August 14, 2019

Paul Bedard
Vice President & General Manager, Hematology & Neurology
Bayer HealthCare Pharmaceuticals
100 Bayer Boulevard
Whippany, NJ 07981

Re: Voluntary Recall of Two Lots of Kogenate® FS Antihemophilic Factor (Recombinant) in the United States

Dear Paul,

We are writing to follow up on our prior letters and communications with you concerning Bayer's recall of two lots of Kogenate® FS Antihemophilic Factor (Recombinant) in the United States. We appreciate that Bayer has shared additional information with us related to its recall strategy, explanation for what allowed the product to become mislabeled and how Bayer has changed its processes as a result, and Bayer's July 19th letter to physicians related to the recall (physician letter). We write today with a number of additional questions regarding statements made in the physician letter as well as other short- and long-term medical consequences for affected patients:

1. In the physician letter, Bayer states that Jivi is not indicated for use in previously untreated patients (PUPs) or in children younger than 12. In your recent letter to us, you indicated that you have not received reports of any children under 12 taking the product. Are you asking medical professionals to proactively notify you of members of either group who may have been exposed to Jivi by virtue of these errors?
2. Please provide an update to us regarding adverse events reported to Bayer. In particular:
    a. Have any allergic reactions been reported to Bayer related to use of the adulterated product?
    b. Have any new instances of inhibitor been reported among patients exposed to the adulterated product?
    c. Have any thrombotic events been reported to Bayer? The physician letter indicates that Jivi's longer half-life and more IUs per vial relative to Kogenate FS "may contribute to increased plasma levels for factor VIII. Elevated plasma levels of factor VIII may be associated with an increased risk of thrombosis, primarily in patients with vascular disease."
3. What is the potential impact for patients who utilize multiple vials for each infusion and may have used both Jivi and Kogenate FS at one time? For example, patients who are prescribed 3000IU of Kogenate may have actually taken 3000IU of Jivi in combination with another 1000IU vial of standard Kogenate. Typically, the two vials would have been mixed and drawn up into one syringe for infusion. Are there any known incompatibilities between the two products related to excipients or potential impact on the efficacy of the combined products?

4. The physician letter indicated that "one patient who may have taken the suspect vials has reported a myocardial infarction." This is extremely concerning, especially given the increased risk of thrombosis acknowledged in the letter. We require assurance that you will share more information about this situation and other adverse events as they become available to Bayer.
5. What is Bayer's plan to monitor and notify the bleeding disorders community about any potential immediate and long-term health consequences that may be associated with the use of the adulterated product? There is considerable and reasonable concern among affected patients and caregivers as well as the broader bleeding disorders community about this situation, which will last beyond the immediate recall.

We look forward to your prompt response with answers to these questions and we would like to keep open lines of communication as this situation continues. Please contact Michelle Rice, Chief External Affairs Officer for NHF (mrice@hemophilia.org) and Kim Isenberg, Vice President – Policy, Advocacy and Government Education at HFA (k.isenberg@hemophiliafed.org) to schedule the call and to respond to our questions.

Sincerely,

Val Bias
Chief Executive Officer
National Hemophilia Foundation

Kimberly Haugstad
President & CEO
Hemophilia Federation of America