

Testimony of Mark Deem

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House of Representatives Energy and Commerce Committee

Subcommittee on Health

“Impact of Medical Device Regulations on Jobs and Patients”

Thank you for inviting me to speak to you today. My name is Mark Deem. A biomedical engineer by training, I have spent 23 years in early stage medical device research and development.

Today, I am a partner in a medical device company incubator called the Foundry. Our job is to partner with physicians to investigate significant unmet clinical needs, and to then invent and develop technologies to better treat patients suffering from those diseases. Over the past 12 years we have founded, funded, staffed and run over a dozen medical device startup companies. We have raised over \$700 million in venture capital. We are inventors on over 250 issued and pending US patents and at their high points, our companies employed over 500 people.

Each company that we start focuses on treating a specific disease or condition that improves the lives of patients, improves public health and reduces health care costs. In a number of cases we have studied existing surgical procedures and pioneered ways to replicate the results of those surgeries without making an incision.

Because of the efforts of my partners and I and the teams we have built, patients who 10 years ago would have had major open heart surgery for cardiac valve disease can now undergo a one hour catheter based procedure to have their valve repaired.

Patients who suffer strokes when blood clots become lodged in their brains, who ten years ago would have been sent to rehabilitation facilities to hope for the best, today can have that clot removed with a tiny device threaded into the arteries in their brains. Patients who present unable to speak or move have walked out of the hospital after this procedure.

Patients with uncontrolled drug resistant hypertension can undergo a 30 minute procedure which lowers their blood pressure by 3-5 times what most hypertension medications can achieve.

I am speaking to you today because those of us who operate on the most fragile end of the medical device ecosystem, the startups, are struggling. Startups are responsible for a huge percentage of paradigm-shifting breakthroughs in patient care. We exist for our patients, but we live on venture capital.

According to reports by Price Waterhouse Cooper and the National Venture Capital Association, between 2007 and 2010, venture capital investment in the medical device sector declined by over 37%. Funding for new startups dropped from 118 new companies in 2008 to 60 in 2010 according to the Dow Jones Venturesource. The primary risk factor impacting investment is the unpredictability of and delays by the FDA. This concern is justified - over the same time period the average time to approval for a PMA device increased by 75%. And many companies never get through the process at all.

And that is the good news – those companies actually obtained approval. There are many examples of the following scenario:

- A company works with the FDA to structure a clinical trial with specific endpoints
- The trial is conducted over 3-5 years at costs of \$50m or more
- Clinical trial endpoints are met only to have the FDA change the metrics and expectations and request a new trial based on those new expectations

Based upon experience, companies and investors have little reason to believe that the outcome will be any different the next time around. Investors withdraw support, companies shut down, jobs are lost, and patient care suffers.

These experiences have led us to fundamentally rethink how we operate. Given the lack of predictability in the US, and the relative stability and predictability of the CE mark system, we are no longer structuring, staffing or operating our companies for first commercial release in the US. We develop our products here, and then run the same large, multicenter randomized trials we would otherwise have conducted in the US overseas. We are then staying there to commercialize the products while we decide when and if to approach the FDA.

As a result, where earlier this decade PMA products were approved on average about a year earlier in the EU, today that is up to four years.

We recognize the challenges and hard work FDA has before them – we value the FDA and its mission to protect and preserve public health. However, we need consistency and clarity to help the FDA achieve its mission of fostering innovation. If it were clear that a fundamentally longer and more complex FDA process really was providing superior safety for our patients, perhaps our complaints would be moot. But the recent study from the Boston Consulting Group shows that the EU safety record is essentially identical to that of the US.

So if we are not increasing safety, why should we be satisfied with a system that is driving investment innovation and jobs overseas? Why should we be satisfied with a system wherein US patients wait up to 4 years longer for access to care that was pioneered in the US? Because the sad fact is, many of those patients simply will not live that long.