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Fentanyl vaccine heads for clinical trials, with goal of saving lives

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A fentanyl vaccine developed by researchers at the University of

Houston is expected to head to clinical trials sometime in the middle of next year, with the hope of being a groundbreaking solution to a deadly crisis.

The vaccine, which has shown success in animal studies, is designed to stop the highly addictive opioid from entering the brain and causing an overdose. Biopharmaceutical startup Ovax acquired the license to produce and test the vaccine in November 2023 and raised over $10 million toward that effort by June.

"We're all incredibly excited," said Collin Gage, the start-up's co-founder and chief executive officer. He added that his company is starting at "ground zero," but he is confident it will one day have a fentanyl vaccine available to the public.

That day may be a long time from now. While public health emergencies, like the COVID-19 pandemic, can accelerate a vaccine's development, testing a new vaccine can take anywhere from five to 10 years—sometimes longer.

Meanwhile, fentanyl overdose deaths have been on the rise in Texas, from less than 80 in 2014 to nearly 2,300 in 2023, according to the Texas Department of State Health Services. The synthetic opioid—made illegally but also available by prescription—is 50 times stronger than heroin and 100 times stronger than morphine, making it the deadliest drug in the opioid crisis.

For fentanyl vaccines, adjuvants are key

The idea of creating an opioid vaccine has drawn scientific attention since the 1970s. Unlike bacteria or viruses, opioids aren't recognized by our immune systems as foreign invaders. But the immune system can be trained to make antibodies in response to an opioid like fentanyl through

a vaccine that links bits of the drug to noninfectious bits of bacteria and uses substances called adjuvants.

Adjuvants are designed to enhance immune response, and are particularly important in vaccines targeting substance use disorders. Past attempts to make these vaccines have been unsuccessful in part because the adjuvants weren't effective enough, said Jay Evans, director of the Center for Translational Medicine at the University of Montana. Evans is also the chief scientific and strategy officer of Inimmune, a Montana-based biotech company developing and testing a variety of vaccines including ones targeting fentanyl and heroin addiction.

The adjuvant in the University of Houston's fentanyl vaccine is an enterotoxin, a chemical produced by the bacteria Escherichia coli and modified to be noninfectious. It was first developed at Tulane University in Louisiana in the early 2000s and has been used in a variety of vaccines, said Colin Haile, a research associate professor of psychology at the University of Houston who led its fentanyl vaccine development. Haile is also an Ovax co-founder and adviser.

"It has been in 15 human clinical trials in combination with other vaccines," he said, referring to the adjuvant used in his team's vaccine. "There have been studies in infants where the results have been fantastic, nearly no side effects."

Other researchers such as David Dowling and Dr. Ofer Levy, both Ovax co-founders, are using adjuvants that haven't been tested in humans but appear to effectively enhance the immune response to vaccines targeting substance use disorders, at least based on animal studies, Dowling said.

Clinical trials littered with challenges

Phase I clinical trials for the University of Houston vaccine are planned

to begin in the second quarter of 2025. Ovax is also in licensing negotiations with Boston Children's Hospital for a fentanyl vaccine developed by Dowling and Levy. If those negotiations are successful, Phase I clinical trials could begin in early 2026.

These trials will aim to establish the vaccine's safety level, potential side effects and optimal dosage. Finding people to take part in them will be a challenge, Evans said.

"Compared to a normal infectious disease clinical trial, it will be more difficult. The FDA (Food and Drug Administration) is pretty adamant that you're not going to test this vaccine in healthy individuals that don't already have some sort of opioid addiction," he said.

"So we need to target patients in Phase I who have a history of opioid use disorder, and that's a harder population to try to recruit. It's going to take longer; the patient population will have more adverse events because they're drug users and they will be harder to track."

Evans added that the stigma around addiction and drug use might make people reluctant to disclose their condition and participate in a clinical trial.

Ovax has yet to decide where it plans to run its Phase I clinical trials, Gage said, but it has been looking at sites in Australia and the Netherlands.

"We're also looking in the United States," he said, "but it's difficult to find the right patient population."

Future clinical trials would need to determine the effectiveness of the vaccine, who would benefit the most and how long immunity would last.

Vaccines as part of the solution

Some critics of fentanyl vaccines say they pull resources from existing treatments for opioid addiction such as buprenorphine, methadone and naltrexone. Some have questioned whether people would seek out the vaccine.

"People have to say they want to be injected, and they have to choose to keep coming back for each injection or infusion," Keith Humphreys, a Stanford University professor of psychiatry and behavioral sciences, told The Washington Post in 2023. "The vaccines do nothing to reduce craving or withdrawal or to motivate anyone to return for more care."

For Haile, a fentanyl vaccine is not the sole solution but another weapon in the fight against the opioid crisis. He and his colleagues at the University of Houston have conducted animal studies investigating how the vaccine affects treatment with buprenorphine, a medication commonly prescribed to manage withdrawals and drug cravings.

The findings have yet to be published but are "quite impressive," Haile said, noting fentanyl vaccines could improve the effectiveness of existing treatments.

"The most important thing to keep in mind is that we're moving as fast as we can go. … We need to get something to market as quickly as possible to address this terrible problem," Haile said. "The ultimate goal is to protect people and save lives."

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