American Pharmacists Association

December 4, 2023

Mr. Scott A. Brinks
Regulatory Drafting and Policy Support Section, Diversion Control Division
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

RE: Docket No. Docket No. DEA-1228P: 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 2024, Notice with Request for Comment

Submitted electronically via www.regulations.gov to Docket No. Docket No. DEA-1228P

Dear Mr. Brinks:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments to the Drug Enforcement Administration (DEA) on their request for comments "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 2024." APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA supports DEA's efforts to address the diversion of controlled substances, however, drug shortages, whether identified by FDA, hospitals, or pharmacies, and patient needs must be considered as a factor when considering aggregate production quotas (APQ) for 2024 and the future. This will make certain that quotas are appropriately adjusted to ensure that patients with legitimate medical needs receive their medications.

APhA also appreciates DEA's November 1, 2023, announcement of upcoming changes to its quota allocation process to be more flexible and resilient in allocation management, including moving to quarterly allocations and increasing manufacturer transparency, and receiving better real-time data on the status of drug production going forward.

Analysis for Proposed 2024 Aggregate Production Quotas and Assessment of Annual Needs (88 FR 75313)

When determining APQs, the DEA is required to consider several elements including: "medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires."

APhA believes these quotas should rely on evidence so that any proposed reductions do not lead to additional drug shortages, delay patient access to necessary medications, or cause patients to turn to less effective alternatives.

Forthcoming Regulatory Changes and Administration of Individual Quotas for 2024 (88 FR 75317)

According to this request for comments, DEA is "considering methods to increase transparency in its quota-setting process in future regulatory proposals," by including stakeholder experiences, findings, concerns, and projections. This may include public notification and an opportunity for input when prescribing rates for controlled substances deviate substantially from the FDA's estimate of future use which could help avoid overly restricting patient access to

Quarterly Allocations

APhA appreciated FDA and DEA's recent joint letter which provided an update on actions both agencies are taking to address drug shortages, specifically related to ADHD medications. In the joint letter, FDA and DEA also stated that some drug manufacturers had allotted production quotas that were not fully used and were on track to fall one billion doses below their quotas.

APhA supports DEA's efforts to require drug manufacturers to apply for quota allotments every quarter to allow DEA the ability to provide any unused allotments to manufacturers that have demonstrated they are using them. Market demand can increase significantly with manufacturing problems,

APhA also strongly urges DEA to amend its proposed quotas to ensure that drug shortages are explicitly factored into APQ limits and adjustments. Additionally, APhA recommends DEA add drug shortages as a factor for setting and adjusting APQ under Sections 1303.11 and 1303.13. In addition, DEA should request relevant drug shortage data from FDA's drug shortage staff when establishing and adjusting quotas for each calendar year.

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Conclusion

APhA appreciates the opportunity to provide feedback on DEA's request for comments on the proposed production quotas for Schedule I and Schedule II controlled substances. APhA also supports DEA's proposed consideration of methods that would increase transparency in its quota-setting process in future proposals. APhA is committed to working with the DEA and other stakeholders to enhance the safety and security of the pharmaceutical distribution supply chain while ensuring patients have access to medically necessary medications. If you have any questions or need any additional information please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Federal Government Affairs