## Transcript Details

This is a transcript of an educational program accessible on the ReachMD network. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/the-drug-report/deas-proposals-for-opioid-regulations/11279/

**ReachMD**
www.reachmd.com
info@reachmd.com
(866) 423-7849

---

DEA's Proposals for Opioid Regulations

Announcer:
You're listening to *The Drug Report* on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to *The Drug Report.* I'm Dr. Linda Bernstein.

The opioid crisis continues to take its toll every day. According to the Centers for Disease Control, about 48,000 US drug overdose deaths involved opioids in 2017. The National Institute on Drug Abuse, reports that more than 130 deaths in the United States daily occur from an opioid overdose. The U.S. economic burden of opioid abuse is equally staggering at $78.5 billion a year, which includes healthcare costs, loss of productivity, addiction treatment, and criminal justice involvement.

The Drug Enforcement Administration announced in September and October of 2019 proposals to reduce the amounts of five Schedule II opioid-controlled substances manufactured in 2020 compared with 2019. The DEA proposed to reduce the amount of fentanyl by 31%, hydrocodone 19%, hydromorphone 25%, oxycodone 9%, and oxymorphone 55%. When combined with morphine, the proposed quota would represent a 53% decrease in the amount of allowable production of these opioids since 2016. The five opioid substances were targeted as a result of the enactment of the 2018 SUPPORT Act, also known as the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act, which requires the DEA to "estimate the amount of diversion of the covered substance that occurs in the United States and make appropriate quota reductions." The SUPPORT Act also helped to establish more treatment programs for opioid abuse as well as strengthen monitoring of controlled substance prescriptions.

They wanted to improve the organization's ability to oversee the production of opioids and further limit excess quantities of the medications that might be vulnerable to diversion for illicit distribution and use. It includes important and necessary changes to DEA's quota regulations. These quota levels align with current manufacturing standards aimed at promoting quality and efficiency, while also ensuring the country has adequate supplies of Schedule II substances necessary for the medical scientific, research and industrial needs of patients nationwide.

In a related matter, more laws and regulations in 2020 will begin to address expanded naloxone access and possible OTC availability. In a September statement by Commissioner of Food and Drug Administration, Norman Sharpless MD, he noted that in response to the crisis, most states and the District of Columbia have passed laws that allow pharmacists to dispense the emergency opioid overdose reversal treatment, naloxone, under a standing order, which substitutes for an individual prescription. Additionally, some states have given pharmacists direct authority to prescribe and sell naloxone to consumers. Yet pharmacists may be unaware of the standing orders or direct authority in their states or are not willing to provide all forms of naloxone to consumers without an individual prescription.

It is important to note that all three forms of FDA-approved naloxone, injectable, auto-injector and nasal spray, currently require a prescription but may be considered as options for dispensing by pharmacies or community distribution and use by individuals with or without medical training to stop or reverse the effects of an opioid overdose.

The FDA is currently working to ensure that this lifesaving drug is accessible, and one of the efforts is making it easier for companies to develop it as an over-the-counter (OTC) product. The goal would be to make naloxone more widely available in every pharmacy as an approved over-the-counter product. The FDA has designed, tested, and validated the key labeling requirements to approve an OTC naloxone product by developing a model Drug Facts Label (DFL) with pictogram instructions so that anyone with access to the drug can

better understand how to administer it. Additionally, this is the first time that the FDA has proactively established and tested a Drug Facts Label to assist with creating an OTC product.

For *The Drug Report*, I'm Pharmacist, Dr. Linda Bernstein.

Announcer:
To access this episode and others from *The Drug Report*, visit ReachMD.com/drugreport, where you can be part of the knowledge. Thanks for listening.