FDA plans modest changes to medical device system

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(AP) -- The Food and Drug Administration is laying out plans to update the 35-year-old system used to approve most medical devices, which has been subject to increasing criticism by public safety advocates.

The agency announced a series of changes it plans to make this year, including streamlining the review process for some low-risk devices. But regulators said they will delay a decision on the most drastic proposals, which would give the government new power to police device makers.

Those proposals, widely supported by public safety advocates, included clarifying the FDA's power to revoke approval for products that prove unsafe or ineffective. Another key proposal would have established a new subset of devices that would require more medical data to gain approval.

But those proposals, unveiled for comment last summer, received strong pushback from device companies, and the FDA said in its report "that implementing them may be problematic."

The device industry's chief trade group, AdvaMed, lobbied against the changes, saying they would make device reviews longer and more expensive, hurting innovation and endangering jobs. The group represents most of the largest device firms, including Medtronic Inc., Stryker Corp. and Johnson & Johnson.

Dr. Diana Zuckerman of the National Research Center for Women and

Families said the FDA's plan suggests "industry lobbyists won, and the public lost."

"Today's FDA report gives the impression that FDA backed down on several safeguards as a result of unfavorable comments," Zuckerman said in a statement. "FDA decisions should not be based on a popularity contest, especially since lobbyists rig the results"

The FDA said it would wait for the guidance of the Institute of Medicine before making a final decision on more sweeping changes. The nonpartisan expert group advises the federal government on medical policy.

The so-called 510(k) system for devices was created in 1976 to grant speedy approval to devices that are similar to products already on the market. It is popular among manufacturers because it is a faster, cheaper path to market than the review process for novel devices, which must undergo rigorous medical testing. Hip replacements and drug pumps are among the devices cleared under the system.

But FDA critics say that high-risk devices, such as heart pacemakers, are increasingly slipping through the 510(k) process without thorough testing and scrutiny.

About 4,000 devices are cleared every year under the 510(k) system, while about 50 devices are approved under the more stringent system.

Last October the FDA took the unprecedented step of acknowledging that a knee repair device cleared via 510(k) in 2008 should not have made it to market. The FDA's two top device regulators who oversaw the device's review have since left the agency.

Beginning in March the FDA said it will make 25 changes to the 510(k)

process, including:

- establishing a database with photos and safety labeling for all devices

- clarifying when companies must submit clinical data for a 510(k) application

- establishing a council of experts within the agency to work on timely device approvals