



# SOCIETY *of*

## PAIN & PALLIATIVE CARE PHARMACISTS

### **Society of Pain and Palliative Care Pharmacists (SPPCP) Position Statement on the Proposed Change of Naloxone to Over-The-Counter (OTC) Status**

February 28th, 2019

The Honorable Scott Gottlieb, M.D.  
Commissioner  
Food and Drug Administration  
U.S. Department of Health and Human Services  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

Subject: Reclassification of naloxone to over-the-counter (OTC)

Dear Commissioner Gottlieb:

The Society of Pain and Palliative Care Pharmacists (SPPCP) oppose reclassification of naloxone to over-the-counter (OTC) use, in lieu of a broader, safer, more uniform, and collaborative approach to ensuring naloxone is readily available. We are concerned about the lack of pharmacist involvement and commensurate education that is an integral part of appropriate naloxone use.

Society Background:

Established in 2015, SPPCP promotes exceptional patient care by advancing pain and palliative pharmacists through education, development, and research in collaboration with the transdisciplinary team. We strive for excellence in patient care by optimizing pharmacotherapeutic outcomes, promoting best practices in pain and palliative care, and supporting quality of life. As a group, we support patient-centered transdisciplinary pain and palliative care teams with the pharmacist as an integral member of the team.

Commensurate with our mission, we offer comments regarding the January 17, 2019 FDA Commissioner Statement “on unprecedented new efforts to support development of over-the-counter naloxone to help reduce opioid overdose deaths”. Although in concept our group is in favor of expanding naloxone availability, we believe that offering naloxone as an over-the-counter (OTC) item without proper

background, victim overdose assessment, training, and appropriate counseling regarding licit and/or illicit drugs, with consideration to appropriate and immediate follow-up by trained emergency personnel (and consideration to actual drug), is not in the best interest of potential overdose victims, caregivers, or the community at large.

Below is a list of specific concerns that we have identified should naloxone become an OTC medication without professional input to:

- Select one of the various naloxone products on the market, as not all patients or caregivers will have the manual dexterity or wherewithal to administer certain dosage forms in an emergency situation;
- Assess and ascertain if an intranasal dosage form is a reasonable option compared to the tradition or automated injectable form. Poor candidates for intranasal will be those with significant intermittent or chronic sinusitis, deviated septum, or regular users of vasoconstricting drugs (i.e. oxymetazoline, phenylephrine, cocaine);
- Counsel persons that are prescribed long-acting or continuous release dosage forms, or medications with extended and/or unpredictable half-lives should be made aware of the short-acting nature of naloxone and discuss the import of notifying 911 immediately after injecting the drug;
- Counsel patients that are prescribed opioids, and their caregivers on the importance of not starting any OTC drugs (or stopping any chronic medications), nutraceuticals, engage in abrupt diet changes, or start any newly prescribed medications without counseling from their pharmacist, due to potential for drug interactions such as cytochrome P450 interactions that could have a profound effect to elevate opioid blood levels with certain medications, and;
- Identify appropriate patients, including those prescribed opioids, and those using illicit opioids, including education and counseling to family members and significant others regarding blunted naloxone reversal in the face of hyper-potent illicit fentanyl derivatives.
- Avoid missed opportunities to discuss and counsel on;
  - the risks of combining opioids with ethyl alcohol or other sedative-hypnotics including but not limited to OTC antihistamines, prescription benzodiazepines, tricyclic antidepressants, certain anticonvulsants, and many more agents.;
  - the importance of learning cardiopulmonary resuscitation (CPR);
  - the importance of having a plan in place in case of an overdose;
  - the importance of keeping prescribed opioids in a safe, locked storage unit to avoid access by intruders or children;
  - naloxone use, especially amongst the most vulnerable low literacy population.
- Pharmacists are the most accessible health care professionals, and are available to foster naloxone education and distribution. We therefore propose and support a new federal class of medication that would require counseling by a pharmacist or licensed pharmacy intern prior to releasing an appropriate naloxone product in order to enhance and ensure public safety.

State of the Opioid Crisis and Naloxone Distribution:

- A. Due to the recent opioid over dose crisis in the United States, various states have enacted legislation to improve access to the life-saving opioid antagonist naloxone. Recent updates in state laws has allowed community pharmacists to dispense naloxone with standing orders and

third party prescribing to any person meeting preset criteria specified in the order, without need for a naloxone prescription. Even with these changes in legislation, community pharmacies have been shown to dispense less naloxone in comparison to community naloxone programs.<sup>1</sup> A retail-dispensed prescription data analysis between 2007 and 2016 found an average increase of 79% of naloxone dispensed in U.S. retail pharmacies in states where the new naloxone access laws have been passed versus states that have not passed similar naloxone access legislation.<sup>1</sup> Since November 22, 2017, all 50 states have now implemented a naloxone pharmacy access law, but only 19 states require pharmacists to have focused naloxone training prior to participation in the prescribing and dispensing of naloxone.<sup>2</sup> Lack of mandatory pharmacist education can be a potential barrier to uptake and practice of newer naloxone dispensing practice in community pharmacies.<sup>2</sup> Mandatory training of pharmacists in the overdose education and naloxone distribution (OEND) process may potentially lift the barriers to naloxone availability in community pharmacies.<sup>3</sup> Furthermore, to encourage pharmacists and large chains to provide this service, Congress should immediately recognize [Bill H.R. 592](#), would enable patient access to, and coverage for, Medicare Part B services by pharmacists in medically underserved communities. The entire country is underserved with regard to opioid overdose deaths. This is due to high potency illicit fentanyl derivatives, accidental opioid deaths from prescribed opioids, and illicit use of prescription opioids that are not prescribed. Support of this bill, and the privilege of qualified pharmacists to prescribe naloxone would ensure ubiquitous but safely monitored naloxone access.

