Labeling Changes for Prescription Opioid Cough and Cold Medicines (FDA Drug Safety Communication)

SciPol Summary

The Food and Drug Administration (FDA) released a drug safety communication changing the safety labeling for prescription cough and cold medicines containing opioids with the ultimate goal of preventing patients under eighteen years of age from using these drugs. In tandem, this rule changes the FDA’s indication for prescribing opioid cough and cold medicines, and encourages health care professionals to limit prescription only to those over eighteen years of age. Furthermore, the FDA communication requires additional safety information about the risks of misuse, abuse, addiction, overdose, and death to the Boxed Warning - the prominent warning label on prescription medications - to inform patients about opioid risks.

The ongoing opioid crisis in the U.S. has pushed governmental engagement on issues involving both prescription and illicit opioids. One of the responsibilities of the FDA is to ensure that drugs are properly labeled and correctly prescribed. After an extensive review by a panel of outside experts, the FDA decided that "the use of prescription, opioid-containing medicines to treat cough and cold in children comes with serious risks that don't justify their use in this vulnerable population." The drug safety communication's new warning label requirement for cough medicines containing codeine and hydrocodone will align the warning labels of these prescriptions with other opioid containing products such as immediate-release opioid analgesics and extended-release and long-acting opioid analgesics.

SciPol Summary authored by Cameron Fox, MA Candidate

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STAT – 'Tis the season for “state of the state” speeches, and governors are using their platforms to take on the opioid crisis, promise improvements in mental health care — and push back against President Trump’s plans to dismantle the Affordable Care Act.

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