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VIA ELECTRONIC SUBMISSION

November 28, 2023

Drug Enforcement Administration
DEA Federal Register Representative / DPW
8701 Morrisette Drive
Springfield, Virginia 22152

**Subject: Comments on Proposed Aggregate Production Quota 2024
 Docket No. DEA-1228P**

TO THE ATTENTION OF DEA FEDERAL REGISTER REPRESENTATIVE/DPW:

The purpose of this correspondence is to file comment regarding the Drug Enforcement Administration's (DEA) Notice with request for comments published in the Federal Register on November 2, 2023, entitled "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."

Pfizer believes that patients who suffer from acute or chronic pain, in particular, within the hospital or institutional setting, should have access to both non-pharmacological and pharmacological therapy, and we are committed to improving patient care by supporting treatment approaches and policies that promote the appropriate treatment for the appropriate patient as determined by a healthcare provider. We understand the gravity of the opioid crisis in the United States and share DEA's concerns. In that respect, Pfizer applauds DEA's efforts to combat opioid abuse and supports efforts by the FDA, CDC, NIDA and the Surgeon General to develop a multifaceted approach to primary prevention, including community-based interventions and education and awareness initiatives that have proven to be effective.

Pfizer is a leading manufacturer of sterile injectable products, including controlled substances, which are used in the hospital setting, administered to patients by a medical professional and are not generally considered a significant source of product diversion. They are also prescribed for patients in hospice for terminal pain. Pfizer is committed to developing innovative, non-addictive medications for chronic pain that can reduce utilization of opioids and help break the curve of addiction. Pfizer also believes that information on disposal options and disposal resources should be accessible to everyone, and that all stakeholders in the supply chain have a role to play in promoting awareness about the various disposal methods and resources available.

We ask that DEA appropriately exercise its authority to reasonably interpret the provisions of the SUPPORT Act to combat abuse where it is most prevalent without adversely impacting patients who have bona fide clinical needs for opioid products, such as patients using such products under the direct care and oversight of a physician in the inpatient setting for surgical procedures and end of life care.¹ In doing so, it is important to note the distinction between manufacturing injectable products administered in a hospital setting and manufacturing oral solid dosage forms distributed to a patient for outpatient use. There are already effective controls in place to prevent diversion of controlled substances in a hospital setting including each manufacturer's own supply chain security, hospital diversion policies and



procedures and product tracking. Accordingly, Pfizer has significant concerns about the proposed rule's potential impact on sterile injectable manufacturers' ability to reliably supply medicines to healthcare providers and patients who need them.

In its summary, DEA stated it "is proposing to establish the 2024 Aggregate Production Quotas (APQ) for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the Assessment of Annual Needs (AAN) for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine." In addition, "For the 2024 quota year, DEA intends to allocate Procurement Quotas (PQ) to DEA-registered manufacturers of schedule II-controlled substances on a quarterly basis. In order to address domestic drug shortages of controlled substances, procurement quota allocations will be divided between quantities authorized for domestic sales and quantities authorized for export sales."

While DEA has provided substantial information in its Notice, several areas of practical application remain unknown:

- How will quarterly Procurement Quota be granted?
- Will Procurement Quota be granted through a letter (electronic) prior to the end of each quarter?
- Released annually or subsequent to each Procurement Quota grant?
- Will Procurement Quota for materials designated for export be granted quarterly? Or annually?

The soon to be effective Quota Management Rules (Document No. 2023-18885) will include quota suspension requirements when the inventory allowance has exceeded the established threshold based on the estimated year end inventory. How will that be affected by the new quarterly Procurement Quota grants?

DEA's proposal to allocate quota on a quarterly basis will make manufacturing lead times, planning schedules, and resource allocation extremely difficult if not untenable. As an example, from the time API is received at a manufacturing plant to the time finished product is ready for shipment, the lead time can be as long as six months, stretching over multiple quarters. Given those timeframes, DEA's proposed quarterly quota grants will likely result in interruptions in supply of sterile injectable products used in the inpatient setting.

DEA does not mention batch sizes in considering quarterly Procurement Quota allocations. In some instances, a single production batch may provide up to a two-year supply of product. Without enough API to make the minimum charge for an FDA-validated process, a quarterly quota grant could not be utilized to manufacture even one batch.

Also unknown is how quota allocation will affect development or other non-commercial quota. Manufacturing and development plans are dynamic and as potential medicines and products are explored, the need for development material will present. Bulk manufacturers and the Aggregate Production Quotas (APQ) and the Assessment of Annual Needs (AAN) are integral to creating and supplying the necessary active pharmaceutical ingredients and/or components. How will quarterly PQ allotments provide the incentive or sufficient support to bulk manufacturers to request manufacturing quota (MQ) when submitting their long-term application needs, when real-time planning and business opportunities are occurring at any time?

Pfizer objects to DEA's proposal to publish or post proprietary business information identifying those companies that have been issued quota and how many have utilized their allocated quota. Manufacturing is often dependent on a supplier's ability to procure manufacturing quota and a client's acquisition of



procurement quota. Sales contracts may pend based on issues outside of the manufacturer's control and not represent an implied hoarding or simple failure to act.

We encourage the DEA to improve its communication and offer timely training or other guidance to address the many questions prior or coincident to the implementation of these changes. Ultimately, better information will assist manufacturers to comply with DEA requirements and reduce the number of quota applications and DEA resources to process those requests.

As a leading research-based health care company, Pfizer share the widespread concern about the growing epidemic of misuse and abuse of opioid medicines. Pfizer supports a multi-disciplinary approach to combat opioid addiction that focuses on the deterrence, detection, and disruption of counterfeit medicines; strengthening of regulatory oversight; supply chain protection; primary prevention fostered by physician and public engagement; proper use, storage and disposal of prescription medicines; support for state efforts to strengthen prescription drug monitoring database programs; and encouragement of policies and programs that ensure access to addiction recovery treatment and rescue support.

Pfizer is very concerned that DEA's proposed 2024 changes in issuing quota on a quarterly basis will be disruptive to the injectables supply chain and that patient care will be negatively impacted as a result. We implore DEA to meet with industry to understand how batch sizes, production scheduling and long lead times impact quarterly allotment of quota, especially for injectable products, prior to making any changes to the issuance quota in 2024.

We welcome a discussion on the matter as soon as possible.

Sincerely,

A handwritten signature in black ink that reads 'Jennifer Walton'.

Jennifer Walton
Senior Vice President, US Policy & Government Relations
Pfizer

¹ It has been well established, including in seminal cases, such as *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* (467 U.S. 837 (1984)), that courts will not second-guess a federal administrative agency's reasonable interpretation of law when it is "apparent from the agency's generally conferred authority and other statutory circumstances that Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute or fills a space in the enacted law."