Comment Re: Small Business Innovation Research and Small Business Technology Transfer Programs Commercialization Benchmark

After reviewing the SBA's Small Business Innovation Research and Small Business Technology Transfer Programs Commercialization Benchmark published on Thursday, August 8, 2013 at page 48538 of the Federal Register, the Small Business Technology Council has a number of concerns with some of the rule changes proposed. This is a serious regulation with serious consequences to hundreds of small business and could be fatal to many firms. SBA's proposal is retroactive in its application and unfairly excludes firms from awards for actions taken prior to the changes in the law and its proposed benchmarks, starts the benchmark process when the award is received instead of when the award is completed, uses the wrong definition of commercialization, includes far too many firms in the process, and does not allow exceptions for extraordinary circumstances.

- **<u>SBA should have complied with the RFA and Paperwork Reduction Acts, even if SBA is not required by law to comply with them.</u>**

This Regulation doesn't comply with Paperwork Reduction or Regulatory Flexibility Acts (RFA). SBA did not seek input from small business. SBA has again ignored the requirement of the RFA to reach out to affected entities for their comments before deciding unilaterally what is best for small business. SBA should have looked for the least burdensome regulation on small business as required by the RFA. Had SBA complied with or even considered the RFA and Paper Reduction Act requirements, it would not have issued such a harsh and burdensome.

The Regulatory Flexibly Act requires agencies to reach out to small business impacted by their action:

> <u>§ 609. Procedures for gathering comments</u>
> (a) When any rule is promulgated which will have a significant economic impact on a substantial number of small entities, the head of the agency promulgating the rule or the official of the agency with statutory responsibility for the promulgation of the rule shall assure that small entities have been given an opportunity to participate in the rulemaking for the rule through the reasonable use of techniques such as—
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> > (1) the inclusion in an advance notice of proposed rulemaking, if issued, of a statement that the proposed rule may have a significant economic effect on a substantial number of small entities;
> > (2) the publication of general notice of proposed rulemaking in publications likely to be obtained by small entities;
> > (3) the direct notification of interested small entities;
> > (4) the conduct of open conferences or public hearings concerning the rule for small entities including soliciting and receiving comments over computer networks; and

(5) the adoption or modification of agency procedural rules to reduce the cost or complexity of participation in the rulemaking by small entities.

(b) Prior to publication of an initial regulatory flexibility analysis which a covered agency is required to conduct by this chapter

- **The Benchmarks should only apply prospectively. It is not fair to exclude a firm for actions prior to the law or regulation.**

SBA is making the its action retroactive and applying the benchmark to what a firm did 10 years ago and excludes firms for actions that took place before the benchmark Federal Registration and before the law changed. Article 1 Section 9 and 10 of the U.S. Constitution is clear that neither the Congress nor any state shall enter into or pass an ex post facto law:

Article 1, Section 9

No Bill of Attainder or **ex post facto Law** shall be passed.

Article 1, Section 10 (in part)

No State shall enter into any Treaty, Alliance, or Confederation; grant Letters of Marque and Reprisal; coin Money; emit Bills of Credit; make any Thing but gold and silver Coin a Tender in Payment of Debts; pass any Bill of Attainder, **ex post facto Law**, or Law impairing the Obligation of Contracts, or grant any Title of Nobility.

While the constitutional language has been held to apply to criminal proceeding, the principle that one should not be punished for actions that happened before a law is enacted is a bedrock principle of American law. The founding fathers thought so strongly about this that they even prohibited the states from enacting ex post facto laws. Here SBA is retroactively excluding firms from the SBIR program for not meeting a standard or benchmark that did not exist at the time of the firm's actions. Retroactive legislation presents problems of unfairness because it can deprive firms of legitimate expectations and place undue burdens on small business. A small business has had no chance to bring itself into compliance with the new law provisions or SBA's new benchmark. It is improper for SBA to retroactively exclude firms from the SBIR Program. SBA is punishing firms for actions they did before the law or regulations were passed.

SBA action is inconsistent with the law and SBA's policy directive.

