United States Senate
WASHINGTON, DC 20510

December 18, 2017

VIA ELECTRONIC TRANSMISSION

Scott Gottlieb, M.D.
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20857

Dear Commissioner Gottlieb:

We have heard from thousands of our constituents about skyrocketing prescription drug prices and have proposed several bills to address this urgent problem—including by allowing for the safe importation of prescription drugs. Earlier this year, we also asked the Office of Management and Budget and the Department of Health and Human Services to use existing statutory authority to allow for individuals to import prescription drugs for personal use.[1] While we appreciate that you have acknowledged that "too many patients are being priced out of the medicines they need,"[2] we are concerned that the Food and Drug Administration (FDA) may be taking actions to scale back the agency's "non-enforcement policy" that currently allows for limited importation of prescription drugs.

Although the Federal Food, Drug, and Cosmetic Act prohibits the importation of unapproved drugs, the FDA has long focused its enforcement efforts on "products apparently intended for the commercial market and on fraudulent products, and those that pose an unreasonable health risk."[3] According to the agency's Regulatory Procedures Manual, "FDA personnel may allow entry of shipments when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user."[4] This non-enforcement policy for prescription drugs with a valid prescription has been FDA's position for many years.

We are concerned that a November 20, 2017 report by *Kaiser Health News* may indicate a change in this longstanding policy. The article notes that FDA sent criminal investigation agents with search warrants into nine Florida stores that help patients buy prescription drugs from pharmacies in Canada. It is our understanding that these stores solely assist patients who prefer to purchase prescription drugs from outside the United States – including by helping patients avoid websites that sell fraudulent or unsafe products – and do not dispense drugs themselves. The report states that these stores, several of which have been open for more than a decade, fear FDA's actions reflect a decision by the Trump Administration to scale back or reverse the "non-enforcement policy."[5]

Additionally, Senators McCain (R-AZ) and Klobuchar (D-MN) have introduced the Safe and Affordable Drugs from Canada Act, which would amend the Federal Food, Drug, and Cosmetic Act to allow for the personal importation of prescription drugs from approved pharmacies in Canada for personal use with a valid prescription. The legislation specifically excludes controlled substances and biologics. Your

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[1] https://www.klobuchar.senate.gov/public/index.cfm/2017/5/klobuchar-mccain-grassley-urge-omb-director-mulvaney-to-use-existing-executive-authority-to-bring-down-prescription-drug-costs
[2] https://blogs.fda.gov/fdavoice/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/
[3] https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm
[4] https://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm
[5] https://khn.org/news/fda-raids-florida-stores-that-consumers-use-to-buy-drugs-from-canada/

endorsement of this legislation would demonstrate the FDA's commitment to lowering prescription drug prices in this country.

Due to our concerns that the FDA actions in Florida may reflect a change in policy, we request that you respond to the following questions no later than January 5, 2018.

1. Has the FDA changed the policy included in the 2016 Regulatory Procedures Manual regarding personal importation of safe prescription drugs from Canada?

2. If so, what is the current policy?

3. Are there any barriers to the certification of importation of prescription drugs from Canada in the following circumstances?

a) The drug is off patent or no longer marketed in the U.S. by the innovator company that initially developed the drug;
b) Significant and unexplained increases in price;
c) No direct competitor drug is currently in the market and introduction of a competitor drug will lower the prices paid by taxpayers and consumers; or
d) The drug is produced in another country by the name brand manufacturer that initially developed the drug or by a well-known generic manufacturer that commonly sells pharmaceutical products in the U.S.

Thank you for your prompt attention to this matter.

Sincerely,

Charles E. Grassley
U.S. Senator

Amy Klobuchar
U.S. Senator