/STTR Policy Directives in April
 - Included many legislative changes made in the last 10 years.
 - Congress has directed the agencies to standardize and simplify their procedures and contract for the SBIR.

The SBA Policy Directive needs to be incorporated into the FAR and DFAR

 Navy has been a program innovator, with a sustained focus on SBIR for new technologies and well-documented results, and multiple policies accelerating tech transitions to the warfighter.

Staffing and Budget

SBTC is concerned that the transfer of SBIR to R&E at DOD is not working nearly as well as it could relating to the SBIR program. Despite the studies showing such strong successes, there is no permanent staff in the SBIR program office at DOD. Solicitations which were due earlier in the year were issued weeks late. While parts of DOD have issued memorandums and directives implementing legislative change to the SBIR program, DOD overall has not. Eight years after SBIR laws were changed in 2011, the FAR and DFAR have still not been updated. We are concerned that DOD is not organizing to most effectively take advantage of the new technology development opportunities offered by the SBIR/STTR program.

Another concern is that the SBA's SBIR/STTR staff and budget are too small. According to the SBA's "Historical Summary, Office of Technology," in 1991, the Office of Technology had a budget of \$907,000 and 10 positions. While I do not have current information, I believe the program is in need of more funding and personnel. Running a multi-billion dollar program with just 3 or 4 people and a very limited budget makes no sense. SBA is behind in submitting its Annual Reports to Congress and only recently issued guidance directing the Agencies to comply with the provisions of the prior Reauthorization bills. Lack of personnel and funds are a serious problem at SBA's Office of Innovation. Some of the 3% Administrative funds should be used for this.



SBIR/STTR Legislative Recommendations

Increase SBIR/STTR Allocation

- Sec 809 Panel recommended increasing SBIR to 7%.
- The SBIR program is remarkably productive, with documented high performance in
 producing technical breakthroughs and commercial success. At this time DOD needs to
 step up its R&E effectiveness, programs that are documented to be remarkably
 productive should be expanded. SBIR is currently only a small 3.2% of the external R&D
 budget, far short of the potential for small business technology to help resolve DOD's
 technology shortfall.
- Despite its success, SBIR is constantly a target for carve-outs or experimental pilot programs diverting funds, like expanded I-Corps or marketing programs. SBTC opposes taking valuable SBIR R&D dollars and diverting them to other purposes.

SBIR/STTR Permanency

- Sec 809 Panel recommends making both SBIR and STTR Permanent.
- Success of the program over 35 years, with dozens of papers and studies proving its
 effectiveness and economic benefits justify making SBIR/STTR permanent.

Require agencies to use 30% of the 3% administration funds for training contracting officials on SBIR

- Lack of training and understanding of the law by contracting officials and program
 offices has been cited by SBTC members as the #1 obstacle for getting Phase III
 contracts.
- SBIR companies often have to educate contracting officers on what the law says when pursuing Phase III funding.
- One purpose of the 3% administration carve-out is to streamline SBIR/STTR awards, there is no better investment of that money than by ensuring that contracting officers know and understand the law, particularly with regards to Phase III preference and SBIR data rights.

Get legislative and Policy Directive changes, especially the new SBA SBIR/STTR policy, incorporated into the FAR & DFAR within 180 days (Appendix A)

- FAR and DFAR regulations have not been updated to reflect the statutory language changes and SBA Policy Directive made by Congress and SBA in this decade.
- Contracting Officials and Program offices regularly ignore or discount statutory law if the
 changes are not reflected in FAR and DFAR because they do not have a legal
 understanding that the statute takes precedence over the Regulations. This lack of
 understanding goes back to the need to provide proper training to agency personnel.
- There is no indication that the FAR and DFAR will ever be updated to include changes by both Congress and the Policy Directive unless Congress compels them to be added.
- Report quarterly on progress for implementing these provisions.
- Update all training manuals procurement docs in 180 days.



Streamline and speed up R&D contracting at DOD

- DOD should issue a standard, simplified contract for Phase I across all agencies. Pilot programs to expedite the contracting process should be implemented.
- Last year the NDAA had a provision requiring DOD to develop a simplified and standardized contracting procedure for Phase I and II.
- Despite the stated goal of the Administration to reduce regulatory burden, new FAR and DFAR regulations are continually being added to DoD contracts. This practice of adding to the regulatory burden of small businesses needs to be reversed. (Firms with fewer than 20 employees already spend 36 percent more per employee than larger firms to comply with federal regulations.) A committee should be established with DoD and small business company leaders to reduce FAR/DFAR clauses in SBIR/STTR contracts with a goal of reducing the number of clauses by 60%. Small business cannot be held to the same regulatory expectations that huge multi-billion dollar defense contractors meet.
- The first payment for Phase I shall be paid on the day the agreement is signed. (The Air Force proved this model can be implemented with its Air Force Pitch Day, which included a standardized Phase I contract, and payment upon signing the contract.)
- Monthly payments shall be in advance for Phase I and II SBIR/STTR programs. This will
 help small companies with cash flow. (Since taxes for many small businesses went up in
 the last tax bill (from 15% to 20%, when large companies obtained huge windfalls), this
 will help keep these small businesses healthy.)
- We support pilot programs that help streamline and simplify the SBIR awarding and contracting process.

Pass Section 813 Panel legislative language from Sec. 21

- "an item or process developed under a contract or subcontract to which the SBIR regulations apply shall be treated as though developed at private expense during the protection period authorized in the SBIR regulations"
- This change clarifies that SBIR data rights protections should be the same as data rights that apply for technology developed at private expense.

Prioritize speedy security clearance for small businesses

- Many small businesses are caught in a Catch-22: they can't submit proposal without security clearance, and can't get security clearance without a contract. The absence of an available security clearance is reported by multiple companies as the reason provided by agency personnel for why Phase III was not awarded to the company that developed the technology.
- There is a severe backlog in security clearances exacerbating the problem.
- If DOD wants innovative, non-traditional businesses to contract with the government, the backlog and difficulty in getting a security clearance is a huge obstacle that needs to be overcome.



Establish Military Medical Evaluation Pilot Program (MMEPP)

- Designed to develop and evaluate new technologies for the battlefield, evacuation and treatment without regard to FDA requirements.
- Warfighter needs are frequently different than civilian medical treatments. FDA
 approvals can delay medical developments for years or decades, denying the warfighter
 the benefits of improved battlefield technology. The MMEPP will expedite development
 and evaluation of new life saving technologies for the warfighter

Other information and data

Some have questioned why small business is so protective of the SBIR Program. Why we do we oppose taking money away from the SBIR Program to fund other ideas or programs?? And why have we opposed changes to the SBIR Program that would loosen the underlying structure and other competitive aspects of the program? To understand how important SBIR is to small business one should look at the comments from the success stories attached.

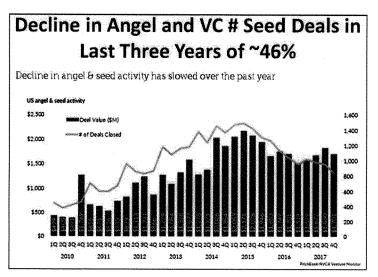
We also do this because we believe the SBIR program is greatly underfunded in comparison to the potential American small business has to help build America' future technological strength. America needs new technology and new technology businesses because **over half of the S&P 500 have disappeared over the past 15 years**, with the future trending to faster obsolescence. While other ideas and programs may have individual merit, funding them by taking money from the truly successful SBIR program to test the other approaches would reduce program R&D dollars to small businesses developing SBIR technologies, and in some cases would divert the money from small businesses altogether to other sectors of the economy. The focus on the SBIR program is on development of technologies selected for their potential to solve Federally-identified mission problems and opportunities, not on business development or commercialization. While SBIR program funding is about one-tenth the share of scientists and engineers in the small business sector (3.5% vs. 33%), and while the small technology-based businesses are doing so well in developing the new technologies and commercializing them, we do not believe the funding should be tapped for other objectives.

So why is this funding so important to small business? For many small business and entrepreneurs, the SBIR Program is the only substantive source of funds and the only hope for the America's innovators to create their new technologies to take to market. To understand the importance of SBIR to small business, one should read the quotes from the success stories companies that are attached further below. To better understand why we are so protective of the SBIR program, we want to discuss the market that small business, inventors and entrepreneurs and changes in the market have made it even more difficult for small technology companies to succeed.



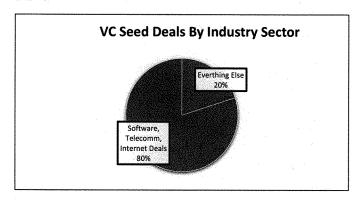
The SBIR program provides the results-based structure to ensure Federal R&D funding actually goes to small businesses to encourage technological innovation and to tap entrepreneurial energies to commercialize those technologies for the benefit of the U.S. economy. America needs the unique solutions provided by these small businesses, and it needs the "disruptive" drive of new technologies from small businesses to invigorate our economy, to maintain competition, and to provide a counter-balance to the labor rationalization that is now underway in larger businesses sending so many of our best jobs overseas.

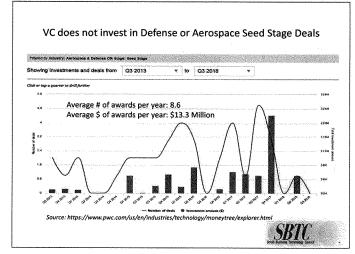
Below we present further information on the financial market facing small business, why it is making it ever more difficult for small technology companies to succeed, and on SBIR success stories.





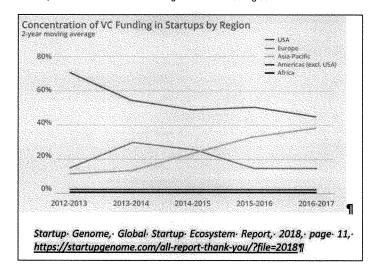
Companies that aren't in software, telecommunications, or the internet have a particularly hard time.







Most importantly, Venture Capital is moving overseas. (This is in part due the weakened patent system in the US.) A smaller VC pool, reduced by about 40% due to investments outside America, makes it even harder for small high-tech businesses to grow.



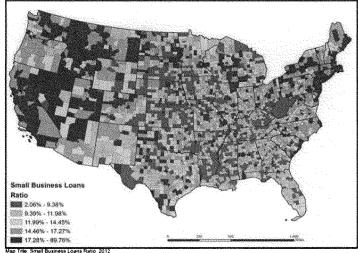


Financing Innovation is difficult

SBIR & STTR are the only Federal programs designed specifically to help small high technology firms grow and succeed. In general, VCs do not support early stage technology creation and development and banks do not lend for this purpose. But even after a technology is created, bank lending to small business is limited, and venture capital is difficult if not impossible to obtain in most areas of the country. For thousands of inventors and small businesses, SBIR is their only hope of funding their inventions, and America's best opportunity to create American jobs.

BANKING: Small business options for financing growth and commercialization of their innovations are very limited. Bank lending has declined dramatically since 2007, and is not readily available for most innovative small businesses, particularly in states in the center of the country. The amount of lending to small businesses by banks is down over \$80 Billion over the last 10 years. According to Professor Cole at Florida Atlantic University, lending to small business is 50% lower than it should be. (SBA Office of Advocacy Study.)The lending market for all small business is challenging. For innovations firms especially those without sales, getting a loan is impossible.

The below chart shows what has been referred to as the "lending desert." The Plains States, the Midwest, and the South are most severely affected.⁶

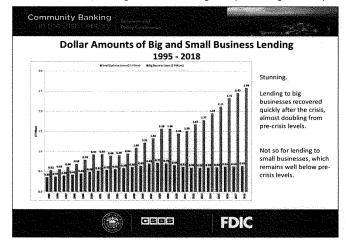


Map Title: Small Business Loans Ratio, 2012

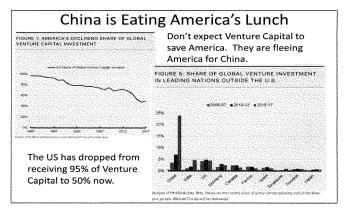
Data Source: CRA small business loan data and Dun and Bradstreet (D&B), 2010



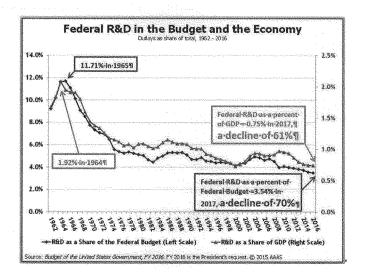
This has not improved since the Great Recession. In fact, Small Business Lending has dropped by \$20 billion since 2010, while big business loans have grown by 79% during that same period.



Funding opportunities in America decline while other countries are making funds available to their small innovative firms.



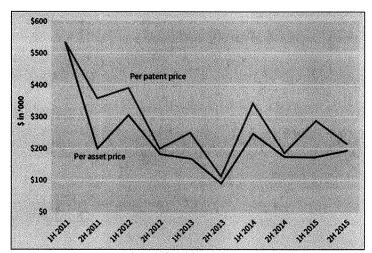






SRENGTHENING PATENTS

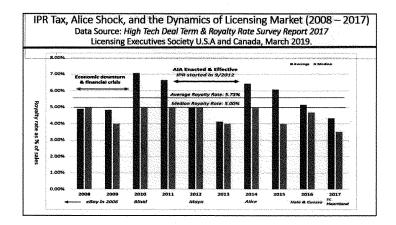
Finally, Patents need to be strengthened. Although it was obvious to SBTC's members that the America Invents Act would be extremely harmful to small business and independent inventors, the full effect of its devastation is now just being felt. The value of patents and patent assets has $\underline{\text{decreased by over }60\%}^7$ in the first few years after passage of the AIA.



The country has seen similar declines in licensing revenues to inventors. The America Invents Act (AIA) and the ensued inter Parties Review (IPR) procedure at Patent Trials and Appeals Board (PTAB) set off the overall declining trend in licensing royalty rate. The average royalty rate has dropped from pre-AIA in 2010 of about 7.1 % to about 4.3 percent in 2017, or about a 40% drop. This particularly adversely affects small business inventors as the lost royalties would traditionally provide the funds to expand a small high-tech business, and the royalty income stream is the only asset from inventions that a bank will use as collateral. Furthermore, in the last eight years, the share of private company licensors has declined substantially. Specifically, small inventing companies (i.e. non-practicing entities (NPEs)) have to a large extent been shut out of the licensing market and the resulting income, due to large companies' adoption of "efficient infringement" practices.



IPR Tax: IPR challenges escalate the risk and uncertainty in patent monetization and increase the patent enforcement costs for private patent owners, both of which depress patent valuation. Since IPR essentially does not affect governmental entities and state universities, it has an effect analogous to an extra tax levied on the private patent owners. The IPR tax discourages private patent owners' participation in licensing markets.⁹



Inventors pay tens of thousands of dollars¹⁰ out of pocket to obtain a patent and frequently wait years for it to issue. ¹¹ Inventing is also high risk, only 5% of patents are licensed or commercialized. ¹² Despite the odds against inventors, they still work to make their dream come true. If they are successful in getting a valuable patent, then they have to enforce it in today's "efficient infringement" ¹³ environment. The decreased use of injunctions encourages prolonged itigation. Before the AIA became fully effective, litigation cost \$3-5 million and took 3-5 years. ¹⁴ Now it takes even longer and is more expensive for the patent holder.

The declining power of American patents has also played a part in the declining investment by venture capital and by angels. This has caused a decline in startups, adversely impacting the economy. This has been particularly detrimental to "flyover" states like those of the central part of the nation, and even states like Florida.

Patents are critical for small business success. They are the shield that allows a company's equity shares and capital expenditures to have protection in building the markets for America's innovative new products. America has been dissipating this shield for several years



The detrimental effects of the America Invents Act (AIA) have caused a shift in economic power to China and elsewhere overseas. China is overtaking America in patenting.¹⁶ Patents protect new products and services and the equity they generate are key drivers for America's future economic strength. China's State Intellectual Property Office (SIPO) processed 34.6 percent of



all patent applications in the world. With over 920,000 total applications, China processed 160 percent more application than the United States.



Comparison of Economic Impact Statements

Source: World IP Organization, "World Intellectual Property Indicators 2017," December 4, 201

SBTC therefore hopes the Senate and the Small Business and Entrepreneurship Committee will help improve America's competitive position in innovation by voting to restore stronger patent rights. We support the STRONGER Patents Act as strong patents will help improve innovation and America's competitiveness.



