

United States Senate

WASHINGTON, DC 20510-4804

COMMITTEES
APPROPRIATIONS
ENERGY AND NATURAL RESOURCES
INTELLIGENCE
VETERANS' AFFAIRS

December 4, 2017

The Honorable Scott Gottlieb
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb,

As you know, our country faces a national crisis. In 2015, we lost more than 33,000 Americans to opioid overdoses¹ and early estimates indicate that that number was even higher in 2016.² As the senior Senator from West Virginia, I have seen this devastation first hand. No state in the nation has been harder hit than mine. In 2016, we lost more than 700 West Virginians and many more have seen their communities and families torn apart. That is why it is so important that we work together and do everything in our power to end this crisis.

That is why I am strongly supportive of your effort to establish the Opioid Policy Steering Committee to strengthen FDA's response to this crisis. I have been very critical of the role that the FDA has played in this epidemic, but I have been heartened to see the changes that the agency has been making to take responsibility for the public health impact of these deadly drugs.

I appreciate the opportunity to submit three commonsense policy changes for the Opioid Policy Steering Committee to consider. I believe that these simple steps could have a dramatic impact in reducing the number of unnecessary and dangerous opioid medications on the market.

First, I strongly believe that the FDA should require mandatory and continuing education for every healthcare provider who prescribes opioids. Too many of our medical professionals have received too little training on the dangers of opioids, signs of addiction, and alternatives to opioids for pain management. We must ensure that they have the information that they need to make medically appropriate decisions for their patients' care.

Second, to strengthen the FDA's new commitment to consider the public health impact of opioid medications, I urge you to seek Advisory Committee guidance and review every opioid product that is currently on the market to determine for each one if the risks outweigh the benefits. These risks include not just addiction and overdose deaths, but also outbreaks of HIV and Hepatitis C that occur when a drug is too easy to abuse. Every opioid that an Advisory Committee determines is more dangerous than beneficial should be immediately removed from the market.

¹ <https://www.cdc.gov/drugoverdose/data/statedeaths.html>

² <https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html>

Third, for every new opioid medication approved, the FDA should remove one or more older opioid medications from the market with a particular focus on those opioids that are not crush-resistant and are more easily abused. There are several dozen opioid extended-release and long-acting opioid medications that have been approved by the FDA and at least two dozen short-acting opioid medications. This market is saturated and we can currently treat everything from short-term, acute pain to excruciating cancer pain. We simply do not need to increase the number of opioid medications on the market.

Again, thank you for the work that you are doing to raise awareness and to promote solutions to address this deadly epidemic. Too many in our communities are losing their lives, families, and futures to opioids and we need to be doing everything humanly possible to help them. These commonsense changes are a critical first step. Thank you for your consideration, and I look forward to continuing to work with you.

Sincerely,

A handwritten signature in blue ink, appearing to read "Joe Manchin III". The signature is stylized with a large initial "J" and "M".

Joe Manchin III
United States Senator