HEARING TESTIMONY

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ON BEHALF OF THE

BIOTECHNOLOGY INDUSTRY ORGANIZATION

BEFORE THE U.S. SENATE COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP

"REAUTHORIZATION OF THE SBIR AND STTR PROGRAMS"

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Good morning Chairwoman Landrieu, Ranking Member Snowe, Members of the Committee, ladies and gentleman. I am Joseph Hernandez, Chief Executive Officer of Signal Genetics, Executive Board member of the Maryland High Tech Council and Reviewer for the National Science Foundation. I am privileged to be here on behalf of the Biotechnology Industry Organization's (BIO) more than 1,200 member companies, academic institutions, state biotechnology centers and related organizations in all 50 states involved in healthcare, agricultural, environmental and industrial biotechnology.

In my career, I have had the privilege of being involved early on in the development of cutting edge biotechnologies such as the DNA microarray, a tool which has revolutionize our knowledge of genetics and the role of our genes play in disease. I was also involved with Digene, a company that revolutionized cervical cancer diagnostics by developing the first molecular test for the Human Papilloma Virus (HPV), the causative agent in cervical cancer. I have licensed technologies from universities, built management teams, received SBIR awards, raised over $30 million in venture capital and launched many products. More recently, I have been involved in the establishment of early-stage companies and have firsthand experience of the challenges and difficulties of getting these companies off the ground. I currently run a personalized medicine company where we use a person's DNA to determine the degree of risk of their cancer and identify the best course of treatment. This approach offers better patient outcomes, but also serves an important role in managing treatment costs. We recently launched our first product in Multiple

Myeloma and look forward to bringing additional similar products to the market. It is with this background of experiences that I offer my comments today.

The role of the SBIR program in bringing breakthrough therapies to the American people is a matter of record. Awards have helped companies fund proof of concept studies which enabled them to attract the private-sector funding required to develop a new treatment or therapy that is ultimately made available to patients. Despite its noble past, the ability of the SBIR program to provide critical funding for medical research projects will remain hampered unless SBIR reauthorization modernizes the program to address the current realties facing small, innovative American biotechnology companies.

As you know, Congress created the SBIR program in the early 1980's because it recognized that promising early stage scientific research all too often failed to be funded through the markets because it was viewed as too high risk. This failure of the markets is often referred to as the "valley of death." As developers of the next-generation of treatments for diseases that would have been considered unapproachable just a decade ago, it is incumbent on our system to find ways to support these risky, yet transformational, therapies that could improve the lives of children and adults suffering from genetic disorders, infectious diseases, cancer, and autoimmune diseases, among others. We want to take advantage of the ground-breaking scientific discoveries in basic research that has been achieved in the last decade at NIH, in academic centers, and in industry and translate them into tangible treatments as rapidly as possible to improve the lives of patients. This holds enormous benefits for the individuals affected, the organizations and companies working on these initiatives, and our society in general.

For twenty years small, domestic biotechnology companies competed for SBIR grants. In addition to providing funding, these grants were a powerful signal to the private sector that a company's research was compelling and possessed scientific and technical merit. However, in 2003 the Small Business Administration's Office of Hearings and Appeals (OHA) ruled that a biotechnology company, Cognetix, did not meet the SBIR size standard because multiple venture capital investors, in the aggregate, owned more than 50% of the company's stock. The ruling, which is not based on the SBIR statutory language, ignores the realities of the marketplace where small biotechnology firms must raise tens of millions of dollars to conduct incredibly time and capital-intensive research. It is estimated that it takes between 8 and 12 years to bring a biotechnology therapy to market and costs between $800 million and $1.2 billion. These small biotech firms typically have fewer than 50 employees, no products on the market, and must raise considerable funds through a combination of angel investors and venture capital firms in order to make a new therapy available to patients.

Since the exclusion of small majority venture-backed companies, the National Institutes of Health (NIH) have documented disturbing trends. There was a 40% decline in the number of applications between 2004 and 2008 and in 2009 the number of new small businesses participating in the program decreased to the lowest proportion in a decade. Additionally, the impact of the recession on small biotechnology companies is still being felt. In fact, according to the National Venture Capital Association, venture capital

companies raised $12.3 billion in 2010 - the 4th consecutive year of decline and the slowest annual period since 2003. A 2009 joint study by BIO and Thompson Reuters found that the economic crisis forced 80% of biotech investors to change their investment approaches. They can no longer afford to invest in high-risk projects characteristic of early-stage biotechnology companies. This trend is expected to continue, making investment in early-stage cutting-edge research, even for a company's lead project, extremely difficult to obtain. In fact, the number of active public biotechnology companies fell 25% from January 2008-2010 and among those still in existence, 38% had less than one year of cash on hand.

SBIR can play a critical role in aiding small biotechnology companies in their early stage research to navigate through the "valley of death," helping small innovative U.S. companies advance, and ensuring that the U.S. maintains its global leadership in biomedical research. Unfortunately, the program's ability to help small innovative life science companies develop breakthrough treatments and therapies that offer hope to patients and potential solutions to our nation's most critical health care needs has been severely compromised by preventing the majority of small biotechnology companies from competing for awards based on scientific merit. To quote the National Research Council's 2009 report, *Venture Funding and the NIH SBIR Program*, "...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." The report goes on to note that the current SBA eligibility rules have "the potential to diminish the positive impact of the nation's investments in research and development in the biomedical area."

Eligibility for small biotechnology companies that are a majority-owned by multiple venture capital companies should be reinstated. This will ensure that awards are provided to small, U.S. biotechnology companies that have the best science and greatest potential to provide treatments and therapies that will improve public health.

It is equally important that the reauthorization clarify SBA affiliation regulations. Under current SBA regulations, when determining the size of a business, the SBA considers the number of direct employees at the business as well as affiliated businesses' employees. In the world of biotechnology venture capital investors, a single venture capital company often has investments in 5-10 other biotechnology companies. As such, a typical small biotechnology company has multiple venture capital company investors, each owning a minority share of the company but often collectively owning more than 50%. An SBIR applicant with 50 employees can be deemed affiliated not only with its venture capital companies who have minority ownership but with hundreds of employees from those venture capital companies' other portfolio companies. This occurs despite the fact that the SBIR applicant has no business relationship with those portfolio companies other than a shared investor.

Not only are these affiliation rules nonsensical, the manner in which they are applied is often a mystery to the small business applying for the SBIR grants. As a result, a small company may certify in good faith that it is eligible for an SBIR grant, only to later find

out that the SBA has affiliated it with a large number of employees at other unrelated companies, thus making the small business ineligible.

BIO believes that the reauthorization should create a more rational and effective affiliation process regarding determinations about an SBIR applicant's investor's portfolio companies. Specifically, affiliation should be based on criteria such as evidence of a mutually beneficial business relationship (contracts, shared profits, etc.) and not by virtue of a shared investor. This common-sense reform will protect the integrity of the program and provide clarity for small business entrepreneurs looking to participate in the program.

At the end of last Congress, the Senate passed a compromise reauthorization bill. BIO supported passage of that bill in the Senate and we still do. It included improvements to the current program in that it would allow majority-venture backed companies to compete for up to 25% of funds at NIH, NSF and DOE and up to 15% in other SBIR programs. The bill also provided language that would direct the SBA to promulgate rules for determining affiliation so as to ensure that such determinations are not based solely on one or more shared investors. It is our hope that the Senate passes a bill that includes these provisions and that the House and Senate will pass a bill that can be signed into law by the President this year.