Testimony of:

Mark B. Leahey, Esq.
Executive Director
Medical Device Manufacturers Association

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"Legislation to Reauthorize the Small Business Innovation Research (SBIR) Program"

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Introduction

Chairwoman Velázquez, Ranking Member Chabot, and Members of the Committee, thank you for inviting me to testify today regarding reauthorization of the Small Business Innovation Research (SBIR) program.

My name is Mark Leahey and I am the Executive Director of the Medical Device Manufacturers Association (MDMA). MDMA is a national trade association representing innovative, entrepreneurial medical technology companies across the country. Our mission is to ensure that patients have timely access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies. With advancements in science, increasing regulatory requirements and market access challenges, significant investments from the government and venture capital are often needed to develop these life enhancing and life sustaining technologies. In return, Americans are living longer, healthier and more productive lives.

One of the cornerstones of government investments in small medical technology companies has been the SBIR program. Resources from the program, in addition to private investment, have greatly contributed to the growth of the medical device industry over the past twenty years. However, as you are aware, the Small Business Administration (SBA) implemented a change that significantly worsened the landscape of the public-private partnership envisioned by the SBIR program. As a result, many promising technologies from smaller companies did not receive SBIR support and patients suffered as a result. Fortunately, this Committee is taking the necessary steps to correct the actions of the SBA and ensure that the SBIR program is restored to its critical role of providing promising, entrepreneurial medical technology companies with the resources needed to develop the clinical solutions of tomorrow. To this end, MDMA supports the current efforts to reauthorize the SBIR program.

Background

The SBIR program was established in 1982 to offer competition-based awards to small private-sector businesses to stimulate technological innovation with the intention that the small business would take the product through to commercialization, all the while helping to stimulate U.S. economic growth and international competitiveness. The SBIR program is structured into three phases:

- Phase I is the feasibility study in which award winners undertake a limited amount of research aimed at establishing an idea's scientific and commercial promise. Phase I awards are generally $100,000 for six months.
- Phase II funds are used to finance more extensive research and development and the grant awards are usually around $750,000 for two years.
- Phase III is the commercialization stage and companies must use non-SBIR funds to get their product into the marketplace.

The SBA establishes the eligibility criteria for participation in the SBIR program. As such, only United States small business concerns (SBCs) are eligible for an SBIR award. The SBC must be organized as a for-profit with its place of business in the United States. It must also be independently owned and operated, and it must meet one of two ownership criteria: it must be at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, or, it must be a for-profit business concern that is at least 51 percent owned and controlled by another (one) for-profit business concern that is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. Finally, the SBC must be small in that it must have no more than 500 employees including affiliates.

Public and Private Investment in Medical Technology

The majority of the most innovative advances in medical technology over the past twenty years have been developed by small, entrepreneurial medical technology companies. These technologies are continually advancing and improving the health care for many Americans everyday. At the same time, these innovative products are reducing long-term health care costs by improving outcomes, reducing hospitalization time and increasing productivity.

The SBIR program was instrumental in the development of many of these medical technologies. However, SBA's interpretation of the term, "individual" has created a barrier for smaller companies to receive SBIR assistance. The development of a medical device often involves the collaboration of public and private investments, including resources financed by various venture capital investors. Since the SBA's reinterpretation of ownership requirements under SBIR, the number of medical technology companies applying for grants has significantly declined. As evidence of the impact of the new rules on medical device and biotech companies, applications for SBIR grants at the National Institutes of Health, the most prolific grantor of SBIR grants to medical technology companies declined by 11.9 percent in 2005 and by 14.6 percent in 2006. In addition to reducing the number of companies receiving grants, one may also conclude that the new interpretation prevented SBIR from supporting those projects that showed the greatest promise for clinical benefit simply because of its ownership structure. The SBIR program should support small companies with promising clinical technologies, regardless of whether venture capitalists have invested a certain amount.

