



National Institutes of Health
Bethesda, Maryland 20892

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The Honorable Hector V. Barreto
Administrator
United States Small Business Administration
409 Third Street, S.W.
Washington, DC 20416-0001

Dear Administrator Barreto:

I am writing to express concern that current Small Business Administration (SBA) limits on eligibility for Small Business Innovation Research (SBIR) awards, in the context of biomedical and public health research, unduly restrict the ability of the National Institutes of Health (NIH) to fund high quality, small companies that receive venture capital (VC) investment. As a result, NIH must turn away many deserving applicants, and the goals of the SBIR program are being undermined. I ask that you consider a waiver to enable NIH to remedy this problem and look forward to discussing it with you.

The legislation establishing the SBIR program was signed into law on July 22, 1982, by President Reagan. As stated in the SBA's *SBIR Program Policy Directive*, "the statutory purpose of the SBIR program is to strengthen the role of innovative small business concerns (SBCs) in federally-funded research or research and development (R/R&D). Specific program purposes are to:

- (1) stimulate technological innovation;
- (2) use small business to meet Federal R/R&D needs;
- (3) foster and encourage participation by socially and economically disadvantaged SBCs, and by SBCs that are 51 percent owned and controlled by women, in technological innovation; and
- (4) increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity and economic growth."

Consistent with these goals, the NIH SBIR program supports a wide array of biomedical and public health R/R&D activities of small, innovative firms. But, in today's high risk biomedical research environment, in areas such as drug development, drug discovery, and therapeutics, fewer than one percent of the innovative, promising projects reach the marketplace. Research in public health and biotechnology is characterized by the following features:

- High and intense capital needs (i.e., up to \$1 billion) to see a product from idea to market;
- Unusually long development time (i.e., 5-12 years);

- Exceptionally high “burn rate” for investment funds;
- Significant investment by venture capital companies (VCCs), many of whom are not owned at least 51 percent by natural persons;
- Multiple rounds of venture capital financing required; and
- Except for the smallest service-oriented entities, majority ownership and control by natural persons or business concerns majority owned by natural persons is extremely unlikely for R&D companies with significant market potential.

Given that the landscape for small business entities in the public health and biotechnology sector presents unique challenges, NIH is concerned that SBA's new eligibility rule, while opening the field somewhat, leaves out many small concerns, and, in turn, substantially damages the NIH's SBIR program. By limiting eligibility to concerns that are owned at least 51 percent by natural persons, or another concern that is itself owned 51 percent by natural persons, the rule disqualifies many highly-deserving small entities. Perversely, this rule 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. NIH believes that the current rule undermines the statutory purposes of the SBIR program to “*stimulate technological innovation*” and to “*increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity and economic growth.*” Furthermore, it 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.

NIH shares SBA's commitment to ensuring that only small business concerns receive SBIR awards. To advance this goal, and ensure that NIH also meets its need to support deserving R/R&D in the biotechnology field, I ask SBA to consider a waiver from certain eligibility standards for some concerns. Specifically, in addition to applicants eligible under current rules, the NIH requests that SBA permit it to award funds to small businesses when:

A concern is owned and controlled, at least in part, by a single VCC or multiple VCCs, provided that at least 51 percent of the concern is owned by U.S. individuals and/or VCC(s) that are owned no more than 49 percent by foreign business entities or individuals, and, provided further, that applicable small business affiliation standards are satisfied.

While many details of this proposal remain to be discussed between our two agencies, and its precise formulation may change as we work together, please understand that NIH aims to ensure that small business concerns with substantial VCC support in the biotechnology and public health R/R&D arena are able to receive SBIR awards from NIH. We do not aim to include concerns that are owned and controlled by large companies and believe that adherence to existing affiliation rules will limit this risk.

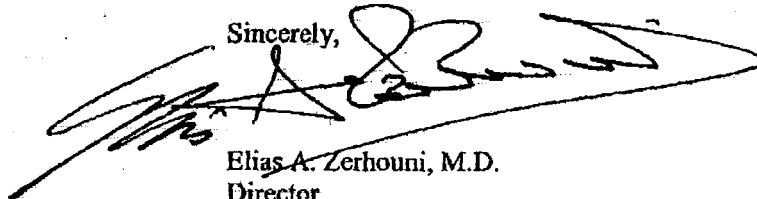
As additional background, I note that this request is not unprecedented. In the past, SBA waived SBIR program parameters and granted NIH the opportunity to make SBIR awards for certain

types of biomedical R&D projects requiring time and dollars above the amounts specified in applicable Policy Directives.

In signing into law the legislation that established the SBIR program, President Reagan stated, *"We in government must work in partnership with small businesses to ensure that technologies and processes are readily transferred to commercial applications."* The program was designed *"to strengthen the role of the small, innovative firms in federally funded research and development, and to utilize Federal research and development as a base for technological innovation to meet agency needs and to contribute to the growth and strength of the Nation's economy."*

In keeping with President Reagan's directive, NIH believes that it must be able to make SBIR awards to many small biotechnology concerns currently excluded from participation. We look forward to working with you on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'E. Zerhouni', written over a horizontal line.

Elias A. Zerhouni, M.D.
Director