

# REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-I-22

Subject: Drug Shortages: 2022 Update

Presented by: Noel Deep, MD, Chair

Referred to: Reference Committee K

---

## INTRODUCTION

American Medical Association (AMA) Policy H-100.956, “National Drug Shortages,” directs the Council on Science and Public Health (CSAPH) to evaluate the drug shortage issue, including the impact of group purchasing organizations and pharmacy benefit managers on drug shortages, and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the United States. This report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue.

## METHODS

English-language reports were selected from a PubMed and Google Scholar search from September 2019 to August 2022, using the text term “drug shortages.” Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the internet sites of the U.S. Food and Drug Administration (FDA), National Academies of Sciences, Engineering, and Medicine (NASEM), U.S. Department of Health and Human Services (HHS), American Society of Health-System Pharmacists (ASHP), and Duke Margolis Center for Health Policy.

## BACKGROUND

CSAPH has issued twelve reports on drug shortages, with the most recent published at the November 2021 Special Meeting.<sup>1</sup> The findings and conclusions of the first five reports are summarized in CSAPH Report 2-I-15, “National Drug Shortages: Update.” The remainder of this report will provide an update on drug shortages since the 2021 report was developed, including specific comment on issues associated with the role of pharmacy benefit managers (PBMs).

## CURRENT TRENDS IN DRUG SHORTAGES

Drug shortages remain an ongoing public health concern in the United States and the AMA continues to monitor the situation and take action when appropriate. Overall, new drug shortages are decreasing; however, a large number of shortages are still ongoing and pose continued problems for patient care. Additionally, new shortages may occur as manufacturing capacity in the pharmaceutical industry is prioritized during the continuing COVID-19 and monkeypox public health emergencies, specifically for the production of vaccines and treatments.

The two primary data sources for information on drug shortages in the United States continue to be the Drug Shortage Program at the FDA and the Drug Shortage Resource Center maintained by

1 ASHP in cooperation with the University of Utah Drug Information Service (see Box 1 for links to  
2 these resources).<sup>2,3</sup> It should be noted that FDA resources also include guidance on drugs which  
3 have had their use dates extended while a known shortage is ongoing.

4  
5 According to current ASHP statistics (see Appendix 1), the downward trend in new drug shortages  
6 over the last few years has continued. At its peak in 2011, there were 267 new drug shortages  
7 reported; in 2021, there were 114. For the first 6 months of 2022, there have been 81 newly  
8 reported shortages. However, while the number of new shortages may be decreasing each year, the  
9 number of active drug shortages has stayed relatively steady (282 active shortages in Q2 2019, 264  
10 shortages in Q2 2022), indicating that individual shortages are taking longer to resolve. For the first  
11 two quarters of 2022, the five classes of drugs with the most ongoing shortages include: central  
12 nervous system drugs (40 total), fluids and electrolytes (36), antimicrobials (30), cardiovascular  
13 (27), and hormones (19). Fluids and electrolytes were not present in last year's top five classes of  
14 drug shortages, indicating a surge in products currently facing shortage.

15  
16 In addition, the number of manufacturers reporting the underlying cause of the drug shortage as  
17 "unknown" has continued to decrease, from 82 percent in 2019 to 42 percent in 2021. Compared to  
18 2020, "business decision" has decreased as well from 14 percent to 4 percent in 2021. Behind  
19 "unknown," "supply/demand" was listed as the second most common reason (27 percent) for drug  
20 shortages by manufacturers in 2021. Beyond issues with manufacturing, ASHP has also reported  
21 that hospitals are having difficulty staffing their pharmacies with experienced staff to proactively  
22 identify, prevent and alleviate gaps in supply.<sup>4</sup>

#### 23 24 *The Food and Drug Administration*

25  
26 The FDA continues to utilize a mobile app to provide up-to-date access to information about drugs  
27 in shortage as well as notifications about new and resolved drug shortages. This mobile app also  
28 gives physicians the ability to report a drug shortage. The FDA Drug Shortages webpage includes a  
29 current shortages list, a link to the mobile app, and additional information (Box 1).

30  
31 The ninth annual report on drug shortages from the FDA to Congress published in early 2022  
32 summarizes the major actions the FDA took in calendar year 2021 related to drug shortages.<sup>5</sup>  
33 During the COVID-19 public health emergency, the FDA continued to closely monitor the medical  
34 product supply chain and as expected, the supply chain was impacted by the pandemic, leading to  
35 supply disruptions or shortages of drug products in the United States. Appendix 2 includes a  
36 breakdown of the FDA's calendar year 2021 metrics, including the number of expedited reviews  
37 (274) and expedited inspections (29).

