CHANGING THE CULTURE OF THE FDA ACT

This legislation would amend the FDA's mission statement to include the agency's responsibility for addressing the opioid epidemic. Specifically, it would add the following language: *"The FDA is also responsible for protecting the public health by strongly considering the danger of addiction and overdose death associated with prescription opioid medications when approving these medications and when regulating the manufacturing, marketing, and distribution of opioid medications."*

Why is this necessary?

In 2014, more than 18,000 people died from prescription opioid overdose. **That's 51 people every day.** It is clear that we are facing an opioid epidemic. It is also clear that the opioid market is flooded with pills. The U.S. makes up only 4.6% of the world population, but consumes 80% of the opioids. In 2012 alone, health care providers wrote 259 million opioid prescriptions – enough for every American to have a bottle.

The FDA plays a critical role in this epidemic as the agency overseeing the approval of these drugs, but to date, the agency has failed to consider the devastating public health impact of its repeated decisions to approve dangerously addictive opioids.

FDA's Actions: We have seen too many examples of the FDA exacerbating the opioid abuse epidemic.

Rescheduling Hydrocodone: Even while hydrocodone was the most widely abused opioid, the FDA delayed for years before finally agreeing to reschedule this powerful narcotic. Since the change went into effect a year ago, we've seen the number of prescriptions for combination hydrocodone products such as Vicodin and Lortab fall by 22%.

Approving Zohydro: The FDA also approved the dangerous drug, Zohydro, when its own experts voted 11-2 against approval due to health and safety concerns. This drug has ten times the hydrocodone of Vicodin and Lortab, with the capability of killing an individual in just two tablets.

Avoiding Its Own Advisory Committee: After the negative feedback following the approval of Zohydro, the FDA approved two new opioid medications, Targiniq and Hysingla, without an advisory committee meeting.

Approving OxyContin for Children: The FDA approved OxyContin for use for children as young as 11 years old without an advisory committee meeting. This decision means that pharma is now legally allowed to advertise OxyContin to pediatricians under certain circumstances – we have seen the devastating impact of this type of advertising and 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.

Pushing Back Against the CDC: Leaders at the FDA, including the director of the division that oversees opioids, actively pushed against the CDC's efforts to complete prescribing guidelines, which represent a reasonable, commonsense approach to help doctors take into account the very real and prevalent danger of addiction and overdose death when prescribing opioids.

The FDA has recently announced that the agency will be taking steps in the right direction to address these problems, including increasing the use of the advisory committees and putting their support behind the CDC guidelines, but these steps are not enough. The entire culture needs to change. Strengthening the FDA's mission statement is a step in that direction.