

United States Senate

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COMMITTEES
APPROPRIATIONS
ENERGY AND NATURAL RESOURCES
INTELLIGENCE
VETERANS' AFFAIRS

December 13, 2017

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

The Honorable Robert Patterson
Acting Administrator
United States Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Dear Dr. Gottlieb and Acting Administrator Patterson:

As the senior Senator from West Virginia, I have seen firsthand the devastating effects of prescription drug abuse on individuals, families, and communities in my state. We lost 884 West Virginians to a drug overdose last year alone. Families and communities in my state and around the country are reeling.

While our focus is appropriately on the devastating impact of prescription opioids, there are other prescription drugs that are also contributing to this crisis. In fact, the West Virginia Board of Pharmacy recently designated the nerve-pain medication gabapentin as a "drug of concern" after the number of overdose deaths related to the drug increased from 36 in 2012 to 106 in 2016.¹ Though gabapentin is currently listed as a Schedule V drug under the United States Controlled Substances Act, West Virginia is not the only state raising concerns about this drug; officials in Kentucky and Ohio have also increased regulation on and surveillance of gabapentin.

A recent study highlighted the increase in abuse of gabapentin. The researchers found that 20% of the patients tested were using gabapentin without a prescription and the significant majority of those patients were using other prescription drugs including opioids, benzodiazepines, and others.² The authors of the study concluded: "Until recently, it was considered to have little potential for abuse however this review has shown that a significant amount of patients are taking Gabapentin without physician consent. This could be due to the fact that recent studies

¹ https://www.wvgazette.com/news/health/as-overdoses-climb-gabapentin-designated-drug-of-concern-in-wv/article_1f2c9ef4-09fc-5115-8ac8-d0b9f0cd3c31.html

² <http://www.abstractsonline.com/Plan/ViewAbstract.aspx?sKey=67c97692-b33b-48a8-9fb5-1bf308bcfba5&cKey=723b5fa2-bc2a-4c02-9a6e-6516bc026c5a&mKey=d4cbe046-6d73-41d9-840f-d1d61d62bcab>

have revealed that Gabapentin may potentiate the ‘high’ obtained from other central nervous system acting drugs.”³

Given the recent rise in overdose deaths associated with gabapentin and the studies funding increased abuse of this drug, I am urging the FDA and the DEA to consider rescheduling this drug and requiring additional risk mitigation measures including physician and patient education around the potential for abuse, addiction, and overdose deaths when this drug is prescribed and used with other dangerous medications, including opioids.

I ask that you provide answers to the following questions:

- 1) Are the FDA and DEA currently investigating the rise in abuse of gabapentin and related overdose deaths?
- 2) Are the FDA and DEA considering rescheduling this drug given the larger public health impact and the potential for abuse when taken with other dangerous medications?
- 3) Is the FDA considering implementing new REMS for gabapentin to ensure that prescribers and patients are fully aware of the danger of this drug when taken with other medications, including opioids?

Thank you for the work that you are doing to address the deadly prescription drug epidemic. Our communities are being torn apart by this scourge, and we must do everything in our power to stop it. Thank you for your consideration, and I look forward to continuing to work with you.

Sincerely,



Joe Manchin III
United States Senator

³ <http://www.abstractsonline.com/Plan/ViewAbstract.aspx?sKey=67c97692-b33b-48a8-9fb5-1bf308bcfba5&cKey=723b5fa2-bc2a-4c02-9a6e-6516bc026c5a&mKey=d4cbe046-6d73-41d9-840f-d1d61d62bcab>