#### 38 39 *The Essential Medicines Report*

40  
41 In May 2022, HHS and the Assistant Secretary for Preparedness and Response (ASPR) released the  
42 first Essential Medicines Supply Chain and Manufacturing Resilience Assessment.<sup>6</sup> A critical  
43 function of this report was to prioritize drugs for increased scrutiny from a previously developed  
44 list of essential medicines.<sup>7</sup> In their report, a group of stakeholders identified 86 medications as  
45 critical or important for minimum acute patient care with no other alternative available. Of the  
46 drugs identified, 56 drugs (65 percent) at the time of publication were in shortage as described by  
47 the ASHP database. Within their report, the group outlines six challenges for addressing drug  
48 shortages: market structure, global competition, labor/workforce, manufacturing processes, supply  
49 chain/distribution, and regulatory barriers.

## *The Drug Enforcement Administration*

Outside of the FDA, HHS and ASPR, the Drug Enforcement Administration (DEA) is another critical federal agency that impacts drug shortages. As part of its regulatory authority under the Controlled Substances Act, the DEA maintains a closed system around the manufacturing of Schedule I and II drugs, as well as List I chemicals (ephedrine, pseudoephedrine and phenylpropanolamine). This closed system means that the DEA requires the registration and continuous oversight of any entity involved in the manufacturing and distribution supply chain of these drugs, including a strict quota on the volume and quantity of a controlled substance that can be manufactured at a given time. Per the DEA, this quota is intended “prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.”<sup>8</sup> The FDA and DEA have an ongoing memorandum of understanding to share information regarding information that may impact drug shortages.<sup>9</sup>

However, there have been several instances where DEA quotas have either directly or indirectly caused a drug shortage of a critically necessary medication. For example, in 2019 the DEA proposed a 53 percent decrease to the overall quota of Schedule II opioids that could be manufactured in 2020.<sup>10</sup> However, by the spring of 2020, there was a surge in demand for injectable opioids to help patients on ventilators fighting COVID-19.

In response to a 2020 joint letter from AMA, ASHP and other stakeholders,<sup>11</sup> the DEA increased the manufacturing quota by 15 percent, yet injectable fentanyl, hydromorphone, and morphine are all still classified as active shortages by ASHP in 2022.<sup>12</sup> Other drugs, such as mixed amphetamine salts for the treatment of attention deficit hyperactivity disorder, are similarly facing decreases in DEA manufacturing quotas while under an active drug shortage.

In light of the opioid crisis, in which medications that help prevent overdose are underprescribed nationwide, supply restrictions may have significant unintended consequences. The potential benefit of supply reduction is that it may discourage the diversion of controlled substances. The potential harm of supply reduction is that patients may suffer serious harm when needed medications are unavailable for any reason. Your Council on Science and Public Health is currently unaware of any evidence that the overall benefits of supply reductions outweigh the overall harms.

## *Pharmacy Benefit Managers*

At the AMA 2022 Annual Meeting, the topic of PBMs and their role in driving drug shortages was specifically raised. PBMs, which serve as an intermediary between health insurers and pharmaceutical companies, have long been a source of scrutiny by our AMA, with a multitude of policies directly calling for oversight or reform of PBM activities.

Concern around PBMs and drug shortages is the potential for manipulating price and access to medications. However, these claims cannot be tested as PBM pricing information has historically been opaque, but that may be changing. On June 7, 2022, the Federal Trade Commission (FTC) announced that it has launched an investigation into vertically integrated PBMs and has specifically cited issues around PBM-owned pharmacies and prior authorizations.<sup>13</sup> In April 2022, prior to the FTC’s decision, the AMA sent a letter urging the FTC to take action and increase PBM transparency.<sup>14</sup> Additional bipartisan legislation, the Pharmacy Benefit Manager Transparency Act of 2022, was introduced on May 24, 2022, and at the time of writing is pending review by the Senate Commerce, Science and Transportation committee. In its current form, the PBM

Transparency Act would require, among other things, for PBMs to file annual reports with the FTC on many of their practices.<sup>15</sup>

Beyond possible manipulations of cost and access, other PBM practices may exacerbate drug shortages or otherwise impact the ability of a practice to mitigate shortages. For example, PBMs may utilize techniques known as “brown bagging,” in which a health plan requires a patient to obtain a medication from a PBM-owned specialty pharmacy and then bring it to the clinic for the practitioner to administer. Previously, the Council on Medical Service has investigated the issue of brown bagging medications in the context of patient care.<sup>16</sup> In the context of drug shortages, brown bagging decreases visibility of the supply chain for hospitals and practices; they are unable to predict which medications are to be needed when, and as such may be unable to procure or adequately plan for future demand.