Partial list of DOD SBIR success stories

3e Technologies (MD)	3
Active Signal Technologies (MD)	5
Analysis, Design & Diagnostics, Inc. (FL)	7
Agile Delta (WA)	10
Airex (NH)	13
Aligned Vision (Assembly Guidance) (MA)	16
Biofire Defense Company (UT)	18
Bluefin Robotics (MA)	21
Cascade Designs (WA)	24
Creare (Cryogenic Machining) (NH)	27
Creare (F-35) (NH)	29
CTSi (Coherent Technical Services, Inc.) (MD)	32
CyPhy Works (MA)	34
Distributed Simulation Technology Inc. (DiSTI) (FL)	37
Evisive, LLC (LA)	39
H.C. Materials Corporation (IL)	42
Insitu (WA)	45
Iowa Thin Film Technologies (PowerFilm) (IA)	48
Light Age Inc. (NJ)	51
Lightwave Electronics Corporation (CA)	53
Mainstream Engineering Corporation (FL)	55
Mechanical Solutions (NJ)	58
Microsensor Systems, Inc. (KY)	60
Monterey Technologies (UT)	63
nanoComposix, Inc. (CA)	66
Net-Bio / ANDE Corporation (MA)	68
Oceanit (HI)	70
Phase Sensitive Innovations (DE)	73
Planetary Systems Corporation (MD)	76
Quick-Med Technology (FL)	78
Sentient Science (ID)	81
Simbex (NH)	83
SIMmersion (MD)	85
Sinmat, Inc. (FL)	88
Syntonics (MD)	91
Total Quality Systems (Contingency Contracting) (UT)	95
Total Quality Systems (Electronic Testing) (UT)	98
Veeco (Emcore) (NJ)	100 101
VT MÄK (MA)	
Webb Research (MA)	
Windmill International, Inc. (NH)	107
Zivko Aeronautics, Inc. (OK)	110

 $\textit{Link to company technologies is } \underline{\textit{https://sbtc.org/wp-content/uploads/2019/05/SBIR-Success-Stories-Book-2019.pdf} \\$



ENDNOTES

As Counsel to the House Small Business Committee, I helped convene the first joint House-Senate Small Business Committee hearings on the subject in 1978. These hearings and report showed that, despite their demonstrated superior efficiencies at innovating, small companies received only 3.5% of federal R&D contract dollars. Today, with far more science and engineering talent at their disposal, and a far more widely acknowledged record of innovations, small companies still receive only 5% of those R&D contract dollars. And SBIR/STTR accounts for more than half of that. before Congress regarding small business and innovation on numerous occasions, as Deputy Chief Counsel for Advocacy at SBA during the Carter Administration, as Chief Counsel during the Clinton Administration, and as Executive Director of SBTC during the George W. Bush, Barack Obama, and Donald Trump Administrations. SBTC represents more companies that are active in the federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program than any other organization. SBTC also serves as the Technology Council of the National Small Business Association, the nation's oldest nonprofit advocacy organization for small business, which represents over 65,000 small-business members in every state and every industry. I appear here today on behalf of both organizations.

Horizon 2020 and the European Innovation Council pilot: a new dynamic for SMEs with breakthrough ideas, https://ec.europa.eu/programmes/horizon2020/en/area/smes

³ <u>lean Baptiste Su</u>, France Creates \$13 Billion Disruptive Innovation Fund, Hopes To Become The Next Startup Republic, Jan 17, 2018, 06:19pm https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17/france-creates-13-billion-disruptive-innovation-17">https://www.forbes.com/sites/jeanbaptiste/2018/01/17

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HIGH TECHNOLOGY ENTREPRENEURS AND THE PATENT SYSTEM: RESULTS OF THE 2008 BERKELEY PATENT SURVE

BERKELEY TECHNOLOGY LAW JOURNAL

Stuart J.H. Graham, Robert P. Merges, Pam Samuelson, & Ted Sichelman, http://ssrn.com/abstract=1429049 The Berkeley

study found that the average out-of-pocket cost to obtain a patient was over \$38,000 (not including invention costs).

Many of SBTC's members wait 6-8 years (and we have an example of a 12-year wait) for a US patient to be issued in arts

such as medical devices or aerospace.

¹² The Real Patent Crisis Is Stifling Innovation, Forbes, JUN 18, 2014,

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**Dynamism in Netreat: Consequences for Negions, markets, and workers, Economic immovation Group, red 2017, http://eig.org/wp-content/uploads/2017/07/Dynamism-in-Retreat-A.pdf.*

15 "And in three of the last four years, at least half of the top ten largest venture investments in the world have occurred outside the U.S." Statement of Scott Kupor Managing Partner, Andreessen Horowitz Chair-elect, National Venture Capital Association before the U.S. Senate Small Business Committee on "Searching for Capital: How Venture Capitalists and Angel Investors Fund Entrepreneurs and Startup Companies" July 14, 2016.



Quotes from SBIR success stories at DOD

- 1. This meant, Chen said, that "the 3eTI technology, funded by DOD SBIR, scaled with chips
- 2. "The SBIR/STTR programs are important to the US commercial market because they give small businesses the chance to actually put new technologies to the test," he said, noting that otherwise, potential solutions are just sitting on a piece of paper as somebody's brainchild. "Every young entrepreneurial type—we were young once—has new ideas they want to try, but might not have the opportunity without SBIR funding."
- 3. Teamed with Dr. Watkins at Woods Hole Oceanographic Institution (WHOI), Duke University Marine Laboratory, and Advanced Acoustic Concepts, Inc., and thanks in no small part to the DOD's SBIR/ STTR program, AD&D has successfully addressed the Navy's marine mammal detection need.
- 4. "The SBIR was crucial to accelerating development of the technology at a critical time when industry was looking to develop a standard for efficient data exchange," said Schneider. "If we had missed this window, industry would have likely developed a standard based on older, less efficient technologies that weren't going to meet DOD needs."
- 5. The SBIR program provided foundational financial and networking support that Sedgewick called "absolutely fundamental" to companies, no matter their size or ambitions. Having access to resources that can help develop new technologies is critical to small business, and drives increased performance for both military and commercial application. "(The SBIR program) sustained us through those couple years which were very tough on the commercial side," he said. "There's still a fundamental need for development in this country that will bridge to the next technology. The diversity provided by the SBIR, in the same way you diversify your stock portfolios, can really be helpful for a company."
- 6. Blake credits the SBIR program for giving his company a shot in the arm when it needed it most, propelling it to the successful position it's in today. "To me, it's an ideal way to drive new technologies," he said. "All new technology has risks, and if the envelope is really being pushed there will be failures. SBIR funding enables the ability to work through failures to achieve new levels of performance that benefit everyone."
- 7. Early SBIR funds awarded to Idaho Technology in 2001 enabled the group to develop the freeze-dried reagents, and additional Air Force SBIR contracts allowed the company to create the rapid PCR machine and further develop the technology for military bio-threat testing.



- 8., "This SBIR funding, as well as internal investment, helped us develop and test our new battery capability down to 6,000 meters. That spun off into a new power line that is now available to everyone.
- 9. "We utilize the SBIR program to facilitate the incorporation of novel technologies that come out of small businesses
- 10. "For multi-dimensional, complex technologies like this," said Rozzi, "SBIR funding is absolutely critical to take something from a nice science project, if you will, to a technology that can be integrated into real machines."
- 11. Toward the end of the Phase II contracts, the technology was transitioned to Creare's affiliate company, Edare, for production, sales, and subsequent technical support. Last year, Lockheed Martin placed the first order of 18 systems with the expectations that additional sales will follow. Initial SBIR funding to build the fastener measure like a cryocooler for the Hubble Space Telescope, a spin-off dedicated to micromachining, licensing of Envelop® protective coverings, and delivery of specialized equipment for aircraft carrier catapults.
- 12. The SBIR funding itself was very important, but the Air Force involvement also facilitated a process where we got connected to key stakeholders at both Lockheed and the Air Force,"
- 13. The SBIR program was a critical part of CTSi's growth, Sanders said. "The SBIR program is what allowed us to get our start, and this would have never happened without the funding and the opportunities that they provided. It's led to a lot of new opportunities and capabilities for CTSI. It's opened up doors for us with all the Services and NASA to use Independently-owned small business successfully researches, engineers, tests, manufactures, and markets gear for outdoor enthusiasts worldwide.
- 14. In order to make the idea a reality, CyPhy Works turned to the Small Business Innovation Research (SBIR) program for development funding. Greiner cited SBIR funding as being vital to the development of the engineering concepts underlying both the pocket-sized drone as well as PARC.
- 15. GL Studio and other technologies developed with SBIR support have helped DiSTI expand to an 80-employee company. "Today, we're growing in the automotive space and the embedd world,"
- 16. "SBIR is an amazing asset to U.S. small business firms...In addition to providing a path to commercialization, it allows inventors to invent!"
- 17. The SBIR-supported innovations by H.C. Materials have benefited both the military and commercial sectors



- 18. Sliwa went on to add that the company wouldn't have survived without the SBIRs. "And the technology that we delivered during that time was the foundation for growing the company,"
- 18. "The Army SBIR helped us cross the valley of death, and we came out the other side with products that we could sell to both civilian and military customers."
- 19. "Other than the funding, which helps any small company, the SBIR program helps with efficiency," said White. "We can sit here all day and try to guess what products we need to make in the future, but if the military comes out with an SBIR solicitation, it gives us that much-needed direction regarding what we need to focus on."
- 20. Like most small businesses, Light Age is undercapitalized, according to Heller, and government programs like SBIR have helped the company "support research and development" over the past three decades.
- 21. Ten or fifteen years ago, anybody who had memory chips in their computer benefitted from a Lightwave laser," said Arbore. "One of the reasons today's microelectronics work as well as they do, and are as cheap as they are, is thanks to semiconductor manufacturing technology that relies on lasers." And thanks as well to the SBIR program and the small businesses that seize their oportunity and run with it.
- 21. Virtually all of the innovation on ECUs began with Mainstream's first SBIR contracts, and he credited that early support with helping to significantly advance the technology.
- 22. MSI's SBIR contracts formed the baseline for developing and commercializing the firm's Sentry™ software, which has two versions.
- 23. The SBIR program, through its support for growing businesses and nascent technologies, provides a launch—pad for passionate innovators looking to develop their ideas. "You have some technical people who have an idea and want to commercialize it, but who know nothing about business or production—
- 24. "I believe in the SBIR program," said NAVAIR's Brian Ramsay. "If we had tried to do this through a regular acquisition process, it would have cost much more money.
- 25. Under the SBIR, the company developed more than 250 variants of nanoparticles. "The SBIR," Oldenburg said, "allowed us to reach out to the nanotechnology and nanosafety communities, and massively accelerated our ability to help out."
- 26. The SBIR program provides a tremendous benefit to our country, allowing small companies to pursue big ideas."



- 27. The SBIR program gave us the flexibility to explore more possibilities."
- 28., Dr. Sullivan credits the SBIR program with reducing the technical and market risks, making it possible for Oceanit to create this innovative technology.
- 28. "The SBIR program gave rise to the birth of our company and kept us from going out of business when times were lean. And it has allowed us to develop the technology
- 29. Along with development, the SBIR program also helped Holemans and his PSC team with the last, crucial piece needed for the Lightband's success: proving it worked in actual missions. Holemans noted that his own success can be attributed in large part to good government leadership, as shown through the SBIR process.
- 30. Liesenfeld noted that the SBIRs "helped us to really better understand what we could do with the technology and show some fantastic research results.
- 31. This small company could not have built this world-class technology without SBIR. As Bolander said, "SBIR was the genesis for the entire technology. There would be no other way for a small company to build this type of technology...we could not have done it without SBIR."
- 32. "The best use of SBIR funding is when you use those funds to drive commercialization forward rapidly and realize that the value of your company can increase dramatically following the use of an SBIR," Greenwald said. "It's not trivial money; it's real, important non-dilutive funding."
- 33. The SBIR funding provided the ability to develop more interactive simulation technology and refine it for specific scenarios, as well as to conduct research studies on the impact of the training that helped give the company's simulations greater credibility in the field. The SBIR also charted a path forward for the small company. "It taught us what products had marketability," Olsen said. "It was transitional as we were trying to spin out as a separate company without a huge organization behind us. It really helped us get moving."
- 34. Had it not been for the SBIR program, we would not have had a successful product because it not only gave us funding, but also it found us an end user who was very willing to work with us,"
- 35. The initial research and development resulted from a Small Business Innovation Research (SBIR) award through the U.S. Special Operations Command (SOCOM) and was later extended by SBIR awards from the Navy and the Joint Tactical Radio System program.
- 36. Air Force SBIR Program helps meet our warfighters' ongoing needs.



- 37. "SBIR awards have allowed the company to grow from a focus on root-cause failure analysis engineering services into the realm of software engineering and development and systems engineering and manufacturing. With support from the SBIR program, the IFDIS is saving lives, improving warfighter and aircraft readiness, and saving many millions of taxpayer dollars in the bargain.
- 38. The company was awarded several DoD SBIR contracts that were crucial in establishing the commercialization of MOCVD systems, McKee said.
- 39. "QuickStrike has been ideal for what you want out of an SBIR project," said Spaulding. "It leveraged our existing product, satisfied the needs of the ASOC and then was commercialized. And it will continue to benefit from COTS product improvements as well."



MAJOR DOD SBIR/STTR SUCCESSES

GPS/WiFi/Bluetooth Chips Physical Research/ Broadcom



GPS on a chip, and combined WiFi and Bluetooth communications used globally in cell phones and U.S. military systems, are derived from a DoD SBIR award to Dr. Reza Rofougaran.

Precision Artillery Versatron/GD

The high-accuracy, longer-range Excalibur, enabled by a DoD SBIR, is a game-changer for U.S. military engagements.



Switchblade Armed Drone AeroVironment

The Switchblade UAV delivers a precision payload of explosives, changing the very nature of warfare.



CMOS Cameras Photobit/Micron

SBIR supported Photobit in developing fast CMOS imagers for military use, now used in all cell phones and most other digital cameras.

Military UAVs Insitu/Boeing

Institu's family of military and civilian UAVs, including ScanEagle and Blackjack, started with a Navy SBIR, making major contributions to safety, security, and mission support.

Portable Satellite Communications GATR/Cubic

A highly portable, inflatable satellite terminal offers communications support for both warfighters and civilian first responders.







Corporations having acquired multiple SBIR-involved Italics=SBIR involved firms March 2019 L3 Communications Recently, L3 divesting several L3:44 16 Titan Corporation (acquired by L3) General Electric Company 15 SAIC 14 12 Agilent Technologies, Inc. BAE Systems; Lockheed Martin; Raytheon, Thermo Fisher Scientific 11 EDO Corporation; General Dynamics; Philips; Teledyne Technologies 10 JDS Uniphase; Perkin-Elmer, Inc.; Pfizer Inc.; 9 Boeing Company, invitrogen Corporation; Johnson & Johnson; Northrup Grumman (Litton); Novartis AG; 8 Becton, Dickenson & Company: Bristol-Myers Squibb; Danaher Corporation; Medtronic, 7 Inc., Sierra Nevada Corporation Allergan, Inc.; Amgen, ATK Inc.; Beckman Coulter, Inc.; Charles River Laboratories, 6 Corning, Inc.; Genzyme Corporation; ICx Technologies, Inc.; ManTech International Corp.; Qiagen NV; Roche Holdings AG; Sanofi-Aventis, SA; Ultra Electronic Holdings plc 3M, Affymetrix. Inc.; Apple Computer; CACI International Inc.; Cubist Pharmaceuticals Inc. 5 Flir Systems, Inc., Gilead Sciences, Inc., GlaxoSmithKline; II-VI, Inc., Microsoft Corporation; Siemens AG; SRA International Inc; Tyco International; Veeco Instruments; W L Gore Inc.

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Economic Impacts National Cancer Institute SBIR/STTR Program (1998-2010)

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Total Phase II Awards	069
Total SBIR/STTR Award Investment	\$787
Rate of Commercialization	53%
Cumulative Sales	\$9,144 (11.62 times SBIR investment)
Follow-on R&D	\$957 (1.22 times SBIR investment)
Total Value of Acquired Firms	\$21,630 (27.48 times SBIR investment)
Total Outside Investment Funding	\$4,260 (5.41 times SBIR investment)
Total Economic Output	\$26,100
Return on Investment	33:1

Swearingen, Will et al, "1998-2018 National Economic Impacts from the National Cancer Institute SBIR/STTR Program" (2019)

dollar amounts in millions *limited sales for acquired firms, licensees, and spinoffs

Major SBIR/STTR Successes

GPS/WiFi/Bluetooth Chips Physical Research/ Broadcom GPS on a chip, and combined WiFi and Bluetooth communications used globally in cell phones and U.S. military systems, are derived from a DoD SBIR award to Dr. Reza Rofougaran.

CMOS Cameras Photobit/Micron

SBIR supported Photobit in developing fast CMOS imagers for military use, now used in all cell phones and most other digital cameras.

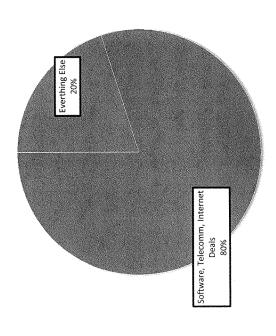
The Market loves SBIR

The Federal government benefits tremendously from SBIR ര technology. Some facts that show that SBIR makes technology. But the market also appreciates SBIR difference include:

- 10% of all VC investments go to SBIR firms
- 19% of IN-Q-Tel investments are in SBIR (*In-Q-Tel* is the strategic investor for the U.S. intelligence and defense communities)
- 829 SBIR related firms have gone public
- 1300 or 9% of SBIR firms have been acquired
- L3 Com, GE, SAIC, BAE, Lockheed Martin, Raytheon, Gen Dynamics, Philips, Teledyne have each acquired 10 or more SBIR Firms

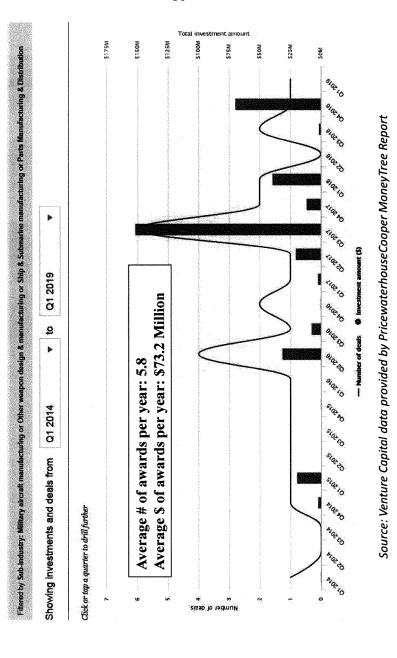
VC Deals Skewed by Industry Sector

VC Seed Deals By Industry Sector



Source: Venture Capital data provided by PricewaterhouseCooper MoneyTree Report data 2012-2016

Venture Capital Does not Invest in Defense Deals



Chairman Rubio. Thank you. Mr. Kota—Dr. Kota.

STATEMENT OF SRIDHAR KOTA, Ph.D., FOUNDER, FLEXSYS, ANN ARBOR, MI

Dr. Kota. Chairman Rubio, Ranking Member Cardin, distinguished committee members, thank you for the opportunity to appear before you today to discuss issues of critical importance to

American competitiveness, this SBIR program.

