

TESTIMONY

ECONOMIC DEVELOPMENT, JOB CREATION & RETENTION IN THE BIOSCIENCE INDUSTRY

PENNSYLVANIA HOUSE OF REPRESENTATIVES

FINANCE COMMITTEE

HARRISBURG, PA

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MAUREEN L. MULVIHILL

PRESIDENT & CEO

ACTUATED MEDICAL, INC.

Good morning Chairman Benninghoff and distinguished members of the House Policy Committee. My name is Maureen Mulvihill and I am President & CEO of Actuated Medical, Inc. Founded in 2006, Actuated Medical is a medical device company that focuses on innovative motion medical devices for clearing obstructed medical tubes in patient, penetrating tissue and enabling the emerging MRI-guided surgical procedure industry. We are a full-service FDA-compliant (ISO 13485 certified) company with U.S. based design, development and manufacturing located in Bellefonte, PA. Actuated Medical's innovations improve patient outcomes and ultimately will reduce healthcare costs. Our commercial successes are due to the entrepreneurial spirit of taking risks and always keeping focus on the end goal – an FDA cleared device with a real clinical need and commercial market.

In just 5 years, Actuated Medical's TubeClear, our first device, was cleared by the FDA and CE Marked. We even have sales in Europe, making this 20 person company from Bellefonte an international company. TubeClear's first in-patient study was a 27 year old soldier. What an emotional day for a small company. Not only did we succeed in our goal of improving a patient outcome, but our first outcome was a U.S. soldier.

Actuated Medical has been recognized as a flourishing entrepreneurial company by Ernst & Young, Central PA Business Leaders and most recently by the Governor's Impact Awards. At Actuated Medical, we provide family sustaining salaries and enhanced benefits that enable our talented team of Pennsylvanians to focus on designing and manufacturing innovative technologies core to our mission of improving patient outcomes.

In 2008 and 2009, Actuated Medical received initial seed funding through the Commonwealth. At our start, private investors were not interested in funding entrepreneurs with a novel idea of bringing motion to medicine. With Commonwealth funding, we conducted the background research, prototype testing and submitted two Small Business Innovation Research (SBIR) grants – one to National Science Foundation and another to National Institutes of Health. From the technology platforms of these 2 grants, Actuated Medical has been awarded \$10 million in federal grants. What an incredible return on investment for the Commonwealth...\$320,000 has

yielded over \$10 million to be invested back into Pennsylvania. Actuated Medical has also utilized the Keystone Innovation Zone (KIZ) tax credit program. For the last 4 years, we have sold the credits in an effort to garner the capital needed to support other indirect costs such as legal and patent fees. To date, Actuated Medical has been awarded 3 U.S. patents and we have several moving through the U.S. and International patent offices. Our intellectual property value continues to grow.

Until July 2012, Actuated Medical had no private investment beyond friends, family and the Commonwealth's investment. Everything changed after TubeClear received FDA clearance and I am proud to share that Actuated Medical currently has more than \$500,000 received or pending from strategic partners with more to come. Due to our recent growth and momentum, we are exploring purchasing a building and doubling our footprint in central Pennsylvania.

Funding from the Commonwealth not only helped to sustain Actuated Medical during our early years, but also helped leverage additional public and private follow-on funding. The financial assistance, and inherent validation of our research which accompanied it, helped grow Actuated Medical to where we are today.

I am here today to tell you my story and let you know that Actuated Medical strongly supports the "Innovate PA" legislation as a means of providing an influx of early stage capital to Pennsylvania's young research and development companies.

As you know, the life sciences industry in the Commonwealth is a significant economic driver. In Pennsylvania there are 2,279 life science business establishments, directly employing more than 80,000 Pennsylvanians. This ranks Pennsylvania among the top state employers in three of the four major life science subsectors – drugs & pharmaceuticals; research, testing & medical labs; and medical devices and diagnostics.

The average annual wages generated from our industry in Pennsylvania are \$8.15 billion. The total Pennsylvania employment impact, including life science-related jobs added through the multiplier effect, total approximately 460,000. Pennsylvania ranks 4<sup>th</sup> among all states in academic R&D expenditures, 4<sup>th</sup> in total research awards from the National Institutes of Health

and 4<sup>th</sup> in life science-related patents. The average annual wage for a life science worker in the Commonwealth is \$90,267 – approximately twice the average private sector wage for all workers in the state.

To ensure the Commonwealth remains competitive in a global economy, in May 2012 Pennsylvania Bio concluded a discussion with more than 40 individuals representing all segments of the life science community around the state. This group included academia, industry, the administration and legislature and collectively formed the Life Science Leadership Advisory Council. Through a series of meetings, conversations and analysis, this Advisory Council identified Pennsylvania's competitive advantages and opportunities to enhance the industry's strength and facilitate future job creation. The Council's work was focused on identifying the tools and partnerships required to build on the strong base of life science companies present in the Commonwealth.

The report that resulted from the Council's work is titled, Life Science Leadership for the Next Decade. A copy of the report has been submitted for the record.

