US opioid epidemic

Opioid crisis haunts frontrunner for top job at US drugs regulator

FDA veteran Janet Woodcock oversaw approval of new painkillers amid worsening epidemic

Janet Woodcock is acting head of the FDA, and is reported to be under consideration by US President Joe Biden to become its permanent leader © BLOOMBERG NEWS

Kiran Stacey in Washington and **Hannah Kuchler** in New York FEBRUARY 4 2021

In more than two decades as a senior regulator at the US Food and Drug Administration, Janet Woodcock oversaw the approval of scores of new opioid drugs that were given a green light even as the painkiller epidemic spiralled out of control.

Now Dr Woodcock is acting head of the entire FDA, and is widely reported to be one of two or three people under consideration by President Joe Biden to become its permanent leader.

However, opposition is building to her potential candidacy, with campaigners accusing her of exacerbating the opioid epidemic by being too willing to approve new pain medications despite mounting concerns over their safety.

Andrew Kolodny, medical director of opioid policy research at Brandeis University's Heller School, said Dr Woodcock had presided over "one of the worst regulatory failures in US history — the opioids crisis that has cost 500,000 lives and millions of cases of addiction".

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Ed Markey and Maggie Hassan, two Democratic senators whose votes will be crucial for approving Mr Biden's pick to lead the FDA, have also signalled concerns about appointing somebody associated with the opioid crisis.

"The FDA's decision-making processes for the approval and labelling of opioid drugs going back decades remain of serious concern," they said in response to a query from the Financial Times about whether they supported Dr Woodcock's potential candidacy.

They added: "It's important that the next FDA commissioner is someone who has demonstrated that they have learned from the FDA's past mistakes, not someone who has been involved in repeating them."

The FDA said in a statement*: "Addressing the crisis of opioid use disorders is an issue of great concern for our nation and is a top public health priority for the FDA . . . We look forward to continuing our work under the Biden Administration and will continue using all of our authorities to address the national opioid crisis on all fronts."

Dr Woodcock, who has worked for the FDA since 1984, is one of the most influential drug regulators in the US. She headed the agency's Center for Drug Evaluation and Research — which is responsible for approving medicines — for two periods, from 1994-2004 and again between 2007-20.

Her appointment as acting commissioner was intended to restore morale at the agency following a turbulent 2020, when it came under fire from Donald Trump, the former president, for being too slow to approve coronavirus vaccines and treatments.

But while Dr Woodcock is widely respected as a scientist and doctor, many campaigners say she failed to take into account the public safety implications of new opioids that were approved under her watch.

Research published in December in the Annals of Internal Medicine showed that between 1997 and 2018, the FDA approved 48 new opioids for acute or chronic pain.

During this period, the number of deaths involving overdoses of synthetic opioids, excluding methadone, skyrocketed.

