

## Devices & Diagnostics Letter

Aug. 30, 2010 | Vol. 37 No. 34

### Lawmakers: Better 510(k) Process Key to Keeping Device Jobs in US

Trying to keep devicemakers, and the jobs they provide, in the U.S., two senators are urging the FDA to be more transparent and predictable in its review of 510(k)s.

Sen. Al Franken (D-Minn.), armed with the frustrations of device companies, will meet with FDA Commissioner Margaret Hamburg Sept. 16 to push for more transparency in the review process.

His colleague, Sen. Amy Klobuchar (D-Minn.), met with Hamburg this summer to discuss slow review times. Klobuchar plans to meet with the commissioner again on other industry concerns.

Delays in review times and the agency's unpredictability in reviewing 510(k)s are hurting U.S. devicemakers trying to compete in the global market, as more and more countries, including China, require devices to be approved in their home country before granting them marketing authorization. As a result, some devicemakers have moved their headquarters to the EU where they can get more timely marketing approval, Klobuchar told *D&DL*.

"Lots of small devicemakers have already moved to Europe, which is unfortunate because many of the most innovative devices come from small companies that are later purchased by larger companies," Klobuchar said. "Small gutsy companies are suffering the most here."

When devicemakers have discussed their frustrations about slow review times and lack of predictability with CDRH officials, they have been told the problem is the result of the center's lack of staffing (*D&DL*, May 3).

To address this shortage, the agency has proposed relying more on a network of non-FDA experts to help review submissions involving complex technology. It also has asked for more funding for staffing (*D&DL*, Feb. 8).

However, Klobuchar said it is unlikely the Senate would hand over more funds to the agency until it demonstrates that it understands that having an opaque and lengthy 510(k) review process is hurting the device industry and causing jobs to leave the country.

"They have to prove steps are being taken," Klobuchar said.

In preparation for his meeting with Hamburg, Franken met recently with several devicemakers in Minnesota. One of the companies told him it had submitted clinical data

to support its submission only to be asked later to conduct a second completely new study, which delayed the market launch of the device.

“This is a difficult situation to be in, especially when it involves small companies, as they don’t have the capital” to withstand such demands and delays, Franken told *D&DL* last week.

During his meeting with the devicemakers, Franken also heard from John Romans, CEO of BioMedix Vascular Solutions, who expressed concerns about a recommendation from the FDA Transparency Task Force to release more information about 510(k) submissions before they had been cleared (*D&DL*, July 26). Releasing such information could potentially violate trade secrets, Romans said.

Franken and Klobuchar agreed that working with the FDA, rather than introducing legislation, is the best way to resolve devicemakers’ concerns about the 510(k) process — thus, their meetings with Hamburg.

On another note, Franken said he expects to introduce a new bill once the Government Accountability Office (GAO) completes its investigation into the incentive disparities in developing drugs and devices for rare diseases. Device companies are given no incentives, but developers of orphan drugs are offered tax credits, exclusivity and an accelerated approval path.

Franken asked the GAO what legislative changes Congress can take to address these discrepancies between the two industries (*D&DL*, July 26). — Virgil Dickson

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