September 24, 2019

Richard Ko
Associate Medical Director, US Medical Affairs
Genentech
1 DNA Way
South San Francisco, CA 94080

Dear Richard,

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.

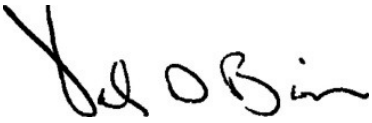
We are writing concerning Genentech's recent notice that a contracted specialty pharmacy, Medvantx, had shipped incorrect length injection needles to patients who receive Hemlibra through the Genentech Patient Foundation. We have a number of questions about how this error occurred; about Genentech's notification of affected patients; and about potential consequences for affected patients. Specifically:

- Please provide verification that Genentech has now successfully contacted all 124 families and 90 health care providers affected by this error.
- Has Genentech notified the FDA about the shipment of incorrect length needles? Is this event considered a recall?
- We understand that a prescription may be required in order to dispense injection needles.
    - Was a prescription provided to Medvantx? Or did Medvantx dispense needles with no prescription?
        - If there was a prescription, who wrote that prescription?
        - If there was a prescription, did the prescription call for the correct needle size? Or did the prescription specify the incorrect length needles?
- Has Genentech received any reports of adverse effects from patients who received and used the incorrect length needles? Does Genentech have any information regarding the health consequences that may result if a patient receives Hemlibra via intramuscular rather than subcutaneous injection?
    - Did any infants receive the wrong size needles?
    - Might a patient who took a loading dose with the wrong size needles need to repeat the loading dose?

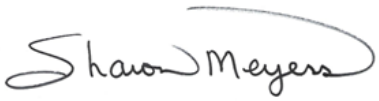
We also ask that Genentech commit to updating NHF and HFA on an ongoing basis of any new information you may receive regarding any reports of adverse events associated with the use of the incorrect length needles.

We look forward to your prompt response with answers to these questions and would like to keep open lines of communication as further information develops. 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) as we continue our discussions.

Sincerely,



Val Bias
Chief Executive Officer
National Hemophilia Foundation



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

Cc:

Medvantx Pharmacy Services
attn: Slater Nash, Chief Pharmacy Officer

Genentech Patient Foundation
attn: Connie Kahng Stephens, Lead Policy & Distribution