FDA urged to investigate use of unapproved anti-opioid implant on prisoners and the homeless

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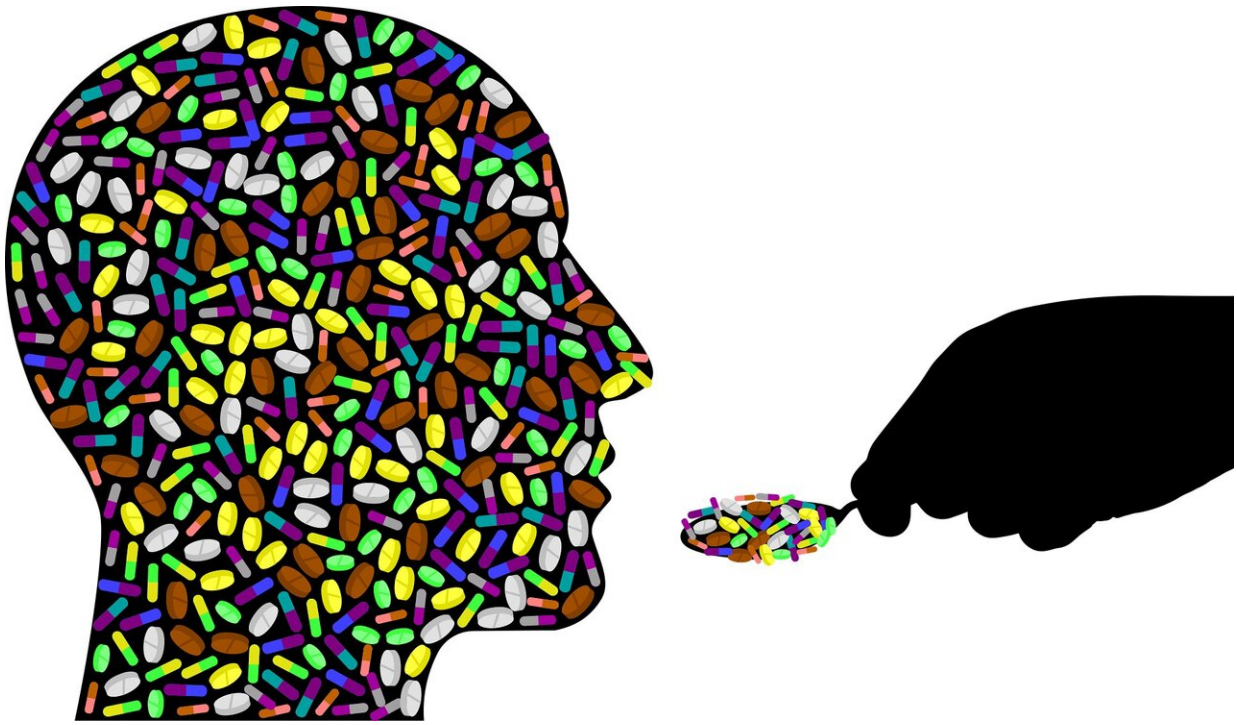

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BioCorRx bills itself as a developer of "advanced solutions" for alcohol and opioid addictions.

But the California-based company has come under fire for plans to test

an unapproved naltrexone implant on Louisiana prison inmates and homeless Philadelphians who are struggling with addiction, in violation of federal laws protecting human research subjects.

Only one prisoner actually received the implant before the Louisiana Department of Corrections discontinued the testing this spring amid criticism, according to the New Republic. And no homeless Philadelphians have received the implant because BioCorRx has failed to get state approvals, said Mel Wells, president of One Day at a Time, the recovery support organization that BioCorRx enlisted to find subjects.

Still, 33 experts in consumer protection, bioethics, human rights, and the law on Wednesday petitioned the U.S. Food and Drug Administration to investigate whether BioCorRx conducted an illegal clinical trial. The petition, filed by the consumer advocacy group Public Citizen, also questioned the legality of BioCorRx's use of the naltrexone implant for an unapproved use—weight management.

"The U.S. has a long and troubling history of exploiting prisoners and other vulnerable groups for medical research," said petition signer Leo Beletsky, Northwestern University professor of law and health sciences. "The apparent clinical trial launched by BioCorRx at the Louisiana State Penitentiary reminds us that even today, we must remain vigilant to prevent such abuses."

One example of such exploitation occurred in Philadelphia's Holmesburg Prison from 1951 to 1974. The medical experiments were led by Albert Kligman, a University of Pennsylvania dermatologist who co-invented the acne medication Retin-A.

Asked for comment about the petition, BioCorRx CEO Brady Granier said in an email: "We've worked hard to battle the current epidemics

plaguing our great nation. BioCorRx welcomes any investigation by the FDA and believes it has done everything regarding its comprehensive program to fight addictions in full compliance with the letter and spirit of the law."

For its part, the FDA said: "We take all complaints and concerns reported to us seriously. The FDA will review the letter and will respond directly to the petitioner."

Naltrexone, which blocks the effects of opioids and alcohol while curbing cravings, is a mainstay of addiction treatment. It has been approved as a daily pill and a monthly injection.

The BioCorRx implant—pellets made to order by a compounding pharmacy—are sewed into the abdomen to release naltrexone for three months. The implant was to be combined with behavioral therapy and peer support, according to company news releases.

Naltrexone pellets have been available from compounding pharmacies and touted by some doctors for years, but the treatment is not covered by insurance because it is not FDA-approved.

Human testing of a drug that is new or has a new dosage form must first be approved by the FDA and by an ethics review board. That board must also approve the informed-consent document, which tells patients that the drug is experimental, and explains both potential risks and benefits.

BioCorRx's program did not meet any of these requirements, according to the petition, which cited company news releases, an agreement with Louisiana prison officials, patient information, and media reports.

Although BioCorRx provided a naltrexone "treatment contract and informed consent" for inmates to sign, it fell far short of protecting

them, the petition contends.

The petitioners are only the latest to sound alarms. In May, the Baton Rouge Advocate published a story about criticism of the implant program. Granier said the program was not a clinical study, even though the company was aiming to get FDA approval.

In the New Republic story in October, Granier again insisted the company did not need review board oversight because it was not technically conducting a clinical trial.

Critics differ. "A drug company should not be allowed to go into a prison and start treating the inmates like unwitting guinea pigs," said Michael Carome, the physician who directs Public Citizen's Health Research Group.

Wells, at One Day at a Time, said he was not aware of the controversy. "I just can't comment on that. I'm just trying to get people off the street. I can't say anything about BioCorRx."

While the New Republic article faulted BioCorRx as "failing to go through proper channels," it also said an implant is a good way to provide a sustained release of Naltrexone. Journalist Amelia Pang also contacted Alvin Dutrich, 39, the first and apparently only Louisiana inmate to get the implant before he was released. He called the pellets "a game-changer" that enabled him to avoid his usual pattern of relapse.