

House Small Business Committee

“Tales of Resilience: Small Business Survival in the Recession”

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On behalf of the Advanced Medical Technology Association

Chairman Graves, Ranking Member Velazquez, and members of the Committee, thank you for holding this important hearing today to highlight the success of small businesses across the country. My name is Mike Minogue and I am the Chairman, President and CEO of Abiomed, a small medical device company located in Danvers, Massachusetts. We make the world's smallest heart pumps that can be inserted percutaneously through a small hole in the leg. Additionally, I serve as chairman of the board of AdvaMed's Emerging Growth Company Council, the division of AdvaMed which focuses on emerging medical device companies.

About the Medical Technology Industry

Abiomed is a member of AdvaMed, the Advanced Medical Technology Association, which represents approximately 500 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of AdvaMed member companies are relatively small companies with sales of less than \$100 million per year—the majority of these companies not yet profitable. The strength and future of the industry lies with these companies, who are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives.

The medical technology industry is an American success story. The industry directly employs more than 400,000 workers nationwide. Typically, for every worker our industry directly employs, another four workers are employed by businesses supplying components and services to our industry and our employees, so that the total numbers generated by our industry exceeds two million.

The jobs our industry provides are good jobs and serve a function that helps patients all over the world. Industry pay levels are 38 percent higher than average pay for all U.S. employment and 22 percent higher than other manufacturing employment. While the number of manufacturing jobs was plummeting across the larger economy, even before the recent economic downturn, employment in our industry was expanding. Between 2005 and 2007, medical technology employment grew 20.4%, adding 73,000 jobs. During the recession, between 2007 and 2008, MedTech employment dropped 1.1 percent, compared to 4.4% for manufacturing as a whole.

What the Committee may not know is that the medical technology industry is heavily skewed toward small companies—the kind of companies that begin with a scientist or doctor with an idea to improve patient care. Almost two-thirds of the 7,000 medical technology firms in the U.S. have fewer than 20 employees. A high proportion of the

breakthrough products in our industry come from these small, often venture-capital funded companies.

And whether the firm is large or small, success in our industry comes only from innovation—the creation of diagnostics, treatments and cures that save and enhance lives. While we are very proud of our contributions to the U.S. economy, we are even more proud of our contributions to improving patient care. For patients, medical progress has been remarkable. Based on the latest available data, between 1980 and 2000, medical progress added more than three years to life expectancy. The death rate from heart disease was cut in half; the death rate from stroke was cut by one-third, and the death rate from breast cancer was cut 20%.

About Abiomed

As the Chairman, President and CEO of Abiomed for the last 9 years, I am acutely familiar with the challenges faced by small businesses every day. We have increased our patients supported by a factor of 10, grown revenue by a factor of 7, raised over \$100 million in cash, and we became profitable last year while incurring no debt.

Abiomed was founded in 1981 in Danvers, Massachusetts, and we've had the fortune of continuing to grow since our founding. We are now a world leader in percutaneous mechanical circulatory support and we offer a continuum of care for heart failure patients. Specifically, our products provide prophylactic to emergency circulatory support for the heart. We believe the optimal clinical outcome for patients is one that restores their quality of life and is the most cost-effective solution for the healthcare system. We continue to publish papers and create new products around this goal. Many of our products are being utilized outside the United States and do not yet have FDA clearances or approvals.

While we have grown, we have incurred net losses since our inception with the exception of this fiscal year. Even though we were profitable for the first time in fiscal 2012, we may incur challenges in the future as we continue to invest in research and development related to our products, conduct clinical studies and registries, expand our commercial infrastructure and look to expand to new markets.

When Abiomed was founded, we were a company of 10 people with no products on the market. Through years of perseverance and hard work, we have now grown to a company of 440 employees and total revenue last year of \$126 million with projections of \$156 million this year. Even despite our country's recent economic hard times, we have continued to grow and add manufacturing jobs. At the start of the recession, in fiscal

2008, Abiomed's total revenues were \$59 million and we had approximately 300 employees.

While I'm proud that my company is a success story and that we have continued to develop and manufacture lifesaving products for patients, not every small company in our industry is as fortunate and many have gone out of business. The current environment is the most critically challenging of my healthcare career. Even with truly innovative products and serious commitment, many emerging growth medical device companies simply do not succeed—especially in the current down economy when investment dollars are scarce and regulatory challenges are growing.

