United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

December 12, 2016

VIA ELECTRONIC TRANSMISSION

President-Elect Donald J. Trump
Trump Tower
725 5th Ave.
New York, NY 10022

Dear President-Elect Trump:

You were recently quoted saying, "I'm going to bring down drug prices. I don't like what has happened with drug prices." I share your concerns about the high price of drugs and write today to begin a dialogue about addressing this problem. In my opinion, there are a number of factors that have resulted in rising prescription drug costs. A lack of drug options in the marketplace, drug company anti-competitive behavior, regulatory backlogs at the Food and Drug Administration (FDA), inefficient and ineffective government bureaucracies, and poor corporate decisions all have contributed to the current crisis.

By way of background, it has been reported that the price of four of the nation's top ten drugs increased more than 100 percent since 2011 and that many other drugs have seen extraordinary price hikes.[1] For example, Turing Pharmaceuticals raised its price of the AIDS drug Daraprim by 5,000 percent—from $13.50 to $750 overnight. Likewise, Valeant Pharmaceuticals increased the prices of the heart drug Isuprel by 525 percent. And Mylan raised its price for lifesaving EpiPens over 400 percent—$57 in 2007 to $600 today.

Many of these drugs do not have competitors in the market, not because they don't exist, but because safety and regulatory approvals have been slow. For example, generic versions of the EpiPen are undergoing additional FDA questioning and have yet to be approved. Meanwhile, approved EpiPen alternatives are available in Europe where consumers pay significantly less for them—ranging from $85 to $131. Regulatory backlogs in the United States have delayed consumer access to many prescription drugs and limited the ability of multiple competitors to participate in the market and bring down drug costs. It is important to balance the need to ensure drugs are safe for patients with getting drugs to patients in a timely manner. This can be achieved even with improvements to the FDA's generic approval process and the introduction of policies that incentivize innovation – changes that would help spur competition and lower prices. Further, the Secretary of Health and Human Services has the authority to

[1] Caroline Humer, "Exclusive: Makers took big price increases on widely used U.S. drugs," Reuters (April 5, 2016). http://www.reuters.com/article/us-usa-healthcare-drugpricing-idUSKCN0X10TH

increase importation of prescription drugs from Canada and other countries. Regulators are standing in the way of progress and the Secretary should be encouraged to use this authority to expand the availability of safe and affordable drugs for the American consumer.

In addition, some drug companies engage in questionable business practices that are designed to thwart laws on the books to promote drug competition. For example, brand drug companies engage in obstruction tactics, exclusionary conduct, exclusive contracting and other monopolistic behavior, while both brand and generic drug companies enter into pay-for-delay deals to decelerate entry of lower cost drugs in the market. Regulatory agencies, and in particular the Federal Trade Commission (FTC), play a critical role in holding companies accountable for gaming the system and engaging in anti-competitive conduct. The FTC's role in preserving a competitive marketplace and protecting consumers is especially important, and due to the dramatic increase of drug prices across the board, the FTC should step up its scrutiny of this marketplace in general.

There are also serious systemic problems within the Centers for Medicare and Medicaid (CMS) impacting the price of drugs and the cost of those drugs to the taxpayers and states. EpiPen, Dilaudid, and Prilosec serve as prime examples. According to information provided to the Senate Judiciary Committee by the Health and Human Services Inspector General (HHS OIG), CMS was notified in March 2009 that these drugs were misclassified as generics under the Medicaid Drug Rebate Program (MDRP). It is unclear what substantive steps the Obama Administration took to fix the problem. The executive branch must use its existing authorities to hold companies accountable for misclassifications.

These misclassifications cost the states and taxpayers hundreds of millions of dollars. Under the MDRP, a brand name drug is subject to a 23.1 percent rebate whereas a generic is subject to a 13 percent rebate. Therefore, companies that produce and sell misclassified drugs have escaped paying the full rebate.[2] In light of the increase in drug prices and the systemic issues discussed herein, I called a hearing with the Justice Department, CMS, HHS OIG, and Mylan to discuss steps the Obama Administration took to address the lack of competition in the prescription drug market and hold companies like Mylan accountable for drug misclassifications. Not only did Mylan refuse to appear before the Committee, the Justice Department and CMS refused to testify as well. Such non-cooperation is unacceptable. Executive agencies have an obligation to uphold the law and hold violators accountable. They must be willing to explain their actions to the Congress and the American people.

Moving forward, I strongly urge your Administration to look at the pharmaceutical landscape and improve the regulatory approval process and enforcement authorities already in place. I urge you to work with the Congress on legislative efforts to address anti-competitive behavior and to alleviate unnecessary regulatory burdens that may be impairing the timely introduction of safe, lower cost prescription drug alternatives in the market. Congress and your Administration can work together to devise policies that incentivize innovation and promote competition to the benefit of patients and taxpayers. I also urge you to reverse the unwillingness

[2] To provide an example of the value of the misclassification, reports have indicated that the Justice Department entered into a settlement with Mylan over its misclassification under Medicaid. The value of the settlement is allegedly $465 million, which is also reportedly too low.

of the executive branch – specifically the failure of the Obama Administration – to fully cooperate with congressional requests, whether it be oversight letters or hearings. Government actions must be disclosed to the public and held out in the open to foster transparency and accountability.

Your strong leadership will be critical in helping to address the high cost of prescription drugs. I look forward to working with you on this important issue for the American people.

Sincerely,

Charles E. Grassley
Chairman
Committee on the Judiciary