Congress of the United States
Washington, DC 20510

October 18, 2019

The Honorable Norman E. "Ned" Sharpless, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

We write to express deep concern for the hypoparathyroidism patients in Vermont and throughout the country who have been affected by the September 5, 2019 recall of the drug Natpara (parathyroid hormone), manufactured solely by Takeda Pharmaceuticals. These patients depend on Natpara and are desperately seeking answers and relief. We urge FDA to work with Takeda as expeditiously as possible to resolve the recall, to use the agency's available drug shortage tools to potentially provide patients with other treatment options, and to ensure patients have full information about when the supply of Natpara will resume and what measures patients can take while they wait.

For the more than 2,000 patients in the United States who rely on Natpara to manage their blood calcium levels, the shortage of available product has potentially dire health consequences. Untreated hypoparathyroidism can lead to heart failure and death. Patients across the country have already been hospitalized due to an inability to get Natpara, and we fear that as more patients run out of Natpara, the number of avoidable hospitalizations – or worse – may increase.

Let us be clear – we strongly support FDA's critical mission to protect the public's health and use its recall authority to protect patients from potentially harmful products. However, we also believe that FDA's responsibility to American patients includes a responsibility to be transparent when possible, a commitment that has not been fulfilled in this case.

Despite the recall now lasting over a month, FDA has not shared any substantive information with patients about how long the recall may last, what steps are being taken to develop short- and long-term solutions, or other patient guidance. On October 2, FDA informed Takeda that it was changing the recall to Class I, requiring all patients to return unused Natpara to the company, escalating fear and concern among patients.[1] Patients need more information in order to make necessary health care decisions, but our constituents have repeatedly contacted FDA and been left confused as to when the drug may become available again, as well as how they should proceed in the meantime. Given that these patients depend on Natpara to prevent serious health complications, this is entirely unacceptable.

As of today, October 18, 2019, FDA's drug shortage database still says, "To be determined. Takeda is actively working to resolve the issue and resume supply. Updates will be provided on an ongoing basis."[2] To our knowledge, no updates have been provided. The most recent update

from Takeda, posted October 9, 2019, states "we will continue to work closely with the FDA until we are able to resolve the issue and resume supply."[3] Takeda's September 26, 2019 update said that "Since this [recall] began on September 5, 2019, our team has been working diligently with the Food and Drug Administration (FDA) on a number of potential solutions to bring this critical medicine back to patients,"[4] but provides no information on those potential solutions or timeframe.

We do know that Takeda and FDA have worked together to develop a temporary Special Use Program for Natpara, which was announced September 24, 2019. Despite initial optimism that this program would be broadly helpful for patients, it appears that the scope of the program is so small that it will only help about one percent of the patients who need Natpara, leaving nearly the entire patient population waiting for a solution.

We therefore reiterate our request that FDA and Takeda leadership work closely together to provide as much information as possible on when the original issue resulting in the recall will be resolved and provide clear guidance for impacted individuals on what options are available to them. We ask that FDA immediately evaluate whether the patients originally intended to benefit from Takeda's Special Use Program are able to do so. Finally, we urge FDA to take all steps within your administration's authority to aid patients impacted by the recall and ensure that Natpara, or any safe and effective alternative, is made available as soon as possible.

Thank you for your attention to this matter. We look forward to hearing from you.

Sincerely,

PATRICK LEAHY
United States Senator

BERNARD SANDERS
United States Senator

PETER WELCH
United States Representative

[1] Takeda Pharmaceuticals, "Information Regarding the US NATPARA (parathyroid hormone) for Injection Recall," (Oct. 9, 2019) (online at https://www.natpara.com/pdf/natpara-recall-information.pdf).
[2] FDA Drug Shortages, "Parathyroid Hormone (Natpara) Injection," (last accessed Oct. 15, 2019) (online at https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Parathyroid%20Hormone%20(Natpara)%20Injection&st=c).
[3] *See* note 1.
[4] Takeda Pharmaceuticals, OnePath, "Latest information about the US recall of NATPARA (parathyroid hormone for Injection," (Sept. 26, 2019) (online at https://www.takeda.com/siteassets/en-us/home/newsroom/natpara-recall/natpara-special-use-program-patient-e-mail-9-26-19.pdf).