For Abiomed, our success is founded on three pillars: innovation addressing a clinical need, scientific evidence, and hard work with execution.

In order to succeed in the medical device industry, which is both highly regulated and highly competitive, the first critical element of success is innovation. Abiomed created the world's smallest heart pump, Impella, which is 1/100th the size of the heart and can pump half to all of its output. Every day, we continue to develop on our breakthrough technologies—making improvements to them as scientific knowledge of the heart increases and as medical treatment progresses. The medical device market is characterized by a rapid innovation cycle, and to be successful companies must push to be on the leading edge of new technologies.

Secondly, in this day of increasing health care costs, scientific evidence around the clinical and economic benefit is critically important. Whenever we develop a new, innovative product, we need to be able to demonstrate that the product provides value to the health care system. These FDA studies and ongoing registries require significant investment and have ongoing maintenance for post-market monitoring, peer reviewed publications and independent cost effectiveness analyses. In summary, we have amassed a compelling collection of clinical and economic data around the use of our products and recently been incorporated into the medical guidelines as determined by the physician societies.

The third pillar—hard work and execution—is fundamental in any industry. A successful company needs to focus on quality, and in Abiomed's case, quality in manufacturing to patient support.

Aside from these three pillars, Abiomed has employed other strategies to succeed during these tough economic times. We are frugal. We cut expenses where we can and spend slowly. Sometimes that means that we invest or spend at a slower pace than we could,

given more positive economic circumstances. But this slow, steady, and frugal approach has allowed us to grow, despite the current economy.

Upcoming Challenges

I remain optimistic that Abiomed will continue to succeed based on the strength of our innovations and impact to patients. However, we do face challenges on the regulatory front. For example, we have several new products outside the U.S. that will require FDA interaction in both review and design of future studies in order to bring these products to the United States. Abiomed believes in patient access to safe and effective medical devices and supports the FDA as a critical partner in our efforts to bring products to the market. Without a strong, effective, and efficient FDA, we cannot have a strong and competitive industry. Specifically in the future, the predictability, consistency and efficiency of FDA decision-making, as well as risk-based standards of evidence to assure the safety and effectiveness of medical technology products, is essential to drive new innovations for patients. We are hopeful that the recently enacted Medical Device User Fee agreement will help to improve the process for all involved parties. While we have not always been pleased with the pace of progress, I would note that the FDA leadership is supportive of initiatives to help smaller companies and is passionate about their mission.

In the reimbursement environment, the Center for Medicare and Medicaid Services (CMS) has a diligent and thoughtful process to analyze clinical data from the real world usage within registries, peer reviewed publications and the FDA approved studies. We will continue to support more publications with the clinical experts in the field, while incorporating the cost effectiveness models.

My biggest concern relates to the medical device tax. Starting on January 1, 2013, medical device companies will face a \$30 billion tax, which was included as part of health care reform. While I am supportive of improving our country's health care system and improving patient outcomes, this tax is misguided and should be repealed.

Studies have estimated that up to 43,000 U.S. jobs will be at risk after the tax goes into effect. The tax will be especially damaging to innovative start-up companies, since start-ups tend to suffer losses in their early years when they are pouring money into research and development, and trying to move a product to market. Since the majority of the industry includes smaller companies that are not yet profitable, this tax increases the time these companies will be operating at a loss. For some, it could truly be the difference between surviving and having to close their doors.

For Abiomed, the impact of the medical device tax will be strongly felt. We're estimating that the tax will cost our company about \$4 million per year. To put this figure into context, we would not have achieved profitability last year. This tax is greater than the cost of providing healthcare coverage for our employees. And it's about 15 percent of our research investments and 10 percent of the expense of our employees. Since we have just achieved profitability, we will have to hire at a slower pace and defer future research projects to offset the new tax. Abiomed supports healthcare reform around patient quality; however, we believe this medical device tax is a separate policy issue and will have negative consequences on innovation.

I am heartened that the U.S. House of Representatives voted in early June, with bipartisan support, to repeal the device tax. I am hopeful that your Senate colleagues will follow your lead. The tax will cost jobs, harm innovation, and could lead to higher costs for patients, which is something that no one wants.

Conclusion

Mr. Chairman, Ranking Member Velazquez, and members of the Committee, thank you for the opportunity to testify today, and thank you for your focus on companies who have been successful, despite the economic downturn. Small businesses are truly the backbone of America's economy—just as they are the backbone of the medical device industry.