

## FDA OKs quick-acting antidote for prescription painkiller overdose (Update)

April 3 2014, by Dennis Thompson, Healthday Reporter

---



Evzio is part of efforts to stem health risks from abuse of drugs such as Oxycontin, Vicodin.

(HealthDay)—People suffering a potentially fatal narcotic overdose now can receive lifesaving treatment from folks around them, using a new device just approved by the U.S. Food and Drug Administration.

Evzio is a hand-held auto injector that delivers a single dose of the drug naloxone into the muscle or beneath the skin. The injector can be carried in a pocket or stored in a medicine cabinet and is meant as an emergency treatment for people who have suffered a known or suspected overdose of powerful pain drugs called opioids.

Opioids include prescription narcotic painkillers such as Oxycontin, Vicodin and Percocet—all of which have shown increasing rates of

abuse in recent years.

They also include the illicit drug heroin, which has increased in popularity and recently led to the death of actor Philip Seymour Hoffman.

The Obama administration is urging all local police and fire departments to equip their officers and vehicles with Evzio, Michael Botticelli, acting director of the White House Office of National Drug Control Policy, said at a Thursday news conference.

Family members and friends of people who are struggling with narcotics addiction or are taking opioids for a medical condition also will be able to equip themselves with Evzio, just by getting a prescription from their physician.

"A family member of someone at risk for opioid overdose could receive a prescription," said Dr. Douglas Throckmorton, deputy director for regulatory programs at the FDA's Center for Drug Evaluation and Research. "Physicians can prescribe to anyone concerned about the risks of possible opioid overdose."

The product is built to be simple and easy-to-use for lay people, FDA Commissioner Dr. Margaret Hamburg said at the news conference.

Naloxone rapidly reverses the effects of overdose and is the standard treatment in such cases. However, current naloxone drugs have to be injected with a needle and their use is typically limited to trained medical personnel, the FDA explained.

Once the device is turned on, it provides verbal instructions on how to deliver the medication, similar to how an automatic heart defibrillator works.

"There was a great emphasis on making it very user-friendly, both the labeling information and the device itself," Hamburg said.

She added that "the last instruction the device gives is to call 911, because this product is not a substitute for emergency care."

The product's simplicity is partially aimed at encouraging police officers to equip and use Evzio, Botticelli said. Officers have been reluctant to administer naloxone injections, and also have been slow to adopt nasal inhalant forms of the medication because overdose treatment is an off-label use, the health officials said.

"We know that the men and women in law enforcement believe that saving a life is more important than making an arrest," Botticelli said.

More than 16,000 people die each year due to opioid-related overdoses, according to the FDA. Drug overdose deaths—driven largely by prescription drug overdose deaths—are now the leading cause of injury death in the United States, surpassing motor vehicle crashes.

The FDA fast-tracked the approval of Evzio, turning the application around in just 15 weeks, Throckmorton said.

The agency noted that repeat doses may be needed because naloxone may not work as long as opioids. Also, people who receive a shot of Evzio may experience "severe opioid withdrawal," the agency added.

There are dangers with quick withdrawal from "opioid depression," the FDA said, with symptoms such as nausea, vomiting, sweating and accelerated heart rate, as well as a risk for spikes in blood pressure, seizures and even cardiac arrest.

Obama administration officials took pains to place the approval of Evzio

in the context of other efforts that are being taken to rein in prescription drug abuse, including:

- Counseling physicians and pharmacists on ways to detect "doctor-shopping" and patients with a drug problem.
- Advancing development of new non-opioid pain medications.
- Further restricting the prescription of medications containing hydrocodone by rescheduling them from Schedule III to Schedule II.

Federal officials are tackling this issue while also weighing the needs of people who rely on these pain medications, said U.S. Department of Health and Human Services Secretary Kathleen Sebelius.

"When addressing the opioid problem, it is important we consider those who rely upon and appropriately use their medication," Sebelius said.

**More information:** The U.S. National Institute on Drug Abuse has more about [opioids](#).

Copyright © 2014 [HealthDay](#). All rights reserved.

Citation: FDA OKs quick-acting antidote for prescription painkiller overdose (Update) (2014, April 3) retrieved 7 May 2024 from <https://medicalxpress.com/news/2014-04-fda-easy-to-use-heroin-overdose-antidote.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--