The report highlights the following five broad recommendations:

- Government and the private sector in Pennsylvania should actively promote the life science industry as a key driver of Pennsylvania's economic competitiveness
- Ensure the continued growth and vitality of the Pennsylvania life science community through ongoing monitoring, evaluation, and action of its stakeholders to maintain the industry's competitiveness – continue to foster interactions like you are facilitating today
- Support the research and development of emerging life science technologies including previous and new life science investments
- Seek investment capital to support early and mid-stage life science companies – we have a history in PA of working together to create investment opportunities for our companies through public-private initiatives
- Encourage the creation of a tax system and business climate that provide a supportive environment for life science industry job creation

For today's hearing I will focus on a couple of key points relative to the need for investment capital to support the life science industry. Through discussions and analysis of data, the advisory council report identified four areas that are slowing our potential for job creation.

1. First is the lack of early stage venture capital. There is a real lack of early stage venture capital that is threatening our ability to realize high growth companies. Early stage capital includes financial support of technologies emerging from our world-class research institutions, financial support of start-up companies enabling hiring early employees and financial support of life science companies before and during regulatory approval by the FDA.
2. Second is a lack of seed capital for innovative entrepreneurs. The life sciences industry transformation is generating new opportunities as the traditional model of large company formation breaks down into companies existing of interdependent smaller units of multiple contracted experts – spurring new entrepreneurs to form start-up companies. To retain those entrepreneurs and encourage job growth in Pennsylvania, these start-ups will need significant capital in the early stage to attract private investment and validate their research. Due to significant upfront costs (e.g., regulatory/patents/manufacturing scale-up), often innovative companies take more than 10 years to become profitable.
3. Third is a need for public/private partnerships. Need for increased public-private partnerships in support of new capital formation. Our work identified new models, such as the effort being discussed today, that allow public support to catalyze a market.
4. Fourth is outreach to small businesses to commercialize Pennsylvania research. We must improve our ability to commercialize our research from our universities and, wherever possible, assets in the laboratories of large pharmaceutical companies that are not being developed. This can only be done with a concerted effort and the capital to support these new technologies.

Around the country new investments are being made in other states in support of early stage capital formation though public-private partnership models. Maryland established the Bio2020

initiative, which will invest \$1.3 billion over the next 10 years to support the MD Biotechnology Center, double the biotechnology investment tax credit, and which provides funding for incubator and capital projects devoted to the biosciences. ***This is in addition a program enacted which is very similar to the insurance tax credit initiative we are discussing today.***

Ohio renewed funding for their Third Frontier program, a 10 year, \$1.6 billion initiative designed to support the overall technology industry in the state, with a new four-year, \$700 million bond, approved by voters in May 2010 which will bring the total investment to over \$2.3 Billion.

The most significant life science economic development competitor to Pennsylvania is Massachusetts, ranked first in the nation by the Milken Institute's Technology and Science Index. With the Massachusetts Life Science Initiative, created in 2008, over \$1 billion is being invested over 10 years.

I also wanted to stress the pattern of entrepreneurship as exemplified by Small Business Innovation Research (SBIR) grant data. Pennsylvania currently ranks #7 for SBIR awards, receiving 4.27% of the awards granted. However, California and Massachusetts receive 21% and 14% respectively of the non-dilutive awards. Pennsylvania needs to enhance the availability of early stage capital or risk losing innovative companies with high growth potential.

Pennsylvania must focus on investing money in getting technology from the lab and into the market place – this investment that will have the greatest impact on Pennsylvania specifically in terms of job creation. The value of technology increases as it develops and is taken from the lab into the market place. If Pennsylvania is going to invest, the greatest return on investment will stem from investing in early stage companies which have shown the ability to get technology to the market, possess technology which fits an unmet market need and have a true desire to take their technology from the lab to the market place.

As the President & CEO of a rapidly expanding small business in Pennsylvania, I'm happy to share my experience and answer your questions on the importance of capital in my industry. Protecting patents, ensuring compliance in a heavily regulated industry and purchasing state of

the art equipment requires significant upfront cost years before a company like mine becomes profitable.

According to literature from the Medical Device Manufacturers Association (MDMA), 80% of medical device companies have less than 50 employees and 98% employ less than 500 employees. Actuated Medical has 20 employees – doubling in size over the last two years. Our plan is to add at least 15 more in the next three years. Also, in the last 6 years Actuated Medical has raised \$12 million, with \$10 million coming from federal government SBIR non-dilutive grants and \$2M from strategic partnerships.

Not only does the influx of capital, as outlined in “Innovate PA”, help attract and grow businesses like mine, but perhaps more importantly, investment from the Commonwealth serves to validate new technologies and leverage significant follow-on investment by angel investors and venture funds. This early stage funding is essential for companies like mine to survive to become profitable, let alone expand, given the significant early stage investment.

I appreciate the opportunity you’ve provided for me today to address this committee. As a key sector to Pennsylvania’s economy, the life sciences industry continues to fuel the innovation pipeline, retain and expand the number of family sustaining jobs in the Commonwealth and deliver novel therapies to fulfill unmet patient needs. Many of these innovations produce significant cost savings in the healthcare system while improving the lives of patients around the world. Collectively we must ensure Pennsylvania remains an attractive location to open and grow a life sciences business, the future of our economy depends on it.

Thank you.