



CONNECTICUT Consumer Protection

UConn | SCHOOL OF PHARMACY

PRESCRIPTION DRUG SHORTAGES IN CONNECTICUT

January 1, 2025

[Abstract](#)

This is a report produced by a select group of members from the DCP and UConn to support state Legislators' understanding of the complexities of drug shortages and a list of potential solutions. These solutions include those that the state can and cannot independently implement.

For the solutions that can be implemented at the state level, the logistics, advantages and disadvantages, and costs of each are explored. We hope that you find this report informative and helpful as you assess and debate these potential solutions.

Drug Control Division, Connecticut Consumer Protection (DCP), Hartford, CT and
University of Connecticut School of Pharmacy (UConn), Storrs, CT.

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Executive Summary

Drug shortages have posed a significant health concern and negatively impacted patient care, health, safety, and service delivery across the health care system. Drug shortages may result in delays, cancellation of services, medical errors, decline in health status, abandonment of therapy, use of inferior options, and increased hospital costs. In Connecticut, 13% of residents are affected by a prescription drug shortage.

The supply of prescription drugs can experience shortages for a number of reasons. The market is unpredictable and manufacturers face challenges in producing adequate drug supply to respond to public demand. Manufacturers cannot ramp up production quickly, making it difficult to respond to changes in demand. Raw materials may not be available from suppliers for drug production. Additionally, while the United States Food and Drug Administration's (FDA) process for generic drug approval is long and challenging, once added to the market, the competition driving the cost of a drug down may cause participants to halt production or exit the market completely. Finally, there are very few manufacturers in the drug supply chain, and a lack of redundancy among manufacturers contributes to drug shortages as well.

The FDA has addressed drug shortages through several initiatives, such as issuing guidance for manufacturers in providing the agency with timely, informative notifications about changes in drug production. However, the FDA cannot require pharmaceutical companies to produce a drug, increase production of a drug, or change how much and to whom the drug is distributed among lawful purchasers.

Individual states have implemented various strategies to mitigate drug shortages. California launched an initiative that made it the first state to produce its own generic prescription drugs, including at least one type of insulin, drugs for chronic and high-cost conditions, and drugs that can be delivered by mail. Nebraska created a statewide dashboard to monitor drug shortages within the state. By proactively tracking supply levels and identifying potential drug shortages, the program helped mitigate the impact on patient care. Massachusetts and Ohio issued guidance on drug shortages. Indiana and New Jersey implemented guidance and policies to address improper use and stockpiling. Other states have included compounding as part of their drug shortage mitigation strategies.

To alleviate or prevent prescription drug shortages in the state of Connecticut, the Department of Consumer Protection recommends:

- Facilitating integration of continuous manufacturing (CM) technologies—a method where materials are constantly processed for production of an end product—and capabilities in Connecticut's drugs supply chain to produce drugs in shortages. CM can be placed within existing pharmaceutical or pharmacy facilities to quickly ramp up drug production during a shortage.
- Implementing an information-sharing platform that tracks data from pharmacies and health systems—such as current inventory of specific drugs, drugs that are no longer available for order, activation of contingency plans—to monitor and predict drug shortages.
- Continue to support DEA's efforts around its controlled substances quotas.
- Invest in stakeholders' research and development to improve redundancy in the drug supply chain, ramp up production during drug shortages, or implement pilot programs.

Background

Pursuant to Section 10 of [Public Act 24-19](#), the Commissioner of Consumer Protection, in collaboration with The University of Connecticut School of Pharmacy, shall study incidences of prescription drug shortages in the state and whether the state has a role in alleviating such shortages. Not later than January 1, 2025, the commissioner shall report, in accordance with the provisions of [section 11-4a](#) of the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to consumer protection and public health regarding such study and any recommendations for legislation that would help alleviate or prevent such shortages.

Summary

For decades, drug shortages have posed a significant public health concern and negatively impacted patient care, health, safety, and service delivery across the health care system. The FDA defines a drug shortage as “a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug” (FDA, 2024b). According to the American Society of Health-System Pharmacists (ASHP), a drug shortage is defined as “a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent” (ASHP, 2018). Drug shortages may result in delays, cancellation of services, medical errors, decline in health status, abandonment of therapy, use of inferior options, and increased hospital costs. In Connecticut, 13% of residents are affected by a prescription drug shortage (Moore, 2024).

