

February 6, 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 Seema Verma
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

I am writing to request information regarding the price Catalyst Pharmaceuticals will charge Medicare and Medicaid for Firdapse, a drug used to treat a rare neuromuscular disease known as Lambert-Eaton myasthenic syndrome (LEMS), and the impact this price will have on patients with LEMS and taxpayers.

As you likely know, Catalyst's drug Firdapse is the only LEMS treatment that is approved by the Food and Drug Administration, meaning every American with LEMS relies exclusively on this drug for treatment. Unfortunately, rather than take this responsibility to patients seriously, Catalyst has exploited their market monopoly. The greedy intent of Catalyst is clear: during a December 13, 2018 call with investors, Catalyst announced that it intended to charge an outrageous annual list price of \$375,000 for Firdapse. Until now, patients with LEMS have been able to access the active ingredient in Firdapse, a chemical called 3,4-diaminopyridine, for free from Jacobus Pharmaceutical.

The unfortunate reality is that the United States pays, by far, the highest prescription drug prices in the world. Although federal and state governments are the largest prescription drug purchasers in the country, Medicare is not permitted to negotiate drug prices directly with drug manufacturers.¹ This remains true despite the president's repeated campaign promises to leverage the government's purchasing power to negotiate better deals on drug prices.

Opportunistic drug companies such as Catalyst are taking advantage of our current health care system for their own profit. In its 2017 annual report, Catalyst said that its "ability to

¹ Centers for Medicare & Medicaid Services, National Health Expenditure Data, Table 19 (Calendar Year 2017), (online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html>).

commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as Medicare and Medicaid.”² Catalyst warned investors that “any cost containment measures...or other healthcare system reforms that are adopted may have a material adverse effect on our business prospects.”³ According to Securities and Exchange Commission filings for 2018, Catalyst conducted market research and determined that “most LEMS patients have insurance coverage,” including approximately “40% Medicare, 15% Medicaid, [and] 10% dually eligible for both Medicare and Medicaid.”⁴ It is abundantly clear that Catalyst expects taxpayers, primarily through Medicare and Medicaid, to foot the bill for its price gouging.

In order to understand the financial and non-financial impact of the high price of Firdapse, I request that you answer the following questions:

1. What is the list price that Catalyst has quoted to Medicare and Medicaid for Firdapse?
2. What is the final price that Medicare and Medicaid will pay for Firdapse, net of any rebates or other price concessions?
3. How many Medicare and Medicaid patients will suffer or die if they cannot afford Firdapse?
4. What is the average out-of-pocket cost Medicare beneficiaries will pay for Firdapse?
5. What is the average out-of-pocket cost Medicaid enrollees will pay for Firdapse?
6. What impact will the price of Firdapse have on Medicare Part D premiums?
7. What impact will the price of Firdapse have on total Medicare drug expenditures?
8. What impact will the price of Firdapse have on total Medicaid drug expenditures, as well as on federal and state government drug expenditures?
9. What impact will the price of Firdapse have on taxpayers, who finance federal government health programs?
10. What steps will your agencies take to stop drug companies such as Catalyst from profiteering off patients covered by Medicare and Medicaid?

I look forward to discussing this important issue with you as soon as possible.

Sincerely,



Bernard Sanders
United States Senator

² Catalyst Pharmaceuticals, 2017 Annual Report (online at <https://ir.catalystpharma.com/static-files/134ffbf7-aefa-4535-a2b9-2b01a44603ff>).

³ *Id.*

⁴ Catalyst Pharmaceuticals, Inc., Securities and Exchange Commission, Form 8-K (Dec. 13, 2018), (online at <https://www.sec.gov/Archives/edgar/data/1369568/000119312518350053/d677721dex991.htm>).