



**Changes in the SBIR Program Threaten  
Biotechnology Company Funding  
September 4, 2003**

**Issue and BIO Position**

- **Recent changes in the Small Business Administration's (SBA) interpretation of eligibility standards for SBIR grants now disqualifies many start-up biotechnology companies with venture capital backing. SBA regulations require that, to be eligible for a grant, a small company must be at least 51 percent owned by one or more individuals. Recently, the SBA has interpreted "individuals" to exclude venture capital and venture funds.**
- **BIO strongly believes the new interpretation threatens an important funding source for emerging or start-up biotechnology companies across America. BIO recently filed comments with the SBA on this issue.**
- **We urge the Administration and Congress to restore the eligibility for SBIR grants to venture capital backed start-up biotechnology companies.**

**Background**

The Small Business Administration (SBA) provides start-up funding to small businesses in a variety of ways. One program is the Small Business Innovation Research program (SBIR). Under the SBIR program, a specific percentage of all federal R&D grant monies are reserved for small business applicants. Although the SBA has authority and responsibility for monitoring, coordinating and reporting the results of the program to Congress, SBIR awards are actually granted by other Federal Agencies (*see* list— Attachment I). These funds provide critical "seed" money to new business innovators.

Small and emerging biotechnology companies often depend on SBIR grants to fund R&D activities. According to a recent (informal) poll of BIO's Emerging Company Section

Board, more than half of the respondents wrote that their companies relied on SBIR grants to fund their products on the way to commercialization. *See* poll summary (Attachment II). SBIR grants in no way sustain emerging biotech companies over the course of the 10 to 15 year development phase to bring a product to market. Most biotech companies must rely heavily on outside investors, and especially venture capital, in order to sustain their R&D efforts.

To qualify for SBIR grants, a small business applicant must meet a variety of eligibility requirements. The size and ownership requirements -- or "size standard" -- limit eligibility to those companies that:

- Are at least 51 percent owned and controlled by one or more *individuals* who are citizens of, or permanent resident aliens in, the United States; and
- Have no greater than 500 employees, including its affiliates.

On January 10, 2001, the SBA Office of Hearings and Appeals (OHA) handed a decision, *CBR Laboratories, Inc.*<sup>1</sup>, that the definition of "individuals" no longer included venture capital backed companies. This new interpretation of "individuals" resulted in the denial of a SBIR grant to CBR Laboratories, Inc. of Boston, Massachusetts because the company was venture capital-backed in excess of 51% [see Attachment III for detailed chronology of events surrounding CBR Laboratories, Inc.].

The CBR Laboratories, Inc. decision was the first interpretation by SBA, disqualifying venture funding as part of SBIR eligibility requirements and putting such funding in conflict with the 51% individually owned standard. In the late spring of this year, BIO became aware of another disqualification due to venture funding after Cognetix, Inc., a biopharmaceutical company based in Salt Lake City, UT. Cognetix received notice that their SBIR grant was similarly denied and that denial was upheld on appeal [see Attachment IV for a chronology of events surrounding the Cognetix, Inc. situation]. BIO heard from a wide range of start-up biotech companies regarding valid fears that this important funding may now be shut off to companies with significant venture capital funding.

Venture capital investment is a prominent source of capital for biotechnology research and development. Before most biotechnology products can become commercially available, years of work and hundreds of millions of dollars of investment capital are required to complete adequate testing and in order to gain product approvals. While there are many different funding strategies, the typical form of investment in promising, early-stage companies is venture capital. Such capital comes from venture funds, whose partnership interests are usually owned by individual investors and pension funds. After the initial seed funding is invested in support of basic R &D and the launch of commercial operations, a typical biotechnology company seeks venture capital investment to allow it to expand its enterprise. Very few biotechnology companies are capable of commercializing their technologies without significant VC backing. This is

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<sup>1</sup> Appeal No. 4423 (2001)

made evident by the fact that VC investments in the biotechnology and medical device industry totaled \$4.7 billion in 2002<sup>2</sup>.

### **The Proposed Rule**

On June 4, 2003, the SBA requested comments on a proposed revision to the SBIR's size standard, "to allow a small business that is owned and controlled by another business concern to be eligible for funding agreements under the SBA's SBIR Program." The proposed rule would add a new clause allowing for-profit businesses that are wholly owned by another entity to meet the size standard if that other entity meets the 51 percent U.S. individual-ownership standard.

Although the proposed change would allow small subsidiaries, such as Limited Liability Corporations, to be eligible for SBIR awards, it fails to address the newly imposed limitation on venture capital backing.

On July 7, 2003, BIO responded to the SBA's request for comments [*See Attachment V*]. BIO's comments cite the legislative history of the SBIR program, as did Cogentix in its appeal, noting that, "When Congress first enacted the SBIR program, it very clearly recognized the symbiotic relationship between venture capital and the SBIR program it was creating and expressly intended to encourage and strengthen that important connection." BIO's comments recommend changes to the proposed regulation that would allow small businesses with venture capital investors to participate in the SBIR program.

### **Contact:**

The Biotechnology Industry Organization (BIO) represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 states. BIO members are involved in the research and development of health care, agriculture, industrial and environmental biotechnology products.

**For other information and any questions, contact Sharon Cohen at 202-962-9200.**

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<sup>2</sup> Money Tree Survey –Price Waterhouse Coopers, [www.pwcmoneytree.com](http://www.pwcmoneytree.com)

## **Attachment I**

### **Federal Agencies Eligible to Participate in the Small Business Administration's SBIR Program**

- Department of Agriculture
- Department of Commerce
- Department of Defense
- Department of Education
- Department of Energy
- Department of Health and Human Services
- Department of Transportation
- Environmental Protection Agency
- National Aeronautics and Space Administration
- National Science Foundation

**Attachment II**

Poll of ECS Board Members on the Effects of the SBIR Size Determination on their Companies  
July 15, 2003

**CONFIDENTIAL**

<b>Company</b>	<b>Co. eligible?</b>	<b>Applied for SBIR?</b>	<b>If yes, how many and how many received?</b>	<b>SBIR used in devp't of lead products?</b>	<b>Comments</b>
A	Don't think so.	Yes	1 for 4	Yes	
B	No	Never--planned to do so this year but weren't aware that would not qualify for Phase 2 portion	N/A	No	
C	No	No	N/A	No	
D	No	No	N/A	No	
E	No	Yes	Received 1; 1 pending	Yes!	
F	No	Yes	Applied for 2, received 1, other is outstanding	No	
G	No	Yes	Two Phase 1 grants: 2 for 2	No, used to fund pilot programs	
H	No	No	N/A	No	
I	No	No	N/A	No	
J	No	Yes	1 for 1: Phase 1 SBIR	One of lead products is currently supported by SBIR grant	
K	Yes	No	N/A	No	
L	Yes	No	N/A	No	
M	Yes	Not at this company, but at another small biotech co. That co. was not 51% owned by individuals.	At other co.: Applied for and got 2 Phase 1 grants	Development of lead products was supported by Phase 1 grants at other co.	SBIR support being sought at GeneEx
N	Yes	Yes	5 for 5	Yes	
O	Yes	Yes	Applied for 2, received 1	Yes	
P	Yes	Yes	0 for 2	No	
Q	Yes	Yes	1, both Phase 1 and 2	Yes	
R	Yes right now, but prob. not in future.	Yes	Applied for 2, received 1	About to start accessing them for lead product development	

## **Attachment II (Continued)**

Analysis: 18 respondents  
10 out of 18 applied for SBIR grants in the past

A slightly different 10 out of 18 said that their companies would not be eligible  
1 out of 18 responded that although their company was eligible now, it probably would not be in the future.

Therefore, 11/18 respondents thought they would be negatively impacted by the new interpretation of the SBIR size determination requirements.

6 of 11 negatively affected companies have applied for and received SBIR grants in the past.

4 of 6 used the SBIR grants that their companies received to develop lead products.

## Attachment III

### Chronology of SBA Size Determination of CBR Laboratories, Inc.

- On September 29, 2000, the SBA Area Office in Boston Massachusetts issued a size determination for CBR Laboratories, Inc. In its decision, the SBA noted that the company did not meet the definition of small business for purposes of the SBIR program. CBR Laboratories, a for-profit corporation, was a wholly-owned subsidiary of the Center for Blood Research, Inc. (CBR), a U.S. not-for-profit 501(c) corporation. SBA explained that CBR Laboratories, which was wholly owned by CBR, was ineligible for SBIR funding because it was not at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States.
- On October 16, 2000, CBR Laboratories appealed the SBA decision. The company argued that the Area Office erroneously interpreted the term “individuals” in its size determination to mean only natural persons, therefore excluding entities such as corporations.
- On November 1, 2000, the SBA denied CBR Laboratories’ appeal. The Agency declared that it correctly interpreted the term “individuals” to exclude entities absent specific criteria for determining whether that entity qualified as U.S. owned. An “individual,” as defined by the SBA in *CBR Laboratories*, can only be a natural person and not an entity—such as a venture capital fund, pension funds or a corporation.

## Attachment IV

### Chronology of Size Determination of Cognetix, Inc.

- On April 7, 2003, the SBA made a “formal size determination” in response to a size determination application submitted by Cognetix. The Agency’s ruling was “[Cognetix] is not at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent residents aliens in, the United States, [Cognetix] does not meet the definition of a small business for purposes of the SBIR program. Therefore, [Cognetix] is not eligible for the Phase II SBIR award.” The SBA cited its decision in the *Size Appeal of CBR Laboratories* appeal as precedent for their decision.
- On April 28, 2003, Cognetix filed an appeal of size determination to the SBA Office of Hearings and Appeals (OHA). The appeal petition alleged that the Area Office committed reversible error in ruling that Cognetix was not a small business for purposes of the SBIR program. Cognetix presented a three-part argument, stating that; 1) applying the *CBR Laboratories* decision would be inconsistent with congressional intent as seen in the legislative history for the SBIR program; 2) the *CBR Laboratories* decision was not controlling because Cognetix was neither wholly-owned by one entity, nor owned by a corporation; and 3) pension funds, and to some extent, venture capital funds, are aggregates of individuals, and, thus, these funds are eligible to be counted under the 51 percent individual-ownership requirement for the SBIR program.
- On May 13, 2003, BIO delivered a letter to SBA Administrator Hector Barreto asking the agency to reconsider its narrow interpretation of the term “individuals.” The letter also pointed out the detrimental effects that the agency’s interpretation would have on small and emerging biotechnology companies.
- On May 29, 2003, the SBA denied the Cognetix’s Phase II SBIR grant, restating its position that, “The term ‘individuals’... means only natural persons and does not include venture capital funds, pension funds, and corporate entities for purposed of an SBIR award. Thus, a firm that is otherwise eligible for an SBIR award is disqualified because it is less that 51 percent owned by natural persons.”
- Subsequent to the May 29, 2003, ruling by the agency, a number of BIO member companies and affiliates have expressed concern regarding SBA’s interpretation of the SBIR regulations.





BIOTECHNOLOGY  
INDUSTRY  
ORGANIZATION

July 7, 2003

Mr. Gary M. Jackson  
Assistant Administrator for Size Standards  
Office of Size Standards  
U.S. Small Business Administration  
409 Third Street SW.  
Washington, D.C. 20416

Dear Administrator Jackson:

The Biotechnology Industry Organization (BIO), is pleased to respond to the request for comments on the U.S. Small Business Administration's (SBA) Proposed Rule to modify the small business eligibility requirements for receiving Small Business Innovation Research Program (SBIR) funding (68 FR 33412) published on June 4, 2003.

BIO is a trade association representing over 1000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. Our membership represents a complete cross-section of the industry, from small, research-based start-ups to mid-sized and large well-established biotechnology companies. The vast majority of BIO members are emerging companies focusing on the research and development of new products, goods or services flowing from biotechnology.

Before most biotechnology products can become commercially available, years of work and hundreds of millions of dollars of investment capital are required to complete adequate testing and to gain product approvals. While there are many different funding strategies, the typical form of investment in promising, early-stage companies is venture capital. Such capital comes from venture funds, whose partnership interests are usually owned by individual investors and pension funds. After the initial seed funding is invested in support of basic R&D, a typical biotechnology company seeks venture capital investment to allow it to launch its commercial operations. Simply put, very few biotechnology companies are capable of commercializing

their technologies without significant VC backing. VC investments in the biotechnology and medical device industry totaled \$4.7 billion in 2002<sup>1</sup>.

## Background

The SBIR program regulations require that, to be eligible for SBIR grants, companies must be “small” (<500 employees) and “[a]t least 51 percent owned and controlled by one or more *individuals*.” 13 C.F.R. § 121.702 (emphasis added). Based primarily on a relatively recent SBA Office of Hearings and Appeals (OHA) decision, the SBA has interpreted the word “individuals” to mean only “natural persons”. . . See *CBR Laboratories, Inc.*, SBA No. 4423. As indicated by the Preamble to the Proposed Rule, however, it quickly became clear to the SBA that *CBR Laboratories* created an unreasonably narrow SBIR eligibility standard because agencies participating in the SBIR program often received proposals from a “concern that is owned by another concern [and] [t]he concern’s size, together with its parent company, will often be below the 500 employee size standard for an award, while its parent is at least 51 percent owned and controlled by one or more U.S. citizens or permanent resident aliens”. 68 Fed. Reg. 33,412 (June 4, 2003). Under the strict interpretation articulated in *CBR Laboratories*, such a company would be ineligible for SBIR funding. The Proposed Rule is intended to restrict the scope of *CBR Laboratories* by finding that a company falling within the above-referenced scenario would be eligible for SBIR funding.

Although BIO fully supports the Proposed Rule’s effort to restrict the application of *CBR Laboratories*, recent events demonstrate that the rule must be further revised because OHA continues to impose unduly restrictive SBIR eligibility standards. Specifically, the National Institutes of Health (NIH)—one of the agencies participating in the SBIR program — has recently applied *CBR Laboratories* to revoke a SBIR grant awarded to an otherwise eligible small business that had significant venture capital and pension investors.. OHA upheld the appeal of the agency’s decision, and in doing so ruled that the word “individuals” in the SBIR size standard excluded not only corporations but also all other forms of artificial entities, including venture capital and pension funds. See *Cognetix, Inc.*, SBA No. 4560. By revoking an award to an otherwise eligible small VC-backed biotechnology company, NIH created another form of the problem that the Proposed Rule was designed to cure.

The impact of the *Cognetix* decision is immediate and severely negative for the emerging biotechnology industry—especially in the current economic climate in which SBIR awards are even more important because of the scarcity of capital. Removing this important funding source for early stage biotechnology companies would penalize the most promising small companies, i.e. those able to win VC backing as well as SBIR funding. In companies that are backed by venture capital funds, the venture capital

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<sup>1</sup> Money Tree Survey –Price Waterhouse Coopers, [www.pwcmoneytree.com](http://www.pwcmoneytree.com)

investment funds generally own more than 51 percent of the company and the “individual” shareholders are the founders, employees, friends of the company, and angel and family investors. This typical combination of venture funding and only modest investment directly by individuals, boosts “non-individual” ownership above the 51 percent level very early in a company’s existence and, in virtually every instance, would render the small business ineligible for SBIR funding. Very few, if any, biotechnology companies are able to fund the clinical and preclinical work needed to validate a technology without venture investment – the cost of development is simply too high to be sustained by individuals. The legislative history of the SBIR program makes it abundantly clear that Congress intended for the SBIR program to assist small businesses to commercialize. Indeed, when Congress enacted the SBIR program through the Small Business Innovation Development Act (P.L. 97-219), it recognized the crucial relationship between venture capital and SBIR program in commercializing promising technologies.

