

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

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<https://oversight.house.gov>

November 2, 2023

The Honorable Robert M. Califf  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Commissioner Califf:

The Committee on Oversight and Accountability is investigating the growing number of critical drug shortages delaying, and in some cases, prohibiting patients from receiving necessary medical care. We seek to understand how the U.S. Food and Drug Administration (FDA) is navigating complex supply chains and reductions in domestic manufacturing as a result of drug price controls included in the Inflation Reduction Act (IRA), which raises the potential for worsening existing drug shortages.

At the time of this letter, the FDA lists 128 drugs currently in shortage on its drug shortage database.<sup>1</sup> Current shortages include important drugs commonly used to treat infections, respiratory illnesses, heart failure, psychiatric conditions, and cancer, and include drugs such as amoxicillin, penicillin, albuterol, Adderall, and cisplatin/carboplatin.<sup>2</sup> Earlier this year, there was a shortage of children's acetaminophen and ibuprofen.<sup>3</sup> The cancer drug shortage has gotten so severe that the FDA temporarily authorized the importation of drugs produced by non-FDA approved Chinese manufacturers.<sup>4</sup> The FDA is failing to ensure vitally important pharmaceuticals remain on pharmacy shelves.<sup>5</sup> In light of these concerns, we request documents and a staff-level briefing to better understand the FDA's response and mitigation strategies to improve and sustain the supply of high quality, life-supporting medications available to Americans.

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<sup>1</sup> U.S. Food & Drug Admin., Drug Shortage Database, *available at* <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm> (last accessed Oct. 16, 2023).

<sup>2</sup> *Id.*

<sup>3</sup> Madeline Halpert, *Children's Tylenol in short supply – here's what parents can do*, BBC (Dec. 21, 2022).

<sup>4</sup> Joseph Choi, *FDA to import more Chinese cancer drugs amid shortage*, THE HILL (Jul. 10, 2023).

<sup>5</sup> Jeff Craven, *Manufacturers seek clarity on FDA's drug shortage notification guidance*, Regulatory Focus, (Jun. 7, 2023). *See also Frequently Asked Questions About Drug Shortages*, U.S. Food and Drug Administration, (Oct. 11, 2023) "FDA responds to potential drug shortages by taking actions to address their underlying causes and to enhance product availability. FDA determines how best to address each shortage situation based on its cause and the public health risk associated with the shortage."

The FDA's problems with critical drug shortages far pre-date the COVID-19 pandemic.<sup>6</sup> There are a variety of reasons for the current state of drug shortages apart from pandemic supply chain delays, including an over-reliance on offshore manufacturing facilities, surging demand for pharmaceuticals, and diminishing manufacturing of generics.<sup>7</sup> One way to improve pharmaceutical supply chain security is to increase domestic manufacturing capabilities.<sup>8</sup> However, in recent decades, pharmaceutical manufacturing—especially for inexpensive generic drugs—has moved offshore to maximize profit margins.<sup>9</sup> In 2022, there were more than 4,000 facilities manufacturing prescription drugs for the United States, and 70% of those facilities were located in foreign countries.<sup>10</sup> Overseas pharmaceutical production is risky, especially when the FDA does not adequately inspect offshore facilities.<sup>11</sup> Recently, eye drops manufactured in an Indian pharmaceutical plant that was not inspected by the FDA caused an outbreak of a dangerous drug-resistant bacteria, causing fourteen cases of vision loss, four incidences of eye loss, and four deaths.<sup>12</sup>

Drug shortages will only be worsened by provisions in the IRA that mandate government price controls for prescription drugs.<sup>13</sup> Price controls ultimately limit profitability for pharmaceutical companies to the detriment of investment in new therapies and treatments.<sup>14</sup> Economists predict that on average, a one percent reduction in drug revenue leads to a 1.5 percent reduction in research and development funding.<sup>15</sup> The IRA's price control provisions will lead to less investment in domestic pharmaceutical production, further exacerbating supply chain insecurity. Increased research and development costs limit pharmaceutical companies' ability to invest in new drugs, ultimately stifling long-term investment in innovation.<sup>16</sup>

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<sup>6</sup> U. S. GOV'T ACCOUNTABILITY OFF., GAO-14-194, DRUG SHORTAGES: PUBLIC HEALTH THREAT CONTINUES, DESPITE EFFORTS TO ENSURE PRODUCT AVAILABILITY (Feb. 10, 2014); U. S. GOV'T ACCOUNTABILITY OFF., GAO-12-116, DRUG SHORTAGES: FDA'S ABILITY TO RESPOND SHOULD BE STRENGTHENED (Nov. 2011).

<sup>7</sup> See Nat'l Academies of Scis., Eng'g, and Med., Consensus Study Report: Building Resilience into the Nation's Medical Product Supply Chains, 100 (2022), available at <https://nap.nationalacademies.org/resource/26420/interactive/#start>.

<sup>8</sup> S. Comm. on Homeland Security & Governmental Affairs, *Short Supply: The Health and National Security Risks of Drug Shortages*, Maj. Staff Report, 118<sup>th</sup> Cong. (Mar. 2023).

