

February 1st, 2008

The Honorable John Kerry
Chairman
Small Business and
Entrepreneurship Committee
428A Russell Senate Office Building
United States Senate
Washington, DC 20510

The Honorable Olympia Snowe
Ranking Member
Small Business and
Entrepreneurship Committee
428A Russell Senate Office Building
United States Senate
Washington, DC 20510

The Honorable Nydia Velazquez
Chairman
Small Business Committee
2361 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20515

The Honorable Steve Chabot
Ranking Member
Small Business Committee
B-363 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20515

The Honorable Bart Gordon
Chairman
Science and Technology Committee
2320 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20515

The Honorable Ralph Hall
Ranking Member
Science and Technology Committee
H2-389 Ford House Office Building
U.S. House of Representatives
Washington, DC 20515

Dear Chairmen Kerry, Velazquez, Gordon and Ranking Members Snowe, Hall and Chabot:

As you consider reauthorization of the Small Business Innovation Research (SBIR) program, we urge you to keep the SBIR program true to its name, a small business program, and that you maintain the current small business standard that has served the SBIR program so well for the past twenty-five years.

SBIR has become one of the most successful technology development programs ever enacted by the federal government. True to its small business design, eighty-five percent of companies competing in the SBIR program employ twenty or fewer persons and the majority of companies employ fewer than five persons.

Now a powerful biotechnology venture capital lobby would like to change this highly successful program by changing the Small Business Administration's (SBA) definition of what a small business is, thus allowing billion dollar venture capital firms to participate

in the SBIR program and compete against true small businesses. Under the changes to the SBIR program proposed by the biotechnology venture capital lobby, virtually all venture capital groups could participate in the SBIR program. Many of these venture capital groups allow foreign investors, meaning that American taxpayers, through the SBIR program, would be financing the scientific and technological advancement, as well as the investment returns, of foreign individuals and corporations.

The venture capital lobby claims that current SBIR eligibility rules prohibit companies in which they have a majority ownership stake from competing with true small businesses for crucial SBIR early stage research and development funding, and that this could delay lifesaving SBIR medicines and technologies. In fact, the record on venture capital firms is that their first investment priority is rapid returns and quick profits, meaning they focus on innovations and technologies with large profitable patient populations, which for them takes precedence over lifesaving breakthroughs. An important question as you consider reauthorization of the SBIR program is: why are billion dollar biotechnology venture capital funds claiming lifesaving medical technologies are going undeveloped because companies they own cannot receive \$750,000 SBIR grants from National Institutes of Health (NIH)? One answer is that, through SBIR, these well funded venture funds want taxpayer dollars to mitigate their early-stage development risk. Why should we change this highly successful small business program to mitigate the risk of billion dollar venture capital firms?

The reality is that the current SBIR program has proven exceptional in producing rapid medical innovation and conducting high risk/reward research, not just for large patient population diseases, but also for the so-called orphan diseases with small patient populations. If the NIH is not doing enough to promote lifesaving breakthroughs, why is the agency not supporting early stage research through large venture capital majority-owned companies with the 97% of its budget that is not set-aside for small business through the SBIR program?

The National Institutes of Health publishes SBIR commercialization success stories. A list is attached that provides just a sampling of medical innovations created through the SBIR program over the past twenty-five years. As you look at these success stories, you will see that some depended on end stage venture capital funding, but most of the others relied on government funding, big business buy-outs, private equity, technology licensing, and even entrepreneurs mortgaging their homes. *Through the SBIR program, these small businesses remained independently owned, enabling them to bring to market innovative healthcare solutions and creating competition for larger venture capital-backed and major medical corporations.* Competition is a proven way of lowering healthcare costs and will remain so if the SBIR program continues as a true small business program. We all need lower healthcare costs.

The SBIR program has from its inception provided a pure small business path into federal research and development for small high-tech businesses and, in return, enabled small business technology and innovation in a broad spectrum of fields, not just health and NIH, but also defense, environment, energy, transportation, space exploration, and

agriculture. That's why the recent National Academy of Sciences study of the SBIR program called it "sound in concept and effective in practice." Critical to the success of the SBIR program in delivering rapid innovation is a highly competitive but level playing field for small businesses to do battle – let the best small business innovation or technology win. These proposed big venture capital changes would put true small businesses for the first time in competition with multi-million dollar venture capital backed businesses. This will end the competitive small business environment that has been the hallmark of the SBIR program.