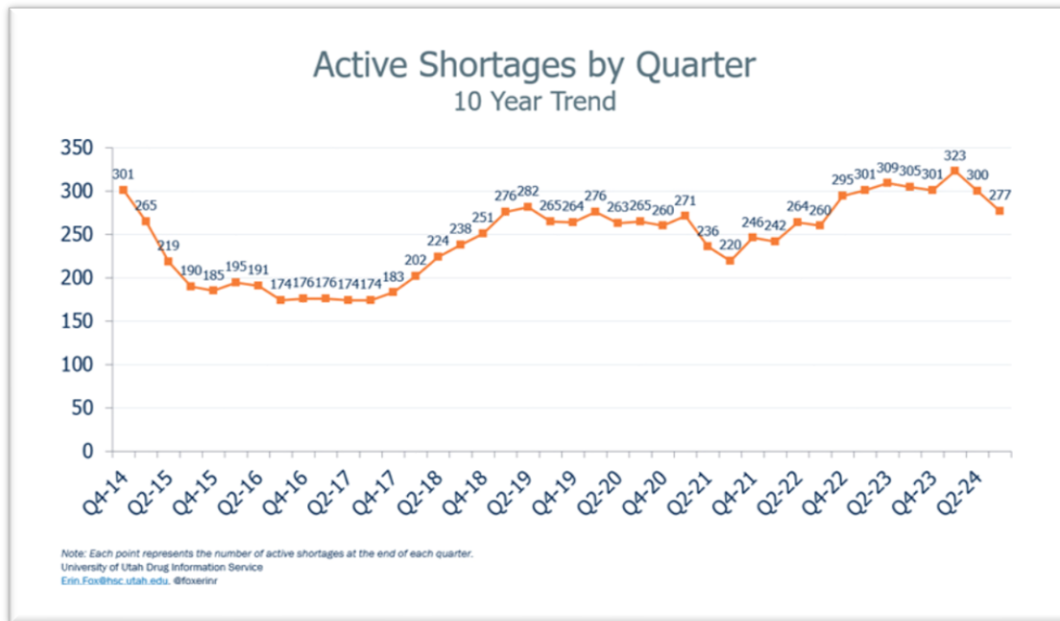
The purpose of this report is to study incidences of prescription drug shortages in the state of Connecticut and whether the state has a role in alleviating such shortages. This report, produced by a select group of members from the Connecticut Department of Consumer Protection (DCP) and the University of Connecticut School of Pharmacy (UConn), provides information on prescription drug shortages at the national and state levels, reasons for drug shortages, consumer and public health considerations, drug shortage mitigation and prevention methods in other states, and recommendations for state legislation that would help alleviate or prevent such shortages. For recommendations that can be implemented in Connecticut, the logistics, advantages and disadvantages, and costs of each are explored. We hope that you find this report informative and helpful as you assess potential solutions.

Prescription Drug Shortage Statistics

Over the past decade, the United States has been experiencing prescription drug shortages nationwide (ASHP, 2024, Figure 1). Starting in the fourth quarter of 2014, the number of shortages decreased from 301 individual drug products to a low of 174 by the end of 2017. However, by early 2018, shortages rose to 200 and fluctuated between 200 and 290 until the end of 2022. Recently, shortages have surged above 290, reaching a record high of 323 in the first quarter of 2024 (ASHP, 2024).

Figure 1

National drug shortages per quarter in the United States over the past 10 years.

