February 26, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Azar and Commissioner Gottlieb:

I understand that the Food and Drug Administration's (FDA) mission includes not only protecting the public health by ensuring medical products have benefits that outweigh their risks, but also "helping to speed innovations" to the public that are "more affordable."[1] FDA recently approved Firdapse to treat a rare neuromuscular disease called Lambert-Eaton myasthenic syndrome (LEMS), and in so doing, a drug that had been available to patients for free for decades through a compassionate use program is now being sold by Catalyst Pharmaceuticals at the outrageous annual list price of $375,000.

Since Firdapse's market entry my office has heard from patients who are unable to get the medicine they need because of this astronomical price. Without this medication, patients with LEMS will suffer and die.

Although I recognize FDA did not specifically intend for its approval of Firdapse to result in Catalyst setting this exorbitant price, FDA's approval of this drug nonetheless led to this result. Catalyst now has at least seven years of exclusive marketing rights during which time the company projects to make hundreds of millions of dollars in profit on a drug that has been available for decades.[2] In light of the drug's shocking price, I urge FDA to announce that it will not take enforcement action against pharmacies or manufacturers that were previously providing 3,4-DAP to patients and are able to resume the distribution of this drug, subject to the same requirements as the drug was available prior to the date of Firdapse's approval.

[1] U.S. Food & Drug Administration, "What We Do," (last accessed Feb. 26, 2019), (available at https://www.fda.gov/aboutfda/whatwedo/).
[2] "U.S. FDA approves Catalyst Pharma's rare disease drug," *Reuters* (Nov. 28, 2018), (available at https://www.reuters.com/article/us-catalyst-pharms-fda/us-fda-approves-catalyst-pharmas-rare-disease-drug-idUSKCN1NX2ZL).

Catalyst may be the most recent company to exploit their monopoly after receiving FDA approval for an inexpensive old drug, but they were certainly not the first. FDA's effort to bring older, unapproved drugs through the approval process may have some laudable benefits, but it has also led to instances where drugmakers use the grant of market exclusivity that accompanies FDA approval to fleece patients and taxpayers. The prices of very old and inexpensive drugs like colchicine, vasopressin, neostigmine, and others have been raised substantially by drugmakers following approval, causing needless suffering and adding to the cost of our health care system.[3]

It is absurd for FDA to claim affordability as central to its mission and tout policy activities that prioritize lower drug prices while simultaneously claiming the agency cannot take steps to lower drug prices.[4,5] You have said that "access to prescription drugs is a matter of public health."[6] I agree, and I also believe that the lack of access we have in this country to affordable prescription drugs is a public health crisis, a crisis that FDA must acknowledge its role in perpetuating and take action to address.

You have personally called out price gouging companies and said that "there's no moral imperative to price gouge and take advantage of patients. FDA will continue to promote competition so speculators and those with no regard to public health consequences can't take advantage of patients who need medicine."[7] Catalyst Pharmaceuticals' decision to set a price of $375,000 is a prime example of price gouging. This price was set without regard to public health and takes advantage of patients who need this medicine to survive.

For all of these reasons, I urge FDA to take action immediately. One action I suggest, an action for which there is similar agency precedent,[8] is to announce that FDA will not take enforcement action against pharmacies and manufacturers who were previously providing 3,4-DAP to patients and are able to resume the distribution of this drug. Thank you for your consideration.

Sincerely,

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Bernard Sanders
United States Senator

[3] Michael Hiltzik, "The little-known FDA program that's driving drug prices higher," *LA Times* (Sept. 23, 2015), (available at https://www.latimes.com/business/hiltzik/la-fi-mh-the-little-known-fda-program-20150923-column.html).
[4] "Statement from FDA Commissioner Scott Gottlieb, M.D., on the Trump Administration's plan to lower drug prices," (May 11, 2018), (available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607495.htm).
[5] "Statement from FDA Commissioner Scott Gottlieb, M.D. on new efforts to empower consumers by advancing access to nonprescription drugs," (July 17, 2018), (available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613692.htm).
[6] *See* note 4.
[7] Scott Gottlieb, M.D., *Twitter* (Sept. 11, 2018), (available at https://twitter.com/SGottliebFDA/status/1039481679218401285).
[8] FDA Statement on Makena (Mar. 30, 2011), (available at http://web.archive.org/web/20110402072831/http:/www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm).