



## MEMORANDUM

**To:** Members and Staff, Subcommittee on Oversight and Investigations

**From:** Majority Committee Staff

**Re:** Hearing on “Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains”

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On Thursday, May 11, 2023, at 10:30 a.m. (ET) in 2123 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled “Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains.”

### I. WITNESSES

- Alex Oshmyansky, MD, PhD, CEO/Founder, Mark Cuban Cost Plus Drug Company
- Anthony Sardella, Chair, API Innovation Center, Adjunct Lecturer & Senior Research Advisor, Center for Analytics & Business Insights, Washington University in St. Louis
- Laura Bray, Founder, Angels for Change
- Fernando Muzzio, PhD, Distinguished Professor of Chemical & Biochemical Engineering, Rutgers University

### II. OVERVIEW

In recent months, reports of drug shortages have dominated news headlines. Patients, parents, caretakers, and health professionals alike have expressed frustration and concern as common antibiotics, children’s flu medication, drugs for asthma, and cancer treatments are unavailable.<sup>1</sup> Parents and pharmacists have resorted to costly and time-consuming searches for unavailable drugs or alternatives and hospitals have had to ration supplies and delay procedures.<sup>2</sup>

Although drug shortages are not a new phenomenon, the number of drugs with shortages has increased. A Senate report found new drug shortages increased 30 percent from 2021 to 2022,

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<sup>1</sup> Korin Miller, *Asthma Medication Shortage is Making Some Families Feel ‘Helpless and Frustrated.’ Here’s What Parents Need to Know*, Yahoo! Life (Mar. 22, 2023), <https://www.yahoo.com/lifestyle/asthma-medication-shortage-albuterol-213438204.html>.

<sup>2</sup> Christopher Rowland, *The Albuterol Shortage is About to Get Worse*, Washington Post (Mar. 1, 2023), <https://www.washingtonpost.com/business/2023/03/01/drug-shortages-manufacturing-albuterol/>; Natalie Haddad, *Central Texas Pharmacies Continue to Experience Child Medication Shortages*, KVUE (Jan. 18, 2023), <https://www.kvue.com/article/news/local/central-texas-pharmacies-continue-to-experience-child-medication-shortages/269-6b45231c-59b2-4745-bdf1-a78a527e7bc6>.

posing a risk to public health and national security.<sup>3</sup> The Food and Drug Administration (FDA) Drug Shortage Database lists over 120 drugs that are currently in shortage.<sup>4</sup> The American Society of Health System Pharmacists Drug Shortages List has over 233 such entries.<sup>5</sup> Drug shortages are also now lasting much longer, in some cases more than eight years.<sup>6</sup>

Drug shortages burden health providers and negatively impact patient care. Nine out of eleven drugs used to treat a form of childhood cancer experienced shortages between 2009 and 2019.<sup>7</sup> A norepinephrine shortage in 2011 was found to increase mortality among patients with septic shock.<sup>8</sup> Studies suggest “responding to drug shortages costs hospitals \$359 million each year in labor costs and another \$200 million each year to substitute drugs in shortage with alternatives.”<sup>9</sup>

### III. BACKGROUND

Generic prescription drugs and drugs administered by injection (“sterile injectables”) are the most prone to shortages and include critical medications such as antibiotics, flu therapeutics, saline, morphine, and cancer drugs.<sup>10</sup> A 2019 FDA report found that the immediate cause of most drug shortages was a manufacturing failure or loss of quality control causing a facility to shut down production.<sup>11</sup>

However, at its root, drug shortages are caused by economic factors.<sup>12</sup> Generic prescription drugs have low or no profit margins due to the extremely low prices that the intermediaries who buy or negotiate drug purchases can extract from manufacturers. This “race to the bottom” in price is possible because consolidation and vertical integration among intermediaries, such as pharmacy benefit managers, wholesalers, and group purchasing organizations, gives them substantial market power to determine the price they will pay for generic drugs. By some estimates, whether these price savings are passed on to plan sponsors, patients, and healthcare providers is disputed.