- B. First responders carrying naloxone to treat opioid overdoses victims has been identified as an early intervention to address opioid related deaths. Police officers in Lorain County, OH demonstrated a decrease in overdose deaths at a rate of  $-4.1 \pm 1.0$  individuals per quarter ( $P < .025$ ), averaging 13.4 deaths per quarter during the 13-month study period from October 2013 through October 2014 after receiving extensive education regarding naloxone use.<sup>4</sup> A mandatory police officer two-hour training was provided by a physician that incorporated basic lifesaving techniques including identifying overdose victims, pharmacotherapy and administration of naloxone, and live return-demonstration practice on naloxone administration techniques.<sup>4</sup> The positive outcomes of the police officer naloxone prescription program were based upon extensive naloxone educational exposure and this is essential for the success of naloxone administration. In an effort to assess the ability of the average consumer to comprehend the instructions for use of an OTC naloxone product, the FDA conducted a multiphase study in 2018 called the Comprehension for OTC Naloxone (CONFER) trial that assessed the ability of the general consumer population to comprehend instructions for responding to an opioid overdose scenario based on the drug facts label (DFL) provided.<sup>5</sup> All individual steps, indication, and signs of overdose concepts met the criteria for comprehension in the overall population but when stratified by literacy level, there were differences in comprehension levels of each primary objective.<sup>5</sup> Two endpoints did not meet pre-specified trial criteria, “call 911 immediately” and “a three-component composite endpoint”.<sup>5</sup> The authors of this study concluded that the data is sufficient to support the OTC indication for intranasal and intramuscular naloxone but acknowledge that there are still some changes that need to be made to the DFL.<sup>5</sup> This is concerning as it is imperative that opioid overdose victims obtain access to 911 as part of their treatment because this was not proven in the CONFER trial study.<sup>5</sup>

Mandatory pharmacist counseling to emphasize the importance of 911 as a mandatory step in opioid overdose treatment can support and enhance patient safe use of naloxone.

- C. In 2015, Australia changed the scheduling of naloxone to over-the-counter (OTC) status, but has also kept prescription status as well for government subsidized naloxone distribution.<sup>6</sup> Australia recognizes that naloxone does not replace other needed resuscitation methods, therefore the requirement for dispensing naloxone by a doctor or pharmacist is still required even though a prescription is not.<sup>6</sup> A reduction in rates of opioid related death from overdose have been documented with state supported overdose education and nasal naloxone distribution (OEND) programs in Massachusetts.<sup>7</sup> This improved outcome of reduction in death is supported by also providing targeted overdose education. This underscores the importance of increasing access to naloxone, but its effectiveness has only been demonstrated when provided with educational instructions for use.<sup>6</sup> For example, Alabama HB 208 was passed into law allowing a physician, dentist, or pharmacist acting in good faith to dispense an opioid antagonist to an individual, family member, friend, or other individual at risk of an opioid-related overdose.<sup>8</sup> Key procedure implementation for the pharmacist prior to prescribing naloxone, involves ensuring the clients are properly trained in overdose recognition, response and naloxone administration.<sup>8</sup> Over a 10-month period between 2014 and 2015 a total of 83 clients were trained and 150 naloxone kits were distributed among heroin and opioid users, concerned friends or family members.<sup>8</sup>
- D. The process of behind-the-counter dispensing is where a nonprescription medication is approved for this use by the FDA, but with additional restrictions requiring pharmacy oversight (e.g., emergency contraception).<sup>9</sup> Pharmacists ensure product availability, continued timely drug information, along with comprehensive patient counseling to enhance safe and effective emergency contraception use.<sup>9</sup> This type of pharmacist model in the United States would ensure a comprehensive approach if or when naloxone prescription labeling category changes to OTC status. Barriers that may affect naloxone access and appropriate use through pharmacists are that patients may decline pharmacist counseling services if provided OTC without pharmacist intervention, costs of OTC product, and for mandatory training of pharmacists.<sup>1,10-11</sup> Several benefits of incorporating behind-the-counter OTC naloxone exist, including pharmacists' ability to query state drug monitoring databases, counseling to reinforce need for 911 engagement amongst other mandatory counseling steps, and identification of cost-saving opportunities as insurance may provide more reasonably priced option for some patients versus OTC as OTC may be too expensive to be placed on an open shelf. The evidence of harm associated with other OTC products has been well documented.<sup>3,12-14</sup>

The Society of Pain and Palliative Care Pharmacists request the FDA consider the following prior to changing of labeling status of naloxone to OTC status:

- a. Require mandatory pharmacist education in overdose education and naloxone distribution (OEND).
- b. Require behind-the-counter pharmacy availability regardless of naloxone labeling status changes to enhanced FDA mandated 7-point label of Drug Facts, Uses, Warnings, Directions, Other Information, Inactive Ingredients, and Contact Information.
- c. Recommend pharmacists be included as essential decision makers as part of the FDA processes and decisions regarding OTC naloxone.

- d. Work with Congress to foster and embrace [Bill H.R. 592](#), which essentially has been accepted in California, Washington, New Mexico, and Ohio.

The SPPCP are frontline pharmacists amongst other healthcare professionals in the midst of the opioid crisis and we are integral health care providers that can also stand as a key resource to lead the charge to improve safety among a huge array of licit and illicit opioid users.

In closing, for the above reasons, the SPPCP urge you to consider the above safe measures if the labeling status of naloxone is changed to OTC status.

Thank you.

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