Opening Hearing Statement for Wednesday, April 13

Special Committee on Aging

"A Delicate Balance: FDA and the Reform of the Medical Device Approval Process"

Good afternoon. I'd like to thank the Members and our witnesses for being here today. We're examining a very important topic: the Food and Drug Administration's management and oversight of the thousands of medical devices countless Americans rely on every day. The overall success of this process has become even more urgent for seniors in recent years.

Innovative technology has provided valuable, life-saving medical devices that have prolonged life and reduced suffering. We must do all we can to make sure that these new medical products are getting to the market quickly and safely. However, the FDA must constantly strive to maintain a delicate balance between safety and innovation. As we will hear this afternoon, it's an extremely difficult assignment.

The medical device industry has understandable concerns that significant changes in the medical device approval process contemplated by FDA could slow the rapid progress of new medical technologies to hospitals, patients, and the marketplace. They have also expressed concerns to the agency about a lack of consistent and clear guidance on how to get medical devices approved.

However, the drive toward getting new technologies to market shouldn't be done at the risk of patient safety. Faulty medical devices, especially those implanted in the body, can have a disastrous impact on the health of those who use them. Today, we will hear a first-hand account of the trauma that occurs when an implantable medical device must be removed due to a recall and device failure. As we hear about the cost to patients, we should not forget the cost of recalls to the health care system as a whole.

We will have an update from the GAO, which has been investigating FDA's handling of the medical device approval process for the last several years. Somewhat disturbingly, this process has remained on the GAO's "high risk" list of government programs for two years.

GAO will also report on FDA's "fast track" approval process for medical devices, which accounts for more than ninety-five percent of all medical device approvals and helps get medium and low risk devices to patients faster.

Finally, a top FDA medical device expert will discuss the complex and daunting challenges of overseeing medical device products in a time of tight budgets and exploding global medical technologies.

I believe we can find ways to improve safety in medical devices without hampering medical innovation. I look forward to hearing the ideas of our witnesses on how we can improve post-market surveillance, improve adverse events reporting and ensure that high-risk medical devices get the safety review they need.

We look forward to hearing your testimony.