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ENERGY AND NATURAL RESOURCES COMMITTEE
ARMED SERVICES COMMITTEE
COMMERCE, SCIENCE, AND TRANSPORTATION COMMITTEE
VETERANS' AFFAIRS COMMITTEE

August 16, 2015

The Honorable Stephen Ostroff, M.D
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Ostroff:

I am disgusted by the Food and Drug Administration's (FDA) recent decision to approve OxyContin for use for children as young as 11 years old. The FDA should be absolutely ashamed of itself for this reckless act. Today, there are 2.1 million Americans abusing or dependent on opioids. In addition, 44 people die every single day as a result of a prescription opioid overdose. These drugs are destroying lives and devastating communities.

I have pleaded with your agency since I became a Senator almost 5 years ago to cease the flood of painkillers that is killing so many people in my state and around the country. Instead, you continue to ignore the agency's purpose and show allegiances with everyone but the people you are charged to protect. It took almost 3 years for the FDA to finally agree with my initial demand to reschedule hydrocodone, even as abuse and overdose deaths rose dramatically. Then, within a day of agreeing to reschedule, your agency approved Zohydro, a pure hydrocodone drug, despite your own advisory committee strongly voting against approval by a vote of 11 to 2 because of the danger of overdose and death. Just when I thought the agency could not be any more reckless, the FDA decides to double down on its ill-advised ways. The decision to approve OxyContin for those as young as 11 is just as foolish and just as deadly as all the other actions for which I've demanded changes. Your callous recommendation endangers the lives of our most precious asset and the nation's future: children.

While other agencies of our government, including the Centers for Disease Control, the National Institute on Drug Abuse, and the Substance Abuse and Mental Health Services Administration, are speaking loudly about the desperate need to do everything in our power to stop the scourge of opioid abuse, the FDA has carelessly continued to approve these addictive and deadly drugs. This recent decision, which will increase the likelihood that children as young as 11 years old will be prescribed OxyContin, is a horrifying example of the disconnect between the FDA approval process and the realities of this deadly epidemic.

An 11 year old's brain has another 14 years before it is fully developed. We have years of evidence that shows that drug use at an early age makes a child more likely to abuse drugs later in life. You have ignored all of this. Instead, under your new guidance, we are literally poisoning our children's brains and setting them up for future drug abuse.

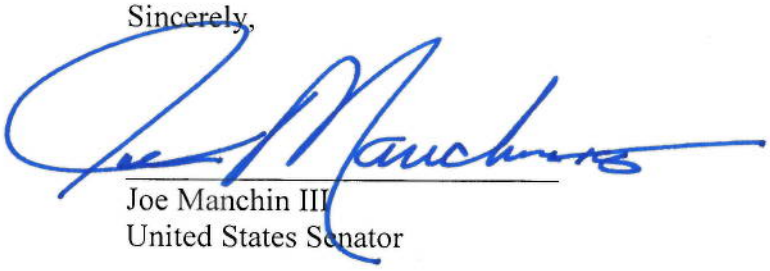
This decision does not increase access to these drugs for young cancer patients or others who may need this drug. Pediatricians prescribe medications that are not specifically approved for use in children all the time. Instead, this decision gives Purdue Pharma – a company that has already pled guilty and paid $635 million in fines for deceiving doctors regarding the addictiveness of OxyContin – the legal right to begin advertising to pediatricians about the use of OxyContin to treat 11-16 year olds under certain circumstances. We have seen the devastating impact of this targeted advertising as the number of opioid prescriptions quadrupled between 1999 and 2012 with a corresponding quadrupling in the number of opioid overdose deaths. Any argument that this is unlikely to increase the number of prescriptions of this drug for these kids is absurd. The FDA is mindful in a variety of contexts, such as tobacco, about the dangers of advertising to children, and yet it ignores all that wisdom with this decision.

Furthermore, this decision – like too many in the past year – was made without the advice of an independent advisory committee. Under the FDA's own regulations, your agency is required to convene an advisory committee when a matter is of significant public interest, highly controversial, or in need of specific type of expertise. There is no sound argument to be made that this decision does not meet every single one of those criteria. Given the extraordinary public health crisis that we are facing and the well-documented damage that dangerously addictive drugs like OxyContin can do to a developing brain, it is difficult to believe that an independent panel of experts would have recommended the approval of this drug in children. Given your agency's decision to bypass this critical step, we will never know.

The American people and the people the state of West Virginia are drowning under the weight of the prescription opioid abuse epidemic. We are losing too many Americans – young and old – and robbing many, many more of their potential. We must do everything in our power to stop the flow of these devastating drugs into our communities, but the FDA is working to do the exact opposite.

I will be calling for a Senate investigation into this decision and the FDA's decisions to approve dangerous and addictive opioid drugs. I cannot sit by while an agency of the federal government facilitates the poisoning of our children and their parents and grandparents. I hope that you will reconsider this decision and begin to work with me and with the other federal agencies that are trying stop the opioid epidemic.

Sincerely,



Joe Manchin III
United States Senator

Cc: The Honorable Sylvia Mathews Burwell, Secretary of Health and Human Services