HEARING TESTIMONY
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BEFORE THE HOUSE OF REPRESENTATIVES COMMITTEE ON SMALL BUSINESS

"REAUTHORIZING THE SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM"

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Good morning Chairwoman Velázquez, Ranking Member Chabot, Members of the Committee, ladies and gentleman. I am Jim Greenwood, President of the Biotechnology Industry Organization (BIO). I am privileged to be here this morning on behalf of BIO.

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in 50 U.S. states and 31 other nations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The overwhelming majority of BIO member companies are small, early stage research and development oriented companies pursuing innovations that have the potential to improve human health, expand our food supply and provide new sources of energy.

The historical role of the SBIR program in bringing breakthrough therapies to the American public is a matter of public record. There are 252 FDA approved biologics that have been developed by 163 companies and affiliates. Thirty-two percent of those companies and affiliates have received at least one SBIR/STTR award. It is clear the SBIR program has played an important role in helping small biopharmaceutical companies obtain critical funding at early stages of research and development. However, I am here today to discuss the future of the SBIR program, not its past. Unless the SBIR Reauthorization updates the program to address the current realities facing small, innovative American companies, the ability of the SBIR program to provide critical funding for therapies and treatments that have the most potential of improving the public health is hampered.

I want to start by commending the Committee for recognizing that SBIR Reauthorization is an appropriate vehicle to foster the important linkage between early-stage R&D funding and new medical breakthroughs. Congress created the SBIR program in the early 1980's in order to utilize the capabilities of small, innovative, domestic companies to fulfill federal research and development needs. Congress recognized that some early

stage, promising scientific research failed to be funded by private-sector capital because it was viewed as too high-risk. This failure of the markets is often referred to as the "valley of death". In biotechnology, the "valley of death" delays potential therapies for HIV, cancer, and infectious diseases from reaching patients, who often lack other comparable alternatives. For twenty years the program worked well for U.S. life sciences companies engaged in high-risk, cutting-edge medical research.

However, in 2003 the Small Business Administration (SBA) Office of Hearings and Appeals (OHA) arbitrarily ruled that a biotechnology firm, Cognetix, did not meet the SBIR size standard because multiple venture capital investors, in the aggregate, owned more than 50 percent of the company's stock. This new interpretation of the SBA's SBIR regulations has denied medical research funding to an untold number of small biotechnology firms over the past several years. The ruling is not based on the SBIR statute, in which Congress specifically encouraged private-sector investment in SBIR applicants.

The ruling ignores the realities of the biotechnology marketplace. Small, emerging biotechnology companies have high and intense capital needs that rely on the involvement of venture capital investment. The Tufts Center for the Study of Drug Development estimated it takes between 8 and 12 years to bring a biotechnology therapy to market and costs between $800 million and $1.2 billion. The majority of small biotechnology companies are without any product revenue for a decade or more. They are generally a collection of research projects with one lead product and an average of 5 other therapies or candidates in early stage/pre-clinical research. Companies generally begin fundraising for lead products in development and raise between $5 million and $15 million in their first round of venture financing, an amount that usually results in multiple venture capital companies collectively owning more than 50% of the companies. However, it is typically the case that no single venture capital company will own more than 25-35% of the equity.

Despite the extensive fundraising a biotechnology company must undertake for the lead products, these funds are not interchangeable to fund the other more early stage research projects. It is for these other projects, in the earliest stage of development but with tremendous potential to benefit the public, that SBIR funding has been critical. Funding from the SBIR program helps to create a path from the spark of an idea to scientific validation and development, and ultimately becoming available to the public.

The ruling is a misinterpretation of the SBA's regulations to ensure that SBIR applicants are U.S.-owned, domestic companies, a goal we fully support. However the use of capital structure as proxy for determining domesticity and the subsequent OHA ruling has had the unintentional consequence of excluding a sizeable portion of the biotechnology industry that would otherwise be eligible to participate in the program. These are companies that have participated in the SBIR program for 20 years prior to this ruling and were a fundamental part of the aforementioned success of the SBIR program. Moreover, these small companies are solely based in the United States and are majority-funded through a combination of U.S.-based venture capital companies and citizens.