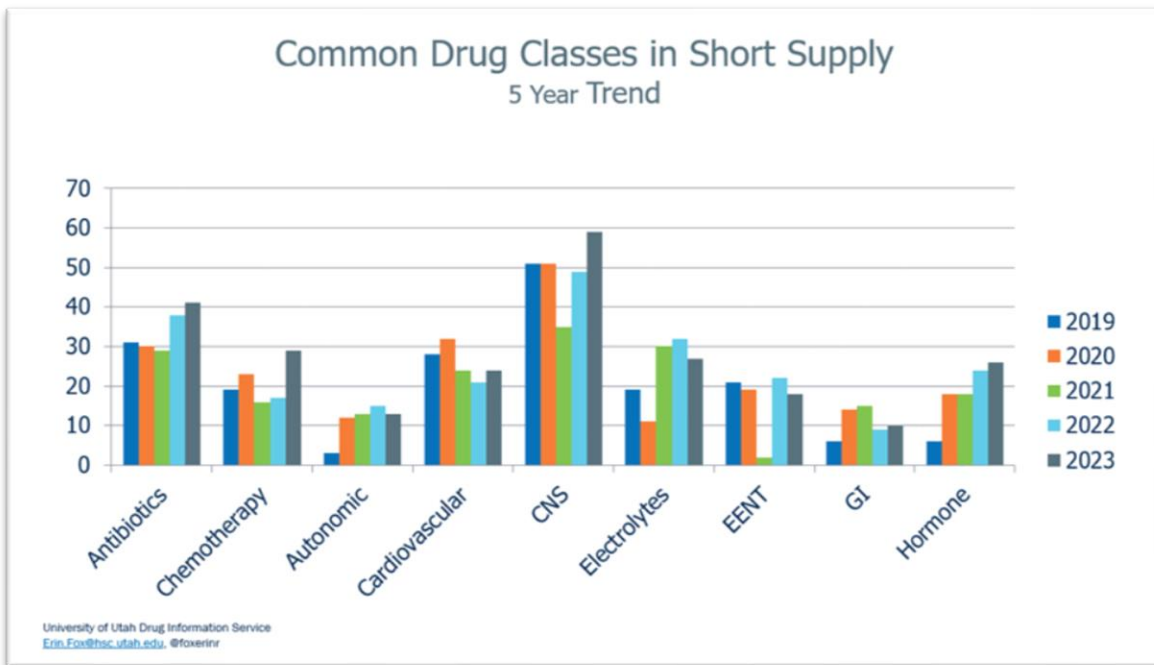


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Shortages can occur in non-injectable drugs (pills, tablets, capsules, solutions, suspensions, or applied on the skin as a patch) or injectable drugs (those that are injected into the fat, muscle, or vein). Drug shortages impact various diseases, as portrayed by the five-year trend data from 2019 through 2023 (see Figure 2). Central nervous system drugs—medications that affect the brain and spinal cord—were the most common drug class to experience shortages, which included a significant shortage of stimulants, such as amphetamine salts to treat attention deficit/hyperactivity disorder, in 2023. Antibiotics, such as amoxicillin, and cardiovascular drugs, such as epinephrine and atropine, also experienced shortages. Chemotherapy drugs do not often experience shortages; however, in 2023, they were the third most common drug class in shortage. Given the specific regimens needed to optimally treat cancer, the loss of drug product in this class can have severe implications for treatment.

Figure 2

Diseases treated by drugs that were in shortage by year, 2019 through 2023.

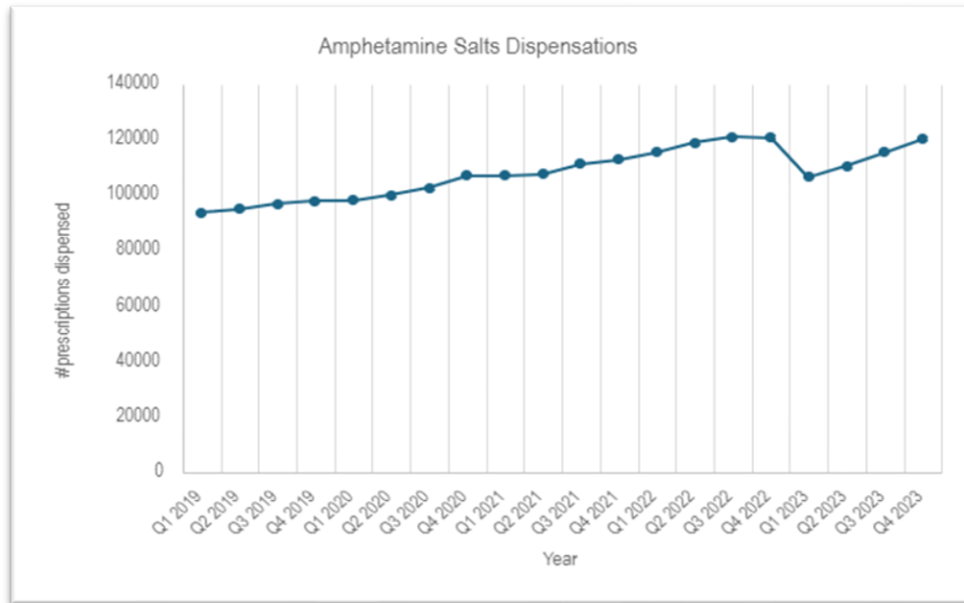


**CNS = central nervous system; EENT = eyes/ears/nose/throat; GI = gastrointestinal
Reprinted from National Drug Shortages Report (p.3), by American Society of Health-Systems Pharmacists. Copyright 2024 by American Society of Health-Systems Pharmacists.*

