

Congress of the United States
Washington, DC 20515

November 12, 2013

Dr. Jeremy M. Levin
President and CEO
Teva Pharmaceuticals
1090 Horsham Rd.
North Wales, PA 19454

Dear Dr. Levin:

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, your company was the sole remaining supplier of the drug. The Food and Drug Administration (FDA) website indicates that you recently informed 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.

Please inform us as to the cause of this shortage and describe the extent to which the limited supply you currently have available can meet the current need for the product. What are your plans to return daunorubicin to full production? What is your best estimate for when full supply may be reached? We strongly urge you to do what you can to reduce or eliminate this critical shortage as soon as possible.



Michael T. McCaul
Co-Chairman
Childhood Cancer Caucus

Sincerely,



Chris Van Hollen
Co-Chairman
Childhood Cancer Caucus