



Hearing Testimony

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On Behalf Of  
**The Medical Device Manufacturers Association (MDMA)**

Before the House Committee on Science and Technology's  
Subcommittee on Technology and Innovation

“Small Business Innovation Research Reauthorization on the 25<sup>th</sup> Program Anniversary”

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Chairman Wu, Ranking Member Gingrey and Members of the Technology and Innovation Subcommittee:

Thank you for inviting me to testify before you today on Small Business Innovation Research (SBIR) grants and the reauthorization of the program.

My name is Anthony Ignagni and I am the President and Chief Executive Officer of Synapse Biomedical, Inc. Synapse Biomedical is a privately-held medical device company located in Oberlin, Ohio. We are a startup company established with the mission of developing, manufacturing, selling and supporting life changing minimally invasive neurostimulation devices used in the diagnosis and treatment of persons with neurological impairment.

Founded in September 2002, Synapse's product portfolio is focused on neurostimulation devices for minimally invasive surgical interventions and respiratory assist. These two areas of medical specialization have come together in our first product, the NeuRx Diaphragm Pacing Stimulation (DPS) System. The founders of the Company have pioneered the innovative use of standard minimally invasive laparoscopic techniques to provide ventilation in persons with respiratory muscle paralysis. This technological advance provides a device that is a low-risk, low-cost alternative to a very invasive procedure that has been performed for thirty-five years.

I am pleased to tell you that our current percutaneous technology has been successful in over fifty patients including the late Christopher Reeve (our third implanted patient). Our technology has demonstrated clinical promise in the pilot series of Amyotrophic Lateral Sclerosis (ALS,

commonly known as Lou Gehrig's disease) patients. The longest implanted patient has used the device for full-time respiratory support for over six years. We additionally have evidence of this technology saving health care costs and potentially saving lives. Our fourth patient implanted was able to save \$13,000 per month in Ohio Medicaid costs by weaning off of a ventilator, moving to a non-ventilator support ward in the nursing home he was in, and then was able to move back home with his elderly mother. He has recently married and is an advocate for people with spinal cord injury on the board of local hospitals.

We also have had several implanted patients in the hurricane affected areas of the South. One young woman specifically lost her home in hurricane Rita and had to go to a shelter. Fortunately she had been already fully weaned off of her ventilator and was able to sustain extended periods without power as our device lasts several weeks on a single replaceable battery. These are just two of the many stories that demonstrate the compelling benefit of our technology.

The NeuRx DPS System is currently being studied in two human clinical trials. The first trial of chronic diaphragm pacing has demonstrated clinical efficacy as a ventilator replacement in chronic respiratory insufficiency with a 97 percent success rate in providing ventilatory support. The second ongoing clinical trial is for diaphragm conditioning stimulation to improve the survival time in ALS, which has shown a preliminary 15 to 20 month survival benefit in the pilot series. Additional feasibility studies have begun to demonstrate the therapeutic implementation of diaphragm stimulation in an acute ventilatory assist trial intended to demonstrate reduction in ventilator associated risks, improvements in cardiovascular function, and maintenance of diaphragm contractile properties in intensive care units. Synapse is at the forefront of the pioneering use of Natural Orifice Transluminal Endoscopic Surgery (NOTES) for our clinically recognized efforts as the seminal application for acute ventilatory assist. Additional trials are planned, beyond the diaphragm, to demonstrate the feasibility of the technology platform in two active research areas of Synapse's founders: chronic abdominal pain and gastroesophageal reflux disease. So, as you can see we are working on very promising and life enhancing technology which serves a very narrow patient population.

Today, I am here to testify on behalf of the Medical Device Manufacturers Association (MDMA), a national organization representing the innovative, entrepreneurial sector of the medical technology industry. MDMA's mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

As a representative of the medical device industry, I thank you for allowing me to share with you my experience in applying for and obtaining a SBIR grant. As you know, the SBIR program was established in 1982 to offer competition-based awards to small private-sector businesses (such as mine) to stimulate technological innovation with the intention that the small business will 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 Small Business Administration 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 for-profit with its place of business in the United States. It must 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.

Synapse's involvement in the SBIR program has provided important support for continued innovation of our technology platform. Our current grants extend the potential use and market potential for our diaphragm stimulation technology in compelling need orphan clinical diseases of spinal cord injury and ALS. Our ability to participate in the SBIR program provides the R&D funds to continue these efforts. Without the SBIR funds we could not support the manpower to apply to continuing the advancement of our platform in these areas.

Synapse is a small business. We have eight full-time employees and one part-time employee. We are actively sponsoring/conducting two pivotal device trials for application of our DPS System in spinal cord injury and ALS. We have recently made our first market application to the FDA for use of the device in spinal cord injury. We have setup a complete clean-room, manufacturing facility, and quality system with ISO 13485 certification and also anticipate submitting for European market approval within approximately one month. To accomplish this we run a very lean and efficient shop. We have spent \$2.5MM since the inception of Synapse to achieve these accomplishments with a very dedicated and motivated staff. Our vision is to build a profitable company based on the sound science of our initial clinical applications. To continue these accomplishments and establish a sound foundation for the company to further build upon, we anticipate spending another \$4MM. To be able to fund these activities and most importantly be able to commit the resources necessary for a 100 patient pivotal trial in ALS to the patients and clinical community, we have had to raise significant venture investments. As indicated in my disclosure statement, we have currently exchanged 49 percent of the company equity to venture and other institutional investors to raise this money. We have retained just over 51 percent of the ownership with the company founders and initial individual angel investors.

Since our device has a Category B1 designation by the FDA and CMS we have been able to charge for the device during clinical trials and have therefore been able to realize total income since our inception of almost \$1MM. This includes awards (for our business plan), SBIR grants, contract manufacturing efforts and reimbursement for clinical study devices. The SBIR program grant funds that we have drawn down to date have been approximately 14 percent of this total. We additionally have another \$200K in current SBIR grants funds available and pending award.

The Committee has asked me to address ways in which the SBIR program could be improved. As I noted before, under the current strict eligibility rules, Synapse is on the cusp of becoming ineligible to apply for a SBIR grant due to the fact that additional institutional investments would put us below the 51 percent owned by individuals' qualification. Our situation is one that is also faced by a majority of companies in the medical device industry as evidenced in part by the decline in applications for SBIR grants since the 2003 rule change. Based on the awards statistics located on the National Institutes of Health's (NIH) website, there has been a significant decline in applications for SBIR grants. In the first year (2004 – 2005), post the rule change, there was a 12 percent decrease in applications followed by an almost 15 percent decrease this past year (2005 -2006). This after NIH had double digit increases in the number of SBIR applications in the two years leading up to 2003.

Some suggestions that I believe would make the program more effective in achieving its goals and therefore improved include:

- Increasing the dollar amount of the Phase I and Phase II awards as they have not changed since 1992, but maintaining these as guidelines, not “caps”;
- Providing agencies with more flexibility in administering the SBIR program; and
- Returning to the previous policy before the 2003 rule change so that all companies can have an equal chance in participating in the Federal grant process. This would mean allowing some companies that are majority owned – in the aggregate- by multiple VCs to participate in the program.

To elaborate on my recommendations, I believe that it would benefit the small businesses that apply for the grants if the Phase I award could be increased to \$150,000 and the Phase II award increased to \$1.25 million. This could potentially encourage companies that are currently not applying for the grants because they think the awards are too low and therefore not worth the time and effort required to submit a successful SBIR application.

I also believe there are opportunities to improve the SBIR program by providing agencies with more administration flexibility. Specifically, I think 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 and those of us in the industry agree 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. Second, 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, I believe small business participation in the SBIR program would increase. I believe the change would be aligned with the four goals of the program. I do not believe that the program would shift to funding only later stage companies, but agencies could be encouraged to keep the balance of the innovation lifecycle in “check”.

Finally, my greatest concern pertaining to the viability of the SBIR program is the need to increase participation of all innovative small businesses in federal research and development, including those with venture backing. A key purpose of the SBIR program, a public-private partnership, is to help entrepreneurs overcome many of the obstacles they face in developing new technologies. The SBIR program as originally designed does this, but its effectiveness is being hampered by the fact that many small businesses are deemed ineligible to participate in the SBIR program based on their financing structure. Further, the program is not meeting its entire goal to stimulate technological innovation. The stimulation - and sustaining- of technological innovation will only be met if all companies regardless of how they are financed are able to apply for SBIR grants; if agencies have the flexibility they need to administer the program according to their needs and needs of the small business community, and the dollar amount of the individual awards are increased to reflect an inflationary adjustment.

Again, thank you for providing me with the opportunity to testify today before the Subcommittee.