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

June 19, 2017

Dr. Scott Gottlieb
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20857

Dear Commissioner Gottlieb,

As you are aware, I am very concerned with the ability of consumers to access prescription drugs at an affordable price. So I was encouraged when at your nomination hearing before the Health, Education, Labor and Pensions Committee and your hearing before the House Appropriations Committee, you testified that bringing down the cost of prescription drugs for the American consumer is one of your top priorities.

In your testimony, you committed that the Food and Drug Administration (FDA) would take three steps to lower the cost of prescription drugs. Specifically, you indicated that the FDA would work to curtail gaming of FDA regulations by drug companies, seek improvements in the approval process for generic drugs, and eliminate the backlog of generic drug applications.

You should know that I agree with many of your ideas to address the accessibility and cost of prescription drugs. In my opinion, a lack of drug options in the marketplace, anti-competitive behavior by drug industry participants, long-standing regulatory backlogs at the FDA, inefficient and ineffective government bureaucracies, and poor corporate decisions all have contributed to the current problem.

In that regard, you have highlighted the Risk Evaluation and Mitigation Strategies (REMS) program as an example of drug companies gaming the FDA regulatory process. In congressional testimony, you stated that the FDA was evaluating how it could "streamline the process the FDA uses to determine whether to waive the requirement that a generic drug applicant and brand company share a single system to ensure safe use." You also testified that the FDA was determining whether it could "waive this requirement more readily than we have in the past in situations where sponsors cannot reach agreement after a reasonable period of time, on the implementation of a shared system."

I share your concerns about abuses within the REMS program. In fact, they have been documented in a recent study, which found that brand drug companies are abusing the REMs program to block $5.4 billion in generic competition annually.[1]

To address this problem, I joined several of my Senate colleagues to introduce S. 974, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. This bill would help the FDA address REMS program abuse, where brand drug makers restrict generic manufacturer access to samples for product testing and where brand drug makers refuse to enter into single, shared distribution system protocols with generic manufacturers. The CREATES Act would deter pharmaceutical companies from denying samples to generic companies, so they can conduct testing to produce cheaper generic alternatives. The bill also would give the FDA more flexibility in making single, shared distribution system determinations.

I also have been concerned with another anti-competitive tactic where brand and generic drug companies enter into agreements where branded companies pay their generic competitors not to compete as part of a settlement. These deals result in decelerating the entry of lower cost drugs in the market. In fact, a recent Federal Trade Commission (FTC) study found that pay-for delay deals cost Americans $3.5 billion per year.[2] S. 124, the Preserve Access to Affordable Generics Act, would crack down on these anti-competitive pay-offs.

I hope that you will take a close look at these two bills as you formulate your strategy to address accessibility and the high cost of prescription drugs. Your support for these bills will help in our shared goal of increasing access and lowing the price of drugs.

In your testimony before the House Appropriations Committee, you indicated that the FDA is working on a drug competition action plan and you expect the FDA to unveil it soon. I look forward to seeing the details of that plan and working with you to implement reforms that will improve choice and affordability of drugs for American patients.

In addition, I encourage you to work with the FTC and the Department of Justice (DOJ) to address anti-competitive behavior in the drug industry. They both play a critical

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[1] http://www.getmga.com/wp-content/uploads/2017/02/REMS_Study_July.pdf

[2] https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf

role in holding companies accountable for gaming the system and engaging in anti-competitive and abusive conduct. The FDA should work alongside the FTC and DOJ to protect consumers and preserve a competitive marketplace.

Thank you for your commitment to increasing accessibility and lowering the cost of drugs for American patients. I encourage you to continue to prioritize this issue as you begin your tenure as Commissioner of the FDA. I look forward to working with you and your team on matters pertaining to the FDA.

Sincerely,

Chuck Grassley

Charles E. Grassley
U.S. Senator

cc: Jeff Sessions, Attorney General
Tom Price, Secretary of Health and Human Services
Maureen Ohlhausen, Acting Chairman, Federal Trade Commission