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Congress of the United States House of Representatives

May 2, 2018

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President Donald J. Trump
The White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

Dear President Trump:

Thank you for bringing attention to the issue of the rising price of prescription drugs. I applaud you for consistently bringing it up on the campaign trail and in your speech to the nation in the coming days. My colleagues and I anxiously await your proposed solutions to this issue, and look forward to working with you to achieve our common goal of lowering the cost of health care.

As the sponsor of H.R. 2051, the Fair Access for Safe and Timely Generics Act (FAST), I am concerned with the issue of brand drug companies abusing the regulatory process after their patent exclusivity has expired to block generic competition from entering the marketplace. The FAST Generics Act would put a stop to this by allowing generic drug companies to seek an injunction when brand drug companies refuse to sell samples necessary for FDA approval. There is another piece of legislation, which is similar to the FAST Generics Act, the CREATES Act. Both address a well-established and well-documented problem – the abuse of FDA’s safety and regulatory rules in order to delay patient access to safe, affordable generic and biosimilar medicines.

In several speeches last year and as part of the agency’s “Drug Competition Action Plan,” FDA Commissioner Scott Gottlieb, M.D., has repeatedly noted how certain brand companies delay negotiations over shared safety protocols and restrict access to drug samples in a deliberate attempt to “forestall the entry of generic drug competition.” To date, the FDA has received more than 150 complaints from manufacturers and by all accounts the problem is growing with a significant majority of these products costing patients thousands of dollars per month.

Unfortunately, the FDA does not have the authority to curtail these anti-competitive tactics on its own and Congressional action is necessary. As such, I believe that passing the FAST Generics Act or CREATES Act is one step that Congress can take to lower the cost of prescription drugs.

I urge you to highlight this problem in your speech to the nation on the rising cost of prescription drugs. A fix for these abuses is something that has bi-partisan support and would represent another significant policy achievement for your administration.

My colleagues and I stand ready to work with you to make this a reality.

Sincerely,



David B. McKinley, P.E.
Member of Congress

CC: Secretary Alex Azar, HHS
Commissioner Scott Gottlieb, FDA
Deputy Assistant Secretary John O'Brien, HHS
Daniel M. Best, Senior Advisor to the Secretary for Drug Pricing Reform, HHS