### *Monkeypox Vaccines*

Amidst the monkeypox public health emergency, there is currently a shortage of vaccinations available in the United States. Two vaccines may be used for the prevention of monkeypox disease.<sup>17</sup> The JYNNEOS vaccine, a third-generation vaccine produced by a small European biotech company, Bavarian Nordic, is approved for the prevention of monkeypox and smallpox disease and the ACAM2000 vaccine, produced by Baxter, is approved for immunization against smallpox disease and made available for use against monkeypox under an Expanded Access Investigational New Drug (EA-IND) protocol. In the United States, there is a large supply of ACAM2000, but this vaccine has more known side effects and contraindications.<sup>18</sup> JYNNEOS is the primary vaccine being used in the U.S monkeypox outbreak.

After its FDA approval in 2019, the Strategic National Stockpile (SNS) was reportedly supposed to procure 120 million doses of JYNNEOS, enough to immunize sixty million people as one element of the U.S. government’s smallpox preparedness efforts.<sup>19</sup> However, as with other supplies in the national stockpile, JYNNEOS inventory was not maintained to an appropriate level due to chronic underfunding as well as the redirection of funds to other purposes, such as shelter for 20 thousand unhoused migrant children at the southern border.<sup>20,21</sup> With a shelf-life of 3 years, millions of doses of JYNNEOS in the SNS had expired.<sup>22</sup> Only 2,400 doses of the JYNNEOS vaccine were available in the immediate holdings of the SNS at the onset of the current monkeypox outbreak.<sup>23</sup> More than 1.1 million doses of the vaccine purchased by the U.S. government were at Bavarian Nordic’s facility in Denmark and required authorization from an on-site FDA inspection before they could be shipped to the U.S.<sup>24</sup>

To help alleviate the shortage, the FDA granted emergency use authorization for intradermal administration of JYNNEOS, which utilizes approximately one-fifth of the total volume of vaccine compared to currently approved subcutaneous administration.<sup>25</sup> In addition, the administration has increased efforts to boost domestic manufacturing, including partnerships with Michigan-based facilities to perform filling and finishing to expedite the distribution of previously ordered vaccines.<sup>26</sup>

### CURRENT AMA DRUG SHORTAGE ACTIVITIES

AMA staff continue to remain engaged in drug shortage activities. Staff are involved in a multi-stakeholder effort to remain current on policies, drug shortage and supply chain issues, and to develop group recommendations on the topics. The effort includes our AMA, the ASHP, the American Hospital Association (AHA), the United States Pharmacopeia (USP), the American Society of Anesthesiologists (ASA), and the American Society of Clinical Oncology (ASCO).

Earlier this year, our AMA additionally sent a letter to leadership of the Senate Committee on Health, Education, Labor and Pensions to advocate for legislation modernizing the medical supply chain.<sup>27</sup> In the letter, the AMA called upon Congress to, among other things:

- Incentivize advanced manufacturing technology and develop new continuous manufacturing technology for critical drugs and active pharmaceutical ingredients;
- Improve the function and composition of the Strategic National Stockpile;
- Improve multinational cooperation on supply chain resilience;
- Incentivize quality and resilience; and
- Replicate asks for critical drug manufacturing transparency and oversight for medical devices and ancillary supplies (e.g., PPE).

## CONCLUSION

The rate of new medical product shortages is decreasing, but individual shortages are lasting longer. Due to the ongoing COVID-19 and monkeypox public health emergencies, the medical supply chain has been under intense, increased scrutiny. The AMA's drug shortage policy is timely and already addresses a variety of issues that are under consideration by the White House, FDA, and other stakeholders. Additional policy modifications have been recommended to reflect ongoing efforts by other organizations interacting with the drug manufacturing space, such as the DEA and FTC.

## RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted and the remainder of the report be filed.

1. Policy H-100.956, "National Drug Shortages" be amended by addition to read as follows:

1. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients.
2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.

