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United States House of Representatives Committee on Small Business

Oversight of the Small Business Innovation Research and
Small Business Technology Transfer Programs

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Executive Summary

- The Biotechnology Industry Organization (BIO) represents over 1,100 innovative biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 states.

- The vast majority of BIO's members, about 90%, are pre-revenue companies whose research is still in the lab or the clinic. Product sales do not fund their groundbreaking research; instead, small biotechs rely on outside sources for innovation capital.

- The SBIR program provides biotech companies an opportunity to obtain funding for early-stage research projects in order to advance their research and development to the point that it can attract the hundreds of millions of dollars from the private sector necessary to develop the initial project into a publicly available new medicine.

- SBIR plays a critical role in supporting small U.S. biotech companies and funding their early-stage research as they navigate the "valley of death," a critical time when the scientific concepts have shown promise but the development is not far enough along to attract later-stage investors that could fund expensive clinical trials.

- BIO strongly supported the SBIR/STTR Reauthorization Act of 2012, which made two vital reforms to the SBIR program:
  - It allowed majority venture-backed companies to once again be able to participate in the SBIR program; and
  - It modified affiliation rules so that SBIR applicants will not be affiliated with their investors' portfolio companies simply on the basis of shared investors.

- The restoration of SBIR eligibility to venture-backed companies will be vital for the success of the program in the biotech industry. Virtually all biotechs depend on venture financing at some point in their development cycle.

- BIO applauds the SBA for issuing eligibility and affiliation rules that implement clear, bright-line tests that will not unduly ensnare growing companies.

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Testimony of Cartier Esham, Ph.D.

Good afternoon Chairman Graves, Ranking Member Velázquez, Members of the Committee, ladies, and gentlemen. My name is Cartier Esham, and I am the Executive Vice President of Emerging Companies at the Biotechnology Industry Organization (BIO). BIO represents more than 1,000 innovative biotech companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place.

The vast majority of BIO's member companies, about 90%, are pre-revenue companies whose research is still in the lab or the clinic. These small businesses – virtually all of which employ fewer than 100 workers – spend more than a decade conducting R&D in their search for groundbreaking medicines and life-saving treatments. During this years-long process of research and clinical trials, biotechs do not have any products to sell. Revenue does not fund the biotech development process, which can cost upwards of $1 billion. Instead, emerging biotech companies rely on outside sources for innovation capital. From early-stage angel investors and government grants to later-stage venture capitalists and public financing, biotechs are constantly searching for the capital to support their research.

The Small Business Innovation Research (SBIR) program provides biotech companies an opportunity to obtain funding for early-stage research projects in order to advance their research and development to the point that it can attract the hundreds of millions of dollars from the private sector necessary to develop the initial project into a publicly available new medicine.

Programs like SBIR are particularly important in a difficult fundraising environment for companies that generally depend on venture capital investment to finance early-stage research. In 2013, first-round venture financings (which support the earliest stages of breakthrough research) were down 35% compared to 2008 and in 2012 they were at a 15-year low.[1] Further, the first round's share of the total venture market is decreasing each year. As a result, breakthrough, early-stage biotech innovation is receiving less funding, meaning that the next generation of promising cures could be left on the laboratory shelf.

The importance of supporting biomedical research and innovation and the development of new treatments and therapies in the United States cannot be overstated, especially in a time where we are driving towards building a 21st century economy while simultaneously facing increased competition from around the globe to sustain our world leadership in biomedical innovation. We must focus on creating and delivering new solutions to our nation's most critical and costly public health issues and work towards continuing to improve the quality of life for patients and their families. For example, by 2030, almost one out of every five Americans – some 72 million people – will be 65 years or older.[2] Every year, American taxpayers spend $203 billion on Medicare and Medicaid expenses related to Alzheimer's, and this cost is projected to reach $1.1 trillion by 2050.[3] As almost 84 cents of every health care dollar spent is for taking care of individuals suffering from a chronic

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[1] PricewaterhouseCoopers, National Venture Capital Association. "MoneyTree Report." https://www.pwcmoneytree.com/MTPublic/ns/index.jsp.
[2] Alzheimer's Association. "2014 Alzheimer's Disease Facts and Figures." *Alzheimer's & Dementia*, Volume 10, Issue 2 (2014). http://www.alz.org/downloads/Facts_Figures_2014.pdf.
[3] Alzheimer's Association. "2014 Alzheimer's Disease Facts and Figures." *Alzheimer's & Dementia*, Volume 10, Issue 2 (2014). http://www.alz.org/downloads/Facts_Figures_2014.pdf.

disease,[4] it could not be more clear that we have a national imperative to find new solutions to how we treat patients and diseases.

