

Coburn Amendment #419 —To prevent the FDA from approving prescription opioids that are subject to abuse without requiring abuse-deterrent formulations.

The abuse of opioid prescription drugs is a growing problem in our country. According to the CDC, more than 16,000 Americans die from opioid drug overdoses each year.¹

Currently, the prescription opioid drugs most likely to be abused are *only* sold in special *abuse-deterrent formulations*. These formulations largely prevent an individual from abusing the drug by crushing it, snorting it, etc.

However, in just a few weeks, unless the Food and Drug Administration acts, these powerful opioid drugs will be available to consumers *without the abuse-deterrent formulations*.

The FDA has defined what it believes are abuse-deterrent formulations of drugs. The FDA has also confirmed it has the legal authority to require that these drugs have abuse-deterrent formulations.

This amendment would simply require FDA to not approve these opioids that are highly-susceptible to abuse, unless those drugs use formulations the FDA finds to be abuse-deterrent.

Without FDA action, patient safety will be at risk.

An opioid is a powerful narcotic drug most often prescribed to help patients in serious, long-term pain. But opioids can highly addictive and have often been abused.

According to the CDC, in 2010, 22,000 Americans died due to drug overdoses of pharmaceutical drugs. Unfortunately, CDC data also shows that about 3 out of every 4 deaths are related to opioid drugs.

Without FDA action, generic forms of these drugs which have been demonstrated to be highly subject to abuse will flood the American market.

To date, a wide range of members of Congress in both parties, more than 45 State Attorneys General, and public health groups have all called on FDA to act to prevent this from happening. Unfortunately, the FDA has yet to act to protect Americans from a predictable public health catastrophe.

¹ http://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html