In Connecticut, drug shortages have affected patients in both retail and hospital pharmacy settings. In retail pharmacies, shortages in stimulants can be observed based on the number of prescriptions dispensed. On October 12, 2022, the FDA's Center for Drug Evaluation and Research (CDER) announced a shortage of immediate-release amphetamine salts (CDER, 2023). This shortage can likely be attributed to a 14% increase in new stimulants prescribed during the COVID-19 pandemic (McPhillips, 2024); in Connecticut, the rising trend can also be observed in Figure 3. Following dispensation data that retail pharmacies report to the Connecticut Prescription Monitoring and Reporting System (CPMRS), the number of amphetamine salts (common brand names: Adderall, Adderall XR, Mydayis) dispensations decreased by approximately 12% during Q1 2023 after the FDA's announcement (see Figure 3). While the therapeutic effects of the amphetamine salts shortage on Connecticut residents were not reported to the CPMRS, qualitative data from Connecticut hospitals suggests that patients are often subjected to seek and/or receive alternative therapies, ration medication, or be left untreated, thus experiencing further delays in treatment, subtherapeutic levels of medication, and decreases in quality of life.

Figure 3

Amphetamine salts prescriptions dispensed in Connecticut by quarter, 2021 to 2023.*



**Specifically, the drug dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate CPMRS (2024), Connecticut Department of Consumer Protection.*

Hospitals in Connecticut have also reported¹ shortages from 2021 to 2023. Yale New Haven Health, the state’s largest health system, tracked over 100 shortages each year across their four hospitals in the state. Stamford Hospital experienced a growing number of shortages, with 22 reported in 2021, increasing to 55 in 2022, and reaching 74 in 2023; Hartford HealthCare also experienced a similar trend. Even beyond prescription drugs, several medical devices and equipment used to administer drugs were in shortage as well, including infusion systems that deliver fixed amounts of medications to patients.

Table 1 outlines specific drugs that hospitals in Connecticut commonly report to be in shortage. Some drug shortages were experienced by more than one hospital, such as gentamicin injection (an antibiotic) and contrast media (dye used for imaging exams) in 2021. Other drug shortages spanned more than one year across various hospitals, such as albuterol nebulizer solution (treats breathing problems) and lorazepam injection (treats anxiety or seizures) in both 2022 and 2023.

¹ The Connecticut Hospital Association sent a survey to its members (68 recipients across 12 health systems and 11 other hospitals), on behalf of DCP, to gather data and information for this report. Five health systems completed the survey, and their responses are included throughout this report.

Table 1
Common drugs in shortage reported¹ by Connecticut hospitals.

2021	2022	2023
<ul style="list-style-type: none"> • Lorazepam injection • Diazepam injection • Dextrose 20% injection • Cefazolin injection • Contrast media • Gentamicin injection* • Bupivacaine injection • Sodium acetate injection • Multivitamin injection* 	<ul style="list-style-type: none"> • Lorazepam injection* • Diazepam injection • Dextrose 50% injection • Cefazolin injection • Contrast media (for imaging exams) • Hydromorphone injection • Albuterol nebulizer solution* • Methylprednisolone injection • Hydrocortisone injection 	<ul style="list-style-type: none"> • Lorazepam injection* • Diazepam injection* • Liposomal doxorubicin* • Hydromorphone (injection and tablets)* • Albuterol nebulizer solution • Ketamine injection • Clindamycin injection* • Bupivacaine injection • Methylprednisolone injection* • Hydrocortisone injection

Note: Common drug shortages that occurred at more than one hospital during the same year are denoted with an asterisk ()*

Compiled by DCP from various Connecticut hospitals, 2024.