We are also facing unprecedented competition from around the globe to be the leader in biomedical research. In 2008, China pledged to invest $12 billion in drug development, and in 2011, the Chinese government named biotech one of seven industries that will receive $1.7 trillion in government funding.[5] Further, the European Union's Innovative Medicines Initiative is pumping $2.65 billion into Europe's biopharmaceutical industry.[6] While America has developed more cures and breakthrough medicines than any other country and is home to over 2,500 biotech companies, this is not a position that will be sustained without continued investment and policies focused on supporting and incentivizing the next generation of biomedical discoveries, treatments, and cures.

Additionally, the U.S. biotech industry is an economic driver, directly employing over 1.6 million workers and supporting an additional 3.4 million jobs.[7] Small companies are the heart of the industry, and SBIR plays a critical role in ensuring that these companies are able succeed and provide the next-generation of medicines to the public.

SBIR/STTR Reauthorization Act of 2012

The mission of the SBIR program is to support scientific excellence and technological innovation through the investment of federal research funds in critical American priorities to build a strong national economy. In 2012, Congress passed the SBIR/STTR Reauthorization Act to ensure that agencies have the most competitive pool of applicants and that grants awarded will be based on the projects that show the most promise in bringing breakthrough and life-saving therapies to the public.

The SBIR/STTR Reauthorization Act of 2012 made two vital reforms to the SBIR program:

- It allowed majority venture-backed companies to once again be able to participate in the SBIR program; and
- It modified affiliation rules so that SBIR applicants will not be affiliated with their investors' portfolio companies simply on the basis of shared investors.

BIO strongly supported these important changes, which allow many small biotech companies to once again participate in the SBIR program and fund early-stage research that will lead to groundbreaking medical advances. Small businesses that are majority-owned by multiple venture capital companies, private equity firms, or hedge funds are now able to compete for 25% of SBIR funding at the National Institutes of Health (NIH), Department of Energy (DOE), and National Science Foundation (NSF), and 15% of SBIR funding at all other participating agencies. Similarly, SBA rule changes directed by the law also created a commonsense approach to affiliation that ensures companies are no longer affiliated with unrelated businesses simply on the basis of having common venture capital investors.

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[4] Anderson, Gerard. "Chronic Care: Making the Case for Ongoing Care." Robert Wood Johnson Foundation 2010. www.rwjf.org/content/dam/farm/reports/reports/2010/rwjf54583.

[5] Buckley, Chris. "China to invest US$1.7 trillion over 5 years in 'strategic sectors': US official." *The China Post* 23 November 2011. http://www.chinapost.com.tw/business/asia-china/2011/11/23/323724/China-to.htm.

[6] Hodgson, John. "€2 billion IMI launched with European pharma." *Nature Biotechnology 26*, 717-718 (2008).

[7] Battelle Technology Partnership Practice. "Battelle/BIO State Bioscience Industry Development 2012." June 2012. http://www.bio.org/sites/default/files/v3battelle-bio_2012_industry_development.pdf

Under the new rules, a small business must meet one of the following ownership requirements at the time of award of an SBIR Phase I or Phase II funding agreement:

- Be more than 50% directly owned and controlled by one or more individuals (who are citizens or permanent resident aliens of the U.S.), other business concerns (each of which is more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the U.S.), or any combination of these;
- Be more than 50% owned by multiple venture capital operating companies (VCOCs), hedge funds, or private equity firms, or any combination of these (but no single VCOC, hedge fund, or private equity firm may hold a majority stake in the small business); or
- Be a joint venture in which each entity to the joint venture must meet the requirements above.

The restoration of SBIR eligibility to venture-backed companies will be vital for the success of the program in the biotech industry. A 2009 National Research Council study conducted stated, "Restricting access to SBIR funding for firms that benefit from venture investments would thus appear to disproportionately affect some of the most commercially promising small innovative firms."[8] The study specifically touched on the lost potential for life-saving research, noting that the VC restriction had "the potential to diminish the positive impact of the nation's investments in research and development in the biomedical area."[9]

BIO applauds Congress for restoring SBIR eligibility to venture-backed companies. Because of this change, innovative biotechs across the country will benefit from early-stage funding for the next generation of cures and treatments.

Affiliation Rules

The SBA's general principles of affiliation state that "affiliation exists when one business controls or has the power to control another or when a third party (or parties) controls or has the power to control both businesses."[10] These specific affiliation rules are important because they determine whether a company or individual should be considered "affiliated" and therefore which businesses' employees should be added to the SBIR applicant's employee count to determine if the company falls below the 500 employee threshold for SBIR eligibility.

