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PhRMA Statement on President Obama's Drug Shortages Executive Order

Washington, D.C. (October 31, 2011) — Pharmaceutical Research and Manufacturers of America (PhRMA) President and CEO John J. Castellani issued the following statement today on President Obama's Executive Order on drug shortages:

"President Obama's Executive Order regarding prescription drug shortages echoes a priority of America's biopharmaceutical research companies – the well-being of patients and their ability to access life-saving prescription medications.

"Patient access to innovative treatments is the cornerstone of our industry. That is why the critically important issue of drug shortages demands our collective attention to ensure patients can access the medicines they need in the most expeditious manner possible. America's innovative biopharmaceutical companies have long worked to prevent drug shortages in advance, and will continue to work closely with the FDA to prevent manufacturing disruptions.

"The implementation of the President's Executive Order must effectively strike a balance between addressing a complex set of rare but nevertheless concerning issues in the manufacturing process while promoting a market environment that fosters accessibility for these needed products. Addressing anticipated occurrences of a drug shortage early in the process helps both health care providers and manufacturers identify treatment alternatives more efficiently, and we will continue to work with FDA to improve upon existing reporting requirements.

"Additionally, price gouging by secondary wholesalers is unacceptable. The 'gray market' presents serious concerns for patient safety as it cannot be assured that the products obtained by providers in this manner have been handled in a way that maintains product integrity.

"While the majority of drug shortages involve generic drugs, with FDA specifically referring to an increase in shortages among 'older sterile injectable drugs,' this problem concerns us all and requires our combined attention.

"As FDA, Congress and other experts have noted, the factors that contribute to drug shortages are complex and multidimensional, and it is important for all of us who provide life-saving medications to work collaboratively to minimize unexpected disruptions in the supply of vital medicines.

"In the instance a shortage is anticipated, an innovator or generic manufacturer is encouraged to notify the FDA in order to address, avert and mitigate drug shortages. In the event there is a discontinuation of sole source, medically necessary drugs, companies are required to inform FDA six months in advance. Manufacturers have stepped up the voluntary reporting of anticipated events that might lead to drug shortages, and according to the FDA, in 2011, this early notification helped prevent over 99 shortages.

"Patients concerned that their medicine may be in short supply have several options available, including visiting the FDA's Current Drug Shortages page to see if the drug has been reported in short supply or talking with your doctor, who may be able to offer another effective medicine.

“It is critical that we seek a more comprehensive understanding of the many circumstances that can lead to a drug shortage as industry, Congress, FDA, patients, providers and other stakeholders try to identify meaningful ways to help alleviate, mitigate and address this critical problem. PhRMA and its members have worked — and will continue to work — diligently to this common goal.”

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated \$49.4 billion in 2010 in discovering and developing new medicines. Industry-wide research and investment reached a record \$67.4 billion in 2010.

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