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Shaping the Destiny of Your Genes

January 21, 2005

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

Re: SBIR participation by companies owned by venture capital firms and other large institutions

Dear Mr. Jackson:

I write in opposition to the proposed changes to the SBIR rules which would permit small companies owned 51% or more by venture capital firms (and other large entities) to compete for and obtain SBIR funds.

My opposition is grounded in two perspectives. I am the founder and CEO of AlphaGenics, an early stage biotechnology company using genomics and computers to develop individualized dietary strategies intended to optimize how a person's genes are working. I am also an adjunct professor of economics and finance at Johns Hopkins University. I created and teach three courses in the Biotechnology Masters Program: Financial Development; Economics of Biotechnology; and Creating the Biotechnology Enterprise. My perspective, therefore, includes historical development of biotechnology funding.

My background includes a Ph.D. in Human Genetics from Michigan, my masters in management from MIT, where I was an Alfred P. Sloan Fellow, and my law degree from American University. I practiced business and technology law for a dozen years, and am admitted to the United States Patent Bar and the bar of the United States Supreme Court. I've been involved in technology enterprises, including computer technology, for 40 years, have taught in a medical school and three business schools, and worked on national health policy for Sec. Joseph Califano during the Carter Administration.

Supporters of the change falsely assert that "VCC investment is crucial to startups in the biotech industry..." This is simply untrue. Very little VCC capital is available today for biotech startups, or early stage biotech companies. This has been true for the past three years, and in fact was true for most of period before the so-called Internet Bubble, when cash flowed into lots of sectors.

VCC's are very risk adverse today. This is a change from a decade ago when most VCC's still practiced the portfolio investment model. If you look at the three technology investment areas: computers, telecom and biotechnology, biotechnology is the riskiest, by far. The reason is that the commercial uncertainty in biotechnology lies in two up-front areas: the science and the regulatory climate. First, early stage biotechnology companies are working the science to develop a solution. There are no guarantees that a solution can be found by a company. And even if a solution is found, there are time consuming and expensive regulatory requirements that must be satisfied before it can be brought to market. This is why the pharmaceutical industry says it takes $800 million and a dozen years to bring a new drug to market.

SBIR funds enable a small company to push their science forward. Success in phase I and then phase II makes the company more attractive for a variety of funding channels, because the risk has been lowered.

The most likely funding channel ironically is not the VCC but larger companies who view the small company's development as potentially filling the large company's product pipeline. Historically, most of the biotech successes obtained early funding from angels and corporate partners, not VCC's. There are notable exceptions of course, such as Human Genome Sciences.

Another reason that the rules should not be changed is the so-called camel's nose under the tent. It will be difficult to argue that small companies owned by other large investors should be blocked from SBIR competition. It is easy to foresee that most of the Fortune-1000 involved in biotechnology would accelerate their venture activities. Even more likely will be new R&D spinouts that are owned by the parent, but are legally small entities. These new spinouts will be backed by internal funds from the parent, and would then compete for the limited pool of SBIR money.

Non-profits will also copy this spin-out model. Universities are becoming more active in spinning out their technologies. Under the proposed rule, they could have a professor become a minority owner of spin-out. The professor could then apply for both an SBIR, from the company, and the traditional R01's from the Universities. Because the SBIR reviews at NIH involve academic researchers, it is not hard to imagine the traditionally successful universities getting additional funds from the SBIR channel in competition with independent small businesses.

Large foundations can do the same. As you know, 501(c)(3) status does not prevent a foundation from owning a for-profit entity. It is the reverse that is prohibited. Thus large foundations would have an interest in funding research through entities it owns in whole or in part (there is no difference between 51% ownership and 99% ownership). Again, this tilts the playing field away from the independently owned biotechnology startup.

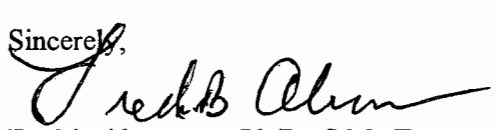
Finally, permitting VCC majority owned companies to compete for SBIR's will dramatically decrease the number of independent biotechnology companies because adding these to the SBIR eligible list will decrease funding for those in the existing pool. This will cause more bio startups to fail because they won't get their SBIR funding. In turn, this shrinking pool will become increasingly dependent on outside funds, which will become more costly. In other words, their cost of capital will rise.

The spiral can continue until the VCC's claim of their role in early stage biotechnology becomes a self-fulfilling prophecy. All the independent biotechnology companies wither and die, and all that's left are VCC and large entity backed companies.

This cannot be the intention of the SBIR program, to permit large institutional investors take control of the early stage biotechnology industry.

Thus, I urge you to reject the proposed changes.

Sincerely,



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