Congress of the United States
Washington, DC 20515

November 12, 2013

The Honorable Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hamburg:

As the co-chairs of the Childhood Cancer Caucus, we write to express our concern over the ongoing shortage of the drug daunorubicin. As you know, daunorubicin is an essential therapy in the treatment of leukemia in children. In fact, daunorubicin is the accepted first-line pediatric treatment for acute myeloid leukemia (AML). If physicians are forced to treat AML with alternative chemotherapeutic agents, they would be risking increased toxicity to children, decreased efficacy, or both.

As of this summer, Teva Pharmaceuticals was the sole remaining supplier of the drug. Teva recently informed the Food and Drug Administration (FDA) that the drug was in limited supply and that it would not return to full production until sometime next year. The FDA website does not list a reason for the shortage, leaving providers little additional information to estimate the potential scope of the disruption.

Members of the American Society of Pediatric Hematology-Oncology report that hospitals are quickly exhausting their remaining supply of daunorubicin, with some institutions having only a few weeks of supply or only enough supply for one more patient. The Children's Oncology Group (COG) is currently conducting clinical trials for children with leukemia that includes daunorubicin, a cornerstone of curative AML treatment, as part of protocols. As a result of the shortage, for children and families who want to participate in clinical research, COG policy now requires the first course of daunorubicin be fully available at the treating hospital before allowing a child to be enrolled. Some children have now been prevented from enrolling due to the shortage.

We also note that despite the passage of needed reforms related to drug shortages in the Food and Drug Administration Safety and Innovation Act of 2012, shortages of essential drugs remain a serious problem in the United States. We must continue to work to identify and address the underlying causes of drug shortages so that we may prevent future instances that put patients at risk.

Based on the information available to the FDA, please inform us as to the cause of this shortage and the plans in place to return daunorubicin to full production. Please also let us know if the FDA has considered importing this drug if patients remain unable to access it domestically. We strongly urge you to do what you can to reduce or eliminate this critical shortage as soon as possible.

Sincerely,

Michael T. McCaul
Co-Chairman
Childhood Cancer Caucus

Chris Van Hollen
Co-Chairman
Childhood Cancer Caucus

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