Reasons for Prescription Drug Shortages

The prescription drug market can be unpredictable, and manufacturers often face the challenge of having adequate drug supply to respond to public demand. When demand for a drug suddenly increases, often times a manufacturer cannot ramp up production quickly enough to prevent a shortage. For example, propofol, an anesthetic, experienced a shortage in 2020 because of an increased demand to maintain sedation in certain COVID-19 patients in intensive care units (FDA, 2020); consequently, health care providers had to use alternative therapies with greater potential for side effects in patients (Sheikh, 2020). A decrease in the supply of one drug can cause consumers or health systems to seek alternatives and begin purchasing other drugs within the same therapeutic drug class or different concentrations or package sizes of the drug in shortage.

Manufacturing facility issues can contribute to drug shortages as well. Manufacturers may stop or reduce production because of shipping delays, natural disasters, damage to the building or equipment, or problems in quality control (CDER, 2024a). For example, many hospitals in Connecticut experienced intravenous fluid shortages after a manufacturing site in North Carolina closed production due to damage from Hurricane Helene in September 2024 (Baxter, 2024).

In some cases, even when manufacturing facilities are operating at sufficient capacities, raw materials, such as active pharmaceutical ingredients (APIs) or excipients (non-active ingredients), may not be available from suppliers for drug production. Common prescription drugs in shortage due to API shortages include amphetamine salts, naltrexone (treats alcohol and opioid use disorders), and methotrexate injection (chemotherapy drug) (FDA, 2024a). In drug formulation, excipients are just as crucial as APIs; they bind, coat, disintegrate, preserve, and flavor the drug product to optimize drug delivery, performance, and effectiveness (U.S. Pharmacopeia, 2024). However, due to the lack of tracking in the excipient supply chain, many types of quality and supply chain issues are unknown (U.S. Pharmacopeia, 2024). This makes it difficult to identify the exact causes of excipient shortages and establish viable solutions.

Complex manufacturing and regulatory requirements can further hinder prompt resolution of drug shortages, making it difficult to attract new manufacturers and increase production to establish redundancy in the drug supply chain (ASPE, 2024). Before commencing production on a generic drug, manufacturers must submit an application to the FDA to demonstrate that the generic drug is equivalent to, and can be substituted for, the same brand-name drug (see Table 2) (CDER, 2017). Because the generic drug application contains complex data and information, the review process may take several years and an average of three review cycles before the manufacturer receives FDA approval for drug production (United States Government Accountability Office, 2019).

Table 2

FDA-Reviewed Items on a Generic Drug Application.

- | | |
|--|--|
| • The generic drug is “pharmaceutically equivalent” to the brand. | • The “inactive” ingredients of the drug are safe. |
| • The manufacturer is capable of making the drug correctly. | • The drug does not break down over time. |
| • The manufacturer is capable of making the drug consistently. | • The container in which the drug will be shipped and sold is appropriate. |
| • The “active ingredient” is the same as that of the brand. | • The label is the same as the brand-name drug’s label. |
| • The right amount of the active ingredient gets to the place in the body where it has effect. | • Relevant patents or legal exclusivities are expired. |

CDER (2017)

Manufacturers are also subject to market economics, which may lead them to produce drugs at the lowest cost. An FDA director noted that “a single generic competitor can lead to price reductions of 30%, while five competing generics are associated with price drops of nearly 85%” (CDER, 2022), creating slim margins for profit. This competition may cause market participants to halt production of a drug or exit the market completely to optimize profitability. With fewer manufacturers in the drug supply chain, a lack of redundancy among manufacturers contributes to drug shortages as well. Further, with many manufacturers and health systems implementing “just-in-time” manufacturing or inventories, drugs are produced and maintained at the minimum amount to satisfy demand. However, this method allows for less flexibility when production of a drug is interrupted due to insufficient backup stock and inability to establish a buffer (Shukar et al., 2021).

In addition to the reasons described above, quotas for controlled substances manufacturing and procurement may affect drug shortage mitigation efforts. Because schedule I and II controlled substances² have a high potential for abuse, the federal Drug Enforcement Agency (DEA) sets quotas to limit the supply of controlled substance APIs to manufacturers (FDA, 2023). Schedule II controlled substances commonly in shortage include opioids for treating pain, such as hydromorphone and morphine, and stimulants. Each schedule I and II manufacturer is required to apply for a quota allotment (DEA, 2017). After the FDA

² DEA classifies drugs into five schedules based on their acceptable medical use and potential for abuse or dependence. Schedule I drugs have the highest potential for abuse and no accepted medical use, while Schedule V drugs have the lowest potential for abuse.

