

F.D.A. Approves Portable Drug Overdose Treatment

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The Food and Drug Administration on Thursday approved an emergency drug overdose treatment for use in homes and other community settings outside hospitals. Federal regulators said that the treatment, an injector filled with a medication that reverses the effects of an overdose, can fit in a pocket or medicine cabinet, and could help stem the rising number of drug overdoses.

The device, called Evzio, delivers a single dose of the drug naloxone through a hand-held device to treat someone who has stopped breathing or lost consciousness from an opioid drug overdose. Naloxone is the standard treatment for an overdose, but until now, has been available only in hospitals and other medical settings, when it is often too late for the patient.

Once turned on, the device would give verbal instruction to whoever was using it about how to deliver the medication, similar to automated defibrillators that hang in airports and other public buildings.

“This is a big deal and I hope gets wide attention,” said [Dr. Carl R. Sullivan III](#), director of the addictions program at West Virginia University. “Many people OD and die from opioids because naloxone is not immediately available to reverse the OD effects. I cannot really see a downside.”

But the new device seems likely to stir concern as well as hope among experts.

“I’m worried that there will be a false sense of security” among drug users, said James Rathmell, chief of the division of pain medicine at Massachusetts General Hospital. “Like, ‘O.K., I’ve got a naloxone pen, we can party all we want, no one is going to die.’” But he added: “On the other hand, it’s a great drug. It’s extremely effective and the downside is very low.”

The drug epidemic has battered states across the country, with drug-induced deaths now outstripping those from traffic crashes. Prescription drugs have driven the epidemic, and account for more than half of all drug overdose deaths. One major category of prescription drugs, opioids, or painkillers, take the lives of more Americans [than heroin and cocaine combined](#). Deaths from opioids have quadrupled in 10 years to more than 16,500 in 2010, according to federal data.

Deaths have continued to climb, despite efforts by states and the federal government. In January 2013, a panel of experts convened by the F.D.A. recommended that it tighten prescribing practices. Last September, the F.D.A. [changed labeling requirements](#), proposing new language that indicates the drugs should be used only by patients who have no other treatment options for their pain.

Federal officials said Thursday that the new device may help reduce the death toll.

“Making this product available could save lives by facilitating earlier use of the drug in emergency situations,” said Dr. Bob Rappaport, director of the division of anesthesia, analgesia and addiction products in the F.D.A.’s Center for Drug Evaluation and Research. He said Evzio was the first drug-device product designed to deliver naloxone outside a health care setting.