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United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

December 19, 2017

CHRISTOPHER R. HIXON, STAFF DIRECTOR
MARGARET E. DAUM, MINORITY STAFF DIRECTOR

Matthew Pauls
President and CEO
Strongbridge Biopharma
900 Northbrook Drive, Suite 200
Trevose, PA 19053

Dear Mr. Pauls:

I write to request information concerning recent a price increase Strongbridge Biopharma instituted for the periodic paralysis treatment Keveyis—formerly Daranide—following its acquisition of the drug from Sun Pharmaceutical Industries Ltd. in 2016.

According to a recent report in the *Washington Post*, the price of Keveyis “has been on a roller coaster in recent years—zooming from a list price of \$50 for a bottle of 100 pills in the early 2000s up to \$13,650 in 2015, then plummeting back down to free, before skyrocketing back up to \$15,001 after a new company, Strongbridge Biopharma, acquired the drug and relaunched it this spring.” As the *Post* has explained, these rapid changes demonstrate “just how much freedom drug companies have in pricing therapies—and what a big business opportunity selling extremely-rare-disease drugs has become.” While Strongbridge has reportedly provided assistance to patients in “navigating their insurance or help in paying for the drug,”¹ these efforts can “deliver short-term savings for patients but lock in higher long-term costs for the system,” while “increas[ing] demand, allow[ing] companies to charge higher prices, and provid[ing] public-relations benefits.”² Moreover, as I noted in a 2016 report with Senator Susan Collins, sudden price spikes in decades-old drugs create anxiety in patients who know “they could lose access without warning” due to changes in insurance plan formularies or the denial of a patient assistant program application.³

¹ *This Old Drug Was Free. Now It's \$109,500 a Year*, Washington Post (Dec. 18, 2017) (www.washingtonpost.com/news/wonk/wp/2017/12/18/this-old-drug-was-free-now-its-109500-a-year/?utm_term=.96e82fc8744a).

² *Why Big Pharma's Patient-Assistance Programs Are a Sham*, Los Angeles Times (Sept. 25, 2015) (www.latimes.com/business/hiltzik/la-fi-mh-pharma-s-sham-patient-assistance-programs-20150925-column.html).

³ Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* (Dec. 2016) (S. Rept. 114-429).

In response to an inquiry from the *Post*, a Strongbridge Biopharma representative reportedly “declined to answer questions about why the company increased the price of the drug earlier this year. Instead, she issued a company statement saying that periodic paralysis affected only 5,000 people in the United States and the drug could provide benefits for those people.”⁴ Yet patients suffering from periodic paralysis and all other Americans concerned about price spikes for rare-disease treatments do, in fact, deserve an explanation of recent company decisions. Accordingly, I ask that you provide the following documents and information:

1. A detailed description of the financial and non-financial factors contributing to your decision to increase the price of Keveyis in 2017;
2. Total gross revenue from the company’s sales of Keveyis to date;
3. Documents sufficient to show the total expense to Strongbridge Biopharma related to the acquisition of Keveyis;
4. Total expenses relating to sales of Keveyis, including the specific expenses relating to manufacturing, marketing, and advertising efforts, as well as the purchase of active pharmaceutical ingredients for Keveyis;
5. Any analyses Strongbridge Biopharma has conducted or commissioned relating to the 2017 price increase or future price increases for Keveyis;
6. Any cost estimates, profit projections, or other analyses relating to current and future sales of Keveyis;
7. Any documents evaluating any product market that includes Keveyis directly or indirectly;
8. A detailed description of any assistance Strongbridge Biopharma provides to Keveyis patients in navigating insurance approval procedures, meeting co-payment requirements, or obtaining free medication, as well as the expenses associated with these efforts;
9. The identity of all company officials responsible for setting the price of Keveyis; and,
10. Any documents relating to the price of Keveyis that Strongbridge Biopharma has produced pursuant to an investigative inquiry by any federal, state, or local government entity.

Please provide your responses as soon as possible, but in no event later than January 16, 2017. If you have any questions related to this request, please contact Courtney Cardin of the

⁴ *This Old Drug Was Free. Now It's \$109,500 a Year*, Washington Post (Dec. 18, 2017).

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Committee staff at Courtney_Cardin@hsgac.senate.gov or (202) 224-2627. Please send any official correspondence relating to this request to Lucy_Balczak@hsgac.senate.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Claire McCaskill". The signature is fluid and cursive, with the first name "Claire" written in a larger, more prominent script than the last name "McCaskill".

Claire McCaskill
Ranking Member

cc: Ron Johnson
Chairman