

Patients for Access to Advanced Therapy for Hemophilia

Citizen Petition

Date: December 30, 2019

Patients for Access to Advanced Therapy for Hemophilia (PAATH) and cosigners submit this petition under 21 USC Part 352 (Misbranded drugs and devices) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to pursue enforcement action if the FDA has not already done so against Bayer U.S., as subsidiary of Bayer AG.

A. Action Requested

Petitioners request the Commissioner to seek enforcement actions, such as one or more administrative orders or consent agreements, against Bayer U.S., Bayer AG that will prevent the reoccurrence of its:

- Mislabeling nearly 1,000 vials of hemophilia A treatment Kogenate FS;
- Improper storage of hemophilia treatment products; and,
- Release of expired hemophilia treatment products to the US consumer market.

In addition, we recommend that the FDA assess whether other factor producers have sufficient safeguards to ensure they will not experience similar events.

B. Statement of Grounds

On July 19, 2019 Bayer issued a voluntary recall (copy attached) of two lots of Kogenate® FS Antihemophilic Factor (Recombinant) 2000 IU vials in the US. Certain vials from these two lots that were labeled as Kogenate® FS actually contain the FVIII hemophilia A treatment, Jivi® antihemophilic factor (recombinant) PEGylated-aucI 3000 IU. The affected lots were distributed from February 5, 2019 to July 15, 2019 from Bayer's distribution sites in Berkeley, CA and Shawnee, KS. Bayer stated that it had alerted the FDA and was working closely with it to manage the recall.

Kogenate® FS is approved to treat or control bleeding in adults and children with hemophilia A. Jivi® is approved to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A. The Jivi® batch expired as of August 2018. This is significant in that the wrong medication could have been administered to a patient, and there is a potential risk that the patient could develop an inhibitor to FVIII as a result.

As patients and advocates for the bleeding disorders community, and as survivors of the contaminated blood supply and blood products of the 1970's and 80's, we are deeply concerned about the quality control failures. We are alarmed that Bayer released more than 900 vials of clotting factor treatment that were not only actually a different product but were also expired.

Why are we so concerned? We are alarmed because Bayer has a history of ethical failure to the hemophilia community. This is not the first time that Bayer has made a profit from selling dangerous product to people with Hemophilia. In the 1980's when Bayer's Cutter Laboratories realized that their Factor VIII and IX products were contaminated with HIV, the financial investment in the product was considered too high to destroy the inventory. Rather, Cutter

misrepresented the results of its own research and sold the contaminated Factor to overseas markets without the precaution of heat treatment recommended for reducing the risk. As a consequence, patients who infused the HIV-contaminated Factor VIII and IX were infected with HIV, developed AIDS. This was a widely publicized incident, which caused one nationally syndicated TV columnist (Joe Scarborough on MSNBC) to label Bayer, "Rat of the Week." See: <https://www.youtube.com/watch?v=spnEaO3yumk>. For a detailed discussion of this incident see the Wikipedia article, 'Contaminated Haemophilia Blood Products.'

Only a small fraction of those affected by viral contamination of Factor still remain. We remember and honor our brothers, now mostly gone, who often said, "All I want from Bayer is a cure ... and my friends back."

Hemophilia patients depend on safe product to live well. We, patients and trusted supporters, should not give a free pass to anyone, or to any corporation, that endangers product safety. The mislabeling of expired Factor VIII warrants appropriate and strong enforcement action on the part of the FDA.

C. Environmental Impact

This petition and action requested is categorically excluded under (A) Claim for categorical exclusion under 21 CFR §25.31.

D. Economic Impact

To be submitted, if requested by the Commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(b) (7)(C) [Redacted]
Signed: George M. Stone, Jr., patient and advocate

On behalf of: Patients for Access to Advanced Therapy for Hemophilia (PAATH) and below listed cosigners

(b) (6) [Redacted]

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Cosigners:

Mark Antell, patient, advocate, Past Vice President, Hemophilia Federation of America; Past Principal in People with Bleeding Disorders and HCV

Ray Dattoli, patient, advocate, Past Vice President, Committee of Ten Thousand

Stephen Long, patient and advocate

Chad Blair, patient and advocate

Rich Vogel, patient, advocate, Past President, Hemophilia Federation of America; Past President Hemophilia Association of New Jersey

Dana Brayshaw, President, Hemophilia Association of the Capital Area (HACA) Board of Directors and the following additional HACA Board members:

- Robin Monin, Vice President
- Callie Victor, Secretary
- Sandesh Mohan, Treasurer
- Melissa Alba
- Artura Jackson
- April Owens
- Jennifer Sleboda
- Michelle Stielper
- Patrick Kanu