- 1 5. The Council on Science and Public Health shall continue to evaluate the drug shortage  
2 issue, including the impact of group purchasing organizations and pharmacy benefit  
3 managers on drug shortages, and report back at least annually to the House of Delegates on  
4 progress made in addressing drug shortages.  
5
- 6 6. Our AMA urges continued analysis of the root causes of drug shortages that includes  
7 consideration of federal actions, evaluation of manufacturer, Group Purchasing  
8 Organization (GPO), pharmacy benefit managers, and distributor practices, contracting  
9 practices by market participants on competition, access to drugs, pricing, and analysis of  
10 economic drivers, and supports efforts by the Federal Trade Commission to oversee and  
11 regulate such forces.  
12
- 13 7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs  
14 by ensuring that such products are not removed from the market or caused to stop  
15 production due to compliance issues unless such removal is clearly required for significant  
16 and obvious safety reasons.  
17
- 18 8. Our AMA supports the view that wholesalers should routinely institute an allocation  
19 system that attempts to fairly distribute drugs in short supply based on remaining inventory  
20 and considering the customer's purchase history.  
21
- 22 9. Our AMA will collaborate with medical specialty society partners and other stakeholders  
23 in identifying and supporting legislative remedies to allow for more reasonable and  
24 sustainable payment rates for prescription drugs.  
25
- 26 10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving  
27 pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to  
28 determine whether such an activity has the potential to worsen drug shortages.  
29
- 30 11. Our AMA urges the FDA to require manufacturers to provide greater transparency  
31 regarding the pharmaceutical product supply chain, including production locations of  
32 drugs, and provide more detailed information regarding the causes and anticipated duration  
33 of drug shortages.  
34
- 35 12. Our AMA supports the collection and standardization of pharmaceutical supply chain data  
36 in order to determine the data indicators to identify potential supply chain issues, such as  
37 drug shortages.  
38
- 39 13. Our AMA encourages global implementation of guidelines related to pharmaceutical  
40 product supply chains, quality systems, and management of product lifecycles, as well as  
41 expansion of global reporting requirements for indicators of drug shortages.  
42
- 43 14. Our AMA urges drug manufacturers to accelerate the adoption of advanced manufacturing  
44 technologies such as continuous pharmaceutical manufacturing.  
45
- 46 15. Our AMA supports the concept of creating a rating system to provide information about  
47 the quality management maturity, resiliency and redundancy, and shortage mitigation  
48 plans, of pharmaceutical manufacturing facilities to increase visibility and transparency  
49 and provide incentive to manufacturers. Additionally, our AMA encourages GPOs and

- 1 purchasers to contractually require manufacturers to disclose their quality rating, when  
2 available, on product labeling.  
3
- 4 16. Our AMA encourages electronic health records (EHR) vendors to make changes to their  
5 systems to ease the burden of making drug product changes.  
6
- 7 17. Our AMA urges the FDA to evaluate and provide current information regarding the quality  
8 of outsourcer compounding facilities.  
9
- 10 18. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine  
11 and consider drug shortages as a national security initiative and include vital drug  
12 production sites in the critical infrastructure plan.  
13
- 14 19. Our AMA urges the Drug Enforcement Administration and other federal agencies to  
15 regularly communicate and consult with the FDA regarding regulatory actions which may  
16 impact the manufacturing, sourcing, and distribution of drugs and their ingredients.  
17 (Modify Current HOD Policy)  
18
- 19 2. That Policy H-440.847, "Pandemic Preparedness," which addresses the adequacy of the  
20 Strategic National Stockpile, be reaffirmed. (Reaffirm HOD Policy)

Fiscal Note: Less than \$1,000

**Box 1. Resources available to assist in mitigation of drug shortages.**

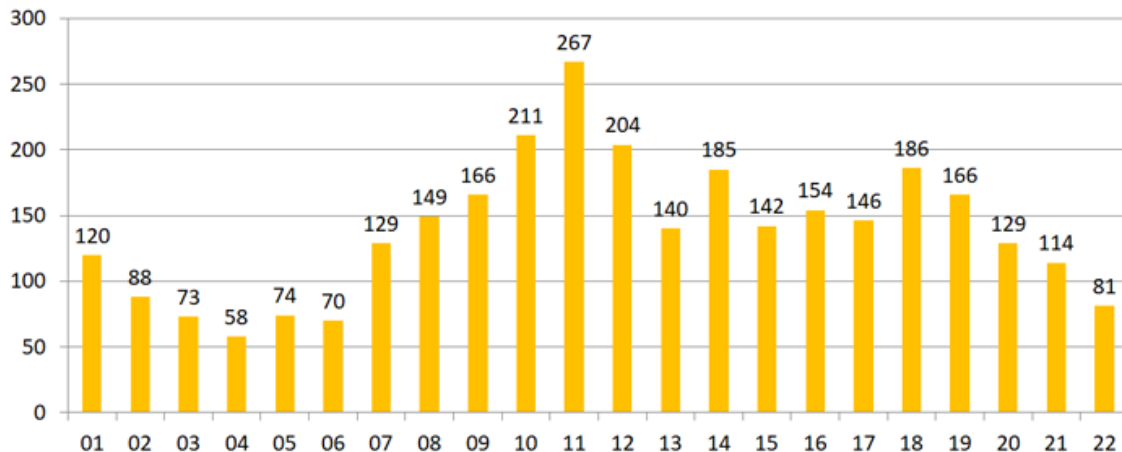
1. [ASHP Resource Center](#)
2. ASHP [list](#) of current shortages
3. [FDA Drug Shortages Page](#) (includes current shortages list, extended use dates, mobile app, and additional information)