My name is Sridhar Kota. I am the founder and CEO of a small business, FlexSys, founded 18 years ago in Ann Arbor, Michigan, with an SBIR Phase II project. I am also a professor of engineering for the last 31 years. For the past 4 years, I have been serving as the founding executive director of a national think tank called MForesight: Alliance for Manufacturing Foresight, with a singular focus on driving U.S. manufacturing competitiveness.

I have been enrolled in the technology policy at the national level for the past 10 years, including a 3-year tenure at the White House

as the assistant director for Advanced Manufacturing.

The SBIR program is one of the crown jewels of our Federal investments in science, engineering, and technology. My company received multiple Phase I, II, and III contracts from the Air Force, Army, NASA, and NSF. Through a Phase II and Phase III Air Force SBIR, we developed the technology to morph the shape of an aircraft wing in flight, eliminating drag-producing flaps, and successfully demonstrated significant fuel savings and noise reduction through 3 years of rigorous flight testing conducted in collaboration with the Air Force and NASA.

The Air Force and NASA actually invested nearly \$70 million on

this project, and we received an SBIR Tibbetts Award.

We are currently working with the Air Force to retrofit military transport vehicles with our technology to yield hundreds of millions of dollars' worth of fuel savings per year on a single fleet alone.

The SBIR program is usually the first step for an informed entrepreneur to demonstrate a working prototype and attract private investment. It helps mature the technology readiness levels beyond

TRL-3 and fuels entrepreneurship and growth.

My company's technology would not have been possible without SBIR funding and sustained investment by the Air Force. Once proven through flight testing, the private sector invested nearly \$5 million, and we made important strides in other commercial applications as well.

Since the goals of this particular project are well aligned with the broader goals of the Air Force, the agency was able to provide sustained funding on a path from research to development to demonstration to deployment.

Not all SBIR projects, even within my own company, benefit from such sustained investments like the Air Force project I just out-

lined.

Although SBIR provides critical initial investment needed to demonstrate the technology to make a working prototype, the follow-on funding to scale manufacturing is usually very difficult to attract in the U.S. Making a one-off prototype is not the same as manufacturing at scale. Sustained investment is needed for process

innovations to mature manufacturing readiness and sufficiently reduce the technical and market risk.

So the vast majority of venture capital funding in the U.S. is devoted to software and biotech, with less than 4 percent invested in hardware startups. So now foreign investors at times, China more often than note, are ready to provide the capital needed for promising technologies demonstrated through SBIR programs and other programs and investing further development, but then the commercial-scale production happens overseas.

So the motivation for Federal investment in taxpayer dollars for R&D is to benefit American taxpayers by creating jobs from new products manufactured from scale in the U.S. The return on investment could be realized in different form by creating national wealth or ensuring national security, enhancing—creating better

health outcomes or energy production.

But if you look at much of the \$150 billion we spend annually on science and technology, that really goes for creating knowledge through basic research. The SBIR share of 3.2 percent is one of the few investments the Federal Government makes to transition that knowledge into national wealth or security to get the real return. So increasing the share from 2.5 to 3.2 was a positive step, and the government has a critical role to play in investing in translational R&D to leverage promising results from basic research.

This is especially true when societal benefits far exceed privatesector benefits. Market forces alone will not bridge this gap in our innovation cycle, and they have not in the last two decades. We really need a national strategy—probably, we are the only developed country without a national strategy—on how to nurture our best ideas domestically. We need to avoid giving away our best

ideas and technology to foreign competitors.

To do that, there are a number of things we could do and just a couple of things I will outline, how to bolster our SBIR program. One is the agency should target SBIR projects that are on their technology roadmap, so that there is a tangible outcome rather than a curious research project. So that is one and is sort of like the Air Force example I gave.

The other one is we need a separate set of funds, something like a DoD Rapid Innovation Fund type of funds so that the successful SBIR projects, we can invest in those to mature manufacturing readiness because, at the end of the day, it is not just a startup.

We have got to create a scale-up and create jobs here.

Finally, the Federal Government should enact strict guidelines in intellectual property generated from SBIR projects to ensure that it is scaled only in the U.S. SBIR awardees should be allowed to license the technology to any form, domestic or foreign, as long as the technology is manufactured at scale only in the U.S. This would not be a burdensome or unreasonable regulation since the taxpayers who funded the research are entitled to a return. Our taxpayer-funded R&D otherwise will continue to be an unintended subsidy for technology used and products produced in other countries.

Our challenges are broad and deep. To put it in perspective, the entire SBIR \$3.5-billion-per-year budget is approximately what we lose to China in a day. If you think about the trade deficits, IP

theft—and no one is talking about. We are willingly giving away our technology every day through our research.

So I outlined a few other suggestions in the written testimony. I want to thank you for giving me this opportunity, and I think SBIR is critical to our national competitiveness. And I hope it continues to flourish far into the future.

Thank you, sir.

[The prepared statement of Dr. Kota follows:]

Sridhar Kota
Founder & CEO, FlexSys Inc.
Herrick Professor of Engineering, University of Michigan
Executive Director – MForesight: Alliance for Manufacturing Foresight

Chairman Rubio, Ranking Member Cardin, distinguished Committee Members—thank you for the opportunity to appear before you today to discuss issues of critical importance to American economic competitiveness: the Small Business Innovative Research (SBIR) program.

My name is Sridhar Kota, and I am the Founder and CEO of a small business, FlexSys Inc. founded 18 years ago in Ann Arbor, Michigan with an SBIR Phase II project. I am also the Herrick Professor of Engineering at the University of Michigan and a professor of mechanical engineering for over 31 yrs. For the past 4 years, I have served as the founding executive director of a national consortium (think and do tank) called MForesight: The Alliance for Manufacturing Foresight, with a singular focus on technology innovation to drive U.S. manufacturing competitiveness. I have been involved in technology policy at the national level for the past 10 years including a 3-year tenure at the White House as the Assistant Director for Advanced Manufacturing.

The SBIR program is one of the crown jewels of our federal investments in Science, Engineering and Technology. The SBIR program is often the first source of funds for an informed entrepreneur to demonstrate a working prototype and attract private investment. It helps mature Technology Readiness Levels beyond TRL-3 (basic research) and fuels entrepreneurship and growth.

My company, FlexSys Inc., has received multiple SBIR Phase I, II and III contracts from the Air Force, Army, NASA, and NSF. Through a Phase II and III Air Force SBIR, we developed the technology to morph the shape of an aircraft wing in flight, eliminating drag producing flaps, and successfully demonstrated significant fuel savings and noise reduction through 3-yrs of rigorous flight testing conducted in collaboration with the Air Force and NASA. The Air Force and NASA invested nearly \$70 million on this project and we also received an SBIR Tibbetts award. We are currently working with the Air Force to retrofit military transport vehicles with our technology to yield hundreds of millions of dollars' worth of fuel savings per year on a single fleet alone.

My company's technology would not have been possible without SBIR funding and sustained investment by the Air Force. Once proven through flight testing, the private sector invested nearly \$5 million in our shape-morphing technology and we have made important strides in other commercial applications. Since the goals of this project are well aligned with the broader goals of the Air Force, the agency was able to provide sustained funding on a path from research to development to demonstration to deployment.

Not all SBIR projects, even within my company, benefit from such sustained investment like the Air Force shape-morphing wing project. Although SBIR provides critical initial investment

needed to demonstrate the technology to make a working prototype, the follow-on funding to scale manufacturing is usually very difficult to attract in the U.S. Making a one-off prototype is not the same as manufacturing at-scale. Sustained investment is needed for process innovations to mature manufacturing readiness and sufficiently reduce the technical and market risk. The vast majority of venture capital funding in the U.S is devoted to software and biotech with less than 4% invested in hardware start-ups. Foreign investors at times are ready to provide the patient capital for promising technologies demonstrated through SBIR programs and invest in further development but commercial-scale production is done overseas.

This problem—commercial-scale production offshore of technology developed here—is significant and growing, and cannot be successfully addressed by SBIR programs alone. Through decades of offshoring manufacturing the nation has eroded our ability to manufacture new advanced technology products to create national wealth from our investments in R&D. As more and more production has moved offshore, companies have found that the necessary suppliers and, more importantly, the technical know-how to develop new products and processes has migrated, too, because it is best done where the factories are. The longstanding strategy of "Invent here, manufacture there" is fast becoming "invent there, manufacture there" — a dangerous trend for a developed country. Our taxpayer-funded R&D is essentially subsidizing foreign countries that are able to create jobs and wealth from American inventions.

Thanks to federal government investments in basic research, the United States still leads the world across a broad spectrum of discoveries including drug discoveries, publications and citations. Being the best in the world in science is important—but it's not sufficient to ensure success. Investments in basic research (science) generate knowledge — scientific discoveries and engineering inventions. Innovation, both technological and business, is about transforming a promising discovery or an invention, through world-class engineering, into a new product or process that meets societal needs. Investments in translational research (engineering) generate engineering methods and manufacturing know-how that are essential to create national wealth and security. Unless we make large and sustained investments in translational R&D, we will continue to offshore innovation and manufacturing. The SBIR program is one of the few programs that invests in translational R&D but it is not sufficient to capture or retain promising technologies to yield desired returns to the nation.

Market Failures in Translational R&D

Restoring U.S. manufacturing leadership and, perhaps more importantly, restoring the nation's ability to capture wealth from the national innovation system with a robust manufacturing base, is a challenge to both the private and public sectors. With its focus on short-term profit maximization, the private sector will continue to offshore manufacturing and R&D if it yields immediate private benefits – and it does. But in manufacturing, societal benefits in the form of national wealth, jobs, and national security far exceed private benefits and, therefore, government has a critical role to play. For instance, the manufacturing sector offers a wide range of job opportunities from blue-collar production workers and supervisors to white collar R&D, design and manufacturing engineers, accountants, business managers, etc. In 2017, the

average U.S. manufacturing worker earned \$84,832 in pay and benefits, 27% more than the average worker in non-farm industries.

The United States is the only developed country without a strategy on how to leverage investments in basic research and the resulting scientific discoveries and engineering inventions to create jobs, wealth and national security. According to OECD 2016 data, of the U.S. federal R&D budget of \$149 billion, only 0.052% (\$773 million) was spent on "Industrial Production and Technology", whereas Germany spent \$4.34 billion. That is six times the amount the U.S spends on translational R&D (Industrial Production and Technology); Japan and S. Korea spend three times and eight times more respectively.

Japan, Germany, and S. Korea have maintained trade surpluses in advanced manufacturing, are well ahead of the United States in their use of industrial robots, and have a greater share of high-technology production in their manufacturing sectors. These countries are not low-wage countries (wages in Germany are 40% higher than the U.S) and their energy costs and pollution abatement costs are higher. Yet, they are competing successfully in global markets. In 2017, the U.S had a \$796 billion trade deficit in goods, whereas Germany, Japan and S, Korea had trade surpluses of \$290 billion, \$25 billion and \$85 billion respectively.

America's private sector, driven by quarterly profit reporting and other short-term considerations, has little appetite for long-term investments in translational R&D needed to mature nascent but promising ideas resulting from taxpayer-funded basic research. Large companies, once reliable sources of corporate R&D to mature new products and processes in this country, no longer have large research budgets and increasingly do their new product development where their factories are—offshore. Most U.S. headquartered original equipment manufacturers (OEMs) derive well over 50% of their revenue from foreign sales – Apple (65%), HP (61.5%), GE (55%), IBM (53%), Caterpillar (54%). These companies employ more than half of their total work force outside the U.S. (J&J -73%, P&G - 73%) and have more than half of their corporate assets outside the U.S. Their corporate interests simply do not align with U.S. national interests to generate wealth and national security from taxpayer-funded R&D.

Start-ups and small and medium-sized manufacturers (SMMs) are the backbone of our manufacturing sector comprising nearly 98% of all manufacturing firms. These firms are often innovative but lack resources to invest in R&D. Unlike multi-national OEMs, these companies prefer to stay in this country. The Small Business Administration already plays a critical role to support these SMMs through SBIR and other programs to strengthen our manufacturing sector.

SBIR and National Innovation

The motivation for federal investment of taxpayer dollars in R&D is to benefit American taxpayers by creating jobs from new products manufactured and scaled in the United States. The return on investment could be realized in different forms – creation of national wealth, ensuring national security by giving our military a technological edge, enhancing health outcomes, or leading the world in energy production. Much of the approximately \$150 billion

spent annually on science and technology (S&T) creates knowledge through much needed basic research. The SBIR share of 3.2% is one of the few investments the federal government makes to transition that knowledge into national wealth and/or security. Increasing the SBIR share from the initial 2.5% to 3.2% was a positive step in bridging the gap between creating knowledge and obtaining a return on investment.

We need a national strategy on how to nurture our best ideas domestically. The federal government has a critical role to play by investing in translational R&D to leverage promising results from basic research. This is especially true when societal benefits far exceed private sector benefits. Market forces alone will not bridge this gap in our innovation cycle.

To avoid giving away our best ideas and technologies to foreign competitors, we must bolster the SBIR program in three ways:

- Agencies should target SBIR projects that are on their technology road-map with an eye
 towards tangible outcomes rather than a curiosity-driven research project. This ensures
 that if and when the Phase II project is successfully carried out, the agency will be
 motivated to take it to the next step rather than leaving the small business to find
 investors on its own.
- A separate set of funds, DoD's Rapid Innovation Fund for example, should be identified for successful SBIR projects to mature manufacturing readiness and to further de-risk the technology.
- 3. The federal government should enact strict guidelines on intellectual property (IP) generated from SBIR projects to ensure that it is scaled only in the U.S. SBIR awardees should be allowed to license the technology to any firm, domestic or foreign, as long as the technology is manufactured at scale only in the U.S. This would not be a burdensome or unreasonable regulation since the taxpayers who funded the research are entitled to a return. Otherwise our taxpayer-funded R&D will continue to be an unintended subsidy for technology used and products produced in other countries. Currently, the SBIR program does an outstanding job in protecting the small business IP from large companies. But once the SBIR project is completed that protection disappears.

Finally, I would like to suggest a few minor changes to the program to make it even more effective.

- SBIR contracts should allow patent expenses. Otherwise, it is very difficult for a starting entrepreneurial business to protect its IP.
- Agencies should be granted flexibility to increase the size of the Phase I, II or III awards if the subject technology development merits the increase.
- 3. The Company Commercialization report instituted by the SBIR program as a score card is an important instrument to assess how effectively a small business contractor is leveraging SBIR funds to attract private investment. Consider establishing a similar score

- card for the agencies to assess how effectively they are utilizing taxpayer dollars in shepherding promising technologies to scale domestically.
- 4. The contracting process for some agencies is very arduous and expensive. We need standardized "SBIR 1040EZ" forms and procedures across all participating agencies.
- To help ensure long-term return on investment, small manufacturing recipients of SBIR funding should have preferred access to other SBA loans and investment funds. This would help to provide the patient capital needed to scale production in the U.S.
- 6. Phase II and Phase III contracts should have some flexibility to allow for mutually-agreed upon meaningful and effective changes to the Statement of Work after the contract is issued.
- 7. Mission-oriented agencies solicit proposals on topics specific to their mission. NSF, on the other hand, solicits proposals on any topic within a broader category of energy, health care, advanced materials etc. Such broader solicitations accommodate a wide range of discoveries and inventions resulting from nearly \$150 billion invested annually in S&T. Additional funding for such SBIR solicitations could offer a pathway from research to ROI.
- 8. SBIR projects are usually managed by a technical program manager in most, if not all, mission-oriented agencies. However, NSF employed several experts with entrepreneurial and engineering expertise to guide its SBIR awardees on effective paths to reduce technical and market risk and to promote entrepreneurship. Other agencies could follow NSF's lead by employing a cadre of such experts to guide the awardees towards successful outcomes.

In conclusion, based on over two decades of my personal experience, I strongly believe that the SBIR program is critical to our national competitiveness and hope it continues to flourish far into the future.

Thank you for giving me this opportunity to share my thoughts.

Chairman Rubio. Thank you. Dr. Hoffman.

STATEMENT OF STEPHEN L. HOFFMAN, MD, FOUNDER, SANARIA, INC., ROCKVILLE, MD

Dr. HOFFMAN. Chairman Rubio, Ranking Member Cardin, members of the committee, thank you for the opportunity to discuss the importance of the SBIR and STTR programs in supporting scientific excellence and technological innovation in the United States.

My company, Sanaria, Inc., was founded in 2003 to commercialize the first FDA-licensed vaccine to prevent malaria, a disease

of unfathomable impact worldwide.

The company started at my kitchen table with an idea and a vision and then transitioned, thanks to a Phase I SBIR grant from NIH, to a team of three personnel, including me, moving into an 800-square-foot facility described in a National Geographic article on malaria, as-I quote-"a dismal mini-mall in Rockville, Maryland."

We were told at the outset by more than 95 percent of our colleagues that it would be impossible to develop the technology to manufacture the vaccine we envisioned in compliance with FDA

regulations. We have proven them wrong.

Thanks to continuous innovation, in large part supported by SBIR grants, our 80 personnel work today at a unique, state-of-theart facility, where we manufacture our malaria products in compliance with FDA regulations, products that have been assessed in clinical trials in seven African and five European countries and at five clinical sites in the United States.

We are now initiating production of what is called Phase III and commercialization-compliant vaccine that will be assessed in clinical trials in the U.S., Africa, Indonesia, and Europe in the next

These clinical trials are intended to provide data to support a Biologics License Application to the FDA by late 2021 and commer-

cialization in 2022.

