October 15, 2019

[Submitted electronically to www.regulations.gov]

The Honorable Uttam Dhillon
Acting Administrator, Drug Enforcement Administration
Attention: DEA Federal Register Representative, DEA-488P
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Re: Docket No. DEA-508P for "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 Administrator Dhillon:

The undersigned organizations thank the Drug Enforcement Administration (DEA) for the opportunity to comment on its proposed reductions of annual production quotas (APQ) for certain Schedule II drugs for 2020.

We support DEA's efforts to combat diversion. However, we are extremely concerned that the proposed rule could exacerbate existing shortages of injectable opioids.

- IV Opioids are Essential to Patient Care: As DEA is aware, hospitals and other providers are currently facing critical shortages of a number of injectable opioid medications, including fentanyl, sufentanil, and hydromorphone. Intravenous (IV) opioids are used in a variety of practice settings within hospitals and ambulatory surgical centers for the treatment of acute, acute on chronic, or chronic pain that cannot be managed because the patient has a contraindication for oral opioid medications. Some opioids, such as fentanyl, also are used for sedation. Injectable opioids are critical to treating the pain needs of patients undergoing interventional procedures (e.g., cardiac catheterization or colonoscopy) and surgeries. These medications are also frequently used in intensive care units for surgical, trauma, burn, or oncology patients, when it is not clinically appropriate to use oral opioids. Having diminished supply of these critical drugs or no supply at all, can cause suboptimal pain control or sedation for patients in addition to creating burdensome workarounds for healthcare staff. Further, it is important to note that injectable opioids are subject to strict diversion control procedures as well as oversight by a number of federal and state authorities. Thus, diversion risk for injectable opioids differs from that of opioids in pill or tablet form.

- Supply Challenges Continue: Although we appreciated DEA's willingness to expedite reallocation of APQ in 2018 to address the IV opioids shortages, supply challenges persist. Thus, we remain concerned that reducing overall APQ will result in an insufficient supply of IV opioids to meet the United States' legitimate needs. We recognize that in setting APQ thresholds, DEA does not differentiate on the basis of drug formulation (i.e., whether the APQ is being used to produce solid oral dosage forms or injectables). Nevertheless, DEA should ensure that they have all pertinent information regarding how APQ is used.

FDA can provide shortage data broken down by dosage form, which will help contextualize the actual supply and availability of medications. This may also provide a clearer picture of diversion risk because, as noted above, there are distinct differences among formulations. Finally, we note that because IV opioid manufacturing requires very specific manufacturing equipment and DEA must approve all changes to APQ allocation, it is highly unlikely that APQ sent to an IV manufacturing site would instead be used to produce solid oral dosage forms.

- Additional Agency Coordination is Necessary: DEA notes that in setting APQ, DEA should consider "[r]elevant information obtained from the Department of Health and Human Services, including from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the Centers for Medicare and Medicaid Services and relevant information obtained from the states." The proposed rule does not explicitly mention or even allude to shortages, suggesting that DEA did not consider current shortages as a factor in setting APQ. We urge DEA to seek input from these agencies and to revise the proposed rule in accordance with their feedback. Additionally, we suggest that DEA establish and utilize regular channels of communication with HHS and its subagencies, particularly FDA. We also encourage DEA, in coordination with FDA and other agencies, to facilitate a public meeting focused on ensuring an adequate supply of injectable opioids while preventing diversion and misuse.

Thank you for your consideration of our comments. We continue to support DEA's efforts to combat the opioid crisis, and we stand ready to assist the agency in any way possible. Please do not hesitate to use our organizations as a resource as you continue this important work.

Sincerely,

American Medical Association

American Society of Anesthesiologists

American Society of Health-System Pharmacists