March 29, 2024

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS Information Collection Request - Reduction in the Inflation Rebate Owed for a Severe Supply Chain Disruption: CMS–10858

Dear Administrator Brooks-LaSure:

Pfizer appreciates the opportunity to provide comments in response to the *Information Collection Request: Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act (CMS-10858).*

Pfizer Mission and Approach to Medicine Shortages

Pfizer is a global biopharmaceutical company dedicated to researching and developing medicines that will benefit patients around the world. As a leading manufacturer of biologics, biosimilars, vaccines, and solid oral dose pharmaceuticals, Pfizer is deeply concerned about drug shortages and their impact on patient access to medically important therapies as well as on the broader health care system. We recognize that preventing and addressing medicine shortages is vital to ensure patients have the treatments they need for optimal health. Manufacturers, policymakers, regulators, and others must work together with urgency to address the underlying market dynamics that create an environment ripe for medicine shortages, with the goal of creating a more sustainable and supply-resilient market in which these critical and essential products are always available.

Generic sterile injectables (GSIs) make up a majority of the current medicine shortages, and our comments focus primarily on that market. The root causes of shortages for these medicines are unique market dynamics where price is too low to sustain multiple market suppliers and investment in manufacturing capacity and upgrades. The biggest challenges for Pfizer's GSI portfolio are responding to the demand volatility caused by a spike in demand due to manufacturers exiting the market, a severe supply disruption experienced by one of a few

suppliers, or contracting policies where our long-term price and volume commitments are not upheld.

Pfizer's first priority is to patients, and we recognize the critical role our medicines play in patient care – that is what is driving our urgency to prevent shortages and, if they occur, resolve them as quickly as possible. We work to provide patients with a consistent and reliable supply of high-quality medicines, and continually monitor the demand for, and inventory of, our products to meet our goal of full recovery when medicine shortages occur. In coordination with the U.S. Food and Drug Administration (FDA), Pfizer prioritizes the review and implementation of shortage corrective actions since we are keenly aware that supply challenges can disrupt patient care and create challenges for physicians to find alternative therapies for patients under their care.

Risk assessments are a part of our manufacturing process and support Pfizer's ability to identify situations that could result in a potential supply disruption and shortage, and to correspondingly implement mitigation measures to reduce risk vulnerability. Site and above-site risk assessments are proactively performed and continually updated to identify potential business continuity risks to critical products. Risks may arise, for example, from natural events (hurricane, tornado, earthquake), human events (pandemic, workplace disturbance, terrorism), and physical threats (information technology infrastructure failure, hazmat spill). Other examples of risk sources include demand (forecast accuracy, signal visibility), supply agility (product complexity, logistics/import), product attributes (product/manufacturing life cycle changes, product/process robustness), business processes (quality, compliance), and infrastructure (backup strategy, contract manufacturing organization (CMO) performance).

We strive to be prepared for and mitigate potential shortages by proactively understanding supply chain risks and undertaking appropriate actions where possible. We have a robust supplier selection program, and all supply chains are mapped to help understand potential supply risks. Other actions include building stock of critical raw materials, qualifying alternate raw material suppliers, registering multiple facilities to manufacture a product, and improving market forecasts. Further, based on risk assessment results, business continuity plans/ recovery strategies are determined, which are activated depending on the scope or impact of an incident or business interruption.

Considerations for Inflation Penalty (Rebate) Reduction Requests for Severe Supply Chain Disruptions or Likely Shortages

The inflation penalty levied on Medicare Part B and Part D medicines under the Inflation Reduction Act (IRA) is an arbitrary cap that could eventually affect the supply of medicines that are at high risk of facing shortages. Congress recognized this concern by including a provision that allowed the Secretary to waive or reduce a penalty in cases where medicines are in shortage or for generics or biosimilars determined to be experiencing severe supply chain disruptions. The law directs CMS to determine when there is a severe supply chain disruption during a calendar quarter or applicable period, such as that caused by a natural disaster or

other unique or unexpected event. CMS must also reduce or waive the inflation rebate amount owed (if any) for a generic Part D rebatable drug if CMS determines that without such reduction or waiver, the drug is likely to be in shortage in a subsequent applicable period.