DEA. 10 July 2018. Drug Scheduling. Retrieved from <https://www.dea.gov/drug-information/drug-scheduling> on 25 November 2024.

announced the amphetamine salts shortage in 2022, a DEA internal analysis of data that year showed that manufacturers only sold approximately 70% of their yearly allotted quota; available data for 2023 also showed a similar trend (FDA, 2023). DEA then requested manufacturers to relinquish any remaining quota allotments if there were no plans to increase production—this would allow the agency to redistribute allotments to other manufacturers (FDA, 2023). Though 17 out of 18 manufacturers informed DEA that they planned to use their remaining allotments and increase production, amphetamine salts have consistently remained on the FDA’s drug shortage database since 2022 (FDA, 2024d). More recently, DEA cited the “lengthy process to reallocate quota” and unused quotas as existing challenges around these limits (Strait, 2024). While quotas were established to prevent abuse and diversion, they may negatively impact a manufacturer’s ability to ramp up production of controlled substances in shortage.

Lastly, in up to 60% of cases, manufacturers are not required to and do not disclose the reasons behind drug shortages (ASHP, 2024). This lack of transparency complicates efforts to predict future shortages because underlying factors remain unidentified and unaddressed.

Consumer and Public Health Considerations

As previously mentioned, prescription drug shortages can negatively impact patients’ medical care and cost burden. Patients may be prescribed alternative therapies, which can be less effective or have additional side effects compared to the drug in shortage (FDA, 2013). Treatments are often rescheduled or canceled, and patients may eventually abandon therapy due to the unavailability of drugs and inability to fill prescriptions—all of which lead to adverse health outcomes (ASPE, 2023). Many drugs in shortage are generic drugs, which can include sterile injectables. Sterile injectables are difficult to produce but remain essential for treating conditions like cancer and autoimmune diseases. Shortages in sterile injectables compromise treatment and can have devastating effects on patient outcomes. With over 20,000 new cancer diagnoses estimated in Connecticut in 2024 (American Cancer Society, 2024), the lack of access to chemotherapy drugs can cause delays or altered treatment plans, increasing the risk for morbidity and mortality (ASPE, 2024). For example, due to a shortage in liposomal doxorubicin (chemotherapy drug), one hospital in Connecticut had to divert a patient to an out-of-state clinic to receive treatment.¹

Connecticut hospitals have also reported operational challenges as a result of drug shortages, such as higher costs and fluctuating staffing demands. Though several in-state hospitals can strategically maintain medication stock if certain shortages are predicted, they often must source more expensive products from non-contracted vendors or 503B outsourcing facilities³ (ASHP, 2023). A 2023 ASHP survey found that drug shortages can increase a hospital’s drug budget by up to 20% (ASHP, 2023). In addition, hospitals in Connecticut reported increased labor needed to manage drug shortages. While some facilities have a dedicated, full-time team to manage drug shortages, other facilities may reallocate staff from direct patient care responsibilities. Regardless, staff are necessary to track drug shortages, regularly count inventory, procure medication, create mitigation strategies, provide education on changes in prescribing practices or safe usages of alternative therapies, and update the facility’s electronic health records system with alerts and alternatives (and reverse them once the shortage is resolved). If staff time and resources are overextended, shortages can increase the risk of patient harm, including medication errors resulting in harm.

³ 503B outsourcing facilities manufacture large batches of drugs for various healthcare settings and can fill patient-specific prescriptions. They produce compounded sterile preparations, are subject to FDA oversight, and must comply with certain requirements ensuring quick and safe production to meet consumer demands efficiently and cost-effectively.

Drug shortages can result in medication errors for several reasons. A 2012 Institute for Safe Medication Practices study reported that during drug shortages, the use of an alternative drug, dosage form, or dosage strength accounted for 27% of patient harm in hospitals (Hughes et al., 2015). Hospitals in Connecticut have also identified instances of shortage-related medication errors (see Table 3).

Table 3

Cases of medication errors associated with drug shortages, reported by a Connecticut hospital.

