



**STATEMENT OF THE
BIOTECHNOLOGY INDUSTRY ORGANIZATION**

**FOR THE HOUSE SMALL BUSINESS SUBCOMMITTEE ON
RURAL ENTERPRISES, AGRICULTURE AND TECHNOLOGY**

**HEARING ON
“THE IMPORTANCE OF THE BIOTECHNOLOGY INDUSTRY
AND VENTURE CAPITAL SUPPORT IN INNOVATION”**

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Chairman Graves, Ranking Member Barrow, Members of the Subcommittee:

Thank you for the opportunity to testify before you today on the Small Business Innovation Research (SBIR) grant program.

My name is Doug Doerfler, and I am President and CEO of MaxCyte, a biotechnology therapeutics company in Maryland. I have led the development of biotechnology companies and products for over 25 years. We founded MaxCyte in 1999, have 20 employees and are developing novel therapeutics using cells that have been modified by our process to treat serious diseases. We have one product in Phase I/II clinical human testing for the treatment of patients with Leukemia and additional products in pre-clinical development for the treatment of lymphoma, breast and ovarian cancers. These programs are in major Universities including Baylor, The University of Pennsylvania and Harvard University. MaxCyte was the proud recipient of a Phase I SBIR grant in 2003 but we are no longer eligible to participate based solely on our source of investment capital.

Today I am testifying on behalf of the Biotechnology Industry Organization (BIO), an organization representing over 1,100 companies, universities, research institutions, state biotechnology associations and affiliates in 50 states.

BIO thanks the Subcommittee for holding this hearing on the SBIR grant program, and applauds the introduction of H.R. 2943, the Save America's Biotechnology Innovative Research Act, by Chairman Graves. We ask your permission to submit for the record a letter in support of Chairman Graves' legislation signed by 281 biotechnology CEOs from 37 states.

BIO represents many established companies in the industry. Over eighty-five percent of BIO members, however, are small, emerging companies with fewer than 500 employees. In fact, more than fifty percent of BIO member companies have fewer than 50 employees. Not surprisingly, the SBIR program has played a critical role in providing necessary financing for small biotechnology companies, including many BIO members.

Unfortunately, however, a recent interpretation by the Small Business Administration (SBA) regarding the eligibility requirements for the SBIR program has prevented the majority of BIO members from participating in the program. Specifically, beginning in 2003, the SBA Office of Hearings and Appeals ruled that companies that were venture capital-backed in excess of 50% were no longer eligible for SBIR grants.

Prior to this ruling, during the 21 years the SBIR program has been in existence, majority venture capital-backed biotechnology companies fully participated in the program.

H.R. 2943 would rectify this problem and allow venture-backed small biotech companies to once again pursue their innovative and cutting edge research under the SBIR program.

By way of background, I would like the Committee to understand the unique aspects of the biotech industry. The average development cycle for biotechnology products is 15 years. Therefore, before most biotechnology products can become commercially available, years of

research and often **hundreds of millions of dollars of capital** are required to complete testing, gain product approval, and build the necessary manufacturing infrastructure. While there are many different funding strategies, the typical form of investment in promising, early-stage biotech companies is venture capital.

In our industry, even the relatively small amount of money a company will raise in its first round of financing (Series A), \$5-8 million, generally will result in the new investors - usually a collection of venture funds - owning more than 50 percent of the company.

Therefore, both SBIR and VC funding is necessary to support the lengthy and costly clinical development process. Limiting government support for this biotechnology R & D risks delaying the discovery and development of promising new therapies for cancer, diabetes, Parkinson's and, significantly, many disease areas where there is less commercial focus, like tuberculosis or diseases that would qualify for an orphan drug classification.

In fact, according to a recent letter from Dr. Elias A. Zerhouni, Director of the National Institutes of Health (NIH) to the SBA, which I would also like to submit for the record, the SBA's current eligibility rule excluding majority venture capital-backed biotechnology companies "...dries up Federal funding for early-stage ideas from small concerns that, by attracting substantial VCC funding, show strong signs of likely success. Many of these concerns are the very entities that, with SBIR funding, offer significant promise for progress in improving public health." Dr. Zerhouni goes on to state that the SBA's rule "undermines NIH's ability to award SBIR funds to those applicants whom we believe are most likely to improve human health, which is the mission of NIH."

While almost all of BIO's member companies will need to raise venture financing to advance their products toward the marketplace, many small biotechnology companies have come to rely upon the SBIR program to fund cutting-edge research in areas where venture capital and other sources of financing are difficult to obtain.

For example, while a company is working on a lead research program, it often comes across new potential indications or new project opportunities that they will need to test before attempting to raise additional money. These new opportunities are precisely the type of research projects that should be eligible for SBIR grants. MaxCyte's project falls into this category.

Last month, BIO conducted a survey to understand the nature and scope of this problem for our industry. 274 companies responded to the survey. We continue to study the responses, but early results confirm that SBA's current SBIR size standard is severely limiting and discouraging small biotechnology companies from participating in the program.

Of the 274 companies surveyed, an estimated 9% reported having been turned down from the program, and an estimated 55% of the respondents said they are no longer applying for SBIR grants. Importantly, 34% of the respondents so far said they delayed or cancelled a research project due to their SBIR ineligibility. These projects included a promising new drug for lupus, a cell therapy for delayed wound healing in diabetes, and therapies to protect cells and organisms against anthrax and radiation exposure.

During MaxCyte's fundraising process in 2003, we submitted a proposal to NIH to do basic research in our technology and expand its capability so one day it may be used for biodefense or pandemic influenza vaccine development. Venture funds were not interested in this project as it was too early and risky but were clearly motivated by our team's ability to obtain the attractive scores for our program through the NIH study section process. We received \$95,000 in funding for our Phase I and subsequently closed on a \$10.7M venture round. We were able to satisfy the rigorous milestones of our project including breakthrough science to prove general concept - but we are now not eligible to participate in any future funding for this project by the SBIR program. Due to this ineligibility, this program has been suspended. This is extremely frustrating since we believe that this project may have a future impact on biodefense and help in the pandemic flu crisis.

The legislative history makes it abundantly clear that Congress intended for the SBIR program to assist small businesses in commercializing their creations and products and to stimulate small U.S.-owned firms to produce innovative technologies. Congress viewed the SBIR program as providing the necessary "proof of concept" to encourage venture capital investment in promising small businesses seeking to bring products from the workshop to the marketplace. Moreover, Congress even created a Phase II SBIR preference for companies that attracted venture capital investment by providing special consideration in the funding review of Phase II proposals. Thus, it is plain that Congress intended to create a research program as much as it intended to create a small business program.

BIO believes that the enormous promise of biotechnology research and development merits exploration and investment on a variety of fronts and by a spectrum of creative, dynamic, and dedicated entities. Biotechnology is a fertile field, from which patients can reap huge benefits - if it is supported by both public and private investment. The rewards of biotechnology are limitless, unless we choose to limit them by limiting who can participate in this effort. I urge the Subcommittee to favorably report H.R. 2943. Thank you for your time and attention to this matter.