## APPENDIX 1

ASHP/University of Utah Drug Information Service Drug Shortage Data

**Figure 1. National Drug Shortages: New Shortages by Year: January 2001 to June 30, 2022**

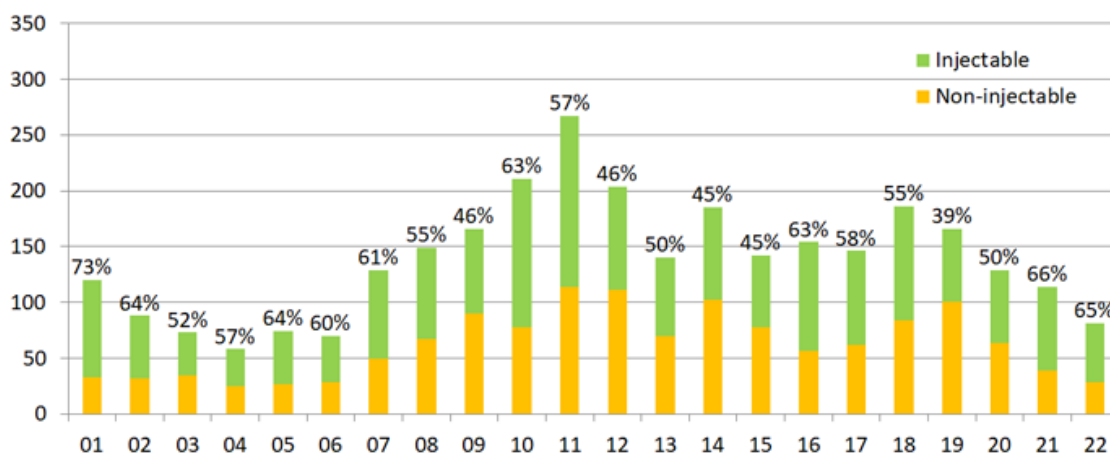


Note: Each column represents the number of new shortages identified during that year.

University of Utah Drug Information Service

Contact: Erin.Fox@hsc.utah.edu, @foxerinr for more information.

**Figure 2. National Drug Shortages: New Shortages by Year - Percent Injectable: January 2001 to June 30, 2022, % Injectable**

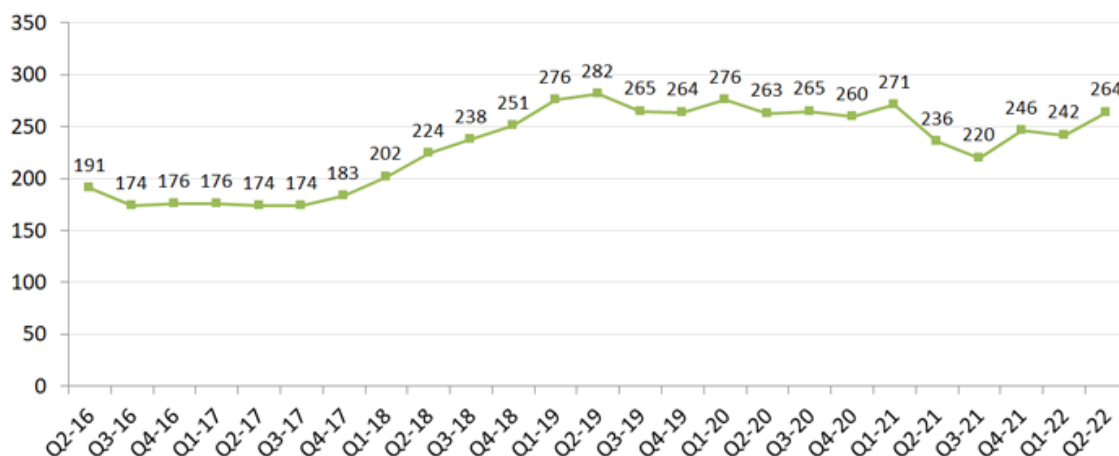


Note: Each column represents the number of new shortages identified during that year.

