

United States Senate

WASHINGTON, DC 20510

September 6, 2017

Dr. Scott Gottlieb
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

Our country is facing an opioid epidemic that is devastating our communities and requires swift action from public officials, health care providers, community advocates, and law enforcement. As you know, the Food and Drug Administration (FDA) has a unique and critical role in using every tool available to work with prescribers and policymakers to craft strong, common sense solutions that tackle the many components of this public health emergency. Indeed, you have made addressing the opioid crisis one of your top priorities as FDA Commissioner.

In May 2017, you established an Opioid Steering Committee at the FDA, explaining, “I believe it is within the scope of FDA’s regulatory tools – and our societal obligations – to take whatever steps we can, under our existing legal authorities, to ensure that exposure to opioids is occurring under only appropriate clinical circumstances, and for appropriate patients.”¹ You asked the Opioid Steering Committee to consider whether FDA should take additional steps to ensure “that the number of opioid doses that an individual patient can be prescribed is more closely tailored to the medical indication.” You also noted that “there are plenty of situations where the best prescription is a two- or three-day course of treatment,” rather than the 30-day supply commonly prescribed to patients in need of an opioid prescription.

We are writing to you today to request that the Opioid Policy Steering Committee consider how “partial fill” policies can help limit the volume of unused medications in circulation and advance our shared goal of curbing the opioid epidemic. Despite efforts to improve prescribing guidelines for acute and chronic pain and educate prescribers accordingly, these dramatic increases in opioid prescriptions have not slowed. High levels of opioid prescribing can lead to a large number of unused medications, which fuels the opioid epidemic. According to the Centers for Disease Control and Prevention, almost 80% of people at the highest risk of overdose obtained pills that were legally prescribed to someone – including

¹ Scott Gottlieb, “FDA Commissioner Asks Staff for ‘More Forceful Steps’ to Stem the Opioid Crisis,” FDA Voice Blog (May 23, 2017) (online at: <https://blogs.fda.gov/fdavoices/index.php/2017/05/fda-commissioner-asks-staff-for-more-forceful-steps-to-stem-the-opioid-crisis/>).

themselves, friends, or relatives.² This means it is critical to limit the number of pills that travel home from the pharmacy in the first place.

Last Congress, we sought to address the significant role that diverted prescription drugs have played in the opioid epidemic, while still providing flexibility for patients and doctors, by introducing the bipartisan, bicameral *Reducing Unused Medications Act*. This bill – which was signed into law in July 2016 as Section 702 of the *Comprehensive Addiction and Recovery Act* – amends the Controlled Substances Act to allow partial filling of any Schedule II prescription, including painkillers such as OxyContin and Vicodin.³

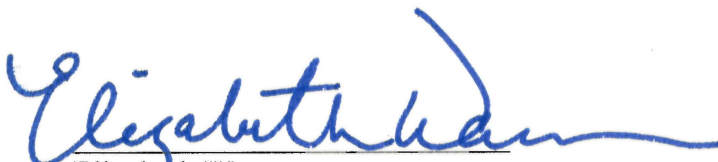
Our idea was simple: empower patients to have a conversation with their health providers and pharmacists about how many prescription drugs they felt comfortable having in their home. For example, the new statute means that a doctor can prescribe a patient two weeks' worth of opioid medication if it is necessary, but the patient or doctor can request that their pharmacist only fill enough for a three day supply – and then, return to the pharmacy if pain persists to pick up the remainder of their prescription. The passage of federal partial fill policy means that this option is now available to doctors and patients across the country, unless specifically prohibited by state law.

We are reaching out leaders across the country, including the governors of all 50 states, and prescriber groups to make them aware of this change in federal law and to inquire about its implementation. We urge the Steering Committee consider how the new partial fill law may help to advance the FDA's goals of better managing the risk of opioids and requiring greater prescriber education.

In the absence of greater reforms, encouraging prescribers to embrace the partial fill option for their patients can help to reduce the number of opioids left over in homes across the country. Educating health care professionals about various methods to limit overprescribing, as well as simple policy tools like partial fill and the safe disposal of unused medication, are all critical ways to address the opioid epidemic.

Thank you for your assistance in responding to this request, and thank you for your work to address this public health crisis.

Sincerely,



Elizabeth Warren
United States Senator



Shelley Moore Capito
United State Senator

² Centers for Disease Control and Prevention, "Prescribing Data" (December 20, 2016) (online at: <https://www.cdc.gov/drugoverdose/data/prescribing.html>).

³ 21 USC 829(f)