Anti-addiction groups call for new FDA chief

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FDA Commissioner Dr. Margaret A. Hamburg poses for a portrait before a newsmaker interview at the Associated Press in Washington, in this May 30, 2014 file photo. In a letter released Wednesday, Sept. 24, 2014 anti-addiction activists are calling for the Food and Drug Administration's top official to step down, saying the agency's policies have contributed to a national epidemic of prescription painkiller abuse. (AP Photo/J. David Ake, File)

Anti-addiction activists are calling for the Food and Drug Administration's top official to step down, saying the agency's policies have contributed to a national epidemic of prescription painkiller abuse.

In a letter released Wednesday, more than a dozen groups ask the Obama administration's top health official to replace FDA Commissioner Dr. Margaret Hamburg, who has led the agency since 2009. The FDA has been under fire from public health advocates, politicians and law enforcement officials since last October, when it approved a powerful new painkiller called Zohydro against the recommendation of its own medical advisers.

The new letter is the first formal call for new leadership at the FDA over the issue.

"We are especially frustrated by the FDA's continued approval of new, dangerous, high-dose opioid analgesics that are fueling high rates of addiction and overdose deaths," states the letter, which is addressed to Health and Human Services Secretary Sylvia Burwell, who oversees the FDA and other health agencies. The groups signing the letter include Physicians for Responsible Opioid Prescribing, a 900-member advocacy group that petitioned the FDA to drastically restrict opioid use. The FDA rejected that petition last year.

A spokesman for the Department of Health and Human Services said opioid abuse "is a serious issue and one that the secretary is focused on."

"Secretary Burwell appreciates hearing from stakeholders on the important issue of prescription opioid abuse, and looks forward to responding to their letter," said Tait Sye, in a statement.

Despite the controversy surrounding painkillers, longtime FDA watchers say Hamburg's job is secure. She has served longer than any FDA commissioner since the 1990s and remains popular with key stakeholders, including committee leaders on Capitol Hill, the pharmaceutical industry and medical groups.

Deaths linked to the addictive medications, including OxyContin and Vicodin, have more than tripled over the last 20 years to an estimated 17,000 in 2011, the most recent year for which the Centers for Disease Control and Prevention reports figures.

The CDC has called on doctors to limit their use of the medications to the most serious cases of pain, such as cancer patients and end-of-life care. But the vast majority of prescriptions written in the U.S. are for more common ailments like arthritis and back pain.

Hamburg has supported broad use of the drugs, noting that 100 million Americans reportedly suffer from chronic pain.

The letter to HHS says the commissioner and the FDA are out of step with efforts by the CDC and other parts of the federal government.

"Dr. Hamburg's support for using opioids to treat chronic non-cancer pain is squarely at odds with efforts by the CDC to discourage this widespread practice," states the letter, which is signed by the National Coalition Against Prescription Drug Abuse and 15 other groups.

The letter appears timed to generate interest in a rally scheduled for September 28. The organizers plan to gather on the national mall and march to the White House to raise awareness of the opioid epidemic.

FDA spokeswoman Erica Jefferson said Hamburg has been "a tireless public health advocate" for over 20 years.

"Preventing prescription opioid abuse and ensuring that patients have access to appropriate treatments for pain are both top public health priorities for the FDA," Jefferson said in a statement.

The calls for Hamburg's resignation come almost a year after the FDA

approved Zohydro, the first extended-release, pure form of hydrocodone ever cleared for the U.S. market. Hydrocodone was previously only available in immediate release, combination pills that contain smaller amounts of the drug.

Commissioner Hamburg has defended the drug's approval by saying that it fills an important medical niche. Older combination pills like Vicodin mix hydrocodone with other drugs like acetaminophen, which can cause liver damage at high levels.

Members of Congress from West Virginia, Massachusetts and Kentucky have introduced bills to ban the drug. And attorneys general from 28 states asked the FDA to revoke the drug's approval or require that the pills be reformulated to prevent users from crushing them for snorting or injection.

But Wednesday's letter also criticizes the FDA for approving drugs that are actually designed to be harder to abuse.

The groups take issue with the agency's July approval of a new painkiller called Targiniq, which combines oxycodone with the ingredient naloxone. The addition of naloxone is designed to block the euphoric effects of oxycodone when it is snorted or injected. But the groups point out that Targiniq tablets can still be abused by simply chewing them—the most common approach to abusing painkillers.

The FDA has faced criticism from lawmakers representing states that have been hardest hit by opioid abuse, including Sen. Joe Manchin of West Virginia, Sen. Charles Schumer of New York and Congressman Hal Rogers of Kentucky.

Media representatives for all three lawmakers declined to comment on the letter. The American Pain Society, which represents physician pain

specialists, also declined to comment for this story.