A limited number of venture capital firms invest in the biotech space, and thus many companies share investors – but the individual biotech companies do not have shared business goals or risks. Before the 2012 SBIR reauthorization, many biotech companies were deemed ineligible because they had multiple investors who owned 10-20% of the SBIR applicant, which was considered large compared to other investors' ownership. Not only were these investors deemed affiliated, but all of their portfolio companies where they owned 10-20% of a company (and their ownership was considered large compared to other owners) were also affiliated to the SBIR applicant.

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[8] National Research Council (US) Committee for Capitalizing on Science, Technology, and Innovation, "An Assessment of the Small Business Innovation Research Program." National Academies Press (2009).

[9] National Research Council (US) Committee for Capitalizing on Science, Technology, and Innovation, "An Assessment of the Small Business Innovation Research Program." National Academies Press (2009).

[10] U.S. Small Business Administration, "Small Business Compliance Guide Size and Affiliation." March 2014. http://www.sba.gov/sites/default/files/affiliation_ver_03.pdf

The SBIR/STTR Reauthorization Act of 2012 explicitly states that affiliation should not be determined solely on the basis of one or more shared investor, a provision that BIO strongly supported. The new rules put in place appropriately focus on determining if indeed the SBIR applicant has shared business goals and risks. Further, the new tests are clear, concise, and consistent so that small companies can more easily determine their eligibility.

Specifically, under the new rules, an SBIR applicant is affiliated to any individual, business, or entity that owns or has the power to control more than 50% of the applicant's voting stock. The rule provides a clear, bright-line affiliation test for companies whose stock is widely held. When determining affiliation based on equity ownership:

- An SBIR applicant is an affiliate of an individual, business, or entity that owns or has the power to control more than 50% of the SBIR applicant's voting equity.
- The SBA *may* deem affiliated an individual, business, or entity that owns or has the power to control 40% or more of the voting equity of the SBIR applicant *based on the totality of circumstances*.
- If no individual, business, or entity is found to control the SBIR applicant, the SBA will deem the Board of Directors to be in control of the SBIR applicant.

BIO strongly supports this rule, and applauds the SBA for implementing clear, bright-line tests that will not unduly ensnare growing companies. In the biotech industry, there are a finite number of investors, which often have investments in the same biotech small businesses – but they remain individual investments for each venture capital firm. Emerging biotechs are generally a collection of research projects with one lead product and an average of five other therapies or candidates in early-stage/pre-clinical research. It is the goal of each investor to succeed in developing and commercializing each individual research project they have funded. The success of each investment is based on scientific outcomes, which are not influenced by the progress of other companies' research within the same portfolio. The new affiliation rules reflect this reality by only determining affiliation if an SBIR applicant is truly controlled by another entity.

Measuring the Success of the 2012 SBIR Reauthorization

On May 15, 2012, SBA published a proposed rule for determining ownership, affiliation, and size standards. On December 27, 2012, SBA published the final rule, which went into effect on January 28, 2013. In May 2013, NIH reissued its SBIR Omnibus Grant Solicitation announcement, and stated that small businesses majority-owned by multiple venture capital operating companies were eligible to apply for those SBIR grants and any other NIH SBIR funding opportunities announced after January 28, 2013. We do not yet have data on how many majority venture-backed companies applied for or were awarded SBIR grants under this new rule as the closing date for applications was January 2014 and many of these applications are still being reviewed.

The SBIR/STTR Reauthorization Act also provides authority for three participating agencies to give Phase II awards to a small businesses concern that did not receive a Phase I award for that research/R&D. This allows companies that may have funded their own Phase I-type research to apply for Phase II funding. In February 2014, NIH announced its SBIR Direct Phase II pilot program. BIO strongly supported this provision in the reauthorization process and will be monitoring NIH's pilot program to determine success.

Lastly, BIO did have some concerns regarding the numerous reporting requirements for companies that are majority backed by venture capital. We will be monitoring our members

to determine whether these requirements are effective or unduly burdensome to small companies. We will also be working to encourage other SBIR participating agencies to 'opt-in' and allow all U.S. *small* businesses the opportunity to compete for SBIR grants.

Conclusion

The extended biotech development timeline, driven by the complicated nature of scientific advancement, means that it can cost more than $1 billion to bring a single life-saving therapy to market. This entire process is undertaken without the benefit of product revenue – instead of using the sale of one product to finance the development of another, growing innovators turn to external sources to fund their breakthrough R&D.

SBIR plays a critical role in supporting small biotech companies and funding their early-stage research as they navigate the "valley of death," a critical time when the scientific concepts have shown promise but the development is not far enough along to attract later-stage investors that could fund expensive clinical trials. Biotech innovators and entrepreneurs use these funds to speed the delivery of the next generation of medical breakthroughs – and, one day, cures – to patients who need them. BIO applauds Congress for making key reforms to the SBIR program to ensure eligibility for innovative small businesses in the biotech industry, and we look forward to continuing to support this vital program.