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December 14, 2018

Dr. Scott Gottlieb
Commissioner
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: FDA-2018-N-3805**

**Re: Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments**

Dear Dr. Gottlieb:

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On behalf of nearly 38,000 members of the American College of Emergency Physicians (ACEP), we wish to provide comments that would help the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committees develop appropriate strategies to increase the availability of naloxone products intended for use in the community.

As emergency physicians, we see every day the devastating effects that the opioid crisis has had on the communities we serve. ACEP believes that access to naloxone, which should be a low-cost medication, must be increased. This is truly a life-saving drug that when used properly can reverse opioid overdoses and save lives. This medication can be administered intravenously, intramuscularly, or intranasally and is effective within minutes. Victims of opioid overdose often completely stop breathing and without respiratory support death is imminent. However, after the prompt injection of naloxone, the victim begins to breathe again and may quickly become fully conscious, rescued from the edge of death. Naloxone has been utilized in hospitals and by fire and emergency medical services (EMS) personnel for decades. The Centers for Disease Control (CDC) has pushed for increasing naloxone administration by EMS personnel in an effort to reduce even more opioid-related deaths.[1]

While we strongly support the wide utilization of naloxone, we want to emphasize ACEP's positions on a number of important issues: 1) guidelines for prescribing naloxone; 2) education and training; and 3) cost. We hope the Committees take these into consideration as they consider the expansion of naloxone treatment.

[1] The Centers for Disease Control, "Expanding Naloxone use could reduce drug overdose deaths and save lives," 24 April, 2015, available at: https://www.cdc.gov/media/releases/2015/p0424-naloxone.html

## Guidelines for Prescribing Naloxone

ACEP believes that an effective naloxone program requires appropriate prescribing guidelines. We support the recommendations established by the Substance Abuse and Mental Health Services Administration (SAMHSA)[2], which encourage physicians to prescribe naloxone to at-risk patients in the following circumstances:

- Discharged from the emergency department (ED) following opioid intoxication or poisoning;
- Taking high doses of opioids or undergoing chronic pain management;
- Receiving rotating opioid medication regimens;
- Having legitimate need for analgesia combined with history of substance abuse;
- Using extended release/long-acting opioid preparations;
- Completing mandatory opioid detoxification or abstinence programs; and/or
- Recent release from incarceration and past abuser of opioids.

## Education and Training

Health care providers that administer naloxone treatment must undergo proper training. They should complete an educational program regarding the signs and symptoms of opioid overdose, naloxone effects and side effects, and indications for naloxone administration. ACEP believes Good Samaritan laws should be implemented in every state that protect health care personnel and civilians from liability when administering naloxone to opioid overdose patients.

We believe that pharmacists should be allowed, but not required, to dispense naloxone over the counter. As with prescribing health care professionals, appropriate related indemnification should be extended to involved pharmacists. If a pharmacist chooses to distribute/dispense naloxone, they should provide the patient with information regarding the signs and symptoms of opioid overdose, the importance of promptly accessing emergency medical services via 911, naloxone effects and side effects, indications for naloxone administration, and at minimum, chest compressions for suspected cardiopulmonary arrest. As the over-the-counter dispersal of naloxone becomes more common, it may also be worthwhile to study the full implications and downstream consequences of this growing trend.

Laypersons should also be allowed to administer this medication for cases of suspected opioid overdose. Seconds matter in overdose cases, and it may be necessary for a bystander who could be a complete stranger (or who could be a friend, family member, or an off-duty EMT, nurse, or physician) to provide the treatment to save a patient's life. A study conducted by the CDC found that at least 26,500 opioid overdoses in the United States were reversed by laypersons using naloxone from 1996 to 2014.[3] While naloxone is relatively safe, it is nevertheless important that any regulatory or legislative efforts to expand naloxone to the public be accompanied by robust public education programs to improve the chances of correct patient selection and proper naloxone administration.

Educating the public can also help address the stigma that often goes along with overdoses. It is a common misperception that a patient rescued from an opioid overdose who wakes up agitated is "angry," that someone has "ruined" his/her "high." That is an extremely rare viewpoint of the patient. The truth is that naloxone can, in opioid-dependent patients, produce a state of naloxone precipitated withdrawal (NPW), which can last an hour, or sometimes several hours (depending on the dose of naloxone administered). This withdrawal state can be very unpleasant, and produces several symptoms, including agitation, anxiety, and restlessness (as well as potentially abdominal pain, vomiting and diarrhea). However, this is certainly an acceptable "adverse" or "side"

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[2] Substance Abuse and Mental Health Services Administration. SAMHSA Opioid Overdose Prevention Toolkit. HHS Publication No. (SMA) 14-4742. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

[3] The Centers for Disease Control, Morbidity and Mortality Weekly Report (MMWR), "Prevention Programs Providing Naloxone to Laypersons — United States, 2014," 19 June 2015, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm

effect of the drug, if the alternative is death or an anoxic brain injury. Therefore, public education may be helpful so that laypersons understand what to expect when administering the drug and are not led to believe that they have injured the recipient of naloxone.

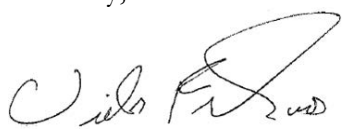
**Cost**

While there has been a movement to increase prompt access to naloxone for opioid overdose victims over the last several years, the price of naloxone in nearly all forms of packaging has been steadily climbing in this country. These rising prices have affected the ability of EMS providers to obtain enough naloxone to treat all the overdose cases they see. In addition, the cost of naloxone products that laypersons can obtain may in some cases be the highest of all, limiting their ability to provide immediate treatment to members of their communities. ACEP urges the Administration and Congress to do everything in their power to ensure that naloxone is available for community use at an affordable price.

Beyond the principles we lay out above, going forward, we recommend scientific research to study the consequences of naloxone distribution. Widespread use of a therapeutic agent should be embraced based on sound scientific evidence of its efficacy to patients. We also recommend societal resources to offer treatment for opioid addiction, including making inpatient and outpatient treatment available to all patients who are in need of treatment, regardless of gender, age, income, education level, or ability to pay.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,



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