TESTIMONY

OF

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Before the House Committee on Oversight and Government Reform

"Pathway to FDA Medical Device Approval: Is there a Better Way?"

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Thank you Mr. Chairman, and members of the Committee, for the opportunity to appear before this Committee.

My name is Erik Paulsen; I represent Minnesota's Third Congressional District and serve as co-chair of the House Medical Technology Caucus. I'd like to share with you why I believe the medical technology industry – an American success story, one that routinely revolutionizes patient care and creates thousands of high-tech jobs – is at risk of drying up and moving overseas.

Promoting made-in America medical devices and encouraging innovation is near and dear to my heart. Across the country, there are 8,000 medical device firms employing 400,000 dedicated, hard working and innovative people.

Currently, the United States is a world leader in this industry. Its supremacy is threatened not by cheap overseas labor or countries with more competitive tax structures, but by the bureaucracy within our own borders.

Whether I'm meeting with medical innovators back home in Minnesota or across the country, I hear the same story: it's getting harder and harder to bring life-saving devices to the marketplace in the U.S. because of a lack of consistency, predictability, and transparency in the Food and Drug Administration's pre-market review processes.

Device companies that deal regularly with the FDA cite many reasons for this inconsistency. One problem is that the FDA seems to be routinely proposing new endpoints midway through the review process. Of course, if new scientific information calls a device into question, the FDA should be allowed to request more information. But many of my constituent companies report that FDA reviewers make new, arbitrary demands late in the product review process.

These inconsistencies are frustrating and costly for all innovators, but small companies in particular cannot keep up when the FDA continually moves the goal posts, which is causing some firms to go out of business.

One Minnesota company, Acorn Cardiovascular, recently had to close its doors due to such inconsistencies. The company had conversation after conversation with FDA staff about how to test its device. Acorn performed a randomized trial, met its targets, and, in the end, thought it would be approved. But reviewers at the FDA moved the goalposts and required a new trial. Because of this, investors shied away, Acorn couldn't raise the capital to perform another multi-million dollar trial and had to close its doors. Ultimately, fifty jobs were lost and a life-saving technology for patients is now not available in the U.S.

Additionally, companies have been frustrated with what appear to be FDA stalling techniques. Many entrepreneurs I've met with have had agency reviewers pursue one line of questioning early in the review process and then switch to a new, previously un-addressed topic, after the third or fourth submission.

In 2008, Xtent, a Menlo Park, CA, coronary stent company, tried to gain approval to start a U.S. clinical trial. Over the next two years, the FDA asked round after round of questions and required long pre-clinical animal trials. At the time, Xtent had clinical experience in hundreds of European patients, some with over three years of follow-up in world-class hospitals. But the FDA refused to consider the data and as a result of the delays, the company closed, 150 employees were laid off, and the assets were sold to foreign interests for pennies on the dollar. Today, the technology is being developed in China and Europe, with no plans to return to the U.S.

This is just one of many examples. If it pleases the Committee, I would like to submit several more for the record.

Thanks in part to inconsistencies like these, we're starting to see our competitive edge disappear. Currently, devices are approved two years earlier in Europe than in the U.S., denying our patients access to life-saving technology. If this trend continues, more companies will look for greener pastures, and take their innovations and their 400,000 high paying jobs with them.

The FDA has a statutory mandate to consider the "least burdensome" means of demonstrating devices meet safety and efficacy standards. Unfortunately, in recent years the agency has abandoned this principle. The least burdensome provisions should force the agency to find an appropriate balance between patient protection and the development of new, life-saving products. I'm working on legislation to restore this balance at the agency and other efforts to modernize and streamline.

It is my hope that today's hearing will help us find that balance and a pathway to a more consistent, predictable, and transparnt FDA pre-market review process to help the medical technology industry continue to be a bright spot of our economy and ensure patient access to life-saving medical technologies.

Thank you again for the opportunity to appear before the committee today.