May 4, 2018

[Submitted electronically via www.regulations.gov]
Drug Enforcement Administration
Attn: DEA Federal Register Representative/DRW
8701 Morrissette Drive
Springfield, VA 22152

RE: Controlled Substances Quotas [Docket No. DEA-480]

The undersigned groups thank the Drug Enforcement Administration (DEA) for the opportunity to comment on its proposed rule regarding controlled substances quotas. Although we support DEA's efforts to combat diversion, we are concerned that the proposed rule is focused on diversion to the exclusion of another critical factor – drug shortages. To ensure that legitimate medical needs are met, it is imperative that drug shortages be considered as aggregate production quotas (APQ) are set and adjusted.

As DEA is aware, hospitals and other providers are currently facing critical shortages of a number of injectable opioid medications, including morphine, hydromorphone, and fentanyl. 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.

In a recent letter to DEA[1], we highlighted the necessity of APQ flexibility until the IV opioid shortages resolve. In response, DEA did adjust APQ limits for certain manufacturers, which we greatly appreciate. However, the injectable opioid shortage is unlikely to resolve in the near term and additional adjustments to APQs will be needed to ensure adequate supplies are available for legitimate medical purposes. Thus, we strongly urge DEA to amend its proposed rule to ensure that shortages are explicitly factored into APQ limits and adjustments. We recommend that DEA add drug shortages as a factor for setting and adjusting APQ under Sections 1303.11 and 1303.13. Further, DEA should request relevant drug shortages data from the Food and Drug Administration's (FDA) drug shortage staff when establishing and adjusting quotas.

In the proposed rule, DEA notes that APQs are meant to provide "adequate supplies for the United States' legitimate needs." Shortages create legitimate needs. As stakeholders representing various areas of health care delivery, we recommend the DEA consider the formulation of opioid when when making quota decisions. Injectable opioids dispensed in clinical settings pose a far lower risk of

[1] Please see Attachment A: Letter to DEA, dated February 27, 2018.

diversion than other dosage forms dispensed directly to patients. Proactively considering shortages when setting and adjusting APQs will safeguard patient health and safety and ensure critical needs are met.

Additionally, the more data DEA has from FDA regarding shortages, the better equipped DEA will be to calculate APQs that meet those needs. While we understand that DEA looks at the basic class of controlled substance when setting quotas, the 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 there are distinct differences among formulations, as noted above.

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. If you have questions, the appropriate contact person for each of the signatories can be found below.

Sincerely,

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Attachment A: Letter to DEA (February 27, 2018)