

# Op-Ed: Federal Seed Funding Programs Create Medical Success Stories



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I lead a small company that created a mechanical system to clear clogs in medical tubes, the TubeClear system. The first patient ever to use the product was a 27-year-old soldier in intensive care at Walter Reed hospital. The seed funding for my device development came from federal programs that some influential members of Congress could now limit or shut down. That would be a colossal mistake.

Congress created the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs to encourage innovations from U.S. high technology startups like mine to meet government and industry needs. Participating agencies include the National Institutes of Health to support small companies to develop technologies to improve the health of U.S. patients. NIH's National Institute of Child Health and Human Development (NICHD), for example, enhances the lives of children and adolescents and optimizes abilities for all. As parents, we all want the best medical devices for our kids, and NIH/NICHD is focused on bringing innovative devices to these fragile patients. Without the SBIR/STTR programs, even such critical needs could go unmet.

Congress has long reauthorized the SBIR/STTR programs with strong bipartisan support. Authorization will expire September 30, 2022, if Congress doesn't act. Detractors argue the private sector should replace program funding, called "America's seed fund." While a bipartisan majority may prevail, and should, opponents also should appreciate why the private sector is unlikely to meet every need for innovation across a dozen participating federal agencies.

I know firsthand. My business pursued private investors for our medical tube clog clearing system. We thought we had an excellent business opportunity, apart from the humanitarian value of helping patients.

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Tubes delivering nutrition, hydration, and medication are common. They're critical for ill patients or even healthy patients awaiting surgery. Tube clogs also are common. An estimated seven million feeding tubes are placed annually. They clog about 25 percent of the time, requiring nurses and caregivers to deal with 1.8 million clogs. Nurses tell us clearing clogs can consume much of their shifts. Worrying about a patient's deprivation of life-sustaining nutrients and medication is stressful for caregivers. Replacing a tube may require surgery, which may be painful and traumatic for fragile patients.

A device system using mechanical motion to clear clogs at bedside, while the tube remains in the patient, seemed like just the kind of innovation investors would embrace. That wasn't the case. The tube market is large but not large enough for investors. Research and development proving safety and effectiveness in patients is lengthy and expensive. Investors told us no.

The SBIR/STTR federal seed funding exists exactly for innovations like mine. Private investment works to spur innovation much of the time but not all the time. A modest investment from the government yields valuable products, creates jobs, and bolsters local, state, and national economies. My small company is applying our principle of mechanical movement to additional medical products that will save and improve lives.

With SBIR/STTR seed funding, small businesses like mine share our technologies far and wide. My company's TubeClear system is serving burn victims at the University of California, Davis, critical care surgical patients at Ohio State University Wexner Medical Center, veterans in Omaha, and more. As we demonstrate safety and efficacy, we'll earn regulatory approvals for more patient applications and settings. We'll draw more customers across health care settings. Nursing homes, where our country's aging population increasingly resides, combined with a caregiver shortage, likely will be a growing setting for using our innovation.

More wounded soldiers, surgical patients, burn victims, veterans, nursing home residents, and others will benefit from more seamless delivery of the medicine, food, and hydration they need in their most vulnerable moments. Anguished family members and swamped doctors and nurses will find relief in artful medical technology, all because Congress saw a need and created a solution. Not all government programs work as intended, but the SBIR/STTR programs works extremely well. Congress should continue its good work by reauthorizing the SBIR/STTR programs for patients nationwide. In turn, businesses like mine will be able to do more than dream of innovations. We'll be able to make them a reality.

As president, chief executive officer, and co-founder of Actuated Medical, a small medical technology device innovator in central Pennsylvania, Maureen L. Mulvihill, Ph.D., serves on the boards of directors of AdvaMed and AdvaMed Accel, a division for small and emerging companies. AdvaMed, short for the Advanced Medical Technology Association, represents more than 450 innovators producing the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

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