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Opening Statement

Rep. Danny K. Davis, Ranking Member

**Subcommittee on Health Care, District of Columbia, Census and the National Archives
Hearing on "FDA Medical Device Approval: Is There a Better Way"**

June 2, 2011

Mr. Chairman, thank you for yielding. The Food and Drug Administration is responsible for ensuring the safety and effectiveness of medical devices that millions of Americans use to help them walk, to help their hearts beat and to help their children regain their health and live a normal and productive life. The regulations that govern the approval of medical devices are there for a critical and simple reason - they save American lives and prevent injury by medical devices that are unsafe or ineffective.

We all understand the importance of protecting jobs and fostering innovation. Illinois is home to hundreds of large and small medical device manufacturers; employing thousands of my constituents and many of these facilities I have visited. I applaud the technological advances being made each day; some of which have allowed close friends and family to lead productive lives. Nevertheless, I fully understand the importance of striking the right balance between innovation and safety.

There are those who believe that the FDA takes too long to review medical devices. For its part, the FDA has offered statistics that the agency says shows it is performing well in this regard. We will hear today from both the FDA and those involved in the medical device industry.

As we listen to the testimony today and consider the views of the witnesses, we cannot lose sight of what is ultimately at stake - the lives of average Americans who rely on the FDA to protect them from faulty medical devices that may cause harm. It is the FDA who bears the awesome responsibility of protecting lives by ensuring that medical devices do what the manufacturers claim they do.

There are those who have suggested that the FDA's approval process for medical devices should be more like the approval process in the European Union. This is troubling to me because in the European Union, medical device manufacturers do not have to show that their product is actually effective in treating the particular ailment it is supposed to treat.

I am sure there isn't anyone in this room who would want a hip implant, a heart stent or any other device in their body that was not effective.

In the past 5 months, at least 15 recalls of medical devices were announced. These recalls involved such products as glucose test strips, catheters, an insulin delivery system and an implantable infusion pump. Last year, there were over 2,500 recalls of medical devices. One of the most widely covered device recalls last year involved hip implants that had already been used in 93,000 patients before they were recalled by the company.

There is no greater responsibility that our government has than to protect the health and lives of its citizens. That is a responsibility that the Congress has bestowed on the FDA. I thank our witnesses for being here with us this afternoon and I look forward to hearing your testimony.

Thank you.

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