My company would not be here today without the support of the SBIR program. SBIR grants are peer-reviewed and awarded to those with the most cutting-edge science and innovation. Because of the credibility of the SBIR program throughout the R&D world, for every single dollar my company has been awarded by the SBIR program, we have been able to raise an additional \$3.50 from other sources. This leveraging of SBIR funds has facilitated our raising approximately \$300 million in direct and indirect funding to support our R&D, manufacturing, and clinical trials.

In addition to the funds received from the SBIR program, funds have come from multiple sources. Three U.S. oil and gas companies and the country of Equatorial Guinea have committed approximately \$85 million to the effort. The Bill and Melinda Gates Foundation and the U.S. DoD have committed approximately \$40 million each to our program. Additional funds have come from governments or foundations in Tanzania, the Netherlands, Germany, and

Switzerland.

The U.S. Government is the largest contributor to the \$4 billion annual international investment in malaria control. The only way to halt this output of funds from our country to fight malaria is to eliminate the disease, and only vaccines have eliminated human infectious diseases.

Because of the SBIR program, we are moving toward the first FDA licensure of a malaria vaccine, a vaccine to be used for elimination. We only manufacture the vaccine in the United States, and because of the technical and scientific expertise and infrastructure we have developed and will need, we are already planning to build the next manufacturing facility in the U.S. to produce approximately 20 times more vaccine than our current facility and create hundreds of new jobs.

The SBIR program is the envy of biotech and biopharmaceutical companies in Europe and other parts of the world. It provides funds that would not ordinarily be there for innovators to launch the R&D needed to get their programs off the ground. Its excellence is maintained because it is a peer-reviewed, merit-based program that rewards scientific and technical excellence and innovation and does not just spread funds to noncompetitive companies as a form of corporate welfare.

In closing, I want to thank the committee for the continued support and renewal of the SBIR/STTR program and encourage you to make it permanent so companies like mine and fellow innovators have the confidence, assurance, and support to keep the United States at the absolute cutting edge of innovation and disease prevention in the world.

Thank you.

[The prepared statement of Dr. Hoffman follows:]

SANARIA

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Testimony of: Stephen L. Hoffman, MD – Chief Executive & Scientific Officer – Sanaria Inc. United States Senate – Committee on Small Business and Entrepreneurship - May 15, 2019

Chairman Rubio, Ranking Member Cardin, members of the Committee, thank you for the opportunity to discuss the importance of the SBIR and STTR Programs in supporting scientific excellence and technological innovation in the United States.

My company, Sanaria Inc., was founded in 2003 to commercialize the first FDA-licensed vaccine to prevent malaria, a disease of unfathomable impact for the U.S., especially our military, and worldwide. The company started at my kitchen table with an idea and a vision, and then transitioned thanks to a Phase I SBIR grant from NIH to a team of three personnel, including me, moving into an 800 square foot facility described in a *National Geographic* article on malaria, as "a dismal strip mall in Rockville, MD." We were told at the outset by more than 95% of our colleagues that it would be impossible to develop the technology to manufacture the vaccine we envisioned in compliance with FDA regulations. We have proven them all wrong.

Thanks to continuous innovation, in large part supported by SBIR grants, our 80 personnel work today at a unique, state of the art facility, where we manufacture our malaria products in compliance with FDA regulations, products that have been assessed in clinical trials in 7 African and 5 European countries, and at 5 clinical sites in the United States. We are now initiating production of what is called Phase 3 and commercialization compliant vaccine that will be assessed in clinical trials in the United States, Africa, Indonesia, and Europe in the next year. These clinical trials are intended to provide data to support a Biologics License Application to the FDA by late 2021 and commercialization in 2022.

My company would not be here today without the initial and continuing support of the SBIR program. SBIR grants are peer-reviewed and awarded to those with the most cutting-edge science and innovation. Because of the credibility of the SBIR program throughout the research and development world, for every dollar my company has been awarded by the SBIR program, we have been able to raise an additional \$3.50 from other sources. This leveraging of SBIR funds has facilitated our raising approximately \$300M in direct and indirect funding. The indirect funding has been primarily to support clinical trials worldwide.

In addition to the funds received from the SBIR program, funds have come from multiple sources. Three U.S. oil and gas companies and the country of Equatorial Guinea have committed approximately \$85M to the effort. The Bill and Melinda Gates Foundation and the US Department of Defense, through the Army and Navy, have committed approximately \$40M each to our program. Additional funds have come from governments or foundations in Tanzania, the Netherlands, Germany, and Switzerland.

Malaria is a complex and extremely difficult disease to combat. From 2015 to 2017, despite an annual international investment of greater than \$4 billion, the 200 million cases and 500,000 deaths caused by malaria annually have not decreased. The U.S. is the largest contributor to

this international effort. The only way to halt this output of funds from our country to fight malaria is to eliminate the disease, and only vaccines have eliminated human infectious diseases. Because of the SBIR program, we are moving toward the first FDA licensure of a malaria vaccine, a vaccine to be used for elimination. We only manufacture the vaccine in the U.S., and because of the technical and scientific expertise and infrastructure we have developed and will need, we are already planning to build the next manufacturing facility in the U.S. to produce approximately 20 times more vaccine than our current facility. This facility and the additional facilities we will need will support the U.S. economy and jobs creation.

The average cost to develop and license a new vaccine or drug is \$2 to \$3 billion. Thanks to the innovativeness required by the SBIR program and our funders, and the lack of investment by the traditional equity and pharmaceutical industry sources of capital, we have had to be extremely efficient, and we expect to get over the finish line of FDA licensure at about 20% of this cost (\$500 million). Once we do so and have an FDA-licensed vaccine, we are confident that the investment potential will dramatically increase.

The SBIR program is internationally unique and the envy of biotech and biopharmaceutical companies in Europe and other parts of the world. It provides funds that would ordinarily not be there for innovators to launch the R&D needed to get their programs off the ground. Its excellence is maintained, because it is a peer-reviewed, merit-based program that rewards scientific and technical excellence and innovation, and does not just spread funds to non-competitive companies as a form of corporate welfare. Once the SBIR program is renewed, or better yet made permanent, I recommend that you continue to provide the authority for individual agencies to have the flexibility of funding at different levels, including jumbo awards, and to eliminate any loopholes that allow companies that are not truly small businesses to participate in the program.

In closing, I want to thank this Committee for the continued support and renewal of the SBIR/STTR program, and encourage you to make it permanent so that companies like mine, and fellow innovators, have the confidence, assurance, and support to keep the United States at the absolute cutting edge of innovation in the world.

Chairman Rubio. Thank you.

I am going to turn it over first to Senator Coons who has to be somewhere.

Senator COONS. Thank you very much, Mr. Chairman and Ranking Member.

Dr. Hoffman, Dr. Kota, those are remarkable stories, reminders

of the power and significance of STTR and SBIR programs.

I just have one question. I would be interested in hearing from you, from any member of the panel. What is the significance of a strong and robust patent system? We have talked about how significant it is to have SBIR investment, how significant it is that we continue to invest in robust Federal research. My concern is that, as two of you described in passing, there are ways in which our Federal patent system has been restructured, even weakened in recent decades. It is, in my view, equally important to have investment in research funding and the ability to show "I have invested something, and I can defend it. I am going to be able to scale it, commercialize it, sell it."

Am I wrong? Are patents largely irrelevant, or is the weakening of our patent system not of significance in this exact field?

Mr. GLOVER. On behalf of my membership, that is a critical—the weakening of the patent system has made it really challenging.

What I wanted to point out was how little money there is to take technology. If you do not have a clear patent, you cannot get money, you cannot take it, no matter what you do. And the reexamination, opening things up has weakened the ability to get money to develop.

Senator COONS. Post-grant review has ultimately weakened our patent system and not being constructive.

Dr. Höffman.

Dr. Hoffman. Yes.

Mr. GLOVER. But publishing the application which started 20 years is the beginning of the decline of how important our growth of—

Senator Coons. All I am trying to do is to prevent further weakening, which is currently being discussed in Judiciary, actively.

Dr. Hoffman.

Dr. HOFFMAN. I agree with the previous speaker that the publication of the information puts all your technology right out there for China.

We have to have a strong patent system so that when we produce and sell in the United States and Europe, at least we can sell at a high margin.

Senator Coons. Right.

Dr. HOFFMAN. But if we are beaten by people who take it right from the bat and sell to other parts of the world where there are 3 billion people at risk for malaria, for example, we are going to lose in the end.

There was one other aspect that I think in the SBIR program that I heard earlier that I was happy to hear is the issue of how long you can retain your IP without patenting it.

For example, we keep knowhow and trade secrets, and in the past, we have had to, based on the program, it has been my understanding, either patent it or divulge it. And if we divulge unique features of our manufacturing that we intend to do here, others can take it.

Senator Coons. Thank you all.

Forgive me. I have another appointment.

Dr. Hoffman, very interesting. I am the co-chair of the Malaria Prevention Caucus. I would love to hear more.

You should be very proud. You have got a remarkable innovator in your State.

Thank you for your patience, Mr. Chairman.

Thank you for what all of you do for a very important program. Chairman Rubio. Thank you.

Ranking Member.

Senator CARDIN. I also thank all of our panelists. There is, I think, agreement here that the amount of funds that we appropriate for research in this country is inadequate, and the government is a major player in research. Those funds on a relative basis have gotten weaker over time rather than stronger.

I know in the last couple budget cycles, there has been a concerted effort by Democrats and Republicans to increase the research budget. So I hope that trend will continue, but we are play-

ing catch-up now, and that is unfortunate.

There was a pretty contentious authorization that got the percentage scaled up to 3.2 to small business from the SBIR program. The testimony here makes a very strong case that that number needs to be reevaluated, and that the amount of research dollars going to smaller companies needs to be increased. So that we should at least take a look at whether the percentages need to be adjusted.

If I am correct, I think that was also part of the recommendation of the 809 Panel that Mr. Glover referred to that was created under the National Defense Authorization Act to take a look at how DoD could have better acquisition policies. Part of that was with small business.

So is there general agreement that we should be taking a look at the statutory set-asides for small business in these programs?

Dr. Hoffman. Yes.

Senator CARDIN. The second thing I—

Mr. EZELL. One thing Congress could possibly consider would be to index the level of SBIR awards at the Phase I and Phase II level to inflation so that they can keep pace for the automatic—so that we can look at raising the levels to keep pace with inflation and giving those automatic adjustments every 5 years.

Senator CARDIN. You are talking about the size of the grant?

Mr. EZELL. I am talking about the size of it.

Senator CARDIN. There was also some conversation that we should be looking at Phase III funding, which we do not today under the SBIR program. I think the previous panel had also mentioned those issues.

Let me mention one other area, and that is I came back and asked the question to our government panel about the administrative funds. Mr. Glover, you mentioned, I think, 30 percent you would like to see go for outreach, and I think the 809 Panel suggested 20 percent for training contract officers. Are the agencies doing an adequate job today?

Mr. GLOVER. No, sir. The agency officials do not even know what a Phase III—every time somebody wins a Phase III, they have to educate that contracting officer about it, what it is, and goes through that. So 30 percent of the money goes to streamlining, expediting the process, and educating the people who make the decisions. Put the money to directly save time on the process, and make sure the money gets through.

Senator CARDIN. So you would like to see 30 percent of the administrative funds go toward educating the contracting officers? Is

that what you-

Mr. GLOVER. PEOs, contracting officers, and streamlining the process. There is no reason we do not have a contract. When you win a Phase I, you get the award. They send you the contract right then. Air Force did it. They can do it for Phase I, Phase II, and Phase III. Just somebody needs to stay on DoD and the agencies and just make that happen.

Senator CARDIN. I do not know if we have exact dollars today on how the administrative funds are being spent. One of the things I would like to see is have better information from the agencies on how they are using the set-aside dollars. I think that would be helpful for our committee, and I will ask our staff to try to get that.

But I take it, at least it is your assessment, that they are not making that type of investment today from the administrative side?

Mr. GLOVER. They are not, and our people, every time somebody wins a contract, they have great technology. They have to go educating the contracting officer and the PEO that Phase III exists and that they can give them an award. And that takes a huge delay.

Senator CARDIN. Of the agencies, are you familiar with all 11 as to some who perhaps are doing a better job than others that might be a model for us to look it?

Dr. Kota. If I can speak to that. Yes. First of all, there are different ways. One is on the contracting side. I think what we really need is a simple, like a 1040-EZ type of thing for SBIR grants. It

looks like Air Force, I just heard that they have one page. There is no reason why all of the agencies are not adapting that

method. Just as an example, for example, NSF, there are a lot of good things they do at NSF on the SBIR program. I can talk about that later, but when it comes to contracting, it is very arduous. My operating officer tells me that it takes \$50,000 of our money, of our effort, to get \$150,000 contract at NSF. It is very painful, their contracting processes.

Senator Cardin. You are saying you spend one-third of the grant money on the

Dr. Kota. Yes, yes. I can—just to get the contract from NSF. But there are other things that NSF does on the other hand that is also—we need to have a system where you are running best practices from all different agencies. NSF has a very good program in terms of not—usually, you have the program managers for your contract or your technical folks, which is a good thing, but NSF not only has folks who are very well versed technically, but also their entrepreneurial mindset, they actually guide the awardees through the various tasks of what it takes to build a business, which I have

not seen in any other agencies we work with. So there is a great program at NSF that I wish other agencies would follow, follow their lead.

So, again, there are good and bad in different agencies, treated differently. Some agencies have taken on these projects that are actually on their technology roadmap, so they can—if it is successful, they can nurture it, continue to invest, and then grow, where some other agencies and some other programs, they just treat it as tax and just do a curious research project. And that is not going to do any good for anybody, including the company that works on them. It wastes more of our time. Then it is more than \$150,000 we are wasting.

Senator CARDIN. I would just encourage us to do exactly what you said. Let us take a look at what is working well and try to do that with other agencies. We have done that on some of the procurement issues generally on meeting not only the letter of the set-aside for small business, but the spirit of it. And some agencies have been much better than others. We have tried to encourage the SBA to use best practices to elevate the compliance of more agencies.

I think we can do the same thing here with the 11 agencies that are under this program, learn from those that have done the right type of outreach, the right type of education of their contract officers, and try to share that information and hold the other agencies accountable to improve.

Thank you, Mr. Chairman. Chairman Rubio. Thank you.

I will just go down here with a question for each.

Mr. Ezell, your testimony outlines the impact of the SBIR and STTR programs as a source of early stage capital for technology; in addition, you mentioned how States have instituted their own programs to further leverage this. What kind of further investment should Congress consider making in the SBIR and STTR programs?

Mr. EZELL. Well, as I outlined in my testimony, I certainly think Congress should be thoughtful about how we can increase the overall level of funding that is getting down to SBIR so we can launch more businesses.

I do think the most fundamental way to grow the SBIR program is to increase the overall level of Federal funding. The United States now has slipped to eighth among OECD countries in our level of national R&D intensity. We have fallen five places in the last 7 years. So this overall lagging Federal investment is affecting every facet of America's research and technology, commercialization enterprise, and I think that is the first place we should address the problem.

Chairman Rubio. I am glad you mentioned that because obviously the capacity is there. The need, it would be filled. Moreover, you mentioned that because it dovetails right into the report that I released today, which is about the decline in investment in both the public and private sector. In the report, we are not as focused on the public-sector part, but we should be because it goes part and parcel with this.

We have had this dramatic shift in our country over the last 30 or 40 years where even in the private side, this drive to maximize short-term returns to investors has come at the direct expense of innovation and development for the future. In a country such as ours with a free economy so reliant on the private sector to drive innovation, any decline, not to mention one as significant as this, and long-term investment in innovation is going to have not just an impact on those particular firms, but all the way down the

chain of providers.

So one of the sources where you do see innovation still is in those industries that have a big customer called the United States of America, primarily the Department of Defense, but also the space industry and alike. So I think for us, the ability to remain competitive is dependent on our willingness to think long-term in the decisions that we make. This includes the government because ultimately we have, I think, reached a point of complacency in some policy circles in this country where we think the stuff will just happen on its own through the magic of creative people out there that are working on this. However, you still need the startup funds to be able to work on the ideas, not to mention be able to commercialize them.

Mr. Ezell. By the way, I am glad you issued that report today. Recently, the Business Roundtable did a study of U.S. Fortune 500 CEOs, and they found that 82 percent of them would cut their R&D in order to meet quarterly Wall Street earnings targets. So I think encouraging more of this longer-term view in investment is absolutely vital.

And there are challenges that American companies have to increase their investments in workforce training by 30 percent over the past decade. So looking at mechanisms like a consolidated R&D tax credit, that includes not just investments in R&D, but also in new capital equipment, and workforce training could be a path that Congress could consider to tackle this long-term investment problem in the United States.

Chairman Rubio. Absolutely. I think that requires us to reorient our priorities in public policy to understand how critical investment is for the future. It is not just going to happen on its own writ large, and some of these technologies are not just critical to eco-

nomic growth. They are critical to our national interests.

Our global leadership and the current technologies of today are critical to our long-term stability and standing in the world. Just think for a moment, had the U.S. not involved itself heavily in the semiconductor industry when it first started, where would we be right now? So many of the other products that have driven the economy would certainly not be headquartered here, not to mention innovated here. Therefore, I appreciate that mention because it is important, and it dovetails to why our public program should also reflect that.

Mr. Glover, you mentioned several times the challenge that China presents to our innovators. Obviously, it is not well documented, the challenges to intellectual property and venture funding, although it strikes me if we do not start investing, they will not be interested in stealing our intellectual property in the future because it will not be ours to steal. It is important.

Program participants in all of this, their milestone in the commercialization happens when they receive a patent. How could we utilize the program?

I think you touched upon this a moment ago, but how could you utilize the program to help navigate awardees through the patent

process so that they ultimately get credit for their ideas?

Mr. GLOVER. Well, the first thing is the SBIR data rights that exist and would strengthen the policy directive are extremely important, and to our members, they often use those data rights to make trade secrets and keep their technology because once they file their patent, their information becomes public. And they find other countries copying it very quickly.

