HEARING TESTIMONY

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BEFORE THE HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY, SUBCOMMITTEE ON

TECHNOLOGY AND INNOVATION

"THE ROLE OF THE SBIR AND STTR PROGRAMS IN STIMULATING INNOVATION AT

SMALL HIGH-TECH BUSINESSES"

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Good morning Chairman Wu, Ranking Member Smith, Members of the Committee, ladies and gentleman. I am Jim Greenwood, President and CEO of the Biotechnology Industry Organization (BIO). I am privileged to be here this morning on behalf of BIO's 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.

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

As you know, Congress created the SBIR program in the early 1980's because it recognized that promising, early stage scientific research all too often failed to be funded through the markets because it was viewed as too high risk. This failure of the markets is often referred to as the "valley of death." The importance of advancing science through the valley of death has never been more important than it is right now as numerous small biotechnology companies are being forced to shelve promising therapies as result of the current economic crisis. In fact in just the last five months, at least 25 U.S. public biotech companies have either placed drug development programs on hold or cut programs all together. These programs include therapies for HIV, cervical cancer, Multiple Sclerosis, and diabetes.

For 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 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 to make a therapeutic commercially available to patients.

The impact of the current economic crises on small biotechnology companies has been and continues to be severe. According to the latest available data, 30 percent of small, publicly-traded biotechnology companies are now operating with less than 6 months of cash on hand, a 90 percent increase relative to 2007. Forty-five percent of these companies have less than 1 year of cash remaining. The total capital raised by the industry in 2008 has seen a steep decline (down 55% in 2008 compared to 2007).

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

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

A small biotechnology companies is generally engaged in several projects with one lead product and an average of 5 other therapies or candidates in early stage/pre-clinical research. Typically, a biotechnology company will begin fundraising for its lead product in development. Companies generally raise between $5 million and $15 million in their first round of venture financing, an amount that often results in multiple venture capital companies collectively owning more than 50% of the company. This is especially the case with very young companies whose valuation may reflect their high-risk, early stage nature. However, it is typically the case that no single venture capital company will own more than 15 to 25 percent of the company's equity.

Despite the extensive fundraising a biotechnology company undertakes for its lead product, these funds are tied to very specific milestones to support the lead product's development. As such, in order to develop secondary or tertiary candidates/therapies a company has to find secondary sources of fundraising capital. At the very earliest stages of development other sources of financing, such as SBIR grants, have been instrumental in advancing research and development in biotechnology.

Opportunity to Strengthen/Restore SBIR Program

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

I will briefly discuss each of these important goals.

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

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

The current SBA interpretation would deem eligible a public company with 499 employees and significant – perhaps hundreds of millions – of dollars in revenue. . However, a private company with 20 employees, no annual revenue and $8 million in venture capital by multiple venture capital funds equaling 56% of the company's equity – even though no one venture capital firm has more than 30% of total equity – is ineligible. A significant number of BIO's emerging companies are ineligible, the majority of which would apply to SBIR if able. These companies are working on breakthroughs for the treatment of diseases such as cancer, Alzheimer's, lupus, and leukemia.

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

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

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

BIO respectfully asks the Committee to reinstate the eligibility of small, VC-backed biotechnology firms to compete for SBIR awards. This will ensure the most competitive pool of applicants and that grants

awarded will be based on projects that show the most promise in bringing breakthrough therapies to the public.

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

It is equally important that the reauthorization clarify SBA affiliation regulations. Under current SBA regulations, when determining the size of a business, the SBA considers the number of direct employees at the business as well as affiliated businesses' employees. Businesses are affiliates of each other if the SBA determines that another business has either affirmative or negative control. Current regulations state that a venture capital company that holds a minority share in another business can be considered an affiliate of that business. If the SBA determines a venture capital company is affiliated with the business, not only are the employees of the venture capital company included in the size determination but so are the employees of other businesses in which the venture capital firm is invested.

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

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

BIO recommends the reauthorization bill provide language to clarify that minority investment by a venture capital operating company does not make that company an affiliate of another company for the purposes of determining size. This is a common-sense measure that will provide clarity and peace of mind for small business entrepreneurs looking to participate in the SBIR program.

Maintain Agency Flexibility

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

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

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

CLOSING REMARKS

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