In the ICR, CMS states that they "do not have information necessary to determine whether manufacturers of Part B and Part D rebatable drugs should have their rebate amount reduced due to either a severe supply chain disruption or a likely shortage" and that "some of the information and supporting documentation needed for CMS to make a determination regarding a severe supply chain disruption and the likelihood of a future shortage are held by manufacturers and are not available to CMS." [1]

Pfizer disagrees that the information required to make these determinations is not available or obtainable by CMS unless manufacturers provide it directly. We believe such a process is duplicative of existing Federal government processes under the FDA with which manufacturers must comply, and would unnecessarily increase administrative burden on drug manufacturers. We urge CMS to coordinate directly with the FDA to obtain the information needed to determine whether an inflation penalty can be waived or reduced.

In accordance with Sections 506C and 506E of the Food and Drug Administration's (FDA) Food, Drug, and Cosmetic (FD&C) Act, all manufacturers of covered and approved prescription drugs or biological products are required to inform the FDA of any manufacturing interruption for a product that could potentially lead to a significant disruption in supply. This mandatory notification process is designed to aid the FDA in complying with Section 506E of the FD&C Act, which requires the FDA to maintain a publicly available list of drugs in shortage. This list is required to provide: (1) the names and nationally determined contributions (NDCs) of the drug or biological product in subject; (2) the name of the manufacturer; (3) the reason(s) for the shortage; and (4) the estimated duration of the shortage.

Pfizer works consistently with FDA reviewers, the Drug Shortage Staff (DSS), and the Office of Compliance (OC) to alert and work with the FDA to avoid or minimize potential supply disruptions, or to expedite the review of submissions to resolve a shortage. We also communicate frequently with DSS to respond and seek to increase production when other suppliers of a product may have supply constraints.

As such, we provide information to FDA regarding an interruption in the manufacturing of medicines which includes situations where there may be a meaningful or severe disruption to supply of active pharmaceutical ingredients (APIs) or finished goods in the United States. For example, when a tornado struck Pfizer's Rocky Mount, North Carolina facility (one of the largest sterile injectable facilities in the world) on July 19, 2023, Pfizer colleagues worked closely with FDA officials, other regulatory bodies, and state and local officials on restoring the

[1] 89 FR 5548. (January 29, 2024). Agency Information Collection Activities: Proposed Collection; Comment Request. https://www.federalregister.gov/documents/2024/01/29/2024-01723/agency-information-collection-activities-proposed-collection-comment-request

facility to full operations and minimizing disruption to the supply of medicines manufactured at the facility.[2] FDA was given a full briefing about the damage to inventory and manufacturing lines as well as the expected return for supplying historic demand. This underscores that we work closely with the FDA when shortages occur, whether temporary or long-term, based on the cause of the disruption and the resulting shortage.

Pfizer commends CMS for recommending that a 506C supply disruption report be the basis for petitioning CMS for a penalty reduction for a severe supply chain disruption or likely shortage given the robust information included in a submission. However, rather than creating duplicative reporting requirements for manufacturers to request a rebate reduction, we urge CMS to coordinate with FDA to identify what existing information is already provided to FDA and streamline the process and any additional information needed from manufacturers to apply for a reduction in the inflation penalty.

Furthermore, FDA recently issued draft guidance outlining the types of information it expects under Section 506C of the FD&C Act from manufacturers (and information from their contracted manufacturers) to provide to the FDA when an expected or existing shortage is being reported.[3] The additional information FDA recommends for manufacturers to submit when notifying the Agency of a permanent discontinuance or interruption in manufacturing concerning a covered finished product should be available to CMS from the FDA, and useful to CMS in determining a severe disruption and avoid needing to provide additional information to initiate penalty reductions.

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Thank you for considering these comments. If you have questions or need additional information, please contact Dina.Brachman@pfizer.com.

Sincerely,

Margaret Davis-Cerone
Senior Director, Head of Federal Policy
US Policy and Government Relations

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[2] Fierce Pharma. (July 24, 2023). Pfizer, FDA work to ease shortage concerns as tornado relief efforts pick up at North Carolina injectables plant. https://www.fiercepharma.com/pharma/pfizer-us-fda-ease-shortage-concerns-tornado-relief-efforts-pick-massive-north-carolina

[3] US FDA. (February 2024). Draft Guidance: Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C Act. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-discontinuance-or-interruption-manufacturing-finished-products-or-active