Medical device companies typically raise multiple rounds of venture capital funding to finance the years of pre-clinical research and development needed to advance a new therapy into clinical trials and, ultimately, gain approval by the Food and Drug Administration for sale to the public. Additional trials may be required to satisfy private and public payers as well. Without the assistance from the private and public sector, the vast majority of medical device companies would not be able to finance the many millions of dollars worth of cutting-edge R&D needed to develop a new medical device.

Legislation

MDMA was very pleased that the House of Representatives voted to proactively address the individual ownership requirement by passing H.R. 3567, the Small Business Investment Expansion Act of 2007, in September of last year. In short, H.R. 3567 amends the Small Business Act to provide that, for purposes of determining whether a small business is independently owned and operated or meets specified small business size standards, the Administrator shall not consider a business to be affiliated with a venture capital operating company (or with any other business that the venture capital operating company has financed) if: (1) the venture capital operating company does not own 50% or more of the business; and (2) employees of the venture capital operating company do not constitute a majority of the board of directors of the business. The legislation further defines a business as "independently owned and operated" if it is owned in majority by natural persons or venture capital operating companies meeting specified requirements, including that there is no single venture capital operating company: (1) that owns 50% or more of the business; and (2) the employees of which constitute a majority of the board of directors of the business.

The clarification of the ownership requirement made in H.R. 3567 is a critical step-forward in returning to the envisioned level of public-private partnership in the development of innovative technologies under the SBIR program. Furthermore, the combination of investment from both SBIR and venture capital is vital to the further development of life-saving medical devices.

Recommendations

As the Committee moves forward with reauthorization of the SBIR program, the Medical Device Manufacturers Association would like to reiterate our support for the SBIR program and offer the following recommendations that will help reestablish the program's success.

First, the reauthorization should include language to restore the participation of venture backed companies similar to those passed in H.R. 3567, especially the redefinition of the ownership requirements for business concerns. It is critical that this language be included so that small, venture-backed medical technology companies are not excluded from the program. This will serve to provide SBIR grants to the most promising technologies which are likely to provide more patients with access to life-saving medical devices.

Second, MDMA believe that increasing the dollar amount of the Phase I and Phase II awards is warranted given the increasing development costs and will provide a greater incentive for companies to participate in the program. These award levels have not changed since 1992. Therefore, Congress should move forward with increasing these awards as proposed under the reauthorization. Providing $200,000 and $1.5 million for Phase I and Phase II awards, respectively, will help provide the necessary incentive to encourage more companies to apply for the grants. If the awards are too low some

companies may determine they are not worth the time and effort required to submit a successful SBIR application.

Third, MDMA supports providing agencies with more flexibility in administering the SBIR program. Specifically, MDMA believes it would be helpful to agencies if a small percentage of the SBIR set-aside could be used for administering aspects of the program. MDMA agrees that it would be appropriate to allow two to four percent of the SBIR funds to pay for activities such as conferences aimed at helping small businesses to compete successfully, commercialization assistance programs to help companies transition to the marketplace, and improved systems for assessing program effectiveness. These resources will help to administer the SBIR program and assist agencies in making improvements to the program without diverting funds from other funding resources.

Finally, it would be beneficial to remove the requirement that a company must have applied for a Phase I grant in order to apply for a Phase II grant. Under the current rules, only companies that have applied for and received a Phase I SBIR grant are eligible to apply for a Phase II grant. If this rule were changed, MDMA believes that small business participation in the SBIR program would increase. This change would also be aligned with the mission of the SBA to strengthen the Nation's economy by enabling the establishment and validity of small businesses. Contrary to what some may argue, MDMA does not believe that the program would shift funding to only later stage companies, but agencies should be encouraged to keep the balance of the innovation lifecycle in "check."

Thank you again for your efforts to improve and reauthorize this important program. MDMA appreciates the Committee's efforts and supports the reauthorization of the SBIR program incorporating the important changes outlines above.