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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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Majority (202) 225-3641

Minority (202) 225-2927

March 27, 2023

The Honorable Robert M. Califf, M.D., MACC
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Califf,

Pursuant to Rules X and XI of the U.S. House of Representatives, we are investigating ongoing drug shortages in the United States including the Food and Drug Administration's (FDA's) response to this public health challenge. The FDA Drug Shortage Database lists over 120 drugs that are currently in shortage.¹ The American Society of Health System Pharmacists Drug Shortages List has over 233 such entries.²

Drug shortages have become increasingly common over the past decade.³ According to the National Academies of Sciences, Engineering, and Medicine, ongoing and active drug shortages have been on the rise over the past several decades and are now lasting much longer.⁴ In recent years, there have been shortages of critical medications such as antibiotics, flu therapeutics, saline, morphine, and cancer drugs.⁵ In fact, new drug shortages in the country saw a 30 percent increase from 2021 to 2022, posing a risk to public health and national security.⁶

¹ U.S. Food & Drug Admin., *FDA Drug Shortages Database*, <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm> (last accessed March 9, 2023).

² Am. Soc'y of Health-System Pharmacists, *Drug Shortages List*, <https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list> (last accessed March 9, 2023).

³ U.S. Food & Drug Admin., *Drug Shortages*, <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>.

⁴ The Nat'l Academies of Sciences, Engineering, Medicine, *Building Resilience into the Nation's Medical Product Supply Chains* 25 (2022), <https://nap.nationalacademies.org/catalog/26420/building-resilience-into-the-nations-medical-product-supply-chains>.

⁵ Am. Soc'y of Health-System Pharmacists, *Drug Shortages Statistics*, <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>; Dylan Scott, *Why Does the US Keep Running Out of Medicine?*, VOX (Dec. 5, 2022), <https://www.vox.com/policy-and-politics/23484040/rsv-flu-amoxicillin-tamiflu-abuterol-drug-shortages>.

⁶ U.S. S. Comm. on Homeland Sec. & Gov't Affairs, *Short Supply: The Health and Nat'l Security Risks of Drug Shortages* 5 (March 2023), <https://www.hsgac.senate.gov/wp-content/uploads/2023-03-20-HSGAC-Majority-Draft-Drug-Shortages-Report.pdf>.

The FDA states that it monitors ongoing drug shortages and works closely with manufacturers and others in the supply chain to understand, mitigate and prevent or reduce any related impacts.⁷ The FDA has also requested additional legal authority from Congress to gain additional access to medical supply chain information. However, it is not clear to the Committee that FDA is effectively using its existing authorities.

For example, section 3112(e) of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136) required, for the first time, companies to report on an annual basis amounts of each listed drug manufactured, prepared, or processed for commercial distribution and information on where active pharmaceutical ingredients and finished dosage forms were made. It is not clear to this Committee what the FDA has done with the new data. To date, the FDA has not publicly released any summary of these reports in an aggregated way that may inform policy makers and provide the data Congress and others need as we examine ways to make sure the supply chain for drugs Americans need is secure.

Accordingly, to assist the Committee in our oversight, please respond to the following questions by April 10, 2023:

1. The total aggregated amount of each listed drug reported for each of calendar years 2020 through 2022 and identify:
 - a. the country of origin engaged in the manufacturing and processing of the drug;
 - b. whether the drug is approved under section 505(a) or 505(j) of the Federal Food Drug and Cosmetic Act;
 - c. whether the drug is listed under the FDA Drug Shortages online database as required under section 506E of the Federal Food, Drug, and Cosmetic Act; and
 - d. whether the drug is listed on the Food and Drug Administration's list of Essential Medicines, Medical Countermeasures, and Critical Inputs list as described in section 3(c) of the Executive Order 13944.
2. How information received under Section 510(j)(3) is being used to inform foreign inspection priorities and mitigate potential drug shortages.
3. The number of registrants required to comply with section 510(j)(3) of the Federal Food Drug and Cosmetic Act who have failed to report information on the amount of a drug

⁷ Mike Snider, *The Latest Drug Shortage: Albuterol. Here's Why the Medical Community is 'Super Concerned'*, USA Today (Mar. 9, 2023), <https://www.usatoday.com/story/news/health/2023/03/09/albuterol-shortage-respiratory-drug-supply-low/11429590002/>.

manufactured, prepared, propagated, compounded, or processed for commercial distribution, if any.