- **SBA should have used the definition of commercialization in the law and SBA's policy directive.**

SBA uses a definition of "commercialization" that is different from the law and different the SBA's own policy directives at 77 FR46806 and 77 FR 46855 Section 4(a) (3). SBA's definition is too narrow and not consistent with the law. The law at Section 5125 adds to the definition of Phase III/commercialization the following provision that SBA does not:

SEC. 5125. CLARIFYING THE DEFINITION OF ``PHASE III''.

(a) Phase III Awards.--Section 9(e) of the Small Business Act (15 U.S.C. 638(e)), as amended by this title, is further amended--

(1) in paragraph (4)(C), in the matter preceding clause (i), by inserting ``for work that derives from, extends, or completes efforts made under prior funding agreements under the SBIR program'' after ``phase'';
(2) in paragraph (6)(C), in the matter preceding clause (i), by inserting ``for work that derives from, extends, or completes efforts made under prior funding agreements under the STTR program'' after ``phase'';

The SBA Policy Directive at Section (3) (f) defines commercialization as:

(f) Commercialization. The process of developing products, processes, technologies, or services and the production and delivery (whether by the originating party or others) of the products, processes, technologies, or services for sale to or use by the Federal government or commercial markets.

- **SBA should use two years from completion of the Phase II award instead of the receipt of award of the Phase II.**

SBA did not use the same definition of Commercialization that Congress used in the Law or SBA used its Policy Directive. DOD has had for many years used the same definition as the law and the policy directive in its Commercialization Achievement Index. SBA only excluded the 2 years since the Phase II award was made. In most cases, it takes 2-3 years for a firm to complete Phase II research. It is unlikely that commercialization will begin before the research and the Phase II is completed. Two years from the date of award is unreasonable.

- **SBA should limit the benchmark to 50 or more SBIR awards completed in the past 5 years.**

Applying the benchmark standard to a firm that has received 1.6 awards (16 phase II awards in a ten year period) a year is unreasonable and not needed. The paperwork burden and regulatory requirements are unnecessarily burdensome and inappropriate. According to SBA analysis there are only 166 firms with more than 15 awards in the last two years. According to Inknowvation.com records, there are 169 firms. SBA has not done the required Paperwork Reduction Act analysis. When it does it will find that it can reduce the paperwork burden on small business by 50% by increasing the number of phase II awards to 25 instead of the 16 it proposes. According to SBA numbers the number of reporting firms would go from 166 to 76. This would reduce the regulatory burden by over 200% without adversely impacting the process. According to Inknowvation the number would drop from 169 to 80. If SBA and or OMB want to further reduce the paperwork and regulatory burden on small business, they could limit the benchmark to firms with 50 or more Phase IIs (5 or more Phase IIs average per year). According to SBA this would reduce the number of impacted firms to 24. This would reduce the paperwork and regulatory burden by 725% again without adversely impacting the process. SBA did not do a cost benefit analysis. Had they done one, it is likely that would have picked a higher number than 1.6 Phase II awards per year for the benchmark threshold.

- **<u>SBA's disqualification of a company should only apply to the agency that the firm does not reach the benchmark of commercializing products for that specific agency.</u>**

SBA doesn't comply with the law that says the one-year exclusion will only apply with one agency. Exclusion of a firm from one agency, as provided in the law, is a problem, but exclusion from all agencies SBIR program will result in some firms not surviving.

SBA proposes to use a data system to exclude firms from the SBIR Program by using a data system and Company Registry that has not been developed and published. It appears that SBA will start excluding firms from the program on June 1st, 2014. Since SBA has not established or published the reporting requirement for its Company Registry, a company cannot take actions or understand the unpublished reporting requirements, companies will be faced with unidentified and unspecified requirements. We strongly urge SBA to use the DOD reporting forms and data fields in their registry. The DOD CACI has been in use for many years and a significant majority of SBIR firms already are using the DOD reporting requirements. We also believe that the new reporting obligation be for current awards. Requiring firms to go back and report commercialization going back over a decade places a significant paperwork and regulatory burden on thousands of SBIR firms. Since most firms maintain records on a calendar year basis, they should be permitted to report on a calendar year basis instead of on a fiscal year. Furthermore, reporting on the previous calendar year should be on July 31st of the year to allow firms to meet agency audits due by June 30th of each year.

