

FDA approves first drug-oozing implant to control addiction

May 26 2016, by Matthew Perrone

Federal health officials on Thursday approved an innovative new option for Americans struggling with addiction to heroin and painkillers: a drug-oozing implant that curbs craving and withdrawal symptoms for six months at a time.

The first-of-a-kind device, Probuphine, arrives as communities across the U.S. grapple with a wave of addiction tied to opioids, highly-addictive drugs that include legal pain medications like OxyContin and illegal narcotics like heroin.

The implant from Braeburn Pharmaceuticals is essentially a new delivery system for an established drug, buprenorphine, which has long been used to treat opioid addiction. But its implantable format could help patients avoid relapses that can occur if they miss a medication dose.

More than 2.5 million Americans are addicted to opioids, according to federal estimates. But less than half are receiving medication-based treatment to help control the problem.

The matchstick-size implant slowly releases a low dose of buprenorphine over six months. Previously the drug was only available as a pill or film that dissolves under the tongue. It is considered a safer, more palatable alternative to methadone, the decades-old standard for controlling opioid addiction.

The FDA previously rejected Probuphine in April 2012, judging the

drug's dose was too low to reliably help the broad range of opioid-addicted patients. Braeburn and partner Titan Pharmaceuticals resubmitted the product with additional data to the FDA and it received a positive endorsement from federal advisers earlier this year.

The FDA said Thursday that Probuphine should be used as part of a multipronged addiction treatment program that includes counseling and other forms of support. Doctors who implant the device must also receive special training to safely insert and remove the device.

FDA officials are spotlighting new treatment options for opioid abuse, after weathering heavy criticism for not acting faster to combat the epidemic of addiction and overdose tied to the drugs.

"We must do everything we can to make new, innovative treatment options available that can help patients regain control over their lives," said Dr. Robert Califf, who became FDA commissioner in February.

Heroin and opioid painkillers caused 28,650 fatal overdoses in 2014, the highest number on record in the U.S. Despite those numbers, experts say buprenorphine remains underused due to federal limits on how many prescriptions each doctors can write, gaps in insurance and a lack of acceptance by doctors.

Along with increasing compliance, Probuphine has the potential to address other problems associated with the oral buprenorphine, including illegal diversion and accidental poisoning in children.

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