Some way to keep the patent information application for SBIR

firms not public would be helpful.

I think there is some incentive for those people who choose to patent like maybe \$10,000 up front when they file the patent and \$10,000 when they get the patent, some kind of a bonus that would

go to the process.

But I think one thing you have to consider, given your focus on investment, the capital gains law has not really helped very—in anything at all. If you invest in—dividends are taxed at the same rate as capital gains, and if you want to encourage investment in high technology and risk, you need to reward them with the tax system. And that has not happened since late in the Clinton Administration.

They put a capital gains tax in, and then a few years later, the ultimate minimum tax, and the lowering investment tax rates made there no advantage to—nobody invest in small business because of the low tax rate, nobody. So you need to throw that into

your question on investment. Would that be incentive?

But the patents, unless they are strengthened, the delay, the reexamination, the uncertainty of whether you have got a patent that will survive and hold up keeps people from investing in a technology for years, and quite frankly, technology happened so quickly, that year's delay minimizes the value of the technology when it finally gets through the patent process.

Chairman Rubio. Dr. Kota, you started your small business, FlexSys, Inc., 18 years ago with a Phase II award. Do you think small business owners and entrepreneurs would be able to find more success if they were able to put initial award funds toward other expenses outside of research and development, such as, pat-

ent and marketing expenses?

Dr. Kota. Absolutely. I think it is very critical for somebody starting out. The SBIR, that is usually the first step, and it is important that SBIR contracts allow patent expenses. They do not now.

Last year alone, we spent close to \$140,000 in patent expenses. We can afford to do that now, but starting out, that \$10,000 patent expense is a lot of money.

So I think SBIR contract should allow the patent expenses. That

is one thing.

And just one more comment I want to make about the patents is that, one thing, we should certainly strengthen our patent system, but also we should worry about there are other countries that

do not necessarily respect any patents. It does not whether you have them or not. Let us keep that in mind.

Also, the business generally should know what aspects you should patent and what trade secrets you should keep. You do not always tell everything out there because that is where you get the learning by doing, and we are losing a lot of that because only when you produce something at scale, the real innovations come about in process innovations. Those are your trade secrets.

Once you do not—if you do not have that manufacturing knowhow, if you do not have the process knowhow, you can have a startup, you are not scaling up, you are not creating national wealth, you are not creating jobs. So that is the fundamental thing we

should keep in mind.

Also, when we talk about investing, it is not how much we invest. It is what we invest in. We have been investing \$150 billion annually on science and technology. At the end of the year, you have close to \$900 billion trade deficit or \$100 billion deficit in advanced technology products. We have been doing this for 10, 20 years now, year after year. Somehow you are not doing the same thing. You are not getting a different result because we are not investing enough in translational research.

Thanks to the Federal Government for investing in basic research. We are still the best in the world when it comes to science, and we hope it continues to be that way. But that alone is not enough to create jobs because you need to convert technology into something, into a product, into a process at scale that society needs, and that requires what is called engineering and manufacturing. And this is where we are losing because what used to bewe have lived in this world of invent here, manufacture there for 20 years, and now it has become invent there, manufacture there. That is actually a dangerous trend.

So just broadly about patenting and IP, I think there is a real intellectual property is about the engineering skills and the manufacturing knowhow that is being-

Chairman RUBIO. To turn an idea into a tangible deliverable.

Dr. Kota. Yes.

Chairman Rubio. Yeah. Dr. Hoffman, in your testimony, you discussed the development of the malaria vaccine and the clinical trials that your vaccine has undergone to be FDA-compliant and SBIR/STTR provides support to innovative businesses, often industries that by nature of the research, the development, all the steps you have to go through require, take much longer to commercialize. It is a little bit different from something that you do not put into your body as an example.

So I was curious if you could speak just a little bit into the value that these programs provide and those industries that are research intensive and that take time to market because of the additional

steps you have to go through before you can do so.

Dr. HOFFMAN. Sure. Thank you for that very perceptive question,

Let me digress a bit to give you an example of just how that works. Many of us will remember that in 2013 to 2015 in West Africa, there was an Ebola epidemic that created hysteria in the world. Billions of dollars were invested in the control of that epi-

demic that caused, during the 2 years of it, 11,000 deaths.

Last week, there were 11,000 deaths from malaria. Many U.S. pharmaceutical companies—Merck, J&J-venture capitalists, private equity banks have invested hundreds of millions of dollars in developing a vaccine for Ebola. One of the reasons why they are doing that is Ebola is caused by a virus. We have vaccines against viruses, smallpox, polio, measles, but there is no vaccine against a human parasitic infection of which malaria is the prototype, and they are afraid of it. They do not have the wherewithal, the stamina to try to go to do something that has never been done before.

So without the SBIR program, we would never have gotten to where we are. It takes an average of 18 years to develop any new vaccine or drug at an average cost of \$2.5 billion. We are going to be on target for 18 years at 20 percent of the cost, about \$500 million.

And there is just one past point I would like to make where I respectfully disagree with one of my colleagues at the other end, and that is that SBIR should be all about science, innovative science and technology, the most cutting-edge work we can do.

We get most of our SBIRs from NIH. We have to go through peer review. Limiting the number of SBIRs that a company can get just because they are good seems to me to be cutting off your nose to spite your face. So there is no reason. It should all be driven by how good it is, how innovative it is, how excellent it is.

Thank you.

Chairman Rubio. Final questions?

Senator CARDIN. Well, I just really want to thank all of our wit-

Dr. Hoffman, thank you for not being discouraged by conventional wisdom that you would never get the FDA to approve your trials because you were in a different field than people were used

And thank you for drawing the timeline on these issues. Americans are impetuous by nature, and they like to see things done quickly. We are not going to get a vaccine for malaria quickly, but the benefits are going to be incredible to mankind.

So I think it is important as we look at evaluations on whether a program is working or not, we have to recognize it is a difference between a small company using innovation to change health care globally that is going to take a long time than someone dealing with a type of product that does not require that type of review and trials, et cetera.

So I think it is important that we understand the differences in evaluations as we look at the success of our innovative programs under the SBA, and I think your testimonies today have helped us understand that.

Dr. Kota, I also want to thank you for your explanations and

what you have gone through.

I think all of you have pointed out that we need to streamline our process. We saw just the huge delays. There is no excuse for a small company to have to put up with that type of bureaucratic nightmare. We are all familiar with how the Pentagon operates can be pretty bureaucratic, and DoD and health are the two largest

areas for these programs.

We have got to cut through that bureaucracy, and I hope that as we look at reauthorization, we can figure out ways to make it easier for you. Spending one-third on the cost of an application is ridiculous. I mean, that is ridiculous. We have got to change that, and I am hoping that the recommendations that come out of the DoD efforts will be able to be used throughout all agencies to get to a much simpler process with small businesses to be able to get your funds particularly under the two programs that we have talked about today.

So your testimonies, all of you, have been very helpful. I appre-

ciate it very much.

I thank you, Mr. Chairman. Chairman Rubio. Thank you.

I want to thank all of you for being here today. I appreciate your willingness, your time and sharing your expertise to assist us and framing these issues to inform the reauthorization of SBIR and STTR.

The hearing record will stay open for 2 weeks. Any statements or questions for the record should be submitted by Wednesday, May 29th, at 5:00 p.m., and with that, the hearing is adjourned. Thank you again.

[Whereupon, at 4:21 p.m., the Committee was adjourned.]

APPENDIX MATERIAL SUBMITTED

Senate Committee on Small Business and Entrepreneurship Hearing May 15, 2019 Follow-Up Questions for the Record

Questions for Mr. John Williams

Questions from:

Chairman Rubio

Administrative Funding Pilot and Other Pilot Programs

In 2011, Congress attempted to help ease the burden associated with administering the programs by enacting an Administrative Funding Pilot Program. Under its parameters, agencies can use up to three percent of their SBIR set-aside budget to do things like conduct outreach, shorten award review timelines, improve data collection, and reduce waste, fraud, and abuse. The Committee has heard positive feedback from agencies about the ways in which this pilot program has allowed them to support the programs, and even develop innovative ways to improve processes and innovate. One example of innovation is the Air Force's efforts in the last year to shorten contracts and make awards much faster, some as short as one day.

OUESTION 1:

Do you believe that this pilot program has been effective? How does use of the pilot differ at different agencies?

SBA RESPONSE:

The pilot program has been highly effective. One of the strengths is that the agencies may use the funding to support several different aspects of administration, outreach, and technical assistance. This flexibility in the level and approach of funded activities is a strength of this pilot program. Some examples of what agencies have funded include expanded outreach, process streamlining, adding staff to their contracting shops, helping firms commercialize, participate in I-Corps training, or developing a commercialization plan. The annual reports summarize the level of funding each agency obligated and highlights agency activity in each of the six focus areas.

QUESTION 2:

Congress extended this, and three other, pilot programs in the fiscal year 2019 NDAA. Can you also speak to the effectiveness of the other three pilot programs and the ways in which agencies are using their authorities?

SBA RESPONSE:

The "Phase flexibility" provision (15 U.S.C. 638(cc)) allows NIH, the Department of Education, and the DoD to make "direct to Phase II" awards, skipping the Phase I process if feasibility has been proven. NIH uses this program the most and they have shown how it accelerates the speed at which technology might get to the market. DoD is using the program more and has shown that it can reduce the time to get technology fielded, an important priority for them. The Department of Education has elected not to use the pilot authority.

The Civilian Commercialization Pilot Program (15 U.S.C. 638(gg)) allows all agencies except the DoD to allocate up to 10 percent of their total SBIR funding awards for technology development, testing, evaluation, and commercialization assistance or for research, R&D, and commercialization of Phase IIs, up to 3 times the Phase II general levels. This program is primarily used by NIH as many medical technologies require higher levels of funding to validate the technology enough to attract the next stage of funding. NASA has also used the program as many of their technologies require additional funding to mature the technology to a level that it can be integrated into a NASA program. As the primary users of this pilot authority, NASA and NIH report the program is valuable in helping them quickly address time sensitive needs.

The Phase 0 Proof of Concept Partnership pilot program (15 U.S.C. 638(jj)) authorizes NIH to use \$5,000,000 of funds allocated under the statute for a pilot program to accelerate the creation of small businesses and enhance the commercialization of research from qualifying institutions. NIH submitted the required report to the requested Congressional Committees on the program on June3, 2019. SBA will review this report and provide a summary of the effort in the FY 2018 Annual Report as directed by the 2019 NDAA.

QUESTION 3:

What recommendations do you have to improve the pilot programs?

SBA RESPONSE:

SBA recommends the Administrative Funding Pilot Program be made permanent.

SBA recommends the Phase Flexibility Pilot Program be made permanent and expanded to all participating agencies.

SBA recommends the Civilian Commercialization Pilot Program be made permanent.

SBA is currently reviewing the Phase 0 Proof of Concept Partnership Pilot Program and will reserve any recommendations at this time.

Outreach

Outreach continues to be challenge for the SBIR and STTR programs, especially in so-called "lower performing states." As such, outreach is one of the congressionally allowable uses of the Administrative Funding Pilot Program, and SBA undertakes an SBIR Road Tour each year to highlight the programs and educate more small businesses about the programs.

QUESTION 4:

How many agencies contract with SBA to use a portion of their Administrative Funding Pilot dollars to conduct outreach through the Road Tour?

SBA RESPONSE:

Starting in FY14, NSF and HHS started to provide funding to SBA for the execution of the SBIR Road Tours. The transfer of funds to SBA continued from these two agencies, except for FY18

when the pilot expired. In FY17, USDA and DOE also provided funding that included Road Tours.

OUESTION 5:

The Federal and State Technology Partnerships (FAST) program is designed to increase awareness and outcomes in lower performing states through a matching program that leverages local commercialization expertise. What is SBA doing to innovate in the FAST program, and what changes should Congress consider to improve the program?

SBA RESPONSE:

FAST provides one-year funding to organizations to execute state/regional programs that can increase the number of SBIR/STTR proposals, which can lead to an increase in the number of SBIR/STTR awards. Beyond impacting states with low SBIR award numbers, the purpose of FAST also includes efforts to increase the participation of women and socially and economically disadvantaged individuals in the SBIR/STTR programs.

The following challenges exist with FAST:

- Only one proposal is allowed per state, preventing a comprehensive competition from taking place. Other SBA programs take into account geographical coverage of services, while still allowing multiple groups in a state to propose, and in some cases, multiple groups per state to hold awards.
- Each year's appropriations schedule varies, which impacts when SBA can release the
 Notice of Funding Opportunity. This shortens the time for awardees to respond and limits
 strategic hiring and programmatic decisions. Greater certainty would enable the program
 to track longer-term outcomes.

SBA Program Management:

- The Office of Innovation and Technology (OI&T) manages FAST, and in the last 3 years
 focused on updating and improving its management to more clearly convey the purpose
 of the program. This includes directing applicants to address areas such as past FAST
 impact in the regional SBIR ecosystem, or, if they are a new applicant, to analyze past
 SBIR support efforts in the state.
- For the past two years, OI&T has held monthly calls with the entire FAST cohort and
 other service providers to share best practices and encourage collaboration across the
 country. Several FAST entities have since partnered together on events and program
 development. This helps new FAST organizations to leverage past successes and connect
 with others.
- FAST and other regional innovation support organizations have participated in Ol&Ts SBIR Train the Trainer program. SBIR Train the Trainer is focused on helping potential applicants and the other new awardees by making available training modules.
- Ol&T facilitates connections between FAST grantees and relevant SBA District Offices and Resource Partners (such as SBDCs or PTACs), leveraging federally-funded resources.
- OI&T shares FAST point of contact information with the participating SBIR agencies, encouraging their use in agency-specific outreach and training activities. SBA's SBIR/STTR Program Managers meetings often include topics relating to FAST awardee

- activities and events. In 2018, SBA also began including the agencies as guest speakers on the monthly call with support organizations to foster additional collaboration and awareness.
- SBA's Office of Performance Management is currently conducting an evaluation of the program in an effort to elicit improved data collection, standardized metrics, and analyze best practices.

Questions for Mr. Joseph Shepard

Questions from:

Chairman Rubio

Administration's Priorities

As we go through the process of reauthorizing the SBA for the first time in many years, it is important to make sure that we utilize the agency's expertise to better understand the on-the-ground effects any changes would have.

OUESTION 1

How can this Committee better equip SBA to manage the SBIR and STTR programs?

SBA RESPONSE:

SBA's role in managing these programs should be revised to codify and strengthen the focus on the following priority areas: commercialization assistance, streamlining, enhanced and more transparent data, complete and timely reporting, and increasing the participation of underrepresented states, women, and minorities in the program.

Reporting Timelines

Mr. Shepard, Congress set a March 30, 2019 deadline for submitting a report evaluating the four pilot programs operating under the authorization of the SBIR and STTR programs. Understanding the difficulties SBA has faced getting data from agencies, Congress also set a deadline for agencies to submit information on the pilots to SBA by December 31, 2018.

QUESTION 2:

Has SBA received the necessary data from agencies to complete and send the report to Congress? If not, have agencies communicated when you will receive this data?

SBA RESPONSE:

SBA submitted the annual report for FY16 on April 10, 2019 to Congress which includes a status on each of the pilots. NIH had not provided a report to SBA on their Phase 0 Proof of Concept pilot until June 3, 2019. While the DoD has provided a report on the Commercialization Readiness Program (section (y)), their reports continue not to address the number and percentage of Phase II awards and incentives (subsection (y)(6)(C)(i) and (iii)).

SBA is in the process of completing the FY17 annual report. As of June 7, 2019, it is going through the OMB inter-agency review process. This report was delayed because SBA did not have the majority of the award data prior to December 31, 2018.

The data from the Commercialization Readiness Program (subsection (y)) and the Phase 0 Proof of Concept Partnership Pilot Program ((ji)) mentioned above was also not available at that time.

Information on Assistance for Administrative, Oversight, and Contract Processing Costs; Pilot Program; and Phase Flexibility (subsections (mm), (gg) and (cc)), is included in both the FY16 and will be included in FY17 reports.

OUESTION 3

If you have received the data, when can Congress expect the report on these pilot programs?

SBA RESPONSE:

SBA intends to have the FY17 annual report submitted to Congress by the close of FY 2019.

Questions from:

Senator Hirono

Requesting the U.S. Small Business Administration's (SBA) continued commitment to supporting small businesses through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs: Mr. Shepard/Williams, the SBIR/STTR programs provide important opportunities for small businesses to compete for research and development funding through annual federal agency allocations. Locally in Hawaii, small businesses have benefited from these programs, through which they have received more than \$50.7 million since 2016.

QUESTION 1:

Can you commit to continuing your support for small businesses through these programs?

SBA RESPONSE:

SBA understands the value these programs have to small businesses and will continue to support them.

Requesting the SBA's continued commitment to funding SBIR/STTR allocations: Mr. Shepard/Williams, the SBA plays an important role in making sure federal agencies comply with statutorily required SBIR/STTR allocations, and I have appreciated the SBA's commitment to working with federal agencies to ensure their compliance.

QUESTION 2:

Within the past three years, have there been any instances where federal agencies have not fully met their statutorily required SBIR/STTR allocations?

SBA RESPONSE:

Based on the way SBA assesses compliance with the minimum spending requirement, there have been instances where SBA believes some federal agencies did not fully meet their minimum allocation levels. Details on agency compliance is included in the SBIR/STTR annual reports provided to Congress.

QUESTION 3:

Can you elaborate on how the SBA works with federal agencies to help them comply with these requirements—including instances where agencies may be out of compliance?

