

September 18, 2009

The Honorable Mary L. Landrieu, Chair
U.S. Senate Committee on Small Business and Entrepreneurship
428-A Russell Senate Office Building
Washington, DC 20510

Dear Madam Chairwoman:

We, the undersigned patient, medical, and health science advocates, request your help in correcting a regulatory interpretation that now stifles promising research that could improve the lives of people suffering from many debilitating diseases. Specifically, we urge you to ensure that the Small Business Innovation Research (SBIR) Reauthorization legislation before your Committee restores full access for majority venture capital-backed biotechnology and medical device companies to apply for SBIR grants.

We firmly hold that the SBIR program should fund the most promising research, that which provides promise and hope for millions of patients. Allowing VC-backed companies to once again fully compete for SBIR funds is critical to bring future life-saving therapies, vaccines, and cures to patients.

The SBIR program awards federal research and development grants to small-business applicants with the goal of commercializing successful, innovative research. Unfortunately, changes in the Small Business Administration's (SBA) interpretation of eligibility standards for SBIR grants now disqualify many start-up biotech and medical device companies, some of which have the greatest potential for successfully bringing a life-saving product to market.

Specifically, SBA regulations now require, to be eligible for a grant, a small company to be at least 51 percent owned by one or more "individuals." The SBA has re-interpreted "individuals" to exclude venture capital companies, thereby disqualifying many bioscience and device companies from receiving these important grants. For the first 20 years of the SBIR program, the term "individuals" was interpreted to allow venture capital-backed biotech and device companies to fully participate in the SBIR program. Under the present interpretation, that participation is no longer possible, and patients suffer as a result.

From the health advocate perspective, we are concerned that the current SBA interpretation eliminates from eligibility research projects that otherwise merit funding because of the financial structure of the company. We hold firmly that the most promising science should move forward and we do not support the current interpretation under which the NIH must turn away otherwise deserving applicants.

Small U.S. biotech and medical device companies are working to develop drugs, vaccines, diagnostics and devices that target more than two hundred diseases, including various cancers, heart diseases, Alzheimer's disease, diabetes, multiple sclerosis, arthritis

and a whole host of rare diseases. For many of these companies, the SBIR program provides critical early-stage funding for innovative research and development (R&D). These small companies take significant risks to conduct breakthrough research and develop "miracle" treatments desperately needed by many patient populations in the U.S. and around the world.

It must be understood, however, that it takes, on average, 10 to 15 years of development to bring a product to market. Although SBIR grants are a critical research funding source, in no way does an SBIR grant sustain emerging biotech or device companies over the course of the development process. Most biotech and device companies must rely heavily on outside investors, primarily venture capital, in order to sustain their R&D efforts.

Both the House and Senate SBIR Reauthorization bills recognize the importance of allowing venture-capital owned small businesses to compete for SBIR funds. Unfortunately, we do not support the VC provision in the Senate legislation (S. 1233), which caps the amount of funding that NIH and other agencies can award to venture capital-backed small businesses. Such a restriction is unnecessary and undermines the merit-based nature of the peer-review grant process at the participating agencies. As the National Research Council wrote in their recent study regarding venture capital and the SBIR program, "Restricting access to SBIR funding to firms that benefit from venture investments would risk disproportionately affecting some of the most promising innovative firms. To this extent, the SBA ruling has the potential to diminish the positive impact of the nation's investments in research and development, especially in the biomedical area." The Research Council also found that VC-backed small businesses that received SBIR grants prior to the 2003 ruling did not harm the program. In our view, it does not make sense to artificially limit the participation of those small businesses that often have the best potential to advance cutting-edge and life-changing early-stage medical research.

As Chairwoman of the Senate Small Business Committee, your leadership is needed to help innovative research move forward in order to foster breakthrough cures. On behalf of patients in America and around the world, and researchers and health advocates, we urge you to reauthorize the SBIR program in a way that allows majority venture capital-backed small businesses to compete on a level playing field with other small businesses, and to eliminate all unnecessary restrictions on their participation in the SBIR program.

Respectfully,

AA CSA Foundation
AIDS Vaccine Advocacy Coalition
Alliance for Aging Research
Alpha-1 Association
Alpha-1 Foundation
American Autoimmune Related Diseases Association

BIO Ventures for Global Health
C3: Colorectal Cancer Coalition
Californians for Cures
CANN - Community Access National Network
Celiac Disease Center at Columbia University
Children's Tumor Foundation
Colon Cancer Alliance
COPD Foundation
Epilepsy Therapy Project
Foundation Fighting Blindness, Inc.
Genetic Alliance
International AIDS Vaccine Initiative
International Cancer Advocacy Network
Kidney Cancer Association
Lung Cancer Alliance
Men's Health Network
Michael J Fox Foundation
MLD Foundation
Muscular Dystrophy Association
National Alliance for Caregiving
National Alliance for Eye and Vision Research
National Alliance on Mental Illness
National Health Council
National Multiple Sclerosis Society
National Organization for Rare Disorders
Parkinson's Action Network
PXE International
RetireSafe
Society for Women's Health Research
The Association for Research in Vision and Ophthalmology
The Asthma and Allergy Foundation of America
The Sturge-Weber Foundation
Vital Options International

cc:

The Honorable Olympia Snowe
The Honorable Nydia Velazquez
The Honorable Sam Graves
The Honorable Bart Gordon
The Honorable Ralph Hall