FDA medical device approvals get external review

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(AP) -- The Food and Drug Administration is asking the government's top medical advisers to review its system for approving certain types of medical devices, which has been criticized by safety advocates and government watchdogs.

The nonprofit Institute of Medicine will conduct a two-year review of FDA's so-called 510k review procedure, which allows device companies to quickly launch products similar to those already on the market.

The announcement Wednesday garnered approval from lawmakers on Capitol Hill who have been skeptical of the FDA program.

"I have long been concerned that the 510k process permits too many devices on the market about whose safety and effectiveness even the FDA is uncertain," said Rep. Henry Waxman. "The result is hundreds of recalls of important devices for serious safety concerns."

The California Democrat chairs the House Energy and Commerce Committee, which oversees the FDA.

The procedure was originally intended to speed the approval of simple devices like bandages and wheelchairs, but in recent years it has been used to approve high-risk devices.

The Government Accountability Office, Congress' investigative arm, recently identified two-dozen device types that were approved without

close scrutiny, including hip replacements and heart implants.

Normally, companies have to submit the results of large patient studies before launching such devices. But by arguing that their devices are similar to other FDA-approved products, companies can speed up the approval process. Under the 510k system, manufacturers simply have to give the FDA 90 days notice of their intent to launch their product.

The FDA said in a statement that medical technology has changed quickly in recent decades "making it an appropriate time ... to review the adequacy of the pre-market notification program."

The Institute of Medicine's review is expected to cost $1.3 million and its findings will be published in March 2011, according to the FDA.

The Advanced Medical Technology Association, which represents device makers like Medtronic Inc. and Boston Scientific Corp., called the 510k process a "well-defined, science-driven method." The trade group urged the institute to seek input from industry experts.

The institute, which advises the federal government on medical issues, is expected to hold two workshops in coming months to gather comments from industry, physicians and patients.