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OTC Naloxone In US: Once Encouraged, Now Stalled

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Executive Summary

FDA, in unprecedented step, in 2018 published a model DFL for an OTC naloxone nasal spray developed in a study it sponsored, and former FDA Commissioner Scott Gottlieb noted a need for OTC naloxone. Four years later, US remains without OTC naloxone.

Young boys or girls in the US can buy enough acetaminophen at grocery stores to cause severe damage to internal organs and potentially death if used unsafely, but they can't purchase a drug which has no abuse potential while preventing opioid overdose deaths.

"They're trusted to go and buy that, and a teenager can't go and buy naloxone?" asked Jeffrey Singer, president emeritus and founder of Valley Surgical Clinics Ltd. in Arizona and a senior fellow at the Cato Institute's Health Policy Studies with more than 35 years in private practice as a general surgeon.

"This this drug that prevents drug overdoses. What's wrong with that?" Singer also asked.

"If you take it and you don't need it, nothing's going happen to you. It's not like it's a dangerous drug. All it can do is displace the opioid that's bound to opioid receptors and render the opioid ineffective. It can't do anything else but that," he added.

The FDA, in what is acknowledged as an unprecedented step, in 2018 published a model Drug Facts label for an OTC naloxone nasal spray developed in a study it sponsored.

As well, former FDA Commissioner Scott Gottlieb noted a need for OTC naloxone.

"That saves a big expense to the manufacturers. Therefore, they're once again inviting you to ask them to make it OTC," Singer said.

"I'm paraphrasing here, but he said something to the effect of, we don't usually do this and this is something we usually ask the manufacturers to do. But we've taken the liberty of doing the research on the labeling that would be required if it would go OTC," he recalled.

Whither OTC Naloxone?

Four years later, though, and after a nonprofit pharma launched in response to the FDA's encouragement has conducted actual use trials and asked for FDA input on a new drug application it's preparing, the US remains without OTC naloxone.

Instead, as opioid overdose deaths continuing climbing in the US, states are authorizing pharmacists to dispense naloxone without prescriptions. Health advocacy groups also have been cleared in some areas to provide the drug without prescriptions.

Actual OTC sales, Singer says, would be more effective and increase the number of deaths prevented by naloxone.

"You still have to go up to the counter, to say to the pharmacist you want it. There's such a stigma attached nowadays. That a lot of people are just reluctant to do it," he said.

"And some pharmacists … refuse to give it to them because they don't want to they feel like they're enabling their habits."

Antacids, Aspirin,
Birth Control On Aisle 1?

Similar to the OTC daily oral contraceptive the FDA has been asked to approve, naloxone should be available on store shelves, Singer added.

"You go into a Walgreens, you pick up a box of Band-Aids and some naloxone, you go to check-out at the cashier – nobody has to know what you're doing. That's the way it should be, and it should be for birth control pills," he said.

"Very similar. Two different types of drugs with two different types of problems but a similar issue."

Nonprofit Harm Reduction Therapeutics LLC has completed necessary studies and plans to submit a switch proposal for a naloxone nasal spray before the end of 2022. Its Phase I trial of its 3-mg nasal spray delivering an atomized form of 0.1-mL naloxone demonstrated the bioavailability of the formulation was bioequivalent to 0.4-mg intramuscular naloxone at 2.5 minutes and at 5 minutes after administration. (Also see "HRT Reports 'Remarkable Achievement' In OTC Naloxone Phase 1 Clinical Trial Results" - HBW Insight, 1 Mar, 2022.)

However, in an online conference on expanding naloxone access earlier in 2022, HRT co-founder and CEO Michael Hufford framed his comments in acknowledging the FDA's difficult work and heavy workload in reviewing and evaluating NDAs and other applications, but was critical of agency officials' response to the firm's outreach on submitting a naloxone OTC switch proposal, including denying Pittsburgh-based HRT's request for expedited review of its switch NDA in the agency's fast track program. (Also see "Drivers For Allowing OTC Naloxone In US Include Social Justice As Well As Public Health Need" - HBW Insight, 31 Mar, 2022.)

Democrat and Republican members of Congress sent letters in April about making naloxone available OTC to pharmaceutical companies with approvals in the US to manufacture Rx naloxone in injection, nasal spray or oral format. (Also see "Naloxone OTC Switch Urged By Congressional Coalition Of 30 Democrats And Republicans" - HBW Insight, 12 Apr, 2022.)