United States Senate
WASHINGTON, DC 20510

May 3, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Gottlieb:

Our nation's unprecedented opioid epidemic, which is killing 115 Americans every day, requires a comprehensive response from all stakeholders. Under your leadership, the U.S. Food and Drug Administration (FDA) has taken positive steps to reduce opioid addiction and overdose, including by expanding the Risk Evaluation and Mitigation Strategy (REMS) to immediate-release opioids, exploring ways to expand provider education, making packaging and labeling changes to protect against overconsumption, and requesting removal of Opana ER from the market due to its abuse potential. We commend you for spearheading these important initiatives. Today, we write to urge you to take additional action to protect Americans from unsafe products that pose disproportionate overdose risk by removing ultra-high dosage opioids from the market.

Ultra-high dose opioids are those which, when taken as directed by the label, exceed the Centers for Disease Control and Prevention's (CDC) threshold for dangerously high daily opioid intake of 90 morphine milligram equivalents. For example, the OxyContin 80mg tablet, can cause fatal respiratory depression when taken by a person without a high opioid tolerance—it is as powerful as 24 tablets of Vicodin. Additionally, the Subsys fentanyl spray comes in doses equal to 58 Vicodin tablets. Given the strength of a single dose of one of these opioids, it is shocking that such products remain on the market in the midst of our nation's opioid epidemic.

A particular concern with ultra-high dose opioids is accidental ingestion, borrowed medication, and recreational use. Studies have shown that 12 million Americans misuse prescription opioids annually, and more than half of all misuse originates with a prescription opioid from a friend or relative. It is our understanding that the FDA may have evidence and adverse events data to understand the scope of misuse from ultra-high dose opioids.

Last year, the National Academy of Sciences issued a report outlining a new framework for the FDA's opioid approval and removal decisions. We were pleased by your endorsement of this new approach that takes misuse potential into account when weighing the risks and benefits of opioid formulations. Given that palliative and cancer-related pain patients who require high opioid doses could still receive adequate treatment with multiple pills, patches, or other formulations, we believe these ultra-high dose opioids can be removed from the market without imposing hardship on those with legitimate pain needs.

We understand that several medical and public health stakeholders have submitted a citizen petition under Section 355(e) of the Federal Food, Drug, and Cosmetic Act, asking the FDA to remove these high-dose opioid pills from the market given their outsized risks. We urge you to heed this important, potentially life-saving request. We appreciate your commitment to using all tools at the FDA's disposal to help address the opioid crisis.

Sincerely,

Richard J. Durbin
United States Senator

Joe Manchin III
United States Senator

Edward J. Markey
United States Senator