University of Utah Drug Information Service

Contact: Erin.Fox@hsc.utah.edu, @foxerinr for more information.

**Figure 3. National Drug Shortages: Active Shortages by Quarter: 5 Year Trend**

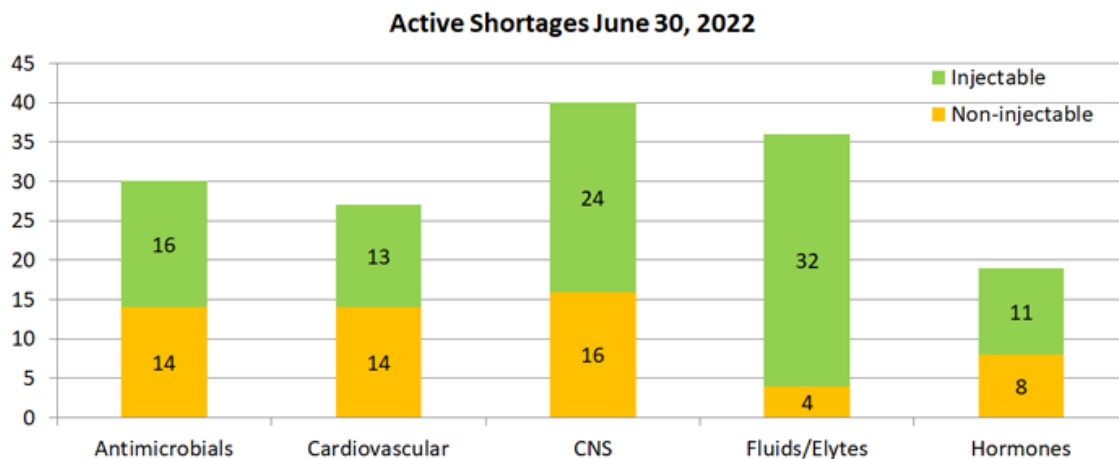


Note: Each point represents the number of active shortages at the end of each quarter.

University of Utah Drug Information Service

Contact: Erin.Fox@hsc.utah.edu, @foxerinr for more information.

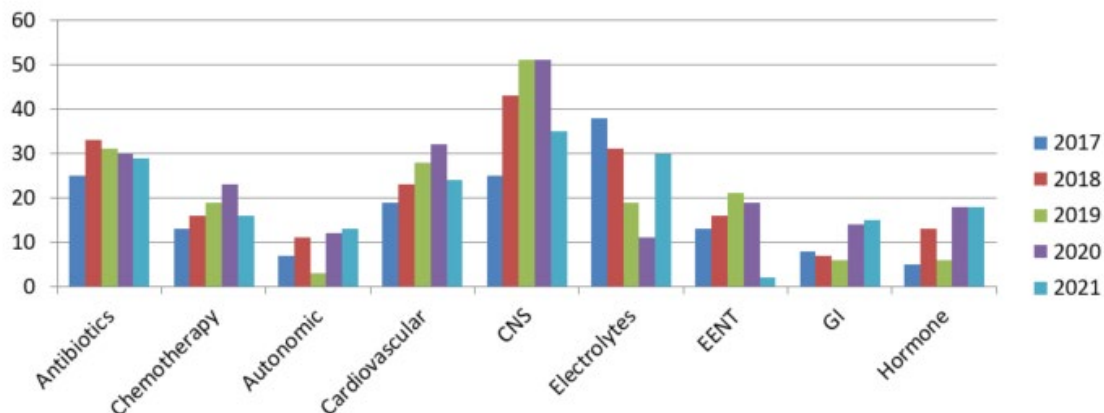
**Figure 4. National Drug Shortages: Active Shortages Top 5 Drug Classes**