SBA RESPONSE:

SBA measures agency compliance using the requirements defined in 15 U.S.C 638 and the SBIR/STTR Policy Directive. The findings are reported to Congress in the SBIR/STTR annual report. Prior to reporting to Congress, the details are provided to the agencies, which subsequently have the opportunity to provide comments. These comments are incorporated verbatim in the annual report. As you will see in the annual reports, it is not always possible for SBA to determine compliance and agencies sometime disagree with SBA's findings or methods of measurement. SBA is working with the agencies and the National Center for Science and Engineering Statistics (NCSES) to ensure accurate measurement and reporting. These details are included in the annual report.

OUESTION 4:

What changes could be made to improve compliance at federal agencies?

SBA RESPONSE:

As described in the annual report, there are several challenges in measuring compliance and assessing if an agency has met compliance. The SBIR/STTR statute (15 U.S.C. 638 § (e)(1)) allows several agencies to exempt portions of their extramural R&D, while some agencies have exemptions from other statutes. SBA recommends codifying all of the intended exemptions within the SBIR/STTR statute.

Also, some agencies measure extramural R&D differently when reporting to NSF's National Center for Science and Engineering Statistics (NCSES) than they do when reporting to SBA. The DoD uses the terms Research, Development, Test and Evaluation (RDT&E), and some of the later stage funding has recently been considered by some DoD components to fall outside the category assessed for SBIR or STTR. These issues create challenges for both the agencies and SBA and are discussed in the SBIR/STTR annual reports.

Requesting the SBA's commitment to removing barriers for women and underrepresented minorities to participate in the SBIR/STTR programs: Mr. Shepard/Williams, in your testimony you highlighted the need for the SBA to work more with woman- and minority-owned firms to help them submit competitive proposals and receive awards. As a strong supporter of broadening participation in business, government, education, and other areas, I appreciate the SBA's commitment to addressing this issue.

QUESTION 5:

Can you elaborate on how the SBA has engaged with woman- and minority-owned firms to help them submit competitive proposals and receive awards?

SBA RESPONSE:

Some of the 11 participating agencies also provide SBA with a portion of their administrative funding for outreach (SBIR Road Tours and conferences) and training (SBIR Train the Trainer

and online tutorials). These efforts primarily target underrepresented populations and states. These efforts are designed to increase SBIR/STTR awareness, provide information about the program, highlight local support resources, and offer access to SBIR/STTR Program Managers.

OUESTION 6

Do you think the SBA could be doing more to engage with woman- and minority-owned firms?

SBA RESPONSE:

SBA is committed to increasing participation among all underrepresented groups. As discussed in previous questions, SBA is focused on ensuring women and minority-owned firms have access to the information and tools to submit competitive proposals and ultimately win more awards.

OUESTION 7:

Besides the Federal and State Technology Partnership (FAST) initiative, through which the SBA supports state and local economic development entities and small business technology centers like the Hawaii Technology Development Corporation (HTDC) in Hawaii, what other steps has the SBA taken to broaden participation for woman- and minority-owned firms?

SBA RESPONSE:

OI&T has leveraged relationships to expand training and awareness to woman and minorities to include training at conferences, marketing of our Road Tours, ensuring that a number of our Growth Accelerators target these communities are a few examples. In Late 2017, the SBA's SBIR road tour visited Hawaii at HTDC's Hawaii Biennial SBIR conference.

QUESTION 8:

Would the SBA consider supporting other initiatives to broaden participation for woman- and minority-owned firms in the SBIR/STTR programs?

SBA RESPONSE:

Yes, SBA will continue to look for ways to increase participation for woman and minority-owned firms. We are happy to review proposals and initiatives with you and your staff.

QUESTION 9

I would ask for your commitment to work with me on this issue.

SBA RESPONSE:

SBA would be glad to work with you.

Requesting the SBA's commitment to removing other barriers to participation in the SBIR/STTR programs: Mr. Shepard/Williams, in your testimony you also highlighted the need for the SBA to reduce the burden on small businesses interested in participating in the SBIR/STTR programs.

QUESTION 10:

What specific recommendations do you have to reduce this burden for small businesses?

SBA RESPONSE:

The GAO is currently conducting a study that will look at agency award timelines and best practices. Findings from this multi-year study should help agencies better understand the options for streamlining and help Congress legislate improvements. Currently, agencies have varied requirements for proposal submission and evaluation. SBA was impressed by the recent changes made by both the Air Force and National Science Foundation to reduce barriers to entry.

The Air Force has experimented with several page proposals and pitch desks, as well as making awards using a one-page contract. They have also greatly reduced the time between Phase I and Phase II.

NSF has implemented a new Project Pitch process. Applicants submit a three-page summary (the Project Pitch), which NSF reviews within three weeks to gauge the proposed project's appropriateness to NSF's small business programs. In response to the Pitch, NSF either invites a full proposal or advises the applicant that his/her project is not a good fit for NSF's programs. Applicants who are invited then submit a full proposal that follows NSF's normal merit review process. All Project Pitch applicants, whether invited or not, receive feedback from the NSF Program Director responsible for that portfolio area. This makes it easier for more entrepreneurs to submit, reduces the number of firms which are required to submit a full proposal, and thus reduces the workload for both the government and small business.

Requesting the SBA's commitment to simplifying the contracting process for the SBIR/STTR programs: Mr. Shepard/Williams, in your testimony you also highlighted the need for the SBA to work with federal agencies to simplify the contracting process in the SBIR/STTR programs.

QUESTION 11:

What specific recommendations do you have to simplify this process?

SBA RESPONSE:

SBA is limited in providing recommendations as the agencies have a number of statutory requirements on how awards are made. The GAO study should provide more clarity on the various issues across agencies as well as identify some best practices. SBA will increase the effort on providing consistent measurement on time from proposal submission, selection, and award, but SBA has no authority when it comes to simplifying agency contracting and grant-making processes. SBA does hold bi-monthly meetings with all the agencies where best practices are shared and challenges discussed. However, SBA does not have the authority to mandate changes in the grant and contract process at other agencies.

Requesting more information about the SBA's SBIR Road Tour in 2019: Mr. Shepard/Williams, in your testimony you mentioned the SBA's SBIR Road Tour, which the SBA launched in 2015 to increase access to and raise awareness about its innovation programs throughout the United States.

QUESTION 12:

The SBA led 18 Road Tours in 2018, and has another 16 planned for 2019—will any of these planned tours take place in Hawaii, and, if so, then will you commit to keeping my office updated as part of the planning process?

SBA RESPONSE:

The SBIR Road Tour had the pleasure of visiting Oahu in September 2017. When selecting the 2019 tour locations, SBA discussed the options with the 11 participating agencies and decided to primarily target regions in which we have not visited. Prior to announcing the tour locations, SBA contacts congressional offices from those locations. We will continue to make you and other offices aware of our activity.

QUESTION 13:

I would also ask that you work with local stakeholders like our SBA district office and other local stakeholders and resource partners who may be interested.

SBA RESPONSE:

SBA will certainly continue to work with local stakeholders and resource partners. Our office engages SBA district offices through field calls and information sharing. Furthermore, support organizations from Hawaii participate on our monthly calls and we are happy to add specific organizations that you suggest that are interested in getting involved.

Senate Committee on Small Business and Entrepreneurship Hearing May 15, 2019 Follow-Up Questions for the Record

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Questions from:

Chairman Rubio

IP Protections

Mr. Glover, in your testimony you mention several times the challenge that China presents to our innovators, particularly when it comes to intellectual property and venture funding. Program participants hit a milestone in the commercialization process when they receive a patent on their idea.

QUESTION 1:

What steps can Congress take to ensure that SBIR and STTR awardees with innovative breakthroughs and technological achievements can better protect their ideas and products?

Citizens and politicians frequently complain about foreign nations and companies stealing America's technology. For many American businesses, however, reality is even starker. Our current national policies give away America's hard-earned technologies on a silver platter. For two decades, the United States has adopted a publish-first policy—making American technologies available for worldwide consumption at a time when inventors have no enforceable rights, while Congress and the Courts have degraded patent rights, making it difficult or impossible to legally protect many small company inventions and the jobs they create in America.

Congress can help SBIR firms protect their data and preserve their rights in a number of different ways. These include:

- Insert SBIR Policy Directive language into the FAR and DFAR within 180 days and codify longer terms for SBIR data rights.
- Eliminate the requirement to patent by small business Federal contractors, allowing companies to keep inventions as trade secrets.
- Prohibit military agencies from requiring data be turned over to DoD for them to be able to make the invention.
- 4. Improve our weakened patent system. (See Appendix A)

- 1. Insert SBIR Policy Directive language into the FAR and DFAR within 180 days and codify longer terms for SBIR data rights. The new SBA SBIR/STTR Policy Directive provides that the SBIR data rights term length was recently simplified. The term length was modified from 5-years from the end of the last SBIR program (which was continuously extended each time a new or modified SBIR was awarded) to 20 years from the date of the contract award. This would be similar to the length of a patent. This provision should be codified and the DOD 813 Panel report recommends that SBIR awards should be treated as though they had been developed with private funds. In addition to the 20-year term commencing from the date of the contract/grant award, it should be clear that the 20-year term for data developed as the result of a contract/grant modification, the term should commence from the date of the contract/grant modification being issued.
- 2. No requirement to patent, allow companies to keep inventions as trade secrets.

 Following the 1999 passage of the so-called American Inventors Protection Act (AIPA), U.S. patent applications have been published as a matter of course. Although the law provides that patent applications "shall be kept in confidence" and that "no information concerning [a patent application] may be given without authority of the applicant," this promise of secrecy is hollow as a matter of practice. Pursuant to the AIPA, the U.S. Patent Office publishes nearly all patent applications within 18 months of filing, unless the inventor submits, at the time the application is filed, a request that the application be maintained in secrecy until issuance. The Patent Office refuses to honor requests that are filed even a day late. Should an applicant decide that she would like to maintain her already-filed patent application in confidence—or if she learns of the Patent Office's publication policy after filing—her only recourse is to abandon the application.

As a result, more than 90% of U.S. patent applications are published within 18 months of filing. Meanwhile, only 48% of "progenitor" applications (the first application in a patent family) filed by small business are allowed by the Patent Office, meaning that nearly half of the time, small businesses expose their technology to competitors without receiving a patent in their initial application. And, total average pendency currently exceeds 30 months according to the USPTO's own statistics, so even in cases where businesses achieve favorable outcomes, American technology is still exposed without patent protection for more than a year on average.

Currently, the SBIR patent rights clause in the Federal Acquisition Regulations (FAR), 48 CFR § 52.227-11 - Patent Rights - Ownership by the Contractor requires the SBIR company to patent new inventions or cede the patent rights to the US Government. This then usually results in the patent being published prior to the granting of a patent. This requirement to apply for a patent should be removed. Small business federal contractors should be allowed to keep the new technology as a trade secret for the 20-year period discussed above.

Prohibit military agencies from requiring data be turned over to DoD for them to be able to make the invention.

Many new recent DoD Requests for Proposal (RFP's) have required that all data be provided to the Federal Government so that the DoD can produce the invention without any requirement to use the small business. This is contrary to the SBIR data rules, but a large

number of DoD contracting officers currently ignore those rules. New legislation needs to make clear that only when an SBIR firm cannot or will not make an invention will the DoD have "March In Rights" to make the invention on its own.

4. Improve our weakened patent system.

SEE APPENDIX A FOR A FULL DISCOURSE ON STRENGTHENING THE PATENT SYSTEM

QUESTION 2:

In reauthorizing the SBIR and STTR programs, what can this Committee do, in your view, to improve and streamline the amount of time it takes for companies to receive R&D funds, while at the same time maintaining the integrity of this program by ensuring that truly small businesses, including businesses in rural areas, are the beneficiaries of these innovation initiatives?

- Require the submission to Congress by agencies of annual reports as called for in Section 854 of PL 115-232, including
 - Reporting on how the agencies are improving and streamlining the amount of time it takes for companies to receive contract awards and receive R&D funds (both are important).
 - Reporting on completion and implementation of model contracts for SBIR Phase I, II and III.
 - Explicitly reference not just SBIR Phase I, II and especially Phase III. Phase III funding, from the regular procurement at DoD, which carries the technology forward to the Warfighter and the marketplace. SBIR companies are having persistent difficulty in getting DoD contracting officers to recognize that work may be a Phase III follow-on to prior SBIR Phase I or II work, or how to structure the contract even if they recognize the Phase III status. This causes such new contracts to get severely delayed and disrupted, and slows progress of the new technology to the field. A model Phase III contract would make it much easier for the contracting officers to know how to handle a Phase III project.

Senator Hirono (Hawaii)

Requesting more information about changes to the SBA's innovation programs: Mr. Glover, during the 112th Congress, before the last reauthorization of the SBA's innovation programs, I introduced legislation to increase federal agency allocations for extramural research and development—from 2.5 percent to 5 percent for SBIR, and 0.3 percent to 0.6 percent for STTR. With the reauthorization in 2011, these amounts were increased. They are now 3.2 percent for SBIR, and 0.45 percent for STTR.

QUESTION 1:

What potential benefit do you see from increasing allocations from their current percentages?

- Better use of Federal R&D dollars: SBIR/STTR projects have remarkably high success metrics – increasing the allocation would invest more of the government's R&D in projects that as a group have remarkably better than average results.
- R&D investments that get paid back double in taxes: Beyond the value of the technologies themselves, the recent studies have concluded that SBIR R&D pays the government back in taxes ~\$2 for every dollar invested, over a 12 year period.
- Better tapping of America's underutilized small business scientists and engineers:
 Overall small businesses receive around 5% of Federal R&D dollars (SBIR being less
 than half of this), yet 31% of America's engineers and scientists work for firms
 employing less than 100 employees. And we all know how uniquely productive small
 business is at creating new technology, new products and new jobs. We are underfunding
 our most productive engineers and scientists.
- Better tapping of American entrepreneurship: Incenting new technology and product creation in entrepreneurial small companies puts those new products in the hands of entrepreneurs who are good at creating new business growth.
- Higher American job payoff: Creating new jobs in small businesses tends to create jobs
 that stay in America it is the large businesses who distribute their jobs worldwide, while
 the small businesses create their jobs at home. And the jobs created by advanced
 technology tend to be high wage.

QUESTION 2:

How would increasing these allocations support small businesses?

• Improve small business resources to support innovation and commercialization opportunity: Small businesses with <100 employees employ over 30% of America's engineers and scientists, but only receive around 5% of Federal R&D funding. Boosting the allocations more close to the proportion of the engineer/scientist in the small business economy would improve small business access to R&D resources, and allow the entrepreneurs better resources to build company intellectual property. This would strengthen small business competitiveness across the world, and better tap into America's uniquely strong entrepreneurial culture.

- Help offset VC tendency to not support early technology stage businesses: VC's are funding products that are already developed (primarily after product development is complete and after market entry has started).
- There is no other external small business funding for innovation: Small businesses do not
 have access to VC \$ for innovation and early product development, because the VC's
 want to invest after the product is more substantially developed. Small businesses do not
 have access to bank money for innovation and early product development because banks
 do not fund such activity without 100% collateral.

QUESTION 3:

What do you believe would be an appropriate increase for these allocations?

- The 809 committee recommended doubling the SBIR allocation from 3.2% to 7%.
- We propose a staged approach: +1.5% in year 1, and 1 percent in each of the next two years. Staging helps the programs work the money in most productively.
- 1.5% boost to start would just offset the planned increases in Phase I and Phase II project sizes: If no overall allocation increase is provided, boosting Phase I and Phase 2 dollar limits would shrink the number of awards if no overall increase is provided. If Phase Is are to grow from \$150K to \$200K (33%) and Phase IIs from \$1 million to \$1.5 million (50%), then the percentage allocation should grow equivalently just to avoid having to cut back on the number of awards.
- Growing use of Phase II enhancement or Phase II+ funding mean additional funds being spent on the proven best project (which is a good concept), but without an overall allocation increase this would mean a decrease in the number of awards.
- Other programs are looking to use SBIR funding to advance their objectives (e.g. Phase 0, VC-owned businesses looking to tap into SBIR funding): Some increase is needed to prevent such "SBIR raids" from taking money from core SBIR projects.

QUESTION 4:

What potential benefit do you see from increasing maximum awards from their current amounts?

- This is merited, as R&D costs are climbing higher and R&D work increasingly involves higher total investments due to its increasing complexity. Increasingly advances in technology are costing more and more to create and demonstrate, as the simpler solutions may have already been done yet there are major improvements to be won with more complete system solutions. System solutions cost more to develop.
- Faster development: More money means the technology will advance faster, which is important in a competitive world.
- There is a downside though, if the overall allocation is not increased. In this case, the
 increase in award size causes a decrease in the number of awards and a narrowing of the
 areas that SBIR technology can be called upon to innovate. The solution is to boost the
 allocation enough to more than offset the dilutive effect of the increase in award
 maximum.

QUESTION 5:

How would increasing these awards support small businesses?

- Without an increase in allocation, increasing award size will result in fewer SBIR awards being made.
- Increased maximum awards reflects the inherently increasing costs in developing new technologies.
- VCs and bank do not support early stage technologies and pre-market products; only SBIR does this. Increasing the award maximum and permitting more Phase IIs (or Phase II enhancements) would provide money towards bridging an innovation forward to be able to attract private capital. This in most cases means developing the product or service to be at a high enough maturity level that it is able to be made and sold, and that will take more money.
- The rest of the world is subsidizing its technology and new technology introduction far more than is the U.S. Increasing SBIR awards would help our companies compete.

QUESTION 6:

Notwithstanding the SBA's ability to fund projects larger than the maximum awards, what do you believe would be appropriate increases for these awards?

- No increase without increasing the allocation.
- Assuming allocation increases, the current approach still makes sense of allowing a regular maximum (e.g. now \$150K/\$1 MM for Phase II with a potentially larger amount (\$200K/\$1.5 million)).
 - A partial solution would be to increase the proportion that could go to the higher levels.
 - o The 200K/\$1.5 million are good first steps for an overall increase.
- Increasing use of Phase II+ or enhancements are a good practice feed the best technologies so they can progress faster to the Warfighter.