Drug in Shortage	Alternative Therapy Used	Associated Medication Error
Fosphenytoin (anti-seizure drug)	Phenytoin (anti-seizure drug)	Phenytoin was administered into the vein at a faster rate than recommended and resulted in patient harm
Betamethasone (steroid)	Dexamethasone (steroid)	Dexamethasone was administered into the vein instead of the muscle for multiple patients
Ketamine injection, 1 milliliter prefilled syringes (anesthetic)	Compounded ketamine injection, 1 milliliter prefilled syringes	The compounded ketamine injection syringes were incorrectly filled by the 503B outsourcing facility with 1.4 to 1.5 milliliters and resulted in incorrect dosing to patients
Pentamidine nebulizer solution (produces a fine mist for inhalation)	Pentamidine injection solution	Pentamidine injection solution was administered into the vein rather than by nebulization
Viscous lidocaine solution, 2% (numbing agent)	More concentrated lidocaine solution	Administering the more concentrated lidocaine solution resulted in an ICU admission

Compiled by DCP from various Connecticut hospitals, 2024.

Drug shortages can lead to higher medical costs for patients and consumers as well (ASPE, 2023). The FDA’s drug shortage database, which was linked to national prescription sales data from 2016-2020, found that even when patients were able to switch to alternative therapies, the price of substitute drugs was at least three times higher than the price of the drug in shortage (ASPE, 2023). In retail pharmacy settings, drugs in shortage saw a 14% increase in price compared to a 1% increase in hospital pharmacy settings. (ASPE, 2023). As previously discussed, drug shortages can result in adverse patient health outcomes, which can then require additional medical care and further increase health care costs (ASPE, 2023). Because of the overall impact on health care spending (i.e., increased drug prices and labor), it is possible that prescription drug shortages can increase health insurance premiums for patients and consumers (ASPE, 2023).

When patients and consumers experience prescription drug shortages, they may try to source the product on their own, such as turning to the Internet to purchase drugs. In a 2021 nationwide survey conducted by the Alliance for Safe Online Pharmacies, 66% of respondents said they would likely buy medication online if it was unavailable at their local pharmacy (ASOP, 2023). However, consumers and patients may

unknowingly buy from online pharmacies that operate illegally without the required regulatory licenses or registrations (Jillani et al., 2023). This increases the risk of harm to a consumer or patient, as these medications offered by illegal, online pharmacies are often unapproved, counterfeit, or otherwise unsafe for use (CDC, 2024).

Prescription Drug Shortage Prevention and Mitigation Methods at the Federal Level and in Other States

At the federal level, the FDA has addressed drug shortages through several initiatives. To monitor and prevent or mitigate shortages, the FDA has issued guidance for manufacturers to ensure they provide the agency with timely, informative notifications about changes in drug production (FDA, 2024c). However, CDER cannot require pharmaceutical companies to produce a drug, increase production of a drug, or change how much and to whom the drug is distributed (among lawful purchasers) (CDER, 2024b).

Individual states have implemented various strategies to mitigate drug shortages. California launched the CalRx initiative in January 2019, and later codified the California Affordable Drug Manufacturing Act into law in 2020, making it the first state to produce its own generic prescription drugs. Considerations for determining which generic drugs the state would produce include at least one type of insulin, drugs for chronic and high-cost conditions, and drugs that can be delivered by mail (NASHP, 2022). California partnered with CivicaRX, a nonprofit drug manufacturer, to develop and produce generic biosimilar⁴ insulin. This involved two main steps: manufacturing APIs and finishing and filling into vials or pens. The CalRx Legislative Report April 2023 highlighted significant achievements of the CalRx insulin program; by controlling the production processing and setting transparent, low prices, California was able to offer insulin at \$30 per vial compared to the standard \$300 (California Health and Human Services, 2023). While CalRx was primarily developed to improve prescription drug accessibility and affordability, the initiative addressed potential insulin shortages by ensuring a steady stock in the drug supply chain.

Nebraska created a statewide dashboard to monitor drug shortages within the state. To assess and communicate drug shortages to patients and doctors, Nebraska utilized a web mapping application for in-state pharmacies to report medication supply status (Nebraska DHHS, 2023). Medication statuses were marked with specific symbols to represent good or normal supplies versus low supplies. By proactively tracking supply levels and identifying potential drug shortages, the program helped mitigate the impact on patient care. Although Nebraska's drug supply shortage dashboard is not currently operational,⁵ and all medication maps have been removed, the information and alerts were available to the public when the dashboard was active.