<sup>9</sup> Eric Sanchez & Fernando J. Muzzio, *Reshoring pharmaceutical manufacturing to the US: Can we do it?* PHARMACEUTICAL TECH. (Feb. 2, 2021).

<sup>10</sup> U.S. GOV'T ACCOUNTABILITY OFF., GAO-22-103611, DRUG SAFETY: FDA SHOULD TAKE ADDITIONAL STEPS TO IMPROVE ITS FOREIGN INSPECTION PROGRAM (2022).

<sup>11</sup> Irena Hwang, *A pandemic-fueled drop in FDA inspections of foreign drug plants*, GOV'T EXEC. (Apr. 27, 2023); U. S. GOV'T ACCOUNTABILITY OFF., GAO-22-103611, FDA SHOULD TAKE ADDITIONAL STEPS TO IMPROVE ITS FOREIGN INSPECTION PROGRAM (Jan. 2022).

<sup>12</sup> Ctrs. for Disease Control & Prevention, *Outbreak of Extensively Drug-Resistant *Pseudomonas aeruginosa* Associated with Artificial Tears* (last updated May 15, 2023), available at <https://www.cdc.gov/hai/outbreaks/crpa-artificial-tears.html>.

<sup>13</sup> Inflation Reduction Act, Pub. L. No. 117-169, 136 Stat. 1818 (2022).

<sup>14</sup> Rita Numerof, *The Inflation Reduction Act: Death by a thousand cuts for the drug industry begins in earnest*, FORBES (Aug. 22, 2022).

<sup>15</sup> Tomas J. Philipson & Troy Durie, *Issue Brief: The impact of HR 5376 on biopharmaceutical innovation and patient health*, Univ. of Chicago (Nov. 29, 2021).

<sup>16</sup> Rita Numerof, *The Inflation Reduction Act: Death by a thousand cuts for the drug industry begins in earnest*, FORBES (Aug. 22, 2022).

Furthermore, illegal pharmacies take advantage of prescription drug shortages by marketing illegal or counterfeit versions of out-of-stock medications such as amoxicillin or Adderall on the internet.<sup>17</sup> Desperation may drive consumers to purchase illegal or counterfeit drugs distributed without the supervision of a licensed pharmacist.<sup>18</sup> The Drug Enforcement Administration (DEA) warns that counterfeit pills are marketed and made to look like legitimate prescriptions and often contain deadly amounts of fentanyl.<sup>19</sup>

It is of vital importance that the FDA monitor and prevent future drug shortages to maintain Americans' health and quality of life. To ensure proper oversight of FDA's drug monitoring capabilities, please provide the following documents and information, covering the time period January 20, 2021, to the present, as soon as possible but no later than November 16, 2023:

1. All documents and communications related to the FDA's work plan for investing in pharmaceutical data and supply chain analytics;
2. All documents and communications related to the FDA's work plan for incentivizing domestic pharmaceutical manufacturing;
3. All documents or communications related to medication shortages during the COVID-19 Public Health Emergency (PHE);
4. All documents sufficient to show the agency's plans for addressing compliance with Coronavirus Aid, Relief, and Economic Security Act (CARES Act)<sup>20</sup> requirements for mitigating drug shortages, including support for:
  - a. Priority reviews for drugs currently in shortage;
  - b. Mandatory manufacturer reporting to FDA related to precipitating events, duration, and anticipated impact of shortages; and
  - c. Overseeing manufacturer risk and redundancy plans;
5. All documents and communications between FDA employees and White House staff regarding drug shortages; and
6. All documents and communications between FDA employees and Department of Health and Human Services (HHS) employees regarding drug shortages.

In addition, please make arrangements to schedule a briefing with Committee staff on this matter as soon as possible, but no later than November 9, 2023.

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<sup>17</sup> Daniella Genovese, *Illegal online pharmacies exploit drug shortages*, FOX NEWS (Dec. 14, 2022).

<sup>18</sup> *Id.*

<sup>19</sup> U.S. Dep't of Justice & U.S. Drug Enforcement Admin., Counterfeit Pills Fact Sheet (Dec. 2022), *available at* [https://www.dea.gov/sites/default/files/2022-12/DEA-OPCK\\_FactSheet\\_December\\_2022.pdf](https://www.dea.gov/sites/default/files/2022-12/DEA-OPCK_FactSheet_December_2022.pdf).

<sup>20</sup> Coronavirus Aid, Relief, & Economic Security Act of 2020, Pub. L. No. 116-136, § 3112.

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To schedule the briefing, ask any related follow-up questions, or schedule the delivery of responsive documents, please contact Committee on Oversight and Accountability staff at (202) 225-5074. The Committee on Oversight and Accountability is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. Thank you in advance for cooperating with this inquiry.

Sincerely,



James Comer

Chairman

Committee on Oversight & Accountability



Lisa McClain

Chairwoman

Subcommittee on Health Care and  
Financial Services

cc: The Honorable Jamie Raskin, Ranking Member  
Committee on Oversight and Accountability

The Honorable Katie Porter, Ranking Member  
Subcommittee on Health Care and Financial Services