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SELECT COMMITTEE ON ETHICS

United States Senate

WASHINGTON, DC 20510 - 3505

January 13, 2014

Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hamburg:

On June 27, 2011, the American Society of Health-System Pharmacists (ASHP) announced a shortage of Doxorubicin (commonly known as "Doxil"). Doxil is a chemotherapy drug used to treat both adults and children who suffer from many forms of cancer. ASHP ascribes this continued shortage to manufacturing issues caused by the closure of the Ben Venue Laboratories facility located in Bedford, Ohio.

The Food and Drug Administration's (FDA) assistance related to the closing of the Ben Venue facility in Bedford has been greatly appreciated by the community, which will be financially devastated by this closure. Continued FDA assistance is essential, as I am concerned about the closure's effects on cancer patients across the country for which Doxil is the prescribed treatment. I urge that the FDA work with Ben Venue and the city of Bedford to help this lab remain a continued source of life-saving drugs.

Recently, a temporary agreement was reached that would enable Johnson and Johnson (J&J) to lease portions of the facility to produce Doxil. While this agreement is short term in nature, it would help provide a domestic source for the essential cancer drug and retain vital manufacturing jobs in Bedford.

In 2012, there were 117 new drug shortages in the United States. In 2011, there were 251. While I am appreciative of the work the FDA has done to decrease the number of shortages, I would like to know more about the agency's strategic plan under the Food and Drug Administration Safety and Innovation Act (FDASIA) to combat imminent and existing drug shortages. I also want to know what the FDA is doing to make use of labs, like Ben Venue, which could be quickly utilized by new manufacturers to continue producing drugs like Doxil to minimize the negative effects on patients who rely on these therapies.

I urge you to reach out to the Bedford community and work with local groups dedicated to bringing a permanent drug manufacturer to the site. While we have come a long way in shortening the list of domestic drug shortages, there are still far too many. The issue of drug shortages must remain a high priority for the FDA.

The FDA should do everything in its power to support prescription drug manufacturing in Bedford. I ask that your team continue to work with local stakeholders and the relevant industry partners to keep the manufacturing of important drugs online in Bedford.

Thank you for your help on this important issue. I look forward to continued collaboration with you.

Sincerely,

A handwritten signature in blue ink that reads "Sherrod Brown". The signature is written in a cursive, flowing style.

Sherrod Brown
United States Senator