University of Utah Drug Information Service

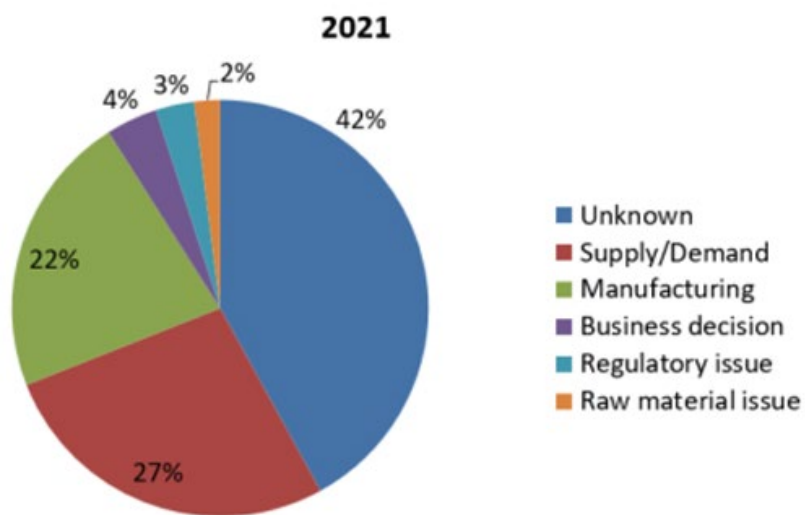
Contact: Erin.Fox@hsc.utah.edu, @foxerinr for more information.

**Figure 5. National Drug Shortages: Common Drug Classes in Short Supply: 5 Year Trend**



University of Utah Drug Information Service  
 Contact: Erin.Fox@hsc.utah.edu, @foxeinr for more information.

**Figure 6. National Drug Shortages: Reasons for Shortages as Reported by Manufacturers During UUDIS Investigation — 2021**



University of Utah Drug Information Service  
 Contact: Erin.Fox@hsc.utah.edu, @foxeinr for more information.

## APPENDIX 2

**Breakdown of CDER's and CBER's Shortage Numbers, CY 2021**

	<b>CDER</b>	<b>CBER</b>
New Shortages	38	3
Prevented Shortages	303	14
Ongoing Shortages	79	4
Notifications	744	33
No. of Manufacturers Notifying	98	23
<b>ACTIONS TAKEN TO MITIGATE SHORTAGES</b>		
Regulatory Flexibility and Discretion	97	0
Expedited Reviews	260	14*
Expedited Inspections	29	0

\* This number includes expedited reviews for eight biologics license application (BLA)/BLA supplements and six lot-release submissions for CBER-regulated products.

## REFERENCES

- <sup>1</sup> Council on Science and Public Health. *Drug Shortages: 2021 Update*. American Medical Association; Nov 2021.
- <sup>2</sup> American Society of Health-System Pharmacists. *Shortage Resources*. <https://www.ashp.org/Drug-Shortages/Shortage-Resources>. Accessed August 1, 2022.
- <sup>3</sup> U.S. Food and Drug Administration. *Drug Shortages*. <https://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>. Accessed August 1, 2022.
- <sup>4</sup> Kate Traynor. *Drug Shortages Worsening, Pharmacists Say*. American Society of Health-System Pharmacists. <https://www.ashp.org/News/2022/03/16/drug-shortages-worsening-pharmacists-say>. March 16, 2022.
- <sup>5</sup> U.S. Food and Drug Administration. *Drug Shortages for Calendar Year 2021*. <https://www.fda.gov/media/159302/download>. Accessed August 1, 2022.
- <sup>6</sup> Department of Health and Human Services. *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*. [https://www.armi.usa.org/wp-content/uploads/2022/07/ARMI\\_Essential-Medicines\\_Supply-Chain-Report\\_508.pdf](https://www.armi.usa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf). Accessed August 1, 2022.
- <sup>7</sup> U.S. Food and Drug Administration. *Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order 13944*. <https://www.fda.gov/media/143406/download>. Accessed August 1, 2022.
- <sup>8</sup> U.S. Department of Justice. *Diversion Control Division*. [https://www.deadiversion.usdoj.gov/prog\\_descrp/](https://www.deadiversion.usdoj.gov/prog_descrp/). Accessed August 1, 2022.
- <sup>9</sup> U.S. Food and Drug Administration. *MOU 225-15-11*. <https://www.fda.gov/about-fda/domestic-mous/mou-225-15-11>. Accessed August 1, 2022.
- <sup>10</sup> Drug Enforcement Agency. *DEA proposes to reduce the amount of five opioids manufactured in 2020, marijuana quota for research increases by almost a third*. <https://www.dea.gov/press-releases/2019/09/11/dea-proposes-reduce-amount-five-opioids-manufactured-2020-marijuana-quota>. Accessed August 1, 2022.
- <sup>11</sup> American Medical Association. *AMA praises DEA allowing increase in controlled substance production*. <https://www.ama-assn.org/press-center/press-releases/ama-praises-dea-allowing-increase-controlled-substance-production>. Accessed August 1, 2022.
- <sup>12</sup> Ed Silverman. *DEA moves to fight shortages of medicines needed for Covid-19 patients*. STAT News. <https://www.statnews.com/pharmalot/2020/04/07/dea-covid19-coronavirus-ventilators-shortages/>. Accessed August 1, 2022.
- <sup>13</sup> Federal Trade Commission. *FTC Launches Inquiry Into Prescription Drug Middlemen Industry*. <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry>. Accessed August 1, 2022.
- <sup>14</sup> American Medical Association. *Letter to FTC re: Solicitation for Public Comment on the Business Practices of Pharmacy Benefit Manager*. <https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Fstructured%2Fbinary%2Fletter%2FLETTERS%2F2022-4-26-Letter-to-Khan-re-FTC-PBM-RFI-v2.zip%2F2022-4-26-Letter-to-Khan-re-FTC-PBM-RFI-v2.pdf>.
- <sup>15</sup> 117<sup>th</sup> Congress of the United States. *S.4293 - Pharmacy Benefit Manager Transparency Act of 2022*. <https://www.congress.gov/bill/117th-congress/senate-bill/4293/text>. Accessed August 1, 2022.
- <sup>16</sup> Council on Medical Service. *Medication "Brown Bagging"*. American Medical Association; June 2016.
- <sup>17</sup> Centers for Disease Control and Prevention. *Monkeypox, Vaccine Considerations*. <https://www.cdc.gov/poxvirus/monkeypox/health-departments/vaccine-considerations.html>. September 28, 2022.
- <sup>18</sup> Centers for Disease Control and Prevention. *ACAM2000 Vaccine*. <https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/acam2000-vaccine.html>. August 9, 2022.
- <sup>19</sup> Erin Banco and Helen Collis. *Before monkeypox outbreak, U.S. officials knew for years they didn't have enough of key shot*. Politico. <https://www.politico.com/news/2022/08/18/u-s-officials-knew-for-years-they-did-not-have-enough-jynneos-vaccine-00052694>. August 18, 2022.

