

## FACT SHEET ON ULTRA HIGH DOSAGE UNIT OPIOIDS

Q: What are Ultra High Dosage Unit (UHDU) opioids?

A: UHDU opioids are formulations that when taken as directed exceed 90 morphine milligram equivalents (MME) per day, a dose the Centers for Disease Control and Prevention (CDC) has determined to be dangerously high.<sup>1</sup>

Q: What is an example of an UHDU opioid?

A: The OxyContin 80 milligram tablet. A patient directed to take one OxyContin 80 milligram tablet twice a day is consuming the equivalent of 240 MME, far exceeding CDC 90 MME upper dose. Because only one pill is taken at a time, the patient and prescriber may not appreciate that this is an extremely high dose.

Q: Why should FDA ask manufacturers of UHDU opioids to remove them from the market?

A: In July 2017, FDA announced it would utilize a new benefit-risk framework proposed by the National Academy Sciences that will consider the public health effects of opioid misuse for removal decisions.

Q: Why is misuse of UHDU opioids grounds for FDA to seek removal?

A: In 2015, 11.5 million Americans are estimated to have misused prescription opioids.<sup>2</sup> The most common motivation for misuse (63%) was to relieve physical pain. Someone who borrows a single dose of an UHDU opioid to use for pain relief could experience life-threatening respiratory depression. An overdose could also occur in the opioid-tolerant patient who accidentally takes just one extra dose or who intentionally takes an extra dose for unrelieved pain. UHDU opioids are equally dangerous when misused for recreational purposes. For example, an opioid naive teenager who makes the mistake of experimenting with an UHDU opioid could suffer a fatal overdose from just one pill.

Q: Are UHDU opioids safe when taken as prescribed?

A: Even when taken exactly as directed for chronic pain UHDU opioids are associated with increased risk for overdose, motor vehicle crashes, neuroendocrine dysfunction, hyperalgesia and other adverse effects.<sup>1</sup>

Q: What are the benefits of UHDU opioids?

A: The main advantage of UHDU opioids is that patients can take fewer pills. Removing UHDU opioids would be unlikely to interfere with treatment of pain or pose hardships. Opioids are available in liquid preparations, patches, sublingual forms, and suppositories for patients who have difficulty swallowing extra pills.

### References

1. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain—United States, 2016. *JAMA*. 2016;315(15):1624-1645.
2. Han B, Compton WM, Blanco C, et al. Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health. *Ann Intern Med*. 2017;167(5)[Epub ahead of print]