

United States Senate

WASHINGTON, DC 20510

June 9, 2017

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

Dear Dr. Gottlieb:

Thank you for your commitment to developing and enacting solutions to help lower the costs of prescription drugs and improve accessibility for American patients. Within the last decade, there has been an unprecedented rise in prescription drug prices. These price increases place previously affordable drugs out of reach for patients and families across the country and have a negative effect on hospitals, providers, and payers.

We are encouraged by your recent remarks indicating the FDA may expedite generic entry for cases when there is limited competition, an issue that we have been working on with a bipartisan group of colleagues in the Senate. We share your commitment to increasing generic competition as a way to help improve access and lower prices. Following the Senate Aging Committee's year-long investigation into sudden price spikes in off-patent drugs, we have been working to enact a series of resulting recommendations to help improve competition and lower prices.

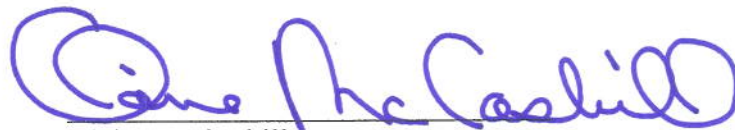
Last month, we introduced legislation that encourages market competition and makes the approval process more efficient for certain generic drugs, particularly in cases where there is insufficient competition. Our bill, the Making Pharmaceutical Markets More Competitive Act (S. 1115), which was approved as part of the Food and Drug Reauthorization Act by the Senate Health, Education, Labor and Pensions Committee, is in line with your recent remarks and would prioritize the review of generic applications where there are three or fewer competitors on the market, provide enhanced communications with eligible sponsors prior to the submission of an application, provide increased transparency, and improve the facility inspection process.

We look forward to working with you in your new role to enact our legislation and develop other common-sense solutions to address rising prescription drug costs.

Sincerely,



Susan M. Collins
United States Senator



Claire McCaskill
United States Senator