February 26, 2020

Ramona Sequeira
President of US Business Unit
Takeda
95 Hayden Avenue,
Lexington, MA 02421

Re: Voluntary Recall of Two Lots of VONVENDI von Willebrand Factor (Recombinant) in the United States

Dear Ramona,

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 Takeda's February 25, 2020 pharmacy level recall of two lots of VONVENDI von Willebrand Factor (Recombinant) in the United States . Our organizations are seriously concerned that Takeda recalled 3425 vials of von Willebrand factor product without explaining the grounds for initiating this recall. We have many questions about the reasons underlying this recall, the manner in which Takeda proposes to conduct the recall, and the communications Takeda has provided and will continue to provide to health care professionals, patient advocacy organizations, specialty pharmacies, and -- most importantly -- patients in the bleeding disorders community.

With this letter, we are initiating an ongoing dialogue so that our organizations can inform the patient community on Takeda'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. Please describe in chronological order the circumstanes that occasioned the recall. i.e.:
    a. What was the date on which the affected lots were manufactured?
    b. What was the date on which Takeda identified an issue with the affected lots?
    c. On what date did Takeda send the affected lots to wholesalers or to other parts of the distribution channel?
2. Have any of the affected lots reached consumers?
3. Takeda states that it "believes" there is no impact on "the sterility, quality, safety and potency" of the recalled product. What is the basis for that belief? The notice on your website says that Takeda has tested the affected product. Please elaborate on the tests conducted and the results of those tests.

4. Takeda indicated to the FDA that it would conduct a pharmacy level recall.
    a. Please define a "pharmacy level recall" and why this is an appropriate level of recall in this instance.
    b. Does a pharmacy level recall mean that patients may not be not be identified and/or notified of the recall?
    c. How many patients received the affected lots?
    d. If patients have received any of the affected lots, how are they supposed to learn of that?
    e. How and to whom should patients return the product?
    f. Can Takeda accurately and definitively track who and where the affected product was distributed to?
5. Have all specialty pharmacies been notified? Have pharmacies been provided with instructions on how and where to return affected product?
6. Have all affected products been returned to Takeda? If not, in what timeframe do you expect that this will occur?
7. Does Takeda intend to inform PPTA's Patient Safety Notification System of the recall?
8. Have any adverse events (including breakthrough bleeding) been reported to Takeda?

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 Sonji Wilkes, Senior Director of Policy, Advocacy and Government Education for HFA (s.wilkes@hemophiliafed.org) to schedule the call and to respond to our questions.

Sincerely,

Dr. Leonard Valentino
President and CEO
National Hemophilia Foundation

Sharon S. Meyers, M.S. CFRE
President & CEO
Hemophilia Federation of America