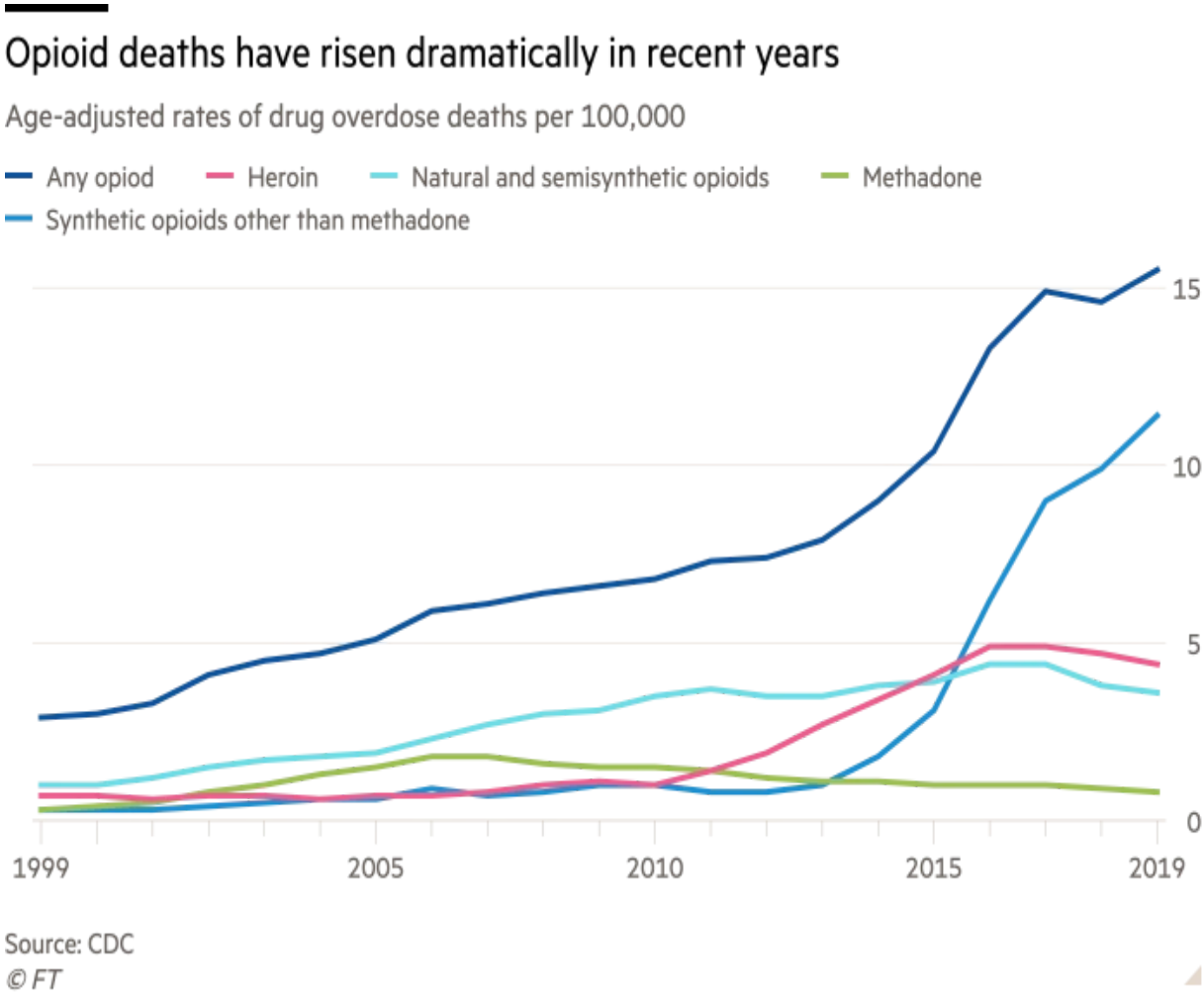
Data from the US Centers for Disease Control and Prevention show the number of such deaths rose from 730 in 1999 — the first year for which it publishes data — to 31,335 in 2018. Its most recent figures showed they rose again in 2019 to 36,359.

Caleb Alexander, a medical professor at the Johns Hopkins Bloomberg School of Public Health and one of the researchers on the AIM paper, said: "The FDA has shown systemic shortcomings over many years and many products in ensuring that these types of drugs are sufficiently safe and effective."

One of the most controversial decisions undertaken during Dr Woodcock's first period as head of the CDER was the 1995 approval of OxyContin, the powerful prescription opioid made by Purdue Pharma. Purdue has since settled criminal and civil charges potentially worth more than $8.3bn in connection with fuelling the US opioid epidemic.

Other more recent decisions have also come under scrutiny, such as the 2013 approval for Zohydro, an around-the-clock opioid for long-term pain, and the 2018 approval for Dsuvia, a potent pill designed to be used in hospitals or on the battlefield.

When the FDA approved Zohydro, it did so despite its own scientific advisory panel voting 11-2 against approval, and without demanding the manufacturer Zogenix include abuse deterrent features intended to make it harder to crush or dissolve for people trying to get high.



And the FDA's approval of Dsuvia overrode objections from Raeford Brown, who chairs the agency's Anesthetic and Analgesic Drug Products Advisory Committee. Dr Brown warned the medicine would result in abuse and deaths within months of being approved.

He told the FT he believed Dr Woodcock had shown "errors in thinking" in the way she had approached opioid approvals during two periods in charge of the administration's CDER.

He added: "[Her history] gives you pause about whether you want to put that person in a position where they are going to have to be thoughtful about our futures."

Others criticise Dr Woodcock for failing to put in place proper post-approval safety procedures for opioids.

In 2011, the FDA started demanding that drugmakers provide data on how often their opioids were being prescribed, what side-effects were being reported and whether patients were sufficiently aware of their risks.

But multiple reviews by the health department inspector general have found companies were not providing the FDA with the data it needed to be able to monitor the use of such drugs.

If Dr Woodcock does take over at the FDA, one decision she will have to make is whether to implement recommendations by the National Academies of Sciences, Engineering, and Medicine, for dealing with the opioid epidemic.

The FDA requested the report, which was published in 2017, but has yet to implement its recommendations, including one that calls for the agency to develop a "strategy for reducing lawful access to opioids".

Campaigners fear that on this and other issues, Dr Woodcock is more likely to back the industry and its calls not to hamper innovation than those who urge more caution in allowing new opioids to reach the market.

Dr Brown said: "When I was working with her, the question always came down to whether you were trying to squash innovation. But in the case of opioids, this is a false argument."

**This article has been updated to reflect that the FDA provided a statement after publication*