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HATCH STATEMENT AT FINANCE COMMITTEE HEARING EXAMINING DRUG SHORTAGES IN AMERICA

WASHINGTON – U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Senate Finance Committee, delivered the following opening statement at a committee hearing examining the impact of drug shortages in America:

Chairman Baucus, thank you for convening today's hearing on such an important issue affecting our nation's patients and caregivers. We have all seen the disturbing stories in the press over the past several months about doctors unable to access critical medical products for their patients, and the impact that these drug shortages have had on patient care. While there is no doubt that increased attention and coordination has occurred between manufacturers and the government to begin addressing this problem, clearly more can be done to mitigate these shortages in the future.

Drug supply shortages are not new. Any product that involves complex manufacturing and distribution could face some supply challenges. What is new is the volume of shortages, the importance of the therapies that are experiencing shortages, and the challenges these shortages present to patients and caregivers. Every year since 2005, drug shortages have become more prevalent and widespread. In 2009, there were 157 products on the FDA's shortage list, and in 2010 that number increased to 178. According to the University of Utah, which keeps track of shortages for the American Society of Health System Pharmacists, the total number of drugs in shortage currently exceeds 275 FDA- approved therapies and continues to grow.

What is the impact of these increasing shortages? This crisis means worse outcomes for our patients, increased costs for caregivers and the government, slower medical advancement, and a persistent undermining of confidence in our country's healthcare system. Many of these drugs in shortage are used in current oncology treatment regimens. Not only are drug shortages impacting current treatments, they are harming future patients by delaying clinical trial results, increasing the length of clinical trials, and raising costs for research organizations.

Our federal payer system is also bearing the cost of drug shortages. Clinicians are forced to scramble to find alternative treatment options for vulnerable patients, often at a much

higher price for both the patient and the government. According to research by Premier, drug shortages could cost U.S. hospitals at least \$415 million annually. This is because more expensive substitutes are often needed, intermediaries significantly mark up the price of these drugs, and there are additional labor costs associated with finding these alternative solutions.

So what is causing this crisis? While this is clearly a complex issue, I believe we must look at the impact of federal programs on the generic injectable market. Seventy-four percent of drug shortages involved sterile injectables in 2010. I do not believe it is simply a coincidence that shortages are disproportionately impacting products with highly complex manufacturing processes that are also some of the lowest priced therapies. And I am not the only one to think that economic incentives play an important role in this issue. As recently highlighted in an article in the *New England Journal of Medicine*, experts contend that federal government pricing and rebate programs are a significant contributing factor to the current drug shortage crisis. The article also notes that there is an “untapped capacity” to produce generics but indicates that incentives to attract new entrants would be required to create redundancy in the market.

Mr. Chairman I ask unanimous consent that this article be included in the record.

Current pricing structures have been very effective at driving generic utilization. However, they may not fully capture or reward the costs associated with the complex development and manufacturing of injectables, as opposed to the more straightforward manufacturing process in the pill market.

The current situation is simply unacceptable, and we must act to address this growing crisis. As most of my colleagues know, I am working on a solution that will continue to improve coordination between manufacturers and the government, but that also addresses some of the federal price control and rebate structures that prevent the true costs of bringing these important medicines to patients from being adequately addressed.

I urge my colleagues to join me in working to solve this problem in the very near future.

Senator Baucus, thank you again for convening this hearing today. I look forward to hearing from our witnesses and having a serious discussion about the steps we must take to address this crisis.

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