Senator Jerry Moran Opening Statement
Committee on Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Prioritizing Public Health: The FDA's Role in the Generic Drug Marketplace

September 21, 2016

(*As prepared for delivery*)

This hearing will come to order.

Good afternoon. Today's hearing will focus on the Food and Drug Administration's role in the generic drug marketplace. I would like to thank Dr. Janet Woodcock for being here today. I greatly appreciate your work at the FDA's Center for Drug Evaluation and Research (CDER) whose mission is to make certain that the public has access to safe and effective drugs.

I would be remiss if I failed to note that, earlier this summer, parents of children who suffer from allergies were suddenly faced with dramatic increases for epinephrine injectors or Epipens. I have an interest in working to ensure that drugs are available to all Americans at affordable prices. The FDA's role in the drug approval process is critical to expanding the pharmaceutical market and driving down costs for consumers.

While drug pricing is not the topic of this hearing, the FDA's responsibility to approve generic drugs in a timely fashion should be part of the larger discussion on pharmaceuticals. And, Dr. Woodcock, you wrote a piece on this topic recently and it is something my colleagues may be interested in reviewing.

With regard to FDA's role in the generic drug marketplace, Congress approved the Generic Drug User Fee Act in 2012 to speed up efforts to bring generic drugs to the market. In the past three years under this act, the FDA has collected $1 billion from generic drug manufacturers, which has translated into hiring an additional 1,000 employees and replacing antiquated information technology systems. However, despite this influx of resources, there are more than 4,000 generic drug applications currently awaiting approval, and the median time it takes for the FDA to approve a generic is now 47 months or nearly four years.

It is my understanding that the FDA is close to finalizing negotiations with industry on a new round of fees and regulatory requirements to address the backlog.

And while Dr. Woodcock cannot speak to specifics of this negotiation, I am hoping that this hearing will allow us to get a better understanding on how the FDA plans to tackle

the generic drug backlog and streamline the drug approval process to increase transparency, efficiency and predictability.

One final note: I would like to take this opportunity to acknowledge Dr. Woodcock's efforts to advance the accelerated approval process for patients who have no other treatment options. I know this is an issue of critical importance to patient advocacy groups, as we see with the recent approval of the first therapy for Duchenne muscular dystrophy, and I want to express my support for your efforts on that front.

I look forward to discussing these topics with our witness today. We have a lot to cover this afternoon, so I will now turn it over to Senator Merkley for any remarks he may wish to give.

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