- **<u>SBA should include a provision for pending and provisional patents</u>**

While we like the patent provision, we think that SBA should have a provision for patent pending and provisional patents. The provision for patents appears to only apply to issued patents. In many art areas such as aerospace and medical devices the Patent Office is taking over 3 years, and as many as 6-8 years to process patent applications relating to biotechnology, many companies that have patent application pending may be excluded from the SBIR program. Also the new Patent Act allows competitors to object to issuing a patent and delay final issue of patent for additional years. SBA should use any patent office approval for benchmark purposes. Even more important, if SBA is going to make the benchmarks retroactive, SBA should have used patent pending as a standard instead of patents issued.

- **<u>An appeals process should be included to give companies a process to challenge bad rulings</u>.**

The benchmark process is new and certainly imperfect and untested process. There should be an appeal process at the impacted agency where special circumstances could be considered. For example, there may be situations where a firm has focused on a technology that the agency recognizes as extremely high risk and where the technology is not likely to be commercialized. There can be instances where agencies change their focus and decide not to award Phase IIs in a whole are. For example, NASA decided a few years ago to stop making any awards of any kind in the area of Aeronautics. Firms that had focused in that the aeronautics were therefore unable to receive any Phase II awards or follow-on funding in aeronautics because of a change in Agency priorities. Other justifications for exceptions could be where patents applications had been pending for over 5 years. A firm may be from a state that few investments from venture capital firms making it difficult to meet the benchmark standard. Agencies

should be able to make exception for exceptional circumstances that prevented firms from meeting the benchmarks. In some cases the technology developed by a firm in Phase I may be so significant and important that an agency that preventing an award to a firm would not be in the public interest. An agency may want to delay the exclusion for a year. SBA may even want to provide a firm a grace period of one year to come into compliance before the exclusion occurs. This would be especially true if SBA used data from years prior to the enactment of the law, and SBA's proposed benchmarks. The more firms included in the benchmark process, the greater the need for flexibility in the exclusion process. Firms should be able to explain special circumstances and an agency should be able to make exceptions to the exclusions where appropriate.

- **Companies with Secret or Confidential technologies may not be legally permitted to disclose the information required**

Because of the sensitive nature of R&D with the military, there are many companies doing business with the DOD that are required to keep their technologies and/or research secret. These companies would likely not be permitted to release details of their work to an SBA database, even if it were kept out of public view. This could create situations where it would appear that small businesses are not compliant with the new regulations, even when they are. SBA needs to take into account the sensitive nature of R&D at the DOD and make sure small businesses aren't being punished for following DOD rules regarding secrecy and confidentiality. This issue further highlights the need for an appeal process as described in the previous bullet point.

- **The commercialization potential of many DOD firms is limited by ITAR regulations restricting sale of technologies with defense application to overseas markets**

Another obstacle that DOD firms will run into when coming into compliance with the new SBA regulations is the International Traffic in Arms Regulations (ITAR) rules regarding sale of "defense articles" to foreign countries, including technologies, research, and technical data. There are many military technologies being developed by DOD small businesses that are never going to be commercialized because they have only military applications. And even many of the DOD technologies that can be commercialized can't be sold overseas because of ITAR rules, thereby limiting the markets that can be utilized. These factors need to be taken into account when analyzing a small business's compliance with new commercialization regulations.

- **Commercialization success is more difficult to achieve at certain agencies than with others**

It is more challenging to commercialize technologies developed by certain Agencies than others, particularly the NSF and NIH. Clinical drug trials can take years to complete, so small businesses could face judgement for noncompliance with commercialization benchmarks while still working through a Phase II. The NIH has also argued that multiple or jumbo (ie over $1 million) Phase II awards will be required before a new drug or medical device is ready for clinical evaluation. The prevalence of these awards at NIH reduce the total number of Phase II awards given out, making it much more difficult for companies at the NIH to meet the set benchmarks. These agency-specific situations should be identified

and accounted for in the commercialization benchmark regulations. Holding companies at the NIH and NSF to the same commercialization standards as the DOD and DOE shows a lack of understanding of the variety of challenges facing companies in different sectors and areas of research, and should be addressed. Different commercialization standards should be applied depending on the agency, not one standard applied broadly across all eleven agencies.

Sincerely,

Small Business Technology Council

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