



Good Morning. My name is Tim Krauskopf and I'm Senior Vice President for CardiacAssist, Inc., a medical device manufacturer based in Pittsburgh, Pennsylvania.

My company manufactures the TandemHeart® PTVA® System. The TandemHeart is a Ventricular Assist Device that saves lives by increasing blood flow and reducing the demands placed on weakened or damaged hearts, yet is used without the need for invasive surgery.

The TandemHeart System can assume all of the heart's pumping function for several hours, days or weeks, benefiting patients who arrive in the emergency room after experiencing damaging heart attacks, as well as those whose hearts are too frail to undergo major procedures without temporary support.

We have begun work on a pediatric version of the TandemHeart pump that is designed to help save the lives of one of our most vulnerable patient populations. This work would not be possible without the more than \$1 million we received from the National Institutes of Health over the past two years through two Small Business Innovation Research (SBIR) grants. Thanks to these grants, we are on the path to successfully developing a breakthrough technology that will give new hope to thousands of infants and children with life threatening heart problems.

I would like to say that our story is typical of the success that medical technology companies have in securing SBIR grants. Unfortunately, new eligibility guidelines mean that many start-up companies will not be able to rely on these grants to help them bring innovative medical technologies to patients.

Over 90% of medical technology firms are small companies having 100 or fewer employees. From innovative heart pumps to new diagnostic tests to implantable monitors, many breakthrough medical technologies emerge from these small, start-up companies, which are dependent on the help of venture financing.

These venture-supported companies are precisely the type of companies the SBIR program was designed to support. However, under current grant eligibility criteria, firms receiving more than 51% funding from venture capital are barred from receiving SBIR support.

Given the very high risk and high costs of bringing a new medical technology to market, it is common that the early investors in the company will own more than 51% of the company in exchange for the high risk capital the venture capital firms provide.

SBIR grants have helped make the U.S. the world's leader in medical devices and biotechnology by providing critical early-stage funding for innovative research. The current eligibility guidelines challenge this successful program by preventing innovative companies from receiving crucial SBIR grant money. This policy will have a devastating effect on the future of the industry and the patients we serve.

Several venture-backed companies have been disqualified from receiving SBIR grants because they cannot meet the 51% individual ownership criteria. Like many early stage medical technology companies, CardiacAssist relies on individual investors as well as venture capital. In fact when we applied for our recently obtained SBIR grant, we did not meet the 51% eligibility criterion.

Thankfully, during the approval process, we were able to raise more funds so that we met all the qualifying criteria. But if we had not, our development efforts to provide seriously ill pediatric patient a potentially lifesaving technology would have stopped.

I doubt any parent whose child was in need of this or other life-saving technologies would understand that development of the device was delayed due to an ownership rule.

On behalf of my company and over 200 AdvaMed member companies, I urge you to support H.R. 2943, the "Save America's Biotechnology Innovative Research (SABIR) Act," to restore the eligibility for SBIR grants to venture capital-backed medical technology companies.