October 27, 2016

Dr. Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Asparaginase Erwinia Chrysanthemi (Erwinaze) Shortage

Dear Dr. Califf,

On behalf of the more than 1,900 multidisciplinary specialists of the American Society of Pediatric Hematology/Oncology (ASPHO) who are dedicated to promoting optimal care of children and adolescents with blood disorders and cancers, I wanted to share the impact that the current Asparaginase Erwinia Chrysanthemi (Erwinaze) shortage is having on patients as well as offer recommendations to the agency in hopes of improving this situation.

Drug shortages are a major concern of ASPHO as we continue to deal with several shortages of critical drugs used in the treatment of pediatric cancer. Asparaginase is a vital component of Acute Lymphoblastic Leukemia therapy (ALL) and is included in many phases of chemotherapy. A recent study from Children’s Oncology Group in T-Lineage ALL found that treatment which includes Pegasparagase is superior to treatment without.1 Omitting this therapy due to the lack of availability can have a negative impact on therapy outcomes.

ASPHO understands that the FDA’s ability to take effective action on shortage situations depends on the relevant manufacturer notifying FDA in a timely fashion of a disruption or possible disruption in supply. To this end, we would encourage the agency to examine current enforcement provisions required by the Food and Drug Administration Safety and Innovation Act (FDASIA) and determine if there are areas that can be strengthened in order to provide potential interventions that may have mitigated or eliminated a drug shortage.

ASPHO is willing to discuss with policymakers market-based incentives to reduce drug shortages. We encourage more analysis to determine what, if any, financial incentives may be necessary for certain manufacturers to maintain their production of critical, low-cost medications. If financial incentives are determined to be needed, through the Medicare program or elsewhere, they should be well-targeted to incentivize only those producers who maintain good manufacturing practices and high quality, fill gaps in shortages, and enhance efficiency. Additionally, non-monetary incentives could be utilized, including allowing for expedited or priority review for pharmaceutical companies who have historically helped fill drug shortage gaps or demonstrated commitment to high quality and efficiency standards.

Thank for your attention to this crucial issue. We look forward to continuing to work with the FDA to ensure that all children with blood disorders and cancer have access to the therapies they need. Should you have any questions, please do not hesitate to contact me or our Health Policy and Advocacy
Manager, Jordan Wildermuth (847/375-6736, jwildermuth@aspho.org). We thank you for your consideration of our comments and recommendations.

Sincerely,

Amy Billett, MD
President

---