



National Association of County & City Health Officials

*The National Connection for Local Public Health*

February 26, 2018

Dockets Management Staff  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

RE: Docket No. FDA-2017-P-5396-0001 for Citizen Petition from Physicians for Responsible Opioid Prescribing; Request for Comments

Dear Commissioner Gottlieb:

The National Association of County and City Health Officials (NACCHO) is writing to provide comments to the Food and Drug Administration (FDA) in support of a citizen petition from Physicians for Responsible Opioid Prescribing to remove ultra-high dosage unit (UHDU) oral and transmucosal analgesics from the market in order to combat the nation's opioid epidemic. NACCHO represents the nation's nearly 3,000 local health departments. These city, county, metropolitan, district, and tribal departments work every day to help ensure prevention and treatment options and resources are available to those affected by the opioid epidemic. NACCHO appreciates FDA's work to seek solutions to address opioid misuse, both prescription and illicit.

Every day 91 Americans die of opioid overdoses. In 2015, 11.5 million Americans are estimated to have misused prescription opioids. The most commonly reported motivation for misuse was to relieve physical pain. The opioid epidemic has been driven by multiple factors including improper or excessive prescribing practices. NACCHO supports the position that FDA should immediately seek removal of oral and transmucosal UHDU opioid analgesics from the market.

Higher prescription opioid doses are associated with increased overdose risk. A Centers for Disease Control and Prevention (CDC) study found that keeping opioid dosages under 50 morphine milligram equivalents (MME) per day reduces overdose risk among a large proportion of patients without significant compromise in the effectiveness of pain management. UHDU opioids exceed 90 MME per dose. Opioids such as OxyContin 80 milligram tablet taken twice a day is the equivalent of 240 MME far exceeding a safe threshold.

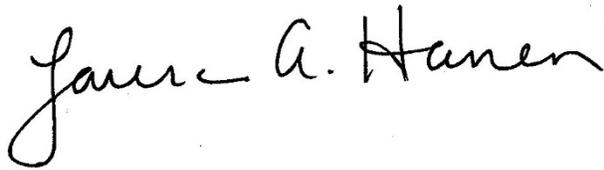
A person prescribed a higher dosage of an opioid is far more at risk to develop an opioid use disorder than a person taking a relatively low dose of prescribed opioids and 15 times more likely to develop an opioid use disorder as a person who has not been prescribed opioids. In



2015, 969,000 youths aged 12 to 17 misused prescription pain relievers, and 3 million young adults aged 18 to 25. The chance for accidental overdose is far greater when prescribed a UH DU opioid. Even when taken as directed, there is an increased risk for overdose, motor vehicle crashes, neuroendocrine dysfunction, hyperalgesia and other adverse effects.

NACCHO appreciates the opportunity to provide input for the FDA on UH DU opioids. As an essential governmental public health partner, we look forward to continuing to work with FDA to combat the opioid epidemic. Please contact Eli Briggs, Senior Director of Government Affairs, for further information at 202-507-4194 or [ebriggs@naccho.org](mailto:ebriggs@naccho.org).

Sincerely,

A handwritten signature in black ink that reads "Laura A. Hanen". The signature is written in a cursive, flowing style.

Laura A. Hanen, MPP  
Interim Executive Director & Chief of Government Affairs