



BIOTECHNOLOGY  
INDUSTRY  
ORGANIZATION

May 13, 2003

Hector Barreto  
Administrator  
U.S. Small Business Administration  
409 3<sup>rd</sup> Street  
Washington, D.C. 20416

Dear Mr. Barreto,

I am writing this letter on behalf of the Biotechnology Industry Organization (BIO), the trade association representing biotechnology companies all over the world, to urge the U.S. Small Business Administration to reconsider its definition of a "small business" for the purposes of the Small Business Innovation Research (SBIR) program.

On April 7, the SBA denied "small company" status to one of BIO's member companies, Cognetix, Inc., because it determined that the majority of Cognetix stock is owned by institutional investors rather than individuals. According to SBA regulations, a company must be at least 51 percent owned and controlled by one or more individuals who are U.S. citizens. The SBA has defined "individuals" to mean only natural persons, not corporations or venture funds. Under this definition, if a company has more than 49 percent of its stock in the hands of U.S. investors who are not "individuals" (such as venture capital operating companies, investment companies, and employee benefit or pension plans), the company would not be deemed eligible for Phase II SBIR grants. This policy is of great concern to BIO because it has broad implications for the viability of emerging biotechnology companies.

BIO represents many different entities and interests, including start-up biotechnology companies working to improve the human condition through the delivery of new products, goods or services flowing from biotechnology. Before most biotechnology products can become commercially available, years of work and millions of dollars of investment capital are required to complete adequate testing and secure the necessary approvals. The vast majority of this funding comes from venture and investment capital. Without such funding, biotechnology companies would not have the resources to develop novel biotechnology products. Indeed companies such as Cognetix would be forced to suspend development of their products and take drastic administrative action.

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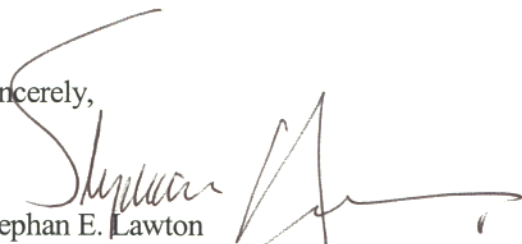
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It is BIO's view that the SBA's position on the definition of small business does not reflect Congressional intent when putting in place the SBIR program. Nor is it consistent with the administration's policy of giving priority to innovation and encouraging advancements in technology.

The biotechnology industry is critical to America's economic development. Small businesses—the intended beneficiaries of the SBIR awards—cannot survive without outside investment. 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 typically owned by individual investors and pension funds benefiting such investors. In addition, some capital comes directly from pension funds. Often, early-stage companies are obliged, because of scarcity of capital, to enter into collaborations with larger biotechnology or pharmaceutical firms for the development of their novel compounds. This typical combination of venture funding, industry collaboration 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.

Many, if not most, biotechnology firms would fail the “individual” test if venture capital investors, larger corporate collaborators and pension funds continue to be excluded from the “51 percent rule” under the SBA's strict interpretation of one regulation. This interpretation would be a heavy blow to the industry and, indeed, the economy. I urge you to closely review this policy and make appropriate changes in SBIR regulations.

Sincerely,



Stephan E. Lawton  
Vice President and General Counsel  
Biotechnology Industry Organization

SEL:ltr

cc: Maurice Swinton, Assistant Administrator, Office of Technology, SBA  
Major Clark, Procurement Officer, SBA  
Paul Noe, Solicitor, Office of Management & Budget