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Opening Statement

Rep. Elijah E. Cummings, 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

Chairman Gowdy and Ranking Member Davis, thank you.

The FDA is responsible for ensuring that medical devices used on patients in the United States are safe and effective in performing the functions they are intended to perform. This is a grave responsibility. Placing an unsafe or ineffective medical device inside a patient is dangerous and life-threatening. Getting this right must be FDA's highest priority.

Some have argued that the European Union reviews and approves medical devices faster than the FDA, but I would urge that speed at the expense of safety is not a tenable solution. As one of our witnesses today, Dr. Jeffrey Shuren, mentioned in an Energy and Commerce subcommittee hearing on this same topic in February, the EU approves devices without requiring that medical device manufacturers actually demonstrate their devices are effective in treating the ailments that they say they will.

If I needed a medical procedure, and certainly if my child needed one, I would want to know that the medical device being used is both safe AND effective. And if Medicare or Medicaid is going to be paying for any part of this procedure, I think the American taxpayer deserves to know that the medical device that they are buying works.

While the FDA's priority must be to ensure that the devices it approves meet these strict standards, the FDA also must ensure that its review process does not impede the development of innovative medical devices. In that respect, I have been encouraged by the FDA's representations that they are meeting their goals for timeliness. It is my understanding that the FDA reviews 95 percent of device applications that are subject to user fees within a timeframe that was agreed to by the medical device industry as part of the Medical Device User Fee and Modernization Act of 2007.

As with any regulatory process, there are likely improvements that can be made in the FDA's medical device approval process. The FDA has acknowledged as much and has announced specific steps it is taking to make improvements.

It is my understanding that there is an ongoing review of the 510(k) process and I look forward to learning more about the progress of this evaluation, as well as other ways that the FDA can improve the approval process without compromising patient safety.

That said, I note that a study conducted by PricewaterhouseCoopers this year, comparing medical innovation and technology in the United States and in other nations revealed that “on a scale of 1 to 9, with 9 as the highest score, the U.S. currently has a total score of 7.1 and is the **global leader in medical technology innovation.**”

According to this study, other developed nations such as the United Kingdom, Germany, France and Japan earned scores ranging from 4.8 to 5.4.

We must work to ensure that the United States remains the world leader in innovation, while also ensuring that the safety and health of the American people is never compromised.

I thank our witnesses for being here today and look forward to their testimony.

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