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<sup>3</sup> U.S. S. Comm. on Homeland Sec. & Gov’t Affairs, Short Supply: The Health and Nat’l Security Risks of Drug Shortages (2023), <https://www.hsgac.senate.gov/wp-content/uploads/2023-03-20-HSGAC-Majority-Draft-Drug-Shortages-Report.pdf>.

<sup>4</sup> U.S. Food & Drug Admin., *FDA Drug Shortages Database*, <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm> (last accessed May 4, 2023).

<sup>5</sup> Am. Soc’y of Health-System Pharmacists, *Drug Shortages List*, <https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list> (last accessed May 4, 2023).

<sup>6</sup> U.S. Food & Drug Admin., *Drug Shortages: Root Causes and Potential Solutions* (2019), <https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions> at 12.

<sup>7</sup> *Id.* at 16.

<sup>8</sup> Emily Vail et al., *Association Between US Norepinephrine Shortage and Mortality Among Patients with Septic Shock*, 317 (14) *JAMA* 1433 (2017), <https://jamanetwork.com/journals/jama/fullarticle/2612912>.

<sup>9</sup> *Drug Shortages: Root Causes and Potential Solutions*, *supra*, note 6 at 20.

<sup>10</sup> 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>.

<sup>11</sup> *Drug Shortages: Root Causes and Potential Solutions*, *supra*, note 6.

<sup>12</sup> *Id.* at 21.

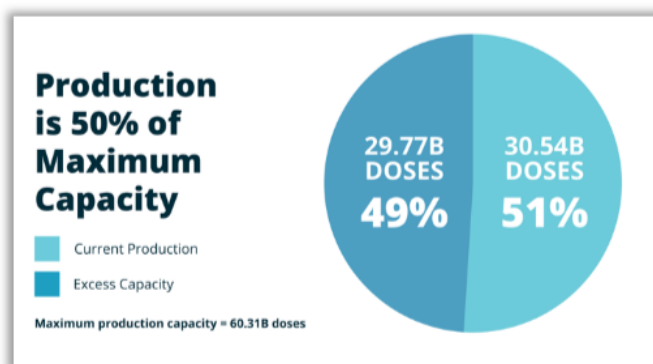


Figure 1: Excess Available U.S. Generic Drug Production Capacity.  
Source: US Generic Pharmaceutical Industry Economic Instability,  
*supra* note 13.

The inability of generic drug manufacturers to realize a reasonable return on domestically manufactured generics has a number of negative outcomes. First, companies are hesitant to invest in advanced manufacturing or to expand their generics business in the U.S. In many cases, a drug that is in shortage will have multiple companies approved to market the drug, but only one or two companies actively manufacturing the drug.<sup>13</sup>

Second, existing U.S. drug manufacturing capacity goes unused. One study found that the U.S. generic drug manufacturing facilities were only operating at 51 percent capacity primarily because expanding production was simply not economically viable.<sup>14</sup> Lastly, the manufacturing of generic drugs is highly concentrated with only one or two companies able to manufacture a generic drug under these market conditions. Forty percent of drugs have a single manufacturer supplying the market.<sup>15</sup> Thus, when a generic drug goes into shortage, it can be extremely disruptive as there is minimal excess manufacturing capacity available to mitigate its impact on patients.

The recent bankruptcy of Akorn Pharmaceuticals is illustrative of how the financial strain on U.S. based generic manufacturers can directly lead to shortages. In February 2023, Akorn Pharmaceuticals announced it was filing for Chapter 7 bankruptcy. Akorn's dissolution triggered a recall of its over 70 products.<sup>16</sup> This recall has in turn triggered shortages in critical medicines such as albuterol where Akorn was one of only two domestic manufacturers.<sup>17</sup> As of April 2023, four drugs made by Akorn have been discontinued with another 14 drugs experiencing severe shortages.<sup>18</sup>

"Race to the bottom" pricing has also pushed generic drug manufacturing offshore to countries like India and China. Around two-thirds of FDA-registered generic drug manufacturing facilities and about 87 percent of generic Active Pharmaceutical Ingredient (API) facilities are located overseas, primarily in China and India.<sup>19</sup> Government subsidies, cheap labor, and lax environmental laws all drive generic drug manufacturing to these countries. Foreign manufacturers

<sup>13</sup> *Id.* at 38.

