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... FDA holds high-profile hearing on opioid overdose epidemic Drug overdose is now the leading cause of unintentional death in the United States, with a record 47,600 people dying of prescription and illicit drug overdoses in 2015, according to the Centers for Disease Control and Prevention. Amid a growing crisis of opioid addiction, the Food and Drug Administration is holding a public hearing on the safety and effectiveness of opioid prescription painkillers, including the controlled-release formulation Vicodin, when used to treat chronic pain. "We are facing a national crisis caused by prescription opioid abuse," Health and Human Services Secretary Sylvia M. Burwell testified. "More than 70,000 deaths in 2014 were tied to opioid overdoses. In the United States, drug overdoses are now the leading cause of accidental death." Burwell said that since 2010, the FDA has granted more than 12,000 applications for opioid-containing drugs and devices. The agency also has issued more than 170 meetings, safety alerts and warning letters to health-care professionals. In her testimony, Burwell said that the agency is looking at 12 new drugs and device applications for extended-release and extended-release-combination opioid formulations — including extended-release formulations of the painkiller OxyContin. "As we consider whether these new formulations are needed, we will continue to evaluate the evidence of addiction and abuse, overdose and death risks, abuse-deterrent mechanisms and other factors that are important for making a safe and effective medical product," Burwell said. She said the agency would consider additional FDA advisory committees on the topic. The new public hearing is the latest in a growing series of public meetings on opioid abuse and addiction organized by the FDA, the Centers for Disease Control and Prevention and several other federal agencies. Over the past year, the two entities have hosted 15 hearings on the topic, each with representatives from the pharmaceutical, medical device and public-health communities. At least 13 such meetings have been scheduled or are scheduled in the coming months, including a meeting by two federal working groups on opioid abuse later this month at the National Institute on Drug Abuse in Bethesda, Md. Drug overdose is now the leading cause of unintentional death in the United States, with a record 47,600 people dying of prescription and illicit drug overdoses in 2015, according to the Centers for Disease Control and Prevention. Amid a growing crisis of opioid addiction, the Food

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