### **Changes Proposed in the Pending Rulemaking**

The Proposed Rule would continue to apply the “51 percent” test but would clarify that a company may be eligible for SBIR funding if it is 100 percent owned by an entity which, in turn, is 51 percent or more owned by “individuals” (who are U.S. residents). Unfortunately, this modification does not address the problem biotechnology companies with venture capital backing are experiencing. As noted above, VC-backed companies are usually more than 51 percent owned by VCs but they are never 100 percent owned by VCs. Moreover, VCs, as entities, are not 51 percent or more owned by US “individuals”.

### **Recommended Changes to the Proposed Rule**

Congress’ intent, when implementing the SBIR program, was to *stimulate small U.S.-owned firms to produce innovative technologies*. When Congress first enacted the SBIR program, it very clearly recognized the symbiotic relationship between venture capital and the SBIR program it was creating and expressly intended to encourage and strengthen that important connection. See S. Rep. No. 97-194, 97<sup>th</sup> Cong., 1<sup>st</sup> Sess. 1981, *reprinted in*, 1982 U.S.C.A.A.N. 512. For example, there is an entire section of the relevant Committee report detailing the importance of encouraging private investment. Indeed, the Committee concluded that concluded that

providing small firms with R&D seed money . . . will encourage additional private investment in these firms. The agency-wide SBIR program outlined in the legislation should facilitate the ability of participating firms to attract venture capital as well as other financial commitments from the private sector.

See Committee Report at 7. Thus, the SBIR program was viewed by Congress as providing the necessary “proof of concept” to encourage venture capital investment in promising small businesses.

Moreover, Congress even went so far as to provide “special consideration in the funding review of Phase II proposals to applicants who are successful in attracting private capital commitments to pursue commercial applications of the Federal research. This special consideration is given by awarding extra points of merit to those proposals that have attracted private sector commitments for follow-on funding.” Report at 7-8. Thus, Congress created a Phase II SBIR preference for companies that attracted venture capital investment. Application of the “51 percent” rule is clearly at odds with Congressional purposes.

Small biotech companies that are successful in attracting venture capital investment are, therefore, a paradigm of SBIR success. Attracting outside capital investment is not only the clear intent of the SBIR program, it is also the type of success that Congress recognized as meriting *more* SBIR support in the form of a Phase II award preference. The current interpretation of the word “individuals” simply cannot be squared with Congressional intent to encourage venture capital investment in small businesses. Without revising the Proposed Rule to correct the *Cognetix* decision, SBA will be foreclosing the very companies that the SBIR program was designed to assist from receiving SBIR awards.

### **Recommended Changes to the Proposed Rule**

BIO recommends that SBA expand the Proposed Rule to allow small businesses with venture capital investors to participate in the SBIR program. This could be accomplished by providing that investments by venture capital be ignored when assessing whether there is 51% ownership. This is analogous to the exception in the affiliation rules under which venture capital investments are ignored in determining the eligibility of companies for small business status. 13 C.F.R. § 121.103(5)(i).

BIO commends the SBA for attempting to address the concerns of small business owners and urges the SBA to make appropriate changes to the current and proposed regulations in order to exclude ownership by venture capital firms as a factor in determining SBIR eligibility. We request that application of these changes be made retroactive to allow companies previously awarded SBIR grants, whose grants were revoked due to the current interpretation of the regulations, the opportunity to continue to receive funding from this important source.

Please contact me at 202-962-9215 or Lila Feisee at 202-962-9502 if you have any questions about these comments.

Sincerely,

BioTechnology Industry Organization

*Stephan E. Lawton*  
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