<sup>14</sup> Anthony Sardella, US Generic Pharmaceutical Industry Economic Instability, Washington University (Apr. 21, 2023) (on file with Committee).

<sup>15</sup> Drug Shortages: Root Causes and Potential Solutions, *supra*, note 6.

<sup>16</sup> Zoey Becker, *After Shutting Down, Akorn Recalls Its 70-plus Products Nationwide*, Fierce Pharma (Apr. 26, 2023), <https://www.fiercepharma.com/pharma/after-shutting-down-operations-akorn-takes-its-70-products-shelf>.

<sup>17</sup> Paige Twenter, *Akorn: From Financial Troubles to a Shutdown and Intensifying Drug Shortages*, Becker's Hospital Review (Apr. 3, 2023), <https://www.beckershospitalreview.com/pharmacy/akorn-from-financial-troubles-to-a-shutdown-and-intensifying-drug-shortages.html>.

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

<sup>19</sup> The White House, Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth (2021), <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>, at 214.

have a record of undercutting the price of U.S. or western made generics to gain a dominate market share, only to increase the price of a generic drastically once they have monopolized a product.<sup>20</sup>

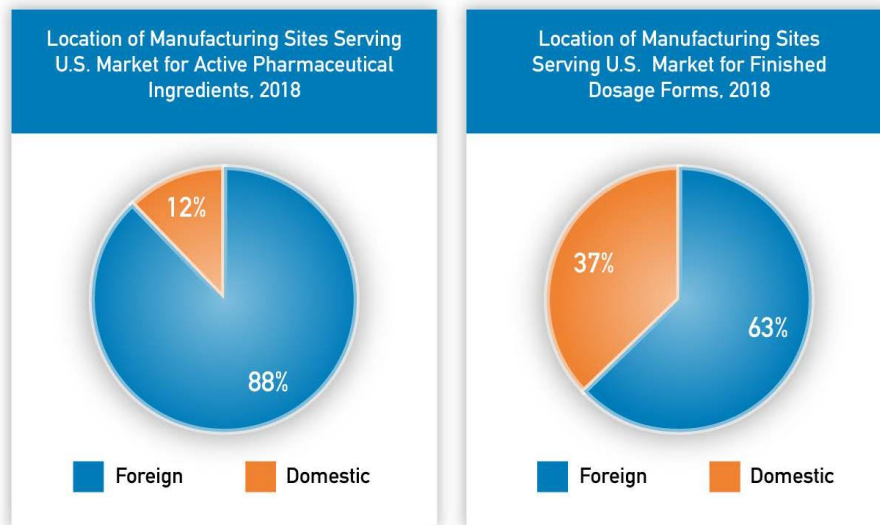


Figure 2: Most manufacturing sites making API and finished dosage forms for the U.S. market were located abroad. *Drug Shortages: Root Causes and Potential Solutions*, *supra*, note 6.

Foreign drug manufacturers also often have poor quality control measures and exhibit a pattern of repeatedly violating FDA regulations.<sup>21</sup>

#### IV. KEY QUESTIONS

The hearing may include discussion around the following key questions:

- Why have drug shortages become so commonplace, and what are some of the factors contributing to ongoing drug shortages?
- How can the U.S. improve the resilience of its current drug supply chain?
- How can the U.S. decrease its dependence on foreign drug manufacturers and improve its domestic manufacturing capacity?
- What are some emerging models that show promise in reforming the current drug supply market?

#### V. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Subcommittee on Oversight and Investigations Majority staff at (202) 225-3641.

<sup>20</sup> *Drug Shortages: Root Causes and Potential Solutions*, *supra*, note 6 at 97-98.

<sup>21</sup> Joseph Keenan, *FDA Slaps Aurobindo with Warning Letter on API Testing Failures, Repeated Violations*, *Fierce Pharma* (Jan 27., 2022), <https://www.fiercepharma.com/manufacturing/fda-slaps-aurobindo-warning-letter-api-testing-failures-repeated-violations>.