APPENDIX A: Strengthening America's Patent System

Improving our weakened patent system.

For over 200 years, patents protected US inventions, allowing our country to grow from an agricultural economy to the world's greatest power. However, in the last two decades, the US has degraded its patent rights so significantly that we have fallen from 1st to 8th in the world in innovation.

This has had a huge impact on our economy. The Federal Reserve Bank has stated that patents are the number one indicator of regional wealth, more important than education or infrastructure. Being a high patenting community means the difference of \$8,600 in two-worker household income. In part, because of the weakening of patent rights since 2000, we have seen fewer new inventing companies being created or growing. In fact, in two-thirds of America's metro areas, companies are dying faster than being birthed. This is having a distressing effect on job growth and on the economy. Holding a patent increases startup employment by 36%, sales growth by 51%, and probability of securing venture capital funding by 53%. Thus, encouraging strong patents leads to more better-paying new jobs.

An American patent, meanwhile, is not the secure asset that it once was. From 2005 to present day, the Supreme Court has issued decisions in more than 20 patent cases, the aggregate effective of which includes:

- Exempting entire categories of innovation from patent protection, and placing a cloud over virtually any technology with an algorithmic or diagnostic component;
- Curtailing a patentee's right to prevent a competitor from stealing their technology by generally rejecting injunctions;
- Overruling decades-old Federal Circuit law intended to protect patents from hindsightmotivated obviousness attacks, and
- Lowering the legal standard for invalidating a patent based on minor drafting errors.

The America Invents Act (AIA) introduced additional post-grant trials presided by judges who are not elected or approved by the Senate. This created another hurdle for inventors by eliminating the presumption of validity and allowing infringers still another chance to invalidate inventor's patents. In fact, the Patent Trial and Appeals Board invalidates about 65% of the entire patents it reviews, and some of the claims in another 16% of the patents. Thus, 80% of PTAB reviewed patents have claims eliminated after the patents have been published, giving this technology to the rest of the world.

The degradation of American patent law is causing many American Venture Capitalists to move their investments from America to China. New legislation such as the STRONGER Patents Act is required to strengthen patent rights.

We need to reverse the ill effects of the AIA and other laws and court cases. The patent laws need to be fixed providing stronger rights to inventors before we expend Federal resources to encourage new inventors to patent and disclose their inventions. Otherwise, this will just cause many new inventors to go into debt and some will lose their house due to the cost of pursuing IP protection. Some of the things that are necessary in correcting the patent laws <u>before</u> we encourage more patenting are:

- 1. Restoring injunctive relief
 - a. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).
 - i. Prior to *eBay*, the Federal Circuit had said that "injunctions should be denied only in the 'unusual' case, under 'exceptional circumstances' and '"in rare instances ... to protect the public interest." '*eBay* at 394.
 - ii. In eBay, however, the Supreme Court held that a federal court should, in "considering whether to award permanent injunctive relief to a prevailing plaintiff," apply "the four-factor test historically employed by courts of equity." eBay at 390.
 - b. Unfortunately, most lower courts have interpreted this to use injunctions extremely rarely. If strong patent rights are to be restored to inventors, encouraging new technology development, the use of injunctions must be the normal remedy. (This would be the Intellectual Property equivalent to the real property removal of a squatter/trespasser from a person's home.)
- 2. Restoring a "grace period"
 - a. Restore a robust two-year grace period
 - i. From 1839 to 1939 (100 years) the grace period was two years.
 - ii. Shortened to one year by The Patent Act of 1939.
 - iii. One-year grace period greatly weakened by AIA of 2011.
 - iv. Due to the increased complexity of inventions, and of commerce generally, since 1939, two years has once again become necessary, to provide the small inventor sufficient time to obtain financial backing, including backing to afford the patenting itself.
 - v. Recreating a robust grace period would seem to require a return to first-to-invent
 - b. At the very least, the word "disclosure," as used in the AIA 35 USC 102(b)(1), should be clarified as applying to any of the potentially patent-barring acts of 35 USC 102(a)(1). Inventors must have the right to make presentations to find funders, partners, or testers without losing their right to patent.
- 3. Eliminate relevancy of whether patent plaintiff is a practicing entity:
 - a. A Non-Practicing Entity (NPE) should have additional remedy of suing for infringer's profits.
 - i. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006) has essentially eliminated the injunction for the NPE, and reasonable royalty is insufficient to stop "efficient infringement."
 - "Prior to 1946 a utility patentee, like a design patentee today, could recover an infringer's profits." Schnadig Corp. v. Gaines Mfg. Co., Inc., 620 F.2d 1166, 1172, 206 USPQ 202, 210 (6th Cir. 1980).

- b. Once again, comparing real property to intellectual property, the eBay result is similar to saying that a person who rents her house does not have the right of exclusivity for herself and her tenant; any stranger can move in and pay reduced rent, or none at all. This needs to be corrected.
- 4. Fixing Section 101
 - Support draft bill revising Sections 100 and 101, released May 22 by Coons, Tillis, Collins, Johnson, and Stivers
 - b. strikes the word "new" from Section 101, since whether an invention is new should be analyzed under other sections of the Patent Act
 - important that it requires a determination of eligibility "only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation"
 - d. important that "[n]o ... judicially created exceptions to subject matter eligibility ... shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated."
- 5. Improvements to PTAB:
 - a. Codify as law, efforts at USPTO discouraging forum shopping, between PTAB or Federal Courts (i.e., do not want a party choosing one forum over the other because a different substantive outcome is expected):
 - PTAB should be a venue of lower cost, higher efficiency, or both, while producing substantive outcomes as similar as possible to Federal Court.
 - Codify USPTO's recent adoption of the Federal Courts' Phillips standard for claim construction.
 - iii. To prove unpatentability, PTAB should also require the same "clear and convincing" burden of proof standard required in Federal Court (and not the current "preponderence of evidence," which should be reserved for ordinary examination).
- Pilot program of patent-specialized courts (such as we have now for bankruptcy and admiralty):
 - a. Propose trying at 5 district courts for 5 years
 - b. Include a lower tier part of pilot program, for cases where the royalties on the products accused of infringement are valued less than \$5M by the inventor. A fast track should be created to have a resolution, including an injunction, in 6 months.
- 7. Trade secrets and SBIR contracts (see above):
 - a. Grantee should be able to identify an invention made during the SBIR program to government under seal, and still keep the invention secret under SBIR data rights for 20 years
 - b. Grantee should have the option of this 20-year trade secret, or to file for a patent as is current practice.
- 8. Patent publication (see above):
 - a. Return to the standard of not publishing patents unless there is a foreign filing, or unless the applicant specifically requests that the patent be filed. Less desirable would be b. below
 - b. In the following exception to publication, under 35 USC 122(b)(2)(B)(i), replace "has not and will not be" with "has not been": "certifying that the invention disclosed in the application has not been the subject of an application filed in another country"

- c. This will allow the applicant 12 months to decide if the patent will be foreign filed (and disclosed at the 18th month), or if the applicant decides not to foreign file, the application will remain secret until the patent issues, or forever if the patent does not issue.
- 9. Experimental Use and On-Sale Bar Exceptions
 - a. Codify judge-made doctrine of excusal of public use or on sale activity on the basis of the experimental use, established in 1877 by City of Elizabeth v. The American Nicholson Pavement Co., 97 U.S. (7 Otto) 126 (1877):
 - i. experimental use can continue even after the invention has been completed and reduced to practice
 - establish a clear "safe harbor," where satisfying the requirements establishes experimental use
 - b. Codify *Medicines Company v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) exception to on-sale bar for "a contract manufacturer's sale to the inventor of manufacturing services where neither title to the embodiments nor the right to market the same passes to the supplier." *Id.* at 1381.
- 10. Provide automatic additional grant, to any SBIR/STTR award, that pays towards cost of patenting. However, this should be funded so as to not reduce the current amount of research being performed, i.e.: not out of the current SBIR allocation.
- 11. The patent life should be extended during any PTAB proceeding, thus an additional day shall be added to the patent life for every day of the PTAB proceeding till final adjudication.

Senate Committee on Small Business and Entrepreneurship Hearing May 15, 2019 Follow-Up Questions for the Record

Follow-Up Questions for the Record	đ	

Questions from:

Chairman Rubio

Limitation of Awards

Questions for Dr. Sridhar Kota

Dr. Kota, you started your small business, FlexSys Inc., 18 years ago with a Phase II SBIR award.

QUESTION 1:

How critical was that initial SBIR grant to your business remaining viable to continue your technological development?

The initial SBIR was extremely critical to start developing the idea beyond a paper study. I was able to build a working prototype to demonstrate the feasibility with funds from Phase I. Then a bigger and a better prototype was built and testing was conducted in Phase II. Standard research grants/contracts from federal agencies do not support this kind of work as most of that funding is devoted to theoretical studies, even in engineering programs. Having a working prototype is the first step to begin any conversation with a potential customer or an investor. SBIR enabled that critical first step.

QUESTION 2:

When you started this business early on, were there agency limitations placed on your initial SBIR award, and if so, what were those limitations?

The only unfortunate limitation was that the SBIR funds could not be used to file patents. It is important for a budding entrepreneur to protect the intellectual property. It would be very beneficial if SBIR allowed patent expenses perhaps with some limits imposed on the maximum allowable amount, e.g. \$10K.

QUESTION 3:

Do you think small businesses would benefit from agencies having more flexibility to increase the size of Phase I or Phase II awards beyond the current flexibility if the particular technology development required it?

My opinion all along has been to grant that flexibility to federal agencies but I heard last week (since my testimony) that agencies have always had the flexibility to grant up to twice the stipulated amount on Phase I and II. However, with all the interactions I have had over 20 years with multiple programs and agencies, no one has ever mentioned this flexibility to change the standard award amount. It is likely that the agencies are either not aware of or afraid to use the flexibility that Congress provided years ago. The current flexibility, if used prudently for only those projects that justify the increase, is adequate.

Award Process

Dr. Kota, as someone who has received multiple SBIR awards from multiple agencies that participate in the SBIR and STTR programs, you have a unique insight into the nuances and differences of the award process at different agencies. It is my understanding you have received awards from Air Force, Army, NASA, and NSF. As you are aware, these are among the largest of SBIR and STTR participating agencies.

QUESTION 4:

If agencies aligned their processes to the extent possible with the goal of creating a more uniformed process, would this improve or enhance awardees' ability to apply for and receive additional grants from other agencies?

Simplifying and standardizing the application process will (a) ease the burden on potential offerors, innovators, and entrepreneurs to participate in the SBIR program and (b) will lower the overhead barrier to entry and allow more time to be devoted to technical proposal preparation and technical work once the contract is in place. There is no reason why the agencies could not agree on a simple set of requirements from formatting to financial justifications and create a "1040EZ style" proposal submission and contracting process to encourage participation by talented lone inventors, start-ups, and small businesses. I think if Congress requires them the agencies will find a way to do it rather than explaining why it cannot be done.

QUESTION 5:

It is logical to conclude that streamlining the proposal and award process can save potential awardees time, but can it also save them money? Please explain.

Absolutely. Of all agencies we have worked with, NSF requires ~3X the investment of other agencies to receive a contract award. This means that we spend \$50k to get a \$150k Phase 1 contract and \$100k to get a \$750k Phase 2 contract. The proposal investment for other agencies is one half that amount for Phase 1 and one fourth for Phase 2 proposals. In addition to the proposal investment, NSF is the only agency that requires a unique indirect rate calculation, where we pull out any IR&D labor from the rates. This immediately means that we lose money performing any NSF contract. With the up-front proposal investment of 15-35%, a reduction in allowed indirect costs, and a profit limited to 7%, working with NSF makes very little business sense. Only funding desperation makes the NSF effort worth it.

It is also worth noting that the paperwork obligation for NSF proposals and awards is very cumbersome compared to the other agencies. For example, an NSF Phase 2 proposal required 18 documents, including documentation of each employee expected to work on the effort and what programs currently consume their time, company commercial history, data management plans, and numerous others. Once the proposal was selected for award, another 40 files were required before the contract would be executed. These files included 3 years of company financial data and tax returns, employee payroll registries, company Articles of Incorporation, historical employee time logs, and a copy of our building lease. NSF is the only agency that requests any of the above information prior to the award. For a small company like ours, this paperwork burden falls on a single individual (who is also an engineer since we cannot afford a contract specialist) and consumes a significant amount of precious time for weeks trying to receive the contract award.

Setting aside the overhead burden, it is very important to emphasize the point I made during my oral testimony that NSF in particular does an outstanding job with its SBIR program in order to truly promote entrepreneurship. NSF employs several experts with entrepreneurial and engineering expertise to guide its SBIR awardees on effective paths to reduce technical and market risk and to promote entrepreneurial success. Other agencies could follow NSF's lead by employing a cadre of such experts to guide the awardees towards successful outcomes. This guidance is particularly important since most start-ups do not have fully understand what it takes to bring an idea to fruition. The NSF iCorp program is another effective means to fuel entrepreneurship. Additionally, NSF solicits proposals on any topic within broader categories such as energy, health care, and advanced materials. Such broader solicitations accommodate a wide range of discoveries and inventions resulting from nearly \$150 billion invested annually in S&T. Additional funding for such SBIR solicitations could offer a pathway from research to return on investment.

QUESTION 6:

With every agency's process being different, do you have any specific suggestions for ways to standardize certain processes, such as proposal submission, contracts, and award-to-contract times across participating agencies?

Regarding general proposal submission, each agency handles the process differently. The DoD tries to be consistent across the branches, but each still desires unique formats and information in a proposal. My recommendation would be a unified system for uploading proposals for all agencies, with a single format and consistent information required. One agency should not require 12 documents (NSF) be generated for a proposal, while another agency seems to administer proposals effectively with only two (DoD). In my opinion, the technical proposal and budget justification are the only two documents that should be needed for submission. A simple form can be filled out with each submission that includes proposal information and an abstract. Our company's Operations Manager maintains seven different login credentials to manage proposals for the various agencies. It seems that one should do it. It also seems very inefficient, from the government and industry perspective, to manage interaction with each agency. Each submission site has its own help line and support staff who, by the way, are generally very helpful. With a standardized process, a single help line would be sufficient and save taxpayers dollars, too. Besides, if we have a single unified process for submission, then we shouldn't need any help after the first time through.

In summary, I recommend all proposals in response to federal solicitations (regardless of agency) use a single solicitation posting system, single proposal submission system, single indirect rate calculation method, and a single proposal submission format. I suspect that many companies simply avoid certain agencies or all, because the proposal effort ROI is not worth it. That means innovative technology is not accessible due to process-related burdens. Those burdens should be solvable.

QUESTION 7:

Should Congress consider taking a more active role in ensuring the technology and jobs coming out of these firms and businesses remain in the United States? If so, how?

The purpose of the SBIR program is to promote innovation and entrepreneurship by investing taxpayers' dollars to transition nascent but promising inventions into new products/processes to create national wealth, ensure national security, realize better health outcomes, or enhance energy production so that the taxpayers who funded the work ultimately get a return on investment. The federal government should enact strict guidelines on intellectual property (IP) generated from SBIR projects to ensure that it is scaled only in the U.S. Not all awardees are interested or qualified to pursue full-volume manufacturing on their own. Therefore, SBIR awardees should be allowed to license the technology to any firm, domestic or foreign, as long as the technology is manufactured at scale only in the U.S.; that is, at least 75% of the value add is created in the U.S. This should be enacted with no waivers or exceptions to begin with — waivers usually are prone to loopholes which can be easily exploited. This would not be a burdensome or unreasonable regulation since the taxpayers who funded the research are entitled to a return. Otherwise our taxpayer-funded R&D will continue to be an unintended subsidy for technology used and products produced in other countries.

Advanced Manufacturing and Commercialization

Dr. Kota, I understand from your testimony that you are a founding executive director of a national consortium called MForesight: The Alliance for Manufacturing Foresight focusing on manufacturing competitiveness.

QUESTION 8:

In the context of commercialization in the SBIR and STTR programs, can you speak to the difference between commercializing a product and scaling production for advanced manufacturing?

My response below is made with the assumption that someone has to manufacture the product before it is commercialized – that is, marketed, sold, distributed, serviced, etc.

We, as a nation, have largely invented products such as flat panel displays, solar cells, cell phones, and lithium-ion batteries, to name a few. The underlying knowledge, in terms of scientific discoveries and engineering inventions, was created from federal government investments of taxpayer dollars in basic research for many years going as far back as the 1970s and 80s. All of the said products are available in domestic and global commercial markets today. We created knowledge, commercial markets, and global wealth but we have not created national wealth or jobs—because we did not manufacture them at scale in the U.S.

Furthermore, by not manufacturing we failed to do the necessary process innovations that provide (the company or the nation) a technological edge to remain relevant, let alone competitive. We now continue to invest taxpayers dollars in R&D on next-generation displays and solar cells such as flexible displays and flexible solar cells. Since we did not manufacture flat panel displays and solar cells in the 1990s, we simply do not have the "industrial commons" — that is the engineering skills, manufacturing know-how, equipment and supply chains—to manufacture next generation flexible displays and flexible solar cells even if we want to.

In summary, we are creating knowledge but not national wealth or security. The taxpayers who funded the early stage research did not reap the benefits through a return on that investment. Although some may argue that taxpayers are benefitting since these products are made overseas and are available at affordable prices to American consumers, they fail to recognize that many are unemployed or under-employed in the service sector and for them, the affordability argument is irrelevant. Manufacturing not only creates much needed high-paying jobs for the middle class in the short term but it also creates process innovations and the knowhow to create industries of the future in the long term. Commercializing without manufacturing has created trade deficits, decimated the industrial Midwest, increased our reliance on foreign suppliers for defense critical items, and created shortages even in medical supplies. Service industries shuffle wealth; manufacturing creates it. Other countries that are working hard to excel in manufacturing will learn sooner than later how to commercialize and distribute as well

as we do. Without manufacturing we lose our comparative advantage on upstream and downstream activities sooner rather than later.