---

<sup>20</sup> Erin Banco and Helen Collis. Before monkeypox outbreak, U.S. officials knew for years they didn't have enough of key shot. <https://www.politico.com/news/2022/08/18/u-s-officials-knew-for-years-they-did-not-have-enough-jynneos-vaccine-00052694>. September 28, 2022.

<sup>21</sup> Adam Cancryn. *Biden admin reroutes billions in emergency stockpile, Covid funds to border crunch*. Politico. <https://www.politico.com/news/2021/05/15/hhs-covid-stockpile-money-border-migrants-488427>. May 15, 2021.

<sup>22</sup> Adam Cancryn. *Biden admin reroutes billions in emergency stockpile, Covid funds to border crunch*. Politico. <https://www.politico.com/news/2021/05/15/hhs-covid-stockpile-money-border-migrants-488427>. May 15, 2021.

<sup>23</sup> U.S. Department of Health and Human Services. Fact Sheet: U.S. Department of Health and Human Services Response to the Monkeypox Outbreak. <https://www.hhs.gov/about/news/2022/07/21/fact-sheet-us-department-of-health-and-human-services-response-to-the-monkeypox-outbreak.html>. September 28, 2022.

<sup>24</sup> Bavarian Nordic Receives U.S. and EU Approvals of its Fill and Finish Vaccine Manufacturing Facility <https://www.globenewswire.com/en/news-release/2022/07/27/2487043/0/en/Bavarian-Nordic-Receives-U-S-and-EU-Approvals-of-its-Fill-and-Finish-Vaccine-Manufacturing-Facility.html>. September 28, 2022.

<sup>25</sup> Food and Drug Administration. *Monkeypox Update: FDA Authorizes Emergency Use of JYNNEOS Vaccine to Increase Vaccine Supply*. <https://www.fda.gov/news-events/press-announcements/monkeypox-update-fda-authorizes-emergency-use-jynneos-vaccine-increase-vaccine-supply>. August 9, 2022.

<sup>26</sup> Lia DeGroot. *HHS Doles Out \$11 Million For U.S.-Based Monkeypox Vax Production*. InsideHealthPolicy. <https://insidehealthpolicy.com/daily-news/hhs-doles-out-11-million-us-based-monkeypox-vax-production>. August 29, 2022.

<sup>27</sup> American Medical Association. Comment Letter to U.S. Senate. <https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Fstructured%2Fbinary%2Fletter%2FLETTERS%2F2022-2-4-Letter-to-Senate-HELP-re-PREVENT-Act-v3.pdf>. February 4, 2022.