The popular aphorism in Washington is, "If it ain't broke, don't fix it." There is absolutely no data that demonstrates the SBA's small business size definition or its clarification has excluded firms with venture capital, stopped important innovations for patient therapies and devices, or that the research of venture capital-owned and controlled firms has better quality or is commercialized more. We urge you to maintain the current small business standard for the SBIR program and keep it a true small business program.

Signed:

Four handwritten signatures in black ink, arranged horizontally. From left to right: Robert F. Johnson, Todd Y., Robert G. Baker, and Michael R. Lyell.

Chairs: NEIA, NSBA, SBANE, SBTC

New England Innovation Alliance (NEIA - Over 40 SBIR companies with a total of 1600 employees).

National Small Business Association (NSBA - The first national small business advocacy organization, representing more than 150,000 small businesses).

Smaller Business Association of New England (SBANE - Representing over 600 businesses, 95% of which meet current small business size standards)

Small Business Technology Council (SBTC - A non-partisan, non-profit industry association of companies dedicated to promoting the creation and growth of research-intensive, technology-based U.S. small business.)

Examples of Commercialization Successes from the NIH SBIR Program

(Includes statements from the NIH SBIR website:
grants.nih.gov/grants/funding/sbir_successes/sbir_successes.htm)

| | | |
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| SBIR funds have allowed ... studies (that) would be difficult to fund with private sector financing | Advanced Brain Monitoring, Inc. | Carlsbad, CA 92008 |
| STTR funding eliminated the need to obtain venture capital, positioning the company for competitive pricing. | Audiology Incorporated | Arden Hills, MN 55112 |
| ...rooted in manufacturing, CasterShoX would not have been able to find funding in the private sector. Without crucial SBIR funding,.... | CasterShoX | Canton, MI 48187 |
| The EMG wearable sensor provides functional performance of muscles, and is used by rehabilitation clinicians and sports trainers | Delsys, Inc. | Boston, MA 02215 |
| Navipro is an addiction prevention and intervention program at 96 substance abuse treatment centers, serving over 12,000 individuals | Inflexxion, Inc | Needham, MA 02464 |
| As a result of SBIR-supported research,... has received private investments totaling over \$20 million | Intelligent Optical Systems | Torrance, CA 90505 |
| Line Scanning Laser Ophthalmoscope is licensed to a major manufacturer of ophthalmic instrumentation,over 250 systems sold this year.....without one dollar of venture capital invested | Physical Sciences Inc | Andover, MA 01810 |
| Lifestyle management programs have generated \$1M in fees this year | Pro-Change, Inc | Kingston, RI 02881 |
| The Navigator nuclear surgical probe accurately identifies sentinel lymph nodes during breast surgery | Radiation Monitoring Devices, Inc | Watertown, MA 02472 |
| The potential success of Calanolide A (HIV treatment) is directly attributable to the NIH SBIR programto develop this product in its early critical stages | Sarawak MediChem Pharmaceuticals | Woodridge, IL 60517 |
| Without the SBIR system it is very hard for young scientists in academia to start a company without going in for venture capital. | Targeting Systems | Santee, CA 92071 |
| (SBIR product) PROKERA™ often eliminates the need for (eye) surgery and provides sight saving benefits. | TissueTech, Inc. | Miami, FL 33173 |
| SBIR funding... to develop, validate, and commercialize a ...blood flow monitoring system.... essential to medical studies of diseases.... | Trasonic Systems, Inc. | Ithaca, NY 14850 |
| (SBIR product) ... being used by thousands of radiologists at over 400 institutions... | Vivalog Technologies | Seattle, WA 98136 |
| Without the ...SBIR program, it is not likely ... (we'd) bring these clinically proven (diabetes) devices into the market | Xilas Medical, Inc. | San Antonio, TX 78249 |
| Thanks to NIH SBIR grants.... Xoran Technologies, Inc. brought its ... (CT) scanners from the research lab to the commercial market in less than 3 years. | Xoran Technologies Inc. | Ann Arbor, MI 48103 |