Massachusetts and Ohio issued guidance on drug shortages, with Ohio providing specific instructions for hospitals, clinics, and other healthcare facilities on how to find drug shortage information, verify licensed 503B outsourcing facilities, and use these facilities to compound drugs on the FDA's shortage list. During the COVID-19 pandemic, Indiana's Board of Pharmacy and Medical Licensing Board issued guidance for prescribers and pharmacists to prevent shortages of drugs used for COVID-19 prevention, cautioning

⁴ A biosimilar is a type of medication that is very similar to a biologic—a drug already approved by the FDA. A biosimilar replicates the reference product biologic in terms of safety, purity and effectiveness. (Department of Healthcare and Access Information, 2023)

⁵ In an email to DCP, Nebraska DHHS explained that the drug supply shortage dashboard was developed in 2023 and coordinated in partnership with the Nebraska Pharmacists Association. If the drug is in need by the general public, the dashboard is then activated to help locate prescriptions in short supply.

against improper use and stockpiling. New Jersey also implemented policies prohibiting prescribers from writing prescriptions for COVID-19 medications that were in short supply for themselves, family, friends, or for stockpiling.

Other states have included compounding as part of their drug shortage mitigation strategies. Compounded drugs are medications tailored to individual patient needs but are not FDA-approved. Compounding is regulated by state boards of pharmacy and the FDA, with outsourcing facilities subject to their own set of standards (FDA, 2018). Mississippi launched the Shortage Response Pharmacy on Demand pilot program in response to hospital drug shortages. North Mississippi Health Services partnered with a technology company that produces medications on demand; this partnership reduced concerns of the vulnerability of generic medications to international supply chain disruptions (NMHS, 2024). Lidocaine—which was on the drug shortage list for over a decade—was the first medication compounded. Missouri also established requirements allowing Class B (hospital) pharmacies to compound and provide medications during shortages (Missouri Register, 2023). Medications can be compounded for hospital patients if the compounded preparation matches the dosage form and strength of the drug in shortage (Missouri Register, 2023).

Fiscal Impact/Considerations

The DCP will provide more specific, appropriate fiscal information depending on the recommendations the legislature decides to pursue. The recommendations below involve various stakeholders within the drug supply chain. If the legislature creates prescription drug shortage mitigation policies, the legislation should account for additional costs and operational resources associated with such policies on administrative agencies and for industry stakeholders.

Department of Consumer Protection Recommendations

To alleviate or prevent prescription drug shortages in the State of Connecticut, DCP recommends the following measures:

- Issue guidance for or require manufacturers that are registered with DCP to report any discontinuation or interruption in the manufacturing of finished prescription drug products or raw materials. In February 2024, the FDA issued guidance to report the same information to the agency (FDA, 2024c). Although this FDA notification is a “non-binding recommendation” and not mandated, it would provide greater visibility in the drug supply chain and allow stakeholders such as other drug manufacturers, 503B outsourcing facilities, health systems, and pharmacies, time to prepare or adapt for an impending drug shortage. Like the FDA guidance, state guidance would also be “non-binding.” This information reflects a national perspective, and the information may not be added to the FDA list immediately. If manufacturers were to report to DCP, it would provide more timely information that would be more directly applicable to Connecticut.
- Facilitate integration of continuous manufacturing (CM) technologies and capabilities in Connecticut’s drug supply chain to produce drugs in shortages. CM is a method where materials are constantly processed for production of an end product (Manufacturing Extension Partnership, n.d.). Certain CM technologies can readily make injectable drugs while minimizing waste of crucial APIs or excipients; some of these technologies contain internal processes for quality testing that can detect issues in real-time to further minimize waste. Comparatively, in traditional production where a whole batch is created prior to quality testing, entire batches may be wasted when quality issues arise.

In addition, certain CM equipment can be placed within existing pharmaceutical or pharmacy facilities, such as 503B outsourcing facilities or hospitals within the state, to quickly ramp up drug production during a shortage. For sterile products, the cost of creating or maintaining separate sterile facilities is reduced if existing facilities are used. Theoretically, the equipment could also be housed within a mobile unit (i.e., a trailer with a clean room) and relocated near areas experiencing drug shortages; this would further optimize the drug supply chain by minimizing product transportation time.

Despite the advