



## National Association of EMS Physicians®

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June 6, 2017

The Honorable Scott Gottlieb, M.D.  
Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner Gottlieb,

On behalf of the National Association of EMS Physicians (NAEMSP), I commend your initial efforts to stem the nation's opioid crisis, including the creation of the Opioid Policy Steering Committee and the review of healthcare professional opioid education. As an organization of highly-trained emergency medical care providers with first-hand experience with both the opioid epidemic and federal opioid regulations, we would like to extend you an offer to learn from our professional expertise and perspective.

In pursuing NAEMSP's mission to provide leadership and foster excellence in the subspecialty of EMS medicine, we have emerged as an industry leader and advocate on federal regulations relating to opioid administration. We have frequently, and intensively, worked with Congress and the U.S. Drug Enforcement Agency (DEA) to inform and guide policy impacting the administration of opioids and opioid overdose reversal agents. This has included writing policy, publishing opioid research, and working on legislative solutions such as the Protecting Patient Access to Emergency Medications Act (S. 916/H.R. 304). Our members, who number nearly 2,000 EMS physicians, researchers, and field practitioners across the nation, are on the front lines of the opioid epidemic every day, saving the lives of patients with acute opioid overdose. NAEMSP publishes the peer-reviewed and top-ranked *Prehospital Emergency Care* journal, as well as a blog and podcast on the most current issues and developments in the emergency medical care field.

NAEMSP unequivocally supports evidence-based education around best practices for the administration and prescription of controlled substances. Opioid education, as mandated by a number of states, is a powerful tool to keep medical care providers cognizant of constantly changing opioid strengths, formulations, and appropriate uses, as new opioid products come to market.

The Centers of Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and National Highway Traffic Safety Administration (NHTSA) recently published a paper in *Prehospital Emergency Care*, outlining evidence from the prehospital environment that illuminates the worsening of the opioid epidemic. In "Multiple Naloxone Administrations Among Emergency Medical Service Providers is Increasing," prehospital data show that not only is there an escalation in the number of overdoses but also in the number and severity of extreme overdoses, leading emergency medical care providers such as NAEMSP members to increasingly administer more than the standard dose of opioid reversal medication. The CDC, FDA, and NHTSA consider this study to be so crucial that they have sponsored this manuscript to be free to the public.

NAEMSP agrees with the DEA that the administration of controlled substances must have appropriate safeguards to avoid abusive diversion. NAEMSP members are responsible for helping patients avoid preventable death in acute medical emergency settings; however we also recognize the immense value



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of efforts to address the systemic issue of opioid abuse, such as through community based programs to provide long-term detox and treatment to patients.

We would be pleased to arrange a conversation between our two groups to discuss how our uniquely experienced perspectives may be of service to your worthwhile goal of easing America's deadly opioid epidemic. We strongly believe that the FDA may have a powerful role in reducing the opioid crisis and we are eager to contribute to this end in any way possible.

Thank you for your consideration.

Sincerely,

Brent Myers, MD, MPH, FAEMS  
President