

United States Senate

WASHINGTON, DC 20510

September 9, 2015

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on
Health, Education, Labor and Pensions
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
U.S. Senate Committee on
Health, Education, Labor and Pensions
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

We write to urge the U.S. Senate Committee on Health, Education, Labor and Pensions to hold hearings on the exponential rise in the misuse and abuse of opioid painkillers and consequent opioid overdose deaths as well as examine the Food and Drug Administration's (FDA) recent decision to approve a frequently abused prescription opioid painkiller known as OxyContin for use by children as young as 11 years old.

Today, there are 2.1 million Americans abusing or dependent on opioids. In addition, 44 people die every day as a result of a prescription opioid overdose. Abuse of opioid painkillers is also linked to abuse of heroin, increased hepatitis C infection rates, increase in HIV transmission and a host of other negative public health outcomes. The increased use and abuse of opioid medications is destroying lives and devastating communities. As we work to stop this crisis, the FDA's decision to approve the use of OxyContin in pediatric patients is a step in the wrong direction, as it may lead to an increase in inappropriate prescribing and use among a population that are already at a higher risk for developing dependency and addiction. The United States Senate must act swiftly to examine this issue and protect a new generation from losing their productive lives to an opioid use disorder.

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 stop the overprescribing of opioids and scourge of related overdose deaths, the FDA has continued to approve and expand the populations who use these addictive and deadly drugs. The FDA's most recent action, which will increase the likelihood that children as young as 11 years old will be prescribed OxyContin, is a troubling example of the disconnect between the FDA approval process and the realities of this deadly epidemic.

While the approval may be intended to be narrow, the trends of the last decade show us that there are likely to be far-reaching consequences. This decision does not increase access to these drugs for young cancer patients or other chronically ill patients who may need this drug, as pediatricians already prescribe medications that are not specifically approved for use in children when it is needed. Instead, the FDA's actions give the producer of OxyContin – a company that, in 2007, 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. Sadly, this increase has been accompanied by a quadrupling in the number of opioid overdose deaths.

Furthermore, this FDA decision was made without the advice of an independent advisory committee. Under the FDA’s own regulations, the agency is required to convene an advisory committee when a matter is of significant public interest, highly controversial, or in need of a specific type of expertise. It is our opinion that this decision meets every single one of those criteria. Given the extraordinary public health crisis that our country is facing and the well-documented damage that dangerously addictive drugs like OxyContin can do to a developing brain, an independent advisory board would have been most useful in aiding FDA in making an appropriate assessment of this decision. The lack of an advisory board and the potential consequences of the FDA’s decision make this an issue ripe for Congressional oversight and in need of a thorough examination by the United States Senate.

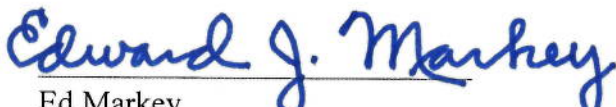
The American people are drowning under the weight of the prescription opioid abuse epidemic. We are losing too many Americans – young and old – and robbing many, many more of their potential. We must do everything in our power to stop the flow of these devastating drugs into our communities.


We strongly urge you to hold hearings into this decision and the public health impacts of the opioid abuse epidemic more broadly. As United States Senators, it is our duty to ensure that the federal government is protecting the citizens of this country, and ensuring that any medications approved by the FDA meet the strictest safety standards. We look forward to working with you to protect our children – and their parents and grandparents – from the scourge of opioid addiction.

Sincerely,


Joe Manchin III
United States Senator


Kelly Ayotte
United States Senator


Ed Markey
United States Senator


Bill Nelson
United States Senator



Tim Kaine
United States Senator



Angus King
United States Senator



Jeanne Shaheen
United States Senator



Mark Warner
United States Senator



Claire McCaskill
United States Senator