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FDA panel favors approval for drug-oozing addiction implant (Update)

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Federal health advisers recommended approval Tuesday for an experimental implant designed to treat patients recovering from heroin and painkiller addiction.

Despite shortcomings in company studies, a majority of Food and Drug Administration advisers said the implant offers important benefits not currently available. The drug-oozing device is intended to be a safer, more reliable approach to controlling cravings and withdrawal symptoms.

"Overall the data did have some problems," said Dr. Thomas Grieger, of the Maryland Department of Health. "But I think clearly there was no evidence of significant risk with this agent and there is evidence of significant benefit and hopefully great promise."

The advisers voted 12-5 in favor of the device from Braeburn Pharmaceuticals. The FDA is scheduled to make its formal decision by Feb. 27.

The matchstick-size implant, dubbed Probuphine, slowly releases a low dose of buprenorphine over six months. Currently buprenorphine is 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. Opioids are a powerful family of drugs that mimic the opium poppy, including medications like oxycodone and illicit narcotics like heroin.

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.

Braeburn executives told panelists Tuesday that its implant could help reduce cases of relapse among chronic drug abusers. Many recovering addicts struggle to stick with their daily medication, putting them at risk of returning to illicit drug use and overdosing.

But panelists questioned whether Braeburn's studies accurately predict Probuphine's success. They cited shortcomings in the company's research including missing urine samples from some study participants. Additionally, many patients received additional drug therapy to control their cravings and symptoms, clouding the picture of the implant's performance.

Ultimately, most panelists said they were swayed by an FDA analysis showing that Probuphine was at least as effective in avoiding relapse as older treatments.

Dr. Rajesh Narendran, of the University of Pittsburgh, said prescribing instructions for the device must be "crystal clear" about which patients should receive it. Braeburn only studied the drug in patients who were already stabilized on low-to-medium doses of buprenorphine.

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.

Another concern raised Tuesday involved the complex surgical procedure needed to put in and remove the rod-like implants, which are inserted under the skin of the arm. According to an FDA review, problems like bleeding and infection were more frequent with

Probuphine than with contraceptive implants that use similar drug-releasing technology.

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 caps on prescribing, gaps in insurance and a lack of acceptance by doctors.

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