

FDA plans tougher review of devices Electronic reports part of program

By Diedra Henderson, Boston Globe Staff | November 10, 2006

WASHINGTON -- The Food and Drug Administration yesterday outlined a plan for tougher monitoring of the safety of medical devices once the products are on the market. It comes just after Democrats , who promise more aggressive oversight of the FDA, wrested control from Republicans in the House of Representatives and Senate.

The FDA said the timing of yesterday's plan was "totally unrelated" to the election outcome. The agency's plan includes an electronic system for reporting serious side effects, to replace the paper reports now filed by medical professionals and patients.

"The entire FDA post-marketing surveillance system is weak both for drugs and devices," said Dr. Steve Nissen , a Cleveland Clinic Foundation cardiologist scheduled to testify at a congressional hearing this month about the FDA. "Unfortunately, adverse event reporting is voluntary and, generally, only 1 to 10 percent of events are reported," Nissen said.

A Democratic-led Congress appears willing to make that and other FDA improvements, starting by shuffling a few key committee chairmen.

Democrats Edward M. Kennedy of Massachusetts , Henry A. Waxman of California , and Bart Stupak and John D. Dingell both of Michigan are poised to head key congressional panels with investigatory powers and FDA oversight.

"With congressional oversight, [the FDA is] going to face a much tougher, much tougher environment," said John Manthei , a partner in the Washington, D.C., office of Latham and Watkins LLP . "Mr. Waxman and Mr. Dingell and Mr. Stupak have made it very clear that FDA is squarely within their crosshairs," said Manthei, FDA counsel for the Medical Device Manufacturers Association .

Kennedy has co sponsored reform legislation that, among other changes, shifts planning for how to handle emerging drug risks to the preapproval phase -- when the FDA has more clout -- and provides more drug-safety funding.

The FDA said that its plan will help it better detect and take action on risks related to thousands of medical devices, such as mesh stents used to prop open clogged arteries, pacemakers, and implantable defibrillators that tame irregular heart beats.

The agency is under fire for underestimating such problems as long-term heart risks attributed to drug-eluting stents, manufactured by companies that include Natick's Boston Scientific Corp . The FDA relied on short-term studies for the approvals. Next month , it will convene an advisory panel to discuss cardiovascular safety data from longer-term use.

In addition to the electronic reporting system for side effects, the FDA already has assembled a network of 350 hospitals that report problems with devices, shortening the time it takes for the agency to learn about problems. Dr. Daniel Schultz , director of the FDA's Center for Devices and Radiological Health , said the agency will more aggressively tap that database.

In addition, medical devices soon could carry "unique identifiers" that make it easier to track them down, permitting more focused recalls of problematic models.