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Opening Statement of Rep. Diana DeGette
Ranking Member, Subcommittee on Oversight and Investigations
“Regulatory Reform Series #5 – FDA Medical Device Regulation: Impact on American
Patients, Innovation, and Jobs”
Subcommittee on Oversight and Investigations
July 20, 2011

Thank you, Chairman Stearns. I appreciate the opportunity to participate in today’s hearing to examine the role of the Food and Drug Administration in bringing medical devices to market as safely and quickly as possible.

This topic is incredibly important to me. One of my daughters has Type I diabetes. So I know first-hand how each day, children living with diabetes must balance their injections with blood sugar monitoring, healthy meals, and daily exercise. Health care costs related to diabetes total more than \$174 billion each year.

We must ultimately find a cure. But right now we must support the work of medical device innovators to develop technologies like insulin pumps and CGM’s that are critical in enabling young people with Type I diabetes to live a healthy life.

We need to make sure FDA has appropriate tools to ensure the medical device approval process helps these innovators and protects patient safety. So I look forward to hearing from Dr. Jeff Shuren, the Director for the Center of Devices and Radiological Health, on ways the current process can be improved.

Last month, FDA took an important step in advancing the development of an artificial pancreas system glucose suspend system, which is the predecessor to a full artificial pancreas system. I look forward to hearing more about the specific steps the agency is taking to assist in the development of these critical devices.

FDA must be able to bring these and other medical devices to market as quickly as possible while ensuring their safety to the American public.

Mr. Chairman, as we hear from our witnesses today, we need to keep in mind that the second part of that sentence – ensuring the safety of patients – is just as important as the first part – bringing devices to market as quickly as possible.

We need to find the right balance, and we cannot pretend that there aren't sometimes trade-offs between safety and speed.

While I am sympathetic to some of the industry concerns we will hear today, I do fear that all too often the device industry and its allies try to blur those trade-offs between safety and speed.

Two studies funded by the medical device industry – one conducted by Dr. Josh Makower and the other by the California Healthcare Institute – that have been heavily cited by my Republican colleagues and by proponents of weakening FDA regulations provide a good example of how facts can be twisted.

Because they have been so heavily cited, Committee staff asked a panel of distinguished outside reviewers to analyze the methodology of these studies. At the staff's request, officials from FDA also submitted comments on the studies.

Mr. Chairman, Democratic Committee staff prepared a supplemental memo summarizing the expert reviews of these industry studies. I ask unanimous consent to include this memo, and the letters from FDA and the independent experts, in today's hearing record.

The reviewers found the following problems with these industry-funded studies:

- The existence of “so many flaws in design and execution that the authors’ conclusions are rendered essentially meaningless.”
- A “woefully inadequate” response rate of only 20%.
- A biased group of respondents that included companies that “had never gone through the process of getting a product reviewed by the FDA.”
- A “subjective,” “apples to oranges,” and “especially troublesome” conclusion regarding the difference in approval times between the European Union and the United States.
- The failure to provide “any evidence that [an U.S.] delay in approval and availability leads to adverse health outcomes.”

The journal editors concluded that the studies would not be fit for publication in a peer-reviewed journal. As we consider the role of the FDA, we must rely on the facts. The expert analysis of these two studies shows the pitfalls of relying on one-sided analyses of problems in the device industry.

Mr. Chairman, there is one way to both speed up the approval process and make patients safer – by making sure that FDA has the resources it needs to get the job done. The Republican budget seeks to cut FDA's funding by approximately \$241 million. These cuts, if enacted, will have a significant impact on the ability of FDA to do its job, including the efficient approval of medical devices. Massive cuts in FDA's budget will lead to the worst of both worlds – failure to protect patients and failure to get devices to the market quicker. We cannot let this happen.

Mr. Chairman, I thank you for holding this hearing today and I look forward to hearing from our witnesses today.