July 26, 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,

The National Hemophilia Foundation (NHF) and Hemophilia Federation of America (HFA) are national non-profit organizations that represent individuals with bleeding disorders across the United States. Our missions are to ensure that individuals affected by hemophilia and other inherited bleeding disorders have timely access to quality medical care, therapies, and services, regardless of financial circumstances or place of residence. Both organizations accomplish this through advocacy, education, and research.

We are writing concerning Bayer's recent voluntary recall of two lots of Kogenate® FS Antihemophilic Factor (Recombinant) in the United States (Kogenate). Our organizations are alarmed and seriously concerned that Bayer released more than 900 vials of clotting factor treatment that were not only actually a different product but were also expired. While we have many questions about how this significant error occurred and how Bayer will ensure that it does not happen again, our letter today is focused on a series of more immediate questions about the recall and its potential effects on our community members.

We would like to schedule a call as soon as possible, so that our organizations can be updated on Bayer's recall strategy, including the specific steps to be taken by the company, the timeline for these steps, and what has been accomplished to date. In addition, we have specific questions that we would like the company to respond to as quickly as possible:

1. The recall notice indicated that the lots being recalled were both mislabeled and had expired in August, 2018 – this leads to the following questions:
    a. Since Jivi was approved in August 2018, were these vials used in the clinical trials? Were there any differences between these trial drugs and the final approved versions?
    b. Is it typical for remaining vials of study drug to be put into circulation once the product has been approved for distribution?
    c. What is Bayer's process for handling or disposing of expired product and the timeframe for this process?

2. Jivi was not approved for patients under the age of 12. Has it been confirmed if any of the recalled lots were distributed to anyone under the age of 12?
3. Bayer indicated to the FDA that it would conduct the recall to the end user. Have all impacted patients been identified and notified of the recall? How many patients were impacted? What have you directed patients to do with affected products?
4. Have all specialty pharmacies been notified? As of early this week, we heard from pharmacies who did not yet know about the recall.
5. Have all affected products been returned to Bayer? If not, in what timeframe do you expect that this will occur?
6. Does Bayer provide any information to the impacted patients or their providers on the potential medical implications of the mislabeled product? Can this information be shared?
7. When did Bayer inform PPTA's Patient Safety Notification System of the recall? The alert was not sent out until Wednesday, July 24.
8. The Bayer press release indicates that the last manufactured date of lots was July 15 but the recall did not occur until July 19th. Why the 4 day delay and what steps were taken during that time?
9. Have any adverse events (including breakthrough bleeding) been reported to Bayer?

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 resolves. 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