



## Strengthen the SBIR Program; Support Bringing Scientific Innovation to the Public

### *Background*

The Small Business Innovation Research Program (SBIR) was established in 1983 to encourage and support continued scientific innovation in America, by helping to fund innovative research that has a focus toward commercialization of a product or service.

As the world's leader in biotechnology, America has benefited greatly from the SBIR program, which has been an essential component in bringing breakthrough therapeutics from the bench to the bedside of patients.

- After twenty successful years of participating in the program, the Small Business Administration ruled in 2003 that companies 51 percent owned by private investors were no longer eligible to participate in the SBIR program.

The SBA's re-interpretation of what defines a 'small business' is preventing some of the most innovative biotechnology companies from participating in the SBIR program at the NIH. If this policy continues, the results could be detrimental for the patients who rely on the development of new biotechnology therapies and treatments. As NIH Director Elias Zerhouni, MD, stated in a letter to the SBA, under the current eligibility standards, **"the NIH must turn away many deserving applicants, and the goals of the SBIR program are being undermined"**.

### *Impact*

As a result of the re-interpretation, the SBIR applicant pool at the NIH has been shrinking and work on life-saving technology is being postponed.

- **Applications for NIH small business grants dropped 12 percent in 2005, 15 percent in 2006 and 21 percent in 2007.**
- **The number of new applicants at the NIH is the lowest it has been in decades.**

The change in the ruling of what constitutes a small business has clearly prevented many small companies from participating, thus decreasing the competition based on scientific merit that goes into granting funds to companies for the SBIR program.

- A significant number of biotechnology firms have delayed or cancelled research projects on diabetes, Alzheimer's, lupus and leukemia among other diseases, due to ineligibility resulting from the rule change.
- SBIR plays a critical role in aiding small biotechnology companies in their early stage research to navigate through the "valley of death" where the concept is too high-risk for private market support. Without these funds, many companies will be forced to delay innovative research projects in the hope that this issue will be resolved.

Ensuring these companies' ability to participate in the SBIR program is essential to continuing America's ability to lead the world in biotechnology innovation.

- 32.45% of firms associated with successfully bringing the 230 FDA-approved biologic therapies to market from 1982-2005 were recipients of SBIR funding.

### ***Restore SBIR Program Eligibility***

Reinstate eligibility for small companies who have venture capital backing to restore SBIR program eligibility.

**Clarify affiliation rules** so that investment by venture capital companies does not qualify affiliates of other companies to be considered when determining size.

- As a result of the current affiliation rules, a small company with 50 employees could be deemed to be affiliated with hundreds of other employees of companies with which the small company has no relationship whatsoever, just because the companies share a common investor.
- BIO recommends the reauthorization bill provide language to clarify that investment by a venture capital operating company does not make that company an affiliate of another company for the purposes of determining size. This is a common-sense measure that will provide clarity and peace of mind for small business entrepreneurs looking to participate in the SBIR program.

**Maintain agency flexibility** so that the missions and goals of each organization can remain intact.

- Various government agencies may structure their SBIR program in different ways to meet differing agency needs. This is a good thing, so long as the original goals of the SBIR program are preserved
- BIO does not believe that a hard cap should be applied to the SBIR grant amounts. Agencies should be the best judge of how to use their SBIR funds to advance science and commercialize new innovations.