FDA Approves Opioid More Powerful Than Fentanyl

By **Sean Woodard** - November 9, 2018

The U.S. Food and Drug Administration (FDA) recently approved expanded medical use of an opioid-based drug. The announcement garnered much criticism from numerous healthcare professionals.

The drug in question is known as sufentanil, a synthetic opioid painkiller that belongs to the fentanyl family.

The FDA's Anesthetic and Analgesic Drug Products Advisory Committee voted to approve a new tablet form of the drug that will be marketed under the name Dsuvia. Committee members passed it with a 10 to 3 vote.

Dsuvia will be used in medical settings to provide pain relief for surgery patients. The 30-microgram tablet dissolves under a patient's tongue. Unlike a pill or injection, the medication can take effect in the person's body at a faster rate.

Some critics of the decision argue that the normal vetting process for drug approval was skirted.

The committee's chairman, who was unable to attend the vote meeting due to a scheduling conflict, stated that the drug's passing will not positively affect measures to reduce the nation's opioid crisis.

Other healthcare professionals argue that the drug's size and potency — allegedly 5 to 10 times more powerful than pharmaceutical fentanyl — could lead to misuse and cause more overdose deaths.

However, supporters counter that the drug will only be allowed for hospital and medical facility use and not available at pharmacies for consumers.

Following Dsuvia's approval, FDA commissioner Dr. Scott Gottlieb issued a press release regarding the decision. He wrote that the oral opioid's pre-measured dosage and ease of use make it ideal in extremely rare cases where patients cannot receive an analgesic in another form in a timely manner.

In addition, Gottlieb stated that the FDA will re-evaluate its drug approval procedures and consider how each future drug will affect the general public and the country's efforts to fight the opioid epidemic.

The Development of Fentanyl and Sufentanil

The late Dr. Theodore H. Stanley of the University of Utah's Department of Anesthesiology, traced the history of fentanyl and its analogs in an article published in the American Pain Society's Journal of Pain in 2014. Fentanyl was first synthesized in 1960 by Dr. Paul Janssen. At the time, researchers considered the analgesic 100 to 200 times more potent than morphine; the U.S. Drug Enforcement Administration (DEA) now clarifies that it is 80 to 100 times more potent than morphine.

The drug was used intravenously for medical procedures in Europe beginning in 1963; however, the FDA did not approve the use of fentanyl until 1968. Many concerns that were raised at the time regarding fentanyl's potency remain relevant today.

Researchers conducted animal studies to observe whether fentanyl could serve as a potential alternative to morphine, which was used as an anesthetic in the 1960s. Based on the results, doctors began testing fentanyl on humans.

During the 1970s and '80s, fentanyl became a common alternative to morphine for surgeries. Its success prompted increased pharmaceutical sales and popularity among healthcare professionals.

Since the 1990s, companies developed other administration methods for fentanyl, including transdermal patches, nasal sprays and oral solutions in the shape of a lozenge or lollipop.

Janssen Pharmaceutica first synthesized fentanyl's analog, sufentanil, in 1974. Medical personnel have used it for acute pain management during and post-surgery. Since 1984, the drug has been given to patients intravenously or via epidurals.

The U.S. National Library of Medicine lists the warnings and side effects associated with sufentanil-citrate, the injectable form of the analog. Like its parent drug, sufentanil can induce respiratory failure and can cause overdoses.

Per the Controlled Substances Act of 1970, the DEA classifies fentanyl and sufentanil as Schedule II drugs — substances that are deemed as acceptable for medical use, despite their high risks of potential abuse and psychological or physical dependence.

Controversy Surrounding Sufentanil and its Potential Uses

According to the U.S. Centers for Disease Control and Prevention, fentanyl and its analogs are accounting for a large number of opioid overdose deaths. Officials noted that between July 2016 and June 2017, 14 fentanyl analogs appeared in nearly 21 percent of opioid overdose death cases, which may explain why some medical professionals believe the FDA should have rejected Dsuvia.

Despite complaints, the tablet will be distributed by a California-based company called AcelRx Pharmaceuticals Inc.

Stanley mentioned in his article that fentanyl may have become a widely accepted opioid analgesic because it had been studied longer and seemed less of an investment risk. However, he clarified that rigorous FDA approval processes and increasing product costs may deter investors from backing future opioid analgesic variants unless sufentanil or other opioids become commercial successes.

As Gottlieb stated, Dsuvia will only be administered by healthcare professionals in a small number of cases.

Some supporters have mentioned that the risk of the medication being stolen from medical offices is relatively low. Results from a 2016 Substance Abuse and Mental Health Services Administration survey appear to confirm this point. According to the data, less than 1 percent of the 11.2 million U.S. citizens ages 12 years or older who had misused prescription pain relievers admitted to stealing the analgesics from a pharmacy, doctor's office or medical clinic.

In addition to its use in medical facilities, the Department of Defense is examining the potential use of Dsuvia on wounded military personnel.

Nonetheless, other healthcare officials believe non-opioid alternatives may better at mitigating chronic pain.

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