Since implementation, this ruling appears to be negatively impacting the competitive pool of SBIR applicants and the program's ability to award projects based on scientific merit and commercialization potential. In fact, applications for SBIR grants at NIH have declined by 11.9 percent in 2005, by 14.6 percent in 2006, and by 21 percent in 2007. Additionally, the number of new small businesses participating in the program has decreased to its lowest proportion in a decade.

Numerous BIO member companies have shared examples with this Committee of promising discoveries that have been shelved or delayed as result of being ineligible for the SBIR program. The Director of the National Institutes of Health, Dr. Elias Zerhourni, said it best in a letter to SBA Administrator Barreto in 2005: *"NIH believes that the current rule undermines the statutory purposes of the SBIR program...It undermines NIH's ability to award SBIR funds to those applicants whom we believe are most likely to improve human health."*

The reauthorization of the SBIR program presents an opportunity to restore the program and ensure the most competitive pool of U.S. small business applicants. The reauthorization presents an opportunity to ensure that grants are awarded on scientific merit and potential to improve public health, and not on capital structure.

It is equally important 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 (even if only it only owns a minority share), not only are the employees of the venture capital company included in the size determination, but so are the employees of all 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, just because the companies share a common investor.

For these reasons, among others, I commend Chairwoman Velázquez, Ranking Member Chabot and the Members of the Committee for their foresight in including a remedy to the eligibility issues affecting small biotechnology and medical device companies in the reauthorization legislation soon to be introduced It is the right thing to do and this is the right time to do it. On behalf of America's biotechnology companies, I look forward to working closely with you to see this much-needed change enacted into law this year.

BIO also supports the proposed provisions in the reauthorization that provide agencies with the flexibility and authority to determine amount of awards and number of times a project can be awarded under Phase II. BIO concurs that one of the great strengths of the SBIR program is that Congress provided the affected departments and agencies with

flexibility in establishing the program. Agencies should maintain the flexibility to award larger grants, if the project they are funding is 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. Agencies should be the best judge of how to use their SBIR funds to advance science and commercialize new innovations.

I would also like to commend the Committee for drafting legislation that re-affirms and fosters the original goals of the SBIR program, namely the commercialization of new technologies by small, innovative American companies. Specifically, BIO supports the modernization and reauthorization of the Federal and State Technology (FAST) Program that will assist agencies in their outreach efforts to areas traditionally underserved by the SBIR program. And secondly, BIO supports the authorization of funds for agencies to develop and expand commercialization programs. These programs will enable the SBIR program to attract the most innovative science companies and provide assistance in the early stages of the process, as well as better equip these small businesses with the tools necessary to achieve commercialization of a new therapy or treatment.

Before I close today I would also like to discuss recommendations that would help ensure taxpayer funds are being used in an efficient and effective manner. The SBIR program is not a basic research program, it is about developing new products for the benefit of society. There have been concerns expressed over the number of grants an individual company may receive from the SBIR program. While BIO supports agency flexibility, we would support reasonable limitations, such as capping the number of awards per company to 5 -10 awards per year/per company. The bill does contain some provisions addressing these concerns by requiring the SBA to release the names of firms that have received multiple Phase I grants and zero Phase II grants and promulgate rules for the agency to address these awardees. We support this effort but are concerned these provisions may not fully address "gaming the system" concerns. For example, a single company that has over 40 Phase I awards and 1 or 2 Phase two awards over a five year period would not be included in this oversight.

No company should make SBIR grants the basis of its business model. SBIR exists to fill the funding void for companies that are raising private capital to do their research and development. Any company that receives excessively large numbers of SBIR grants year after year, without commercializing technology, is probably not the type of company in which the federal government should be investing taxpayer resources. We look forward to working with the Committee to ensure the intent of these provisions is fully realized.

The 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.

Again, thank you for the opportunity to testify today. I would be happy to answer any questions Members of the Committee might have.