Could an implant be the new weapon against opioid, heroin addiction?

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The U.S. Food and Drug Administration is expected to decide this week whether to approve a new weapon in the war against heroin and prescription opioid addiction.

The Probuphine implant by Braeburn Pharmaceuticals of Princeton, N.J., would be the first FDA-approved implant for opioid dependence and the longest-acting treatment to address the growing problem.

When inserted under the skin of the upper arm, four small, flexible Probuphine implants provide a continuous, six-month dose of buprenorphine, which helps curb the withdrawal symptoms and drug cravings that characterize opioid addiction.

Opioids are a class of narcotic pain medications that include prescription drugs like methadone, oxycodone, Percocet and codeine, along with the illegal drug heroin.

From 2000 to 2014, the rate of opioid overdose deaths has increased 200 percent, sparking a nationwide crisis that has captured the attention of police and politicians alike.

Today, an estimated 2.5 million Americans are addicted to opioids, according to a Braeburn press release. About 500,000 struggle with illicit opioids like heroin, while the other 2 million are addicted to prescription opioids, the press release said.

Currently, buprenorphine for opioid dependence is available in the U.S. only in pill form and as a film that dissolves under the tongue. Both versions can be easily sold illegally, used by others and ingested accidentally by children.

Experts say implants lessen those risks and make it easier for patients to stick to their buprenorphine regimen.

Implants would also discourage relapses by making it harder for patients to discontinue usage when they want to get high, said Michael Sheehan, medical director at Operation PAR, a nonprofit drug treatment provider in the Bradenton, Fla., area.

"An implantable version that people don't have a choice about taking out and stopping is a significant advance," Sheehan said. "I've been waiting for this medication for the last four years."

His wait may soon be over. Behshad Sheldon, chief executive of Braeburn, said the company is finalizing negotiations with the FDA about the product's label, which she said "usually doesn't happen if you're not going to get approved."

"But, you know, nothing is ever 100 percent," Sheldon added. "We are cautiously optimistic."

In clinical testing by Braeburn, 86 percent of people who received the implant remained free of illegal drugs, compared to 72 percent of those who used the buprenorphine film.

An FDA advisory panel voted 12-5 in January to recommend that the agency approve the implant for use in stable patients taking eight milligrams per day or less of the buprenorphine film.

Although the FDA usually follows advisory panel recommendations, the implant does have its detractors.

Diana Zuckerman, president of the National Center for Health Research, a nonprofit education and advocacy group, said it's unclear how safe and effective the implant is because there's been only one major study - and it lasted only six months.

Opioid addiction is not a six-month problem," Zuckerman said. "So you want to see what happens not only in the first six months, but in the next six months."

At an FDA hearing in January, Tracy Rupp, the center's director of public health policy initiatives, provided a list of reasons why the implant should not be approved.

In explaining the center's position, Zuckerman said some trial participants with implants needed supplemental doses of buprenorphine film, suggesting the implant wasn't helping them. But these patients weren't counted as "nonresponders" to the implant, Zuckerman said.

In a statement, Braeburn said 82 percent of the trial patients who got the actual implant never required supplemental buprenorphine.

Zuckerman said Braeburn also counted participants as testing "negative" for illegal drug use when they missed scheduled urine screenings. She said drug users typically avoid the tests to hide drug use. But Braeburn said the FDA's analysis counted the missing tests as "positive" for opioid use.

In addition, there was no incentive for participants to avoid urine tests because they weren't penalized for testing positive, said Dr. Scott Segal, president of the Segal Institute for Clinical Research in Miami, which

helped test the implants.

Because 84 percent of participants in the implant study were white, Zuckerman also said questions remain about the implant's effectiveness across other race and ethnic groups. Segal, who has tested other drug treatment medications, said he had never perceived any demographic differences in responses to medications that treat drug dependence.

Sheehan, of Operation Par, said Zuckerman's criticisms of the "little details" may be valid, but did not justify an FDA denial of approval for the implant.

"It's like picking a car," Sheehan said. "Do you want to have a limit on the number of cars available? Or do you want to have a choice of which car is most effective for an individual? The implantable form is not for everybody. But certainly there are a number of people who would really appreciate it and benefit a lot from it being available."

In March, President Barack Obama announced a plan to double - to 200 from 100 - the number of patients to whom a qualified physician can prescribe buprenorphine. The drug is a key part of medication-assisted treatment programs that address addiction through drug and behavioral therapies.

Carolina O., a 34-year-old restaurant worker in Hallandale, Fla., who participated in the clinical trial, said she felt no pain when the device was inserted. And it never bothered her throughout the six-month trial.

"I even forgot that it was in my arm," she said.

In the study, 23 percent of implant patients had an adverse site reaction when the product was removed or inserted. Most were described as "mild," like slight pain or redness. Four percent had a mild skin infection

that required a topical antibiotic, Shelton said.

Each of the four implants are 26 millimeters long - about the size of a small matchstick - and 2.5 millimeters in diameter, roughly the width of an uncooked piece of spaghetti. Doctors have to be trained to insert and remove the product. Both procedures take 15 to 20 minutes.

Shelton said in the coming weeks the company would train about 2,200 doctors nationwide on how to insert and remove the product - if it's approved.