Minn. legislators to FDA: Don't tread on device makers

Mass Device

A pair of Minnesota legislators are lobbying against changes the Food & Drug Administration proposes for its 510(k) clearance protocol the industry says will hurt innovation and the states economy.

U.S. Sen. Amy Klobuchar (D:Minn.) and Rep. Erik Paulsen (R:Minn.) sent a letter to FDA Commissioner Dr. Margaret Hamburg [1], warning that overzealous regulation would hurt start-ups struggling to raise venture capital in a weak economy.

Klobuchar

Paulsen

"Bringing a new medical device to market typically involves millions, sometimes hundreds of millions, of dollars in upfront research and development costs," wrote Klobuchar, chair of the Senate Commerce Subcommittee on Competitiveness, Innovation and Export Promotion [2], and Paulsen, chair of the Medical Technology Caucus [3]. "The suggested changes could threaten the availability of often relied on equity investments."

Calls to both Klobuchar's and Paulsen's offices seeking an explanation of the specific changes to the 510(k) program that concern the legislators were not immediately returned.

The letter comes about a week after Dr. Jeffrey Shuren [4], director of the agencys Center for Devices and Radiological Health, met with local industry officials in a

town hall forum [5] in Bloomington, Minn.

Heres the full text of the letter:

May 25, 2010

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hamburg,

Thank you for your service in your role as Commissioner of the Food and Drug Administration (FDA). We are writing to express concerns regarding the FDAs proposed changes to the 510 (k) approval process for medical devices.

This is an issue of particular importance to our home state of Minnesota. Our state has led medical innovation for more than 60 years and boasts more than 400 medical device companies that together employ over 50,000 people. In the last few weeks, weve had the opportunity to speak with a number of medical device companies, many of which attended the FDAs town hall meeting on May 18, 2010 in Bloomington, Minnesota regarding recent changes in the FDAs approval process.

We support your agencys goal to improve the FDAs policies and procedures to ensure only safe and effective devices reach the marketplace. We also applaud your willingness to meet personally with our states medical device industry to discuss how they can have the most productive collaboration. This is essential for American patients to continue to have access to the best, most advanced medical technology possible.

However, we are concerned that some policy changes under consideration by the FDA would add new and unnecessary regulations, resulting in an even longer and more complicated approval process.

In addition to creating an undue regulatory burden, these changes would increase the time, cost and risk associated with developing new medical technology.

Bringing a new medical device to market typically involves millions, sometimes hundreds of millions, of dollars in upfront research and development costs. The suggested changes could threaten the availability of often relied on equity investments. Already, FDAs increasingly slow and inconsistent approval system has dampened investment in small medical device firms. In the last two years, venture capital funding alone dropped by one-third. Efforts to further restrict the approval process would only compound those declines, jeopardizing 83% of jobs in the medical technology sector and threatening our nations $5.4 billion trade surplus in medical device exports.

For decades, the FDA and the medical device industry enjoyed a successful partnership– one that allowed them to ensure new products were appropriately vetted, and innovative technologies were adequately supported. We urge the FDA to maintain that tradition of cooperation today, and to reject proposals that unduly burden small businesses and suppress the development of promising medical breakthroughs.

Thank you for your consideration of this important issue.

Sincerely,

Amy Klobuchar
United States Senator

Erik Paulsen
United States Representative

SOURCE [6]

Source URL (retrieved on *04/27/2015 - 8:30am*):
http://www.mdtmag.com/news/2010/05/minn-legislators-fda-dont-tread-device-makers?qt-recent_content=0

Links:
[1] http://www.fda.gov/AboutFDA/CommissionersPage/default.htm
[2] http://commerce.senate.gov/public/index.cfm?p=CompetitivenessInnovationandExportPromotion
[3] http://paulsen.house.gov/index.cfm?sectionid=138&sectiontree=2,77,138
[4] http://www.fda.gov/AboutFDA/CentersOffices/ucm193990.htm
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