Why Doesn't the Surgeon General Seek FDA Reclassification of Naloxone to OTC?

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The Surgeon General issued an "Advisory on Naloxone and Opioid Overdose" today, drawing attention to the effectiveness of the opioid overdose antidote naloxone. The drug, approved for use since 1971, is an effective remedy that can be safely administered by lay personnel who receive basic instructions. The Advisory cites researchdemonstrating that community-based overdose education and naloxone distribution reduces overdose deaths, and points out that first responders in most states and communities are now equipped with the drug.

Because naloxone is available only by prescription, most states have developed workarounds to make it more available to patients and, in some cases, third parties who have proximity to medical and non-medical opioid users. This way, witnesses to an overdose can be capable of rescuing the victim. This usually involves a state authorizing pharmacists to prescribe the drug or, in many cases, the state health director, acting as the state's physician, issuing a "standing order" to pharmacists to distribute it.

The Advisory lists a number of conditions and situations that might place a person at risk of opioid overdose and encourages such people, or people who know them, to avail themselves of naloxone. It supports efforts at wider distribution at the community level.

Unfortunately, because of the stigma that has developed in association with opioid use, many opioid patients are reluctant to speak to the pharmacist and request a naloxone prescription. In some states, the naloxone will not be prescribed to third parties who know an opioid user. Also, numerous instances have been reported where pharmacists are reluctant to prescribe the antidote, believing they are "enabling" a drug abuser.

Recognizing this obstacle to naloxone distribution, Australia made it available over-the-counter in 2016, making it as easy to purchase as cold remedies or antacids. This way medical and nonmedical opioid users can discreetly make a purchase and check out at the cash register without having to answer any questions or face scrutiny from a pharmacist. The drug has been over-the-counter in Italy for over 20 years.

Based upon an August 2016 blog post, the Food and Drug Administration thinks it is reasonable to consider reclassifying naloxone as over-the-counter, and the FDA Deputy Director stated in

the post that the agency would be willing to assist manufacturers in submitting applications for reclassification. But FDA regulations allow the commissioner to order a rescheduling review and allow petitions for OTC rescheduling from "any interested person"—not just drug manufacturers.

I've argued here that the FDA Commissioner should order an expedited reclassification review, and, if the Commissioner is unwilling to do so, then the Secretary of Health and Human Services—or even Congress—can see that it occurs. I've also contended that state legislatures—or even governors—as interested parties, can formally request an FDA review.

The Surgeon General's April 5th Advisory singing the praises of naloxone and calling for its wider distribution in communities across the nation makes it obvious that the Surgeon General is an interested party. Because he thinks naloxone should be used more to reduce overdose deaths, the Surgeon General should formally request that the FDA Commissioner order an expedited review of naloxone in hopes that it will be available over-the-counter as quickly as possible.

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