4. With respect to the current albuterol shortage:
 - a. Please provide details on the extent of this shortage.
 - b. What is FDA's understanding of the underlying cause of the shortage of this drug?
 - c. What steps is FDA taking to address the current crisis?
 - d. When does FDA expect a resolution of this shortage?
 - e. What preemptive risk reduction measures did FDA take to mitigate or prevent shortages of this drug?
5. With respect to the current shortage of Pluvicto:⁸
 - a. Please provide details on the extent of this shortage.
 - b. What is FDA's understanding of the underlying cause of the shortage of this drug?
 - c. What steps is FDA taking to address the current crisis?
 - d. When does FDA expect a resolution of this shortage?
 - e. What preemptive risk reduction measures did FDA take to mitigate or prevent shortages of this drug?
6. With respect to the current shortages of cisplatin and fluorouracil:⁹
 - a. Please provide details on the extent of this shortage.
 - b. What is FDA's understanding of the underlying cause of the shortage of this drug?
 - c. What steps is FDA taking to address the current crisis?
 - d. When does FDA expect a resolution of this shortage?
 - e. What preemptive risk reduction measures did FDA take to mitigate or prevent shortages of this drug?

⁸ Jennifer Calfas & Melanie Evans, *Shortages of Last-Ditch Drug for Advanced Prostate Cancer Worries Doctors*, Wall St. J. (Mar. 16, 2023), <https://www.wsj.com/articles/shortage-of-last-ditch-drug-for-advanced-prostate-cancer-worries-doctors-18de193d?ns=prod/accounts-wsj>.

⁹ 'People Will Die from This': 4 Cancer Drugs Are in Short Supply, Advisory Board (Mar. 21, 2023), <https://www.advisory.com/daily-briefing/2023/03/21/drug-shortage>.

7. With respect to the current shortage of methotrexate:¹⁰
 - a. Please provide details on the extent of this shortage.
 - b. What is FDA's understanding of the underlying cause of the shortage of this drug?
 - c. What steps is FDA taking to address the current crisis?
 - d. When does FDA expect a resolution of this shortage?
 - e. What preemptive risk reduction measures did FDA take to mitigate or prevent shortages of this drug?
8. With respect to the current shortage of Bacillus Calmette-Guerin (BCG):¹¹
 - a. Please provide details on the extent of this shortage.
 - b. What is FDA's understanding of the underlying cause of the shortage of this drug?
 - c. What steps is FDA taking to address the current crisis?
 - d. When does FDA expect a resolution of this shortage?
 - e. What preemptive risk reduction measures did FDA take to mitigate or prevent shortages of this drug?
9. With respect to the current shortage of amoxicillin:¹²
 - a. Please provide details on the extent of this shortage.
 - b. What is FDA's understanding of the underlying cause of the shortage of this drug?
 - c. What steps is FDA taking to address the current crisis?
 - d. When does FDA expect a resolution of this shortage?

¹⁰ Am. Soc'y of Health-System Pharmacists, *Current Drug Shortage: Methotrexate Injection*, <https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=282&loginreturnUrl=SSOCheckOnly> (last accessed March 24, 2023).

¹¹ Tina Reed, *Drug Shortages Upend Hospitals Care, Cancer Treatments*, Axios (Mar. 21, 2023), <https://www.axios.com/2023/03/21/drug-shortages-upend-cancer-treatments>; see also End Drug Shortages Alliance, *Implications of the National BCG Drug Shortage* (2023), https://www.enddrugshortages.com/files/BCG_White_Paper.pdf.

¹² Trish Hartman, *Amoxicillin, Over the Counter Medication Shortages Impacting Pharmacies Across Region*, ABC 6 Philadelphia (Mar. 7, 2023), <https://6abc.com/antibiotics-shortage-amoxicillin-adderall-over-the-counter/12925992/>.

- e. What preemptive risk reduction measures did FDA take to mitigate or prevent shortages of this drug?
10. With respect to the current shortage of acetaminophen and ibuprofen:¹³
- a. Please provide details on the extent of this shortage.
 - b. What is FDA's understanding of the underlying cause of the shortage of this drug?
 - c. What steps is FDA taking to address the current crisis?
 - d. When does FDA expect a resolution of this shortage?
 - e. What preemptive risk reduction measures did FDA take to mitigate or prevent shortages of this drug?

Please also provide a briefing for the Majority staff of the Energy and Commerce Committee after sending your written response. If you have any questions, please contact the Majority Committee staff at (202) 225-3641. Thank you for your attention to this request.

Sincerely,



Cathy McMorris Rodgers
Chair
Energy and Commerce Committee



Brett Guthrie
Chair
Subcommittee on Health



H. Morgan Griffith
Chair
Subcommittee on Oversight and Investigations

cc: Frank Pallone Jr., Ranking Member, Energy and Commerce Committee
Anna Eshoo, Ranking Member, Subcommittee on Health
Kathy Castor, Ranking Member, Subcommittee on Oversight and Investigations

¹³ Tina Reed, *Why We (Still) Can't Find Any Children's Tylenol*, Axios (Jan. 5, 2023), <https://www.axios.com/2023/01/05/why-childrens-tylenol-shortage>.