



December 13, 2018

Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
White Oak Campus
10903 New Hampshire Ave.,
Silver Spring, MD 20993-0002

RE: [Docket No. **FDA-2018-N-3805**] 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 Commissioner Gottlieb:

On behalf of 53,000 members, the American Society of Anesthesiologists® (ASA) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee's request for input and advice on strategies to expand availability of naloxone for community use corresponding with the committees' joint meeting.

ASA strongly supports widespread access to naloxone, a life-saving medication that can rapidly reverse an opioid overdose to individuals who may witness an overdose in order to reduce the incidence of opioid overdose fatalities. Expanding the awareness and availability of this medication to laypersons including first responders, family members and caregivers of high-risk individuals is a key part of the public health response to the opioid epidemic. Naloxone is commonly used by trained medical personnel and first responders but its use among laypersons has recently increased as part of an effort to reduce opioid overdose deaths. ASA recommends that prior to receiving access to naloxone, non-medical personnel receive education and training on how to recognize an opioid overdose, and on effective resuscitation and post-resuscitation care, which includes administering naloxone and calling emergency services.

ASA recommends that physicians consider co-prescribing naloxone with an opioid for patients at high risk of overdose when it is clinically appropriate to do so. Patients at high risk of overdose include individuals who are prescribed a daily dose equivalent to 100 milligrams of morphine or more, have an underlying respiratory condition such as sleep apnea, have a history of a non-opioid substance use disorder or a mental health

disorder, or are currently prescribed a benzodiazepine or other sedative/hypnotic. Physicians should be educated on the risks and benefits of co-prescribing naloxone with an opioid and provide advice on the management of opioid overdose. Co-prescribing requires that physicians are prepared to educate patients and family members on the risks and to ensure they have the appropriate training to act in the event of an overdose. Additional research is needed to determine which other patient populations receiving prescription opioids should be co-prescribed naloxone and ASA advises FDA to explore working with partners, such as the NIH, on this research.

As the FDA is likely aware, the Surgeon General, Jerome Adams, M.D., recently announced an [Advisory on Naloxone and Opioid Use](#). The advisory states, “Increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic.” The Society is encouraged to see one of our fellow physician anesthesiologist members leading this effort. This advisory should be utilized and shared widely, as it outlines: information about the lifesaving drug, criteria to identify those with elevated risk for an opioid overdose, information for patients, the public and health care providers.

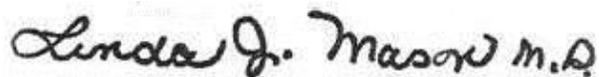
ASA encourages the federal government and private insurers to provide coverage for naloxone. ASA believes physicians should be authorized to prescribe naloxone to a third party (i.e. a family member or friend of a patient at risk of an opioid overdose). Health care professionals who prescribe and dispense naloxone should be immune from professional sanction and criminal and civil liability related to that activity. First responders and bystanders should be immune from criminal and civil liability related to administering naloxone to an individual experiencing an opioid overdose. The American Medical Association (AMA) Opioid Task Force, comprised of several medical organizations and provider groups working together to address the opioid epidemic, and which ASA is a member, strongly encourages widespread access to naloxone, along with broad Good Samaritan protections to individuals who assist those experiencing an overdose.

In 2013, ASA worked with the White House Office of National Drug Control Policy (ONDCP) to develop an [Opioid Resuscitation Card](#), which helps friends and family members identify and treat someone suspected of an opioid overdose. ASA still distributes this card to physicians, patients and lawmakers, in a wallet-size friendly format, so that individuals can carry it with them. The card is also available for free download on ASA’s website and has been distributed to over 300,000 Fraternal Order of Police members. The organization would welcome the opportunity to partner with the FDA and disseminate this card widely.

Management of opioid overdose with first responder or third-party administration of naloxone is expected to reduce the proportion of witnessed opioid overdoses which result in death, but it does not address the underlying causes of opioid overdose. Expanding access to naloxone is only one step in a positive direction towards preventing opioid overdose fatalities and improving public health.

Thank you for your leadership in addressing the opioid epidemic and acknowledging the importance of access to naloxone in communities across the nation. ASA appreciates the opportunity to provide comments as the FDA continues to work on this issue and would welcome the opportunity to work with the agency in any capacity.

Sincerely,

A handwritten signature in black ink that reads "Linda J. Mason M.D." The signature is written in a cursive, flowing style.

Linda Mason, M.D., FASA
President
American Society of Anesthesiologists