



September 2, 2020

Brian Puglisi, PharmD
Quality Assurance Manager Global Quality
CSL Behring, LLC

Paul Stapel
Director, Quality Assurance
Ferring Pharmaceuticals, Inc

Re: Pharmacy-Level Recall of desmopressin nasal spray (Stimate)

Dear Mr. Puglisi and Mr. Stapel,

The National Hemophilia Foundation (NHF), the Hemophilia Federation of America (HFA), and the Hemophilia Alliance are writing as national organizations that represent individuals with bleeding disorders and hemophilia treatment centers (HTCs) in the United States.

Since the announced recall of desmopressin nasal spray (Stimate) manufactured by Ferring Pharmaceuticals and licensed and distributed in the U.S. by CSL Behring in mid-July, all of our organizations have sought additional information from you so that we can advise patients and providers in the US about this concerning situation. We have been disappointed by the lack of transparency your companies have provided. Your response to the first letter sent by NHF and HFA lacked answers to most questions and attempts by all of us to follow up by email have either been ignored or answered inadequately. Your actions fall far short of the best practices identified by stakeholders in the January 2020 Bleeding Disorders Safety Summit, which included our three organizations among a broad group of stakeholders, including CSL.

We write today not only to reiterate our outstanding questions, listed below, but also to raise concerns about the recall process itself. We have been contacted by community members who have had difficulty with the recall process as outlined in the [patient letter from CSL](#). Other patients seek more information about the remuneration process, since they have incurred significant out-of-pocket costs for a product that is no longer safe for them to take and cannot be replaced.

1. Please describe, specifically and in chronological order, how and when the product deviation was discovered, and what steps are being taken to correct the deviation and prevent it from recurring.
 - a. During what time period were the affected products manufactured?
 - b. Please provide a detailed timeline with dates of
 - i. Ferring's discovery of the product deviation
 - ii. Ferring's notification of CSL Behring that there was a problem with the product
 - iii. Ferring's notification of the U.S. Food and Drug Administration
 - iv. Ferring's and/or CSL Behring's notification of U.S. recipients

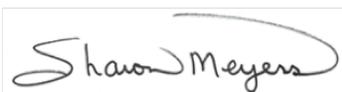
2. Has Ferring halted production of the product?
 - a. If yes, do you expect that production will resume? When?
 - i. When would U.S. distribution resume?
 - b. Has Ferring and/or CSL Behring notified the FDA of possible shortages of the product?
3. Based on available website information, recalls were announced in other countries as early as July 10, 2020. Why did it take so long to notify patients in the U.S.?
 - a. Why was the initial determination made to conduct a pharmacy level recall?
 - b. What were your reasons for expanding the recall to the customer/end user level?
4. Community members have reported difficulty in navigating the recall processes set up by CSL Behring.
 - a. Have you improved these processes and/or provided recall personnel with additional training?
 - b. Are recall personnel able to give patients specific information about remuneration for their out-of-pocket costs associated with recalled product?
5. Are there other skus of desmopressin acetate in sufficient concentrations to treat people with bleeding disorders? If so, are they readily available for US patients?

We would like to schedule a call with you to discuss these outstanding questions. We look forward to your prompt response with answers to these questions. Please contact Nathan Schaefer, Vice President of Public Policy for NHF (nschaefer@hemophilia.org), Sonji Wilkes, Senior Director of Policy, Advocacy and Government Education for HFA (s.wilkes@hemophiliated.org), or Joe Pugliese, President and CEO of the Hemophilia Alliance (joe@hemoalliance.org) to schedule a call to respond to our questions.

Sincerely,



Leonard A. Valentino, MD
 President and CEO
 National Hemophilia Foundation



Sharon Meyers, EdD, CFRE
 President and CEO
 Hemophilia Federation of America



Joe Pugliese
 President and CEO
 Hemophilia Alliance