



October 10, 2019

Re: DEA-508P

The Honorable Uttam Dhillon  
Acting Administrator  
Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, VA 22152

**Re: Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020**

Dear Acting Administrator Dhillon:

On behalf of 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the proposed notice that establishes the 2020 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act.

ACEP is concerned that the DEA is proposing to decrease the aggregate production quotas for several schedule II controlled substances. While we support the DEA's ongoing effort to make sure opioids are used for their intended purposes, we also want to make sure that patients in serious need of injectable opioids are able to receive these medications. We are facing a significant drug shortage problem in this country. A report from the Government Accountability Office (GAO) from 2014 found that both new shortages and ongoing shortages have increased each year since 2007.<sup>1</sup> The GAO report also conducted interviews with providers, who reported that the shortages led to "delays in or rationing of care, difficulties finding alternative drugs, risk associated with medication errors, higher costs, reduced time for patient care, and hoarding or stockpiling of drugs in shortage. During a shortage, providers may have to cancel or delay procedures, which can have detrimental health effects on patients. Providers may also have to ration care by prioritizing the patients who have a greater need for the drug."<sup>2</sup> The GAO concluded that the main cause of drug shortages were manufacturer production issues.<sup>3</sup>

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<sup>1</sup> United States Government Accountability Office, "Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability," February 2014.

<https://www.gao.gov/products/GAO-14-194>.

<sup>2</sup> Ibid.

<sup>3</sup> Ibid.

With respect to emergency medicine, the shortage crisis affects drugs across all classes of medications. As of September 2019, there are 92 preparations of 45 emergency care medications that are in shortage, including most forms of adenosine, atropine, bicarbonate, calcium, dextrose, dopamine, epinephrine, fentanyl, furosemide, labetalol, lidocaine, magnesium, lorazepam, and paralytic agents.<sup>4</sup> This will have a significant impact on emergency patient care.

These drug shortages last for months, or longer, and constitute a significant risk to patients. Patients need access at all times to medications that are used to treat life-threatening conditions. ACEP is extremely concerned that drug shortages have jeopardized the safety of our patients, especially during and after natural disasters and other mass casualty events. The overall effect on our nation's hospitals from Hurricane Maria in 2017 show just how fragile our current system is. Hurricane Maria destroyed much of Puerto Rico's drug and intravenous fluid manufacturing industry, and for months after the Hurricane hit, hospitals around the country were facing drug shortages, including injectable opioids, because they have no alternatives to acquire certain vital medications.

Drug shortages are exacerbated after such large-scale events both because of the need for supplies to react to the disaster, as well as the impact and disruptions disasters can pose to the supply chain and manufacturing of certain drugs, requiring the need to find temporary alternatives to alleviate potentially short-term shortages. As such, we see the issue of drug shortages as a substantial threat to our nation's preparedness and response capabilities. We were therefore extremely pleased to see that the Food and Drug Administration (FDA) convened a Drug Shortages Task Force in July 2018 that is looking for holistic solutions to address the underlying causes of drug shortages. We encourage you to continue working with the FDA and other stakeholders on this critical endeavor.

As the Drug Shortages Task Force prepares its report to Congress on the root causes of drug shortages, we urge the DEA to maintain the current aggregate production quotas. While there is no simple solution to dealing with drug shortages, and some factors are beyond the control of the DEA, the DEA must set appropriate production quotas of controlled substances to ensure that hospitals and emergency departments have enough drugs and treatments to care for the patients they serve.

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](mailto:jdavis@acep.org)

Sincerely,



Vidor E. Friedman, MD, FACEP  
ACEP President

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<sup>4</sup> ACEP Now, "Emergency Departments Need Plan to Deal with Drug Shortages," Augustine, James J., 2017, August 15, <https://www.acepnow.com/article/emergency-departments-need-plan-deal-drug-shortages/?singlepage=1&theme=print-friendly>.