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November 7, 2013

Pravina Raghavan
Director of Innovation & Technology
US Small Business Administration
409 3rd St SW
Washington, DC 20024

Dear Mrs. Raghavan,

The Small Business Technology Council (SBTC) writes you today to address a recent effort by the National Institutes of Health to obtain permission from the SBA to increase the maximum size of SBIR Phase II awards beyond what the agencies are currently allowed by law to award. We believe that allowing the NIH to exceed statutory limits on Phase II Award sizes could have seriously damaging unintentional consequences to small businesses and would be against the law.

The biggest concern the SBTC has about allowing NIH to increase Phase II award sizes is that this will reduce the total number of Phase II awards given out at a time when private financing for medical startups is becoming harder and harder to come by. According to a recent article in the Wall Street Journal[1], since 2007 venture capital investment in medical device and equipment firms has dropped 40%, while biotechnology firms have seen a drop of 28% in venture funding over the same period. Furthermore, bank financing for small businesses has dropped 22.6% over the last five years.[2] With private financing of small businesses and medical startups on a steady decline, allowing the NIH to reduce the number small businesses they award SBIR Phase II grants to could very likely drive many small firms out of business while seriously harming America's capacity for producing new medical innovations.

Another unintended consequence of reducing the number of Phase II awards is the possibility of small businesses being kicked out of the SBIR program for failing to meet the Phase I to Phase II transition rate benchmark, as well as the new commercialization benchmarks. SBA's proposed new regulations for commercialization benchmarks did not take into account the consequences of a drastically reduced number of Phase II awards by the NIH. One "jumbo-sized" award from the NIH could wipe out 5 to 10 regular sized Phase II awards making it exceedingly difficult and even potentially impossible for many medical industry small businesses to grow and develop

[1] Walker, Joseph "Funding Dries Up for Medical Startups" *Wall Street Journal* 4 Nov. 2013
[2] Why Small Business Lending Isn't What It Used to Be, Study for the Federal Reserve Bank of Cleveland, *Ann Marie Wiersch and Scott Shane, 08.14.13,*
http://www.clevelandfed.org/research/commentary/2013/2013-10.cfm.

their technologies in order to meet their benchmarks. The SBTC therefore believes that the proposed NIH action will set many small businesses up for failure, by requiring them to meet almost impossible requirements due to the NIH's actions resulting in fewer Phase II awards.

The NIH has attempted to increase the size of SBIR phase II awards for a long time, under the argument that medical-based technologies often cost more than technologies in other agencies to develop. While this is no doubt true of many medical technologies, it certainly isn't true for all medical technologies, and it is worth remembering that the entire SBIR program accounts for less than 3% of NIH's R&D budget. If the NIH finds it necessary to award a $10 million grant to develop a medical technology, we see no reason they can't allocate part of the other 97% of their budget to that purpose.

Section 5103 of the National Defense Authorization Act for Fiscal Year 2012 provided guidelines for the maximum award size of $150,000 for Phase I and $1,000,000 for Phase II. Congress also allowed the agencies some discretion to exceed those limits in some cases. The law () states:

> *No Federal agency may issue an award under the SBIR program or the STTR program if the size of the award exceeds the award guidelines established under this section by more than 50 percent.*[3]

In addition, in circumstances where agencies make awards in that exceed the award guidelines, the law requires the agencies to track and maintain certain information:

> ''(2) MAINTENANCE OF INFORMATION.—*Participating agencies shall maintain information on awards exceeding the guidelines established under this section, including—*
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> > *''(A) the amount of each award;*
> > *''(B) a justification for exceeding the guidelines for each award;*
> > *''(C) the identity and location of each award recipient; and*
> > *''(D) whether an award recipient has received any venture capital, hedge fund, or private equity firm investment and, if so, whether the recipient is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms.*
>
> *''(3) REPORTS.—The Administrator shall include the information described in paragraph (2) in the annual report of the Administrator to Congress.*[4]

Congress was explicit that whenever these limits were exceeded by up to 50%, the agency would have to maintain records and report to the SBA Administrator and then to Congress. Congress made it quite clear; these were not just guidelines, but rules that were to be strictly enforced by the Government. However, Congress allowed for an exception in very rare circumstances, on a case by case basis, the agencies could request a waiver:

[3] 15 USC §638(a)
[4] 15 USC §638(aa)(2)

''(4) WAIVER FOR SPECIFIC TOPIC.—Upon the receipt of an application from a Federal agency, the Administrator may grant a waiver from the requirement under paragraph (1) with respect to a specific topic (but not for the agency as a whole) for a fiscal year if the Administrator determines, based on the information contained in the application from the agency, that—

''(A) the requirement under paragraph (1) will interfere with the ability of the agency to fulfill its research mission through the SBIR program or the STTR program; and

''(B) the agency will minimize, to the maximum extent possible, the number of awards that do not satisfy the requirement under paragraph (1) to preserve the nature and intent of the SBIR program and the STTR program.

''(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to prevent a Federal agency from supplementing an award under the SBIR program or the STTR program using funds of the Federal agency that are not part of the SBIR program or the STTR program of the Federal agency.''.[5]

So, the SBA Administrator may grant a waiver for a "**SPECIFIC TOPIC**", only when justified by the agency that failure to do so will interfere with its research mission. And then, it can only do so with a minimum number and the agency will preserve the nature and intent of the SBIR/STTR programs.

It is SBTC's opinion that before the SBA Administrator even starts to consider allowing any topic to exceed the expanded limits of over 50% of the guidelines (jumbo award, more than $1,500,000 for a Phase II or more than $225,000 for a Phase I), the Administrator should first review the full report from the agency specifically outlining the four articles of information as required under the "Maintenance of Information" section of the law. Then, the review must include the analysis that only by allowing the topic award by a single bidder to not only exceed the guideline, but the strict limit of 50% more than the guideline (jumbo award), can the agency avoid interfering with the ability of the agency to fulfill its research mission through the SBIR program or the STTR program; and that only by making the jumbo award using SBIR funds can the agency preserve the nature and intent of the SBIR program and the STTR program.

In addition to the method for granting case-by-case award size waivers as proscribed by law, the agencies also have the power to make jumbo awards through the SBIR's Commercialization Readiness Pilot (CRP) program. This pilot program, in section 5123 of the 2011 SBIR reauthorization bill, grants agencies the power to set aside as much as 10% of its SBIR funds for awards as large as $3 million for the purpose of commercialization assistance to companies trying to transition promising technologies to the marketplace. No blanket waiver for award sizes can be justified before the agency has used the CRP to the full extent possible and can prove that the jumbo awards it has given out under this program better meet the agency's mission than regular size awards.

[5] 15 USC §638(aa)(4)

By decreasing the numbers of Phase I and Phase II awards provided to others, the agency will reduce the numbers of successful small businesses and act to the detriment of the agency's SBIR/STTR mission. One also needs to ask what jumbo awards will do to encourage or discourage participation by women, minority and disadvanted persons.

We urge the SBA to continue to stand firm in refusing to allow NIH to exceed their statutory award size limits, and ensure that the total number of SBIR phase II awards at the NIH are not reduced at a time when American small businesses can least afford to lose this important funding.

Sincerely,

Jere W. Glover
Executive Director
Small Business Technology Council

cc: Edsel Brown, SBA
Kevin Wheeler, Senate Committee on Small Business and Entrepreneurship
Kristen Granchelli, Senate Committee on Small Business & Entrepreneurship
Joe Hartz, House Small Business Committee