QUESTION 9:

What role, if any, should Congress and the SBIR and STTR programs play in leveraging firms to this type of scaling?

The SBIR program is one of the few programs that invests in translational R&D but it is not sufficient to capture or retain promising technologies to yield desired returns to the nation. Start-ups and small and medium-sized manufacturers (SMMs), the backbone of our manufacturing sector, are often innovative but lack resources to invest in R&D. The Small Business Administration already plays a critical role to support these SMMs through SBIR and other programs to strengthen our manufacturing sector, but arguably could do more.

The federal government should incentivize the SBIR awardees with additional funds in the form of contracts or loans to nurture successful projects all the way to manufacturing. Otherwise, we risk losing technology developed, beyond basic research, through SBIR to other countries. Specifically, a separate set of funds, DoD's Rapid Innovation Fund for example, should be created and earmarked for successful SBIR projects to mature manufacturing readiness and to further de-risk the technology. SBIC program funds may be leveraged to lower private sector risks to invest in the capital investments needed to build pilot/full-volume production facilities and capabilities.

Government has an important role to play beyond funding basic research because the private sector is not interested in creating national wealth, only private quarterly profits. They offshore whatever makes sense to reap short-term gains to shareholders. This is especially true when societal benefits far exceed private sector benefits. Venture capital firms are truly risk-averse and shy away from the patient capital investments needed for manufacturing. Less than 4% of venture capital funds are invested in hardware/manufacturing – the majority is invested in software and biotech. Therefore, the federal government has a critical role to play to shepherd successful SBIR projects beyond Phase II all the way to pilot/full production in order to ensure a return on investment of taxpayer dollars. This can be done through SBIC, DoD early procurement, loan guarantees, etc.

Senate Committee on Small Business and Entrepreneurship Hearing May 15, 2019 Dr. Stephen L. Hoffman's Answers to Follow-Up Questions for the Record

QUESTION 1:

Given Sanaria's humble beginnings at your kitchen table, how vital was that first National Institute of Health SBIR Phase I grant to your success, and would your company be where it is today in the fight against malaria had you not received this initial award over 15 years ago?

I am certain that Sanaria would not be where it is today without the first NIH SBIR Phase I grant. In fact, Sanaria may not have survived at all. In 2002, I was Senior Vice President of Biologics at Celera Genomics, the company that sequenced the human genome, and the most notorious biotech company in the world at the time, and I was on the way to becoming the most highly cited author in the world for scientific publications on malaria. Yet more than 95% of my colleagues thought it would be impossible to develop the type of whole parasite vaccine that I envisioned, because it would be impossible to manufacture in sufficient quantity and to FDA standards.

However, these colleagues also thought that if the vaccine could be manufactured, it would be highly protective. I resigned my position at Celera and started Sanaria. The first NIH SBIR Phase 1 grant, which came through in July of 2003, allowed us to move from the kitchen table to a very small, 800 square foot laboratory space in Rockville, MD where we were able to demonstrate that we could develop the methodology to manufacture this vaccine. I had been in the U.S. DoD R&D community for 21 years, but could not find any other sources of funds at the time. In fact, as I implied at the Senate testimony, despite the unfathomable impact of malaria, no U.S. pharmaceutical company, venture capital firm, or investment bank has to my knowledge invested significant amounts (more than \$1-2 million) in malaria vaccine development in the past three decades. This is in large part, due to the fact that the development of a highly effective malaria vaccine is considered to be too difficult a task.

If we had not received the first NIH SBIR Phase I grants, I seriously doubt that we would have been able to move forward, and it is really unlikely that Sanaria would exist today and be on the path toward the first FDA-licensed malaria vaccine. The SBIR program is vital to facilitate the growth of ideas and disruptive technologies and innovations that are often deemed too risky for private funding.

QUESTION 2:

How critical was the success you had through attaining SBIR awards to acquiring funds from additional sources?

The answer to this question follows directly from the answer to the first question. When we started Sanaria, it was an idea with no funding, and I could not raise funds from private sources, the DoD or the Bill and Melinda Gates Foundation, because we had no data or results. With the funds from the SBIR grants we were able to demonstrate that we could manufacture the vaccine, and with these data in hand, we received an initial \$1.4M grant in 2005 and a \$29.3M grant in late 2006 from the Bill and Melinda Gates Foundation that enabled us to manufacture the vaccine in compliance with FDA standards, and conduct the first clinical trial.

Our vaccine was not successful in our first clinical trial completed in 2010, and our funding from all sources other than the SBIR funding was essentially eliminated. The subsequent innovations we were able to develop and introduce using SBIR funds allowed us to move from a situation in which many thought we would go out of business, to our current status of having in the past few years increased our clinical manufacturing facility size by 50%, our overall facility size by 30%, and our staff by more than 80%, and having been able to conduct clinical trials at 5 sites in the U.S., 7 countries in Africa, and 5 countries in Europe.

Since the founding of Sanaria, for every dollar received through SBIR grants, we have brought in another \$3.50 to fund our operations from other sources. To say that our success in the SBIR program has been critical to acquiring funds from additional sources is a vast understatement.



Senate Committee on Small Business and Entrepreneurship "Reauthorization of the SBA's Innovative Programs" Senator Jim Risch May 15, 2019 2:30 PM

Statement:

As many of you know, the Federal and State Technology
Partnership Program, known as FAST, provides grants of
\$125,000 to applicant organizations from underrepresented
states, like Idaho, to increase the number of SBIR and STTR
proposals and awards.

I believe it is vital that the SBIR and STTR resources be accessible to rural states like Idaho. However, valid concerns have been raised from the Boise Small Business Development Center (SBDC) who administers the funding in Idaho that have me concerned the program needs serious reform before it can be authorized.

Specifically, Idaho has received more than \$600,000 of FAST funding in the last five years and has only been able to claim two awards totaling about \$200,000. The Idaho SBDC has determined the matching requirement combined with the amount of effort it takes to administer the program outweigh the benefit to the SBDC. Burdensome red tape like that attached to this grant could make these resources even less accessible to Idaho's small businesses.

For this reason, I am pleased the Committee held this hearing to discuss the importance of the Small Business Innovative Research (SBIR) program and the Small Business Technology Transfer (STTR) program. Both programs encourage American small business formation and innovation to compete in the global marketplace. Through this reauthorization, I will work to ensure more Idaho businesses have access to these resources and

look forward to working with the Chairman and Ranking

Member to achieve that goal. Thank you. I yield my time.



May 20, 2019

Renee Bender, Professional Staff Member U.S. Senate Committee on Small Business and Entrepreneurship 428A Russell Senate Office Bldg. Washington, D.C. 20515

RE: Economic Impacts from Federal SBIR Programs

Dear Ms. Bender,

We are very pleased to submit this letter, which addresses the economic impacts of federal Small Business Innovation Research (SBIR) and related Small Business Technology Transfer (STTR) programs. Knowledge of these economic impacts may be useful as Congress considers reauthorization of the federal SBIR enterprise.

TechLink, a federally funded technology transfer center at Montana State University, has been conducting economic impact studies of SBIR, STTR, and federal agency technology transfer programs since 2012. In 2015, we completed the first-ever comprehensive economic impact study of a federal agency SBIR/STTR program in partnership with economists at the University of Colorado Boulder. That study, commissioned by the Air Force, analyzed the economic outcomes and impacts of all Air Force Phase II awards from 2000-2013. We conducted similar comprehensive studies for the Navy and National Cancer Institute (NCI) SBIR/STTR programs, which were completed in 2016 and 2018, respectively. Recently, we finalized a study of the entire Department of Defense (DoD) SBIR/STTR program, focusing on the economic Impacts of all Phase II awards initiated by 13 DoD components since 1995. All of these studies had a company response rate of well over 90%.

Our studies conclusively demonstrate that these SBIR/STTR programs have succeeded at meeting the major economic goals of the enabling 1982 SBIR legislation—spurring technological innovation, helping meet federal government R&D needs, and achieving private-sector commercialization of innovations from federal funding investments. In fact, our studies demonstrate that these programs have provided an outstanding return on investment (ROI).

For example, according to our findings, 58% of the Air Force Phase II awards resulted in sales of new technology products and services. Additionally, we found that the Air Force's investment of \$4 billion in Phase II awards resulted in total sales of \$14.7 billion, including \$4.4 billion in

sales of new technology to the U.S. military, with total nationwide economic impacts of \$48 billion. This represents a 12:1 economic impact ROI. The study of the similarly sized Navy SBIR/STTR Program discovered comparable total sales, \$7 billion in new technology sales to the U.S. military, and a 19:1 economic impact ROI. The NCI SBIR/STTR Program, which is smaller than the two DoD programs, generated total sales of new cancer treatment and diagnosis related technologies of \$9.1 billion, with total economic impacts of \$26.1 billion—a 33:1 ROI. The results of the entire DoD SBIR/STTR Program have not yet been cleared for public release. However, preliminary results approved for release show a 23:1 ROI in economic impacts.

Beyond these economic impacts, our studies reveal that many highly successful new technologies were developed through these programs. For example, the DoD studies found that the following revolutionary new technologies resulted from DoD SBIR/STTR awards:

- GPS on a chip, and combined WiFi and Bluetooth communications used globally in cell
 phones and U.S. military systems
- CMOS "camera on a chip" technology, now used in virtually all cell phones and most other digital cameras
- Many of the leading military unmanned aerial vehicles (UAV), including the ScanEagle, Blackjack, and Switchblade
- The high-accuracy, longer-range Excalibur artillery shell, which provides a major technological advancement for U.S. military engagements
- The primary laser used in Lasik eye surgery, which has restored the sight of countless U.S. citizens and enabled Air Force pilots to keep flying

The NCI study revealed that more than half of the SBIR/STTR awards resulted in sales of new cancer treatment and diagnosis related technologies. Furthermore, over 400 awards resulted in new treatment options, improving treatments for tens of thousands of cancer patients and likely saving thousands of lives.

In conclusion, the economic impact studies conducted by TechLink—the first-ever such studies of federal SBIR/STTR programs—demonstrate that these programs have more than achieved the major economic goals of the original enabling 1982 SBIR legislation and have provided an outstanding return on investment for the federal government. We hope this information will be helpful to your Committee as it considers reauthorization of the federal SBIR enterprise.

Sincerely,

Brett Cusker (Col. Ret.) Executive Director

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TOM RIDGE

May 29, 2019

The Honorable Marco Rubio
Chairman
Senate Committee on Small Business
and Entrepreneurship
Washington, DC 20510

The Honorable Ben Cardin Ranking Member Senate Committee on Small Business and Entrepreneurship Washington, DC 20510

Dear Chairman Rubio and Ranking Member Cardin:

On behalf of numerous state, local, university and nonprofit organizations around the country, SSTI thanks you for your leadership on reauthorizing the U.S. Small Business Administration's (SBA) innovation programs. The May 15th hearing on this issue addressed many important policy implications for American competitiveness, and we appreciate the opportunity to add our perspective for the record.

SSTI, a nonprofit organization founded in 1996, strengthens initiatives to create a better future through science, technology, innovation and entrepreneurship. The members that comprise our network work with researchers and entrepreneurs to transform American innovations into new solutions, products and jobs. These organizations provide technical assistance, business development services, investment capital and other support to scale innovations into economic opportunity.

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are the most important tools for supporting innovation related to the SBA. A multi-year review by the National Academies found that SBIR/STTR successfully produced commercialization outcomes¹ and their analysis adds to numerous stories of individual business successes catalyzed by the programs. Many organizations, including many SSTI members and those represented by the panelists on the May 15th hearing, are willing to testify to the importance of the overall program.

The administrative funds authorization (15 U.S. Code § 638mm) is a noteworthy "pilot" program within the SBIR/STTR code. Enabling agencies to use a portion of their allocation for administration facilitates program outreach, information availability, and commercialization assistance. The SBA's recent fiscal year 2016 report² presents a wide range of agency uses of these administrative funds, including participating in the SBIR Road Tour, hosting webinars targeting rural companies, establishing an application assistance

¹ National Academies of Sciences, Engineering, and Medicine. (2016). Capitalizing on Science, Technology & Innovation: An Assessment of the Small Business Research Program (Phase II). Washington, DC: National Academy of Sciences. Available: http://sites.nationalacademies.org/PGA/step/sbir/

² U.S. Small Business Administration. (2019). Annual Report FY 2016. Washington, DC: SBA. Available: https://www.sbir.gov/sites/default/files/FY16%20SBIR%20Annual%20Report%2004082019. master%20FINAL%20Signe d%20Copy%20adobe%20version%204.10.19%20%28002%29.pdf

program for underrepresented entrepreneurs, providing commercialization assistance to hundreds of businesses, and reducing the time between applications and awards. These activities are intrinsically logical and valuable to the operation of the federal government's primary tool for cultivating innovation. The SBA report further shows that the agencies are tracking—and achieving—tangible outcomes. We urge the committee to continue enabling these technical assistance, program improvements and outreach activities by making the administrative funds pilot permanent.

A second pilot of note is the Phase 0 proof-of-concept program (15 U.S. Code § 638jj) for the National Institutes of Health (NIH). This authorization has enabled the creation of commercialization-focused centers at medical sciences innovation clusters around the country (in Kentucky, Minnesota and New York). SSTI strongly supports a model designed to leverage federal funding through regionally-based public-private innovation strategies, and we look forward to seeing NIH's report on the model's impacts.

The Federal and State Technology Partnerships Program (FAST; 15 U.S. Code § 657d) also leverages federal funding through local commercialization expertise, as well as a local funding match. FAST seeks to increase awareness and outcomes in states that do not have a strong record in winning SBIR/STTR awards or to underrepresented entrepreneurs in any state. By working through state-level organizations, the program is able to reach the right potential audience and provide the most useful assistance as efficiently as possible. For example, lowa's assistance and mentoring network saw 86 applicants win 19 awards in FY 2018 alone, and Tennessee's initiative so far has led to 33 applications with (at least) six awards. For states that have placed in the bottom half of all states by number of awards, support for SBIR/STTR outreach and technical assistance is important.

FAST requires legislative changes, however. The program needs to be reauthorized and should be given an authorization and appropriation that enables larger FAST awards. Under the current funding opportunity, awards are capped at \$125,000, which is not enough to facilitate a significant impact across a state—particularly not a state that, by definition, is attempting to play catch-up with its peers. Awards of \$300,000 seem more appropriate to delivering FAST services.³ The program would also benefit from allowing SBA to receive more than one application per state. Currently, the FAST statute provides for only one application, which limits the competitive nature of the award and bars otherwise competitive candidates from consideration.

Ideally, FAST would be just one element within a toolbox of support for technology- and innovation-focused new businesses, which require special knowledge of technology transfer opportunities and regulation, market development and customer identification strategies, and structural considerations related to capital access. SBA has developed initiatives to provide some additional support for these businesses. The Growth Accelerator Fund Competition (GAFC) provides a small boost to accelerators around the country—the current funding opportunity provides \$50,000 to as many as 60 winners—and the Regional Innovation Clusters program (RIC) provides sector-specific support. Unfortunately, neither initiative is currently authorized, leading to much uncertainty for potential applicants.

³ We recognize that SBA is providing awards of \$125,000 in an attempt to balance appropriations of \$3 million—far less than the program's original \$10 million authorization level—against attempting to keep as many states as possible engaged in the program.

RIC's model of funding organizations that have expertise in a specific region and industry is particularly valuable for technology development. Each region has its own innovation strengths and weaknesses, and an organization within the area is often best-equipped to provide business assistance for maximizing its regional opportunities. The sector-specific approach is effective for new companies with a business-to-business sales model, which can greatly benefit from early introductions to key industry stakeholders, as well as in sectors with unique structural concerns that require expertise, such as energy's regulatory environment. Indeed, RIC is facilitating regional growth, such as Milwaukee seeing more than 100 pilot demonstrations and the formation of six new companies as part of a local, water-focused initiative, or northwest Arkansas experiencing 97 new products/services launched with more than \$77 million in private capital invested.

While FAST, GAFC and RIC provide targeted support for technology- and innovation-focused companies, these efforts do not provide adequate scale relative to the range of prospective businesses that could benefit from assistance. In total, these programs receive only about \$9 million in annual appropriations. For comparison, consider the level of investment in SBA's flagship innovation-focused programs: \$3 billion for SBIR/STTR and \$2.5 billion-\$4 billion per year for the Small Business Investment Company program (SBIC). SBIR/STTR is primarily for technical development of an innovation, while SBIC's primary activity is funding for companies at stages beyond venture capital. A significant gap exists between the business stages served by these two SBA programs, and yet funding for FAST, GAFC and RIC, which benefit companies in this gap, is just 0.15 percent of what is spent by the flagship programs to assist companies at either end of the gap.

The committee should test a new program to provide support to companies looking to bridge SBIR/STTR and SBIC that provides substantial assistance related to scaling sales and operations while attracting initial capital. Ideally, this program will leverage state- and local-level organizations that have demonstrable expertise in commercialization assistance, as well as connections to early-stage capital. Such a program, if operated at adequate scale, will be able to assist more companies in making a successful transition from the technology development stage to commercial success. An alternative approach would be to fund FAST, GAFC and RIC with a substantially higher appropriation. While this would be an improvement on the current situation, a new program instead provides the opportunity for entrepreneurs to receive one-stop technology and business support at once and is therefore the more complete solution.

Once again, we appreciate the committee's attention to reauthorizing the SBA's innovation programs. Better policies and greater investment in technology commercialization can yield a greater return on our research and development investment. SSTI and our members stand ready to work with you and the U.S. Senate Committee on Small Business and Entrepreneurship throughout this process.

Sincerely

Dan Berglund President and CEO

SSTI

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