

Scientists create fentanyl vaccine to combat opioid epidemic

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To combat the fentanyl epidemic in the United States, researchers at the University of Houston have created a fentanyl vaccine that could help prevent overdoses. They aim to test the vaccine in a human trial within the next year.

Fentanyl is a synthetic opioid drug that kills hundreds of Texans every

year, according to the Texas Health and Human Services Commission.

The vaccine will need FDA approval before people can use it. According to Johns Hopkins University, that process can take five to 15 years, and sometimes longer. The process can be sped up during a public health emergency where no alternate treatments exist. The first COVID-19 vaccines were created, tested and given emergency use authorization by the FDA in under a year.

In a study published last year in the journal *Pharmaceutics*, the Houston researchers reported that their vaccine triggered production of antibodies against fentanyl in rats and decreased the amount of fentanyl in rats' brains. The researchers' vaccine received praise from Governor Greg Abbott, who visited the University of Houston last year to congratulate the team.

"This vaccine has the potential to save millions of innocent lives from fentanyl poisonings & addiction," he said in a Tweet.

A different approach to opioid addiction

Fentanyl is 50 times stronger than heroin and 100 times stronger than morphine, according to the CDC. Once consumed, it enters the brain quickly, making it highly addictive. Fentanyl activates two brain pathways that release dopamine, a chemical that can cause feelings of pleasure and euphoria.

Since fentanyl can be mixed into cocaine, methamphetamines and counterfeit pills, people can ingest it without knowing, leading to accidental poisoning and death. The Texas Department of Health and Human Services estimates that over 800 people died of unintentional fentanyl-related causes in 2020, and over 1500 in 2021 using provisional data.

Doctors can prescribe maintenance medications like methadone and buprenorphine for those recovering from opioid addiction. These drugs are opioids, but they can reduce opioid cravings and withdrawal symptoms.

The effectiveness of these medications depends on how they're made, the opioid being misused and access to the medications. Recovering patients can relapse after they leave treatment and are especially vulnerable to overdose deaths, said Colin Haile, a research associate professor at the University of Houston.

"Clearly, the medications that we have to address opioid use disorder and overdose are not working," said Haile, who led the team that created the vaccine.

The vaccine's effect on rats

Haile's team created a vaccine that could tell the human body to produce antibodies against fentanyl. If a vaccinated person consumes fentanyl, the antibodies could attach to the drug, preventing it from getting to the brain and inducing a "high" or potential overdose. The fentanyl would remain in the blood, eventually passing through the kidneys and out the body.

In the published study, Haile's team said the vaccine successfully produced antibodies against fentanyl in rats. The vaccine also blocked one of the effects of fentanyl: pain relief. Compared to unvaccinated rats, vaccinated rats also had decreased fentanyl levels in their brains when fentanyl was administered 20 weeks after their first vaccination.

"The effect was pretty incredible," Haile said. "I've never seen anything like this, ever."

The vaccine produced antibodies that attached to fentanyl but not to methadone or buprenorphine, meaning that vaccinated people could potentially still take those medications to treat opioid addiction. The antibodies also did not bind to morphine or oxycodone, two other opioids.

Getting the vaccine to people

Haile's main goal is to get the vaccine to humans. His team is working to produce clinical-grade levels of the vaccine so that they can perform FDA-required toxicology studies and receive approval to begin Phase 1 clinical trials with people. Haile is hopeful that this can happen within the next 12 months.

If the Phase 1 trial is successful, the team will need to conduct additional clinical trials before submitting the vaccine for final FDA review.

This vaccine is not the first of its kind. A handful of research teams across the country are studying vaccines against opioids like fentanyl that have shown promise in rats and non-human primates like rhesus monkeys. Marco Pravetoni, a professor of psychiatry at the University of Washington School of Medicine, has tested a fentanyl vaccine in rats.

Pravetoni said Haile's team used a specific adjuvant—an ingredient which boosts the immune response to a vaccine—that is not as common in [opioid](#) vaccine research.

"It's kind of exciting to see that this group is trying to advance a fentanyl vaccine with a new adjuvant, and I think that adjuvant [works] pretty well," said Pravetoni, who was not involved with Haile's study.

The adjuvant was developed by collaborators at Tulane University School of Medicine, Haile said, and has already been proven safe in

clinical trials with people. He added that this may help the vaccine gain FDA approval to begin human trials more quickly.

When Haile created the vaccine, he first saw it as a tool to prevent relapses. Since publishing his research, he's been contacted by parents worried about their kids being inadvertently exposed to fentanyl in counterfeit ADHD medication or other drugs. This made him see another potential use for the vaccine: preventing accidental fentanyl poisoning.

Abbott also suggested to Haile during his visit that the [vaccine](#) could be used to prevent side effects from [fentanyl](#) exposure in DEA agents who may handle it at the border.

It's been a challenge getting to this point, Haile said, but the work is paying off.

"It's not just paying [off] well for me and my colleagues," he said. "It's going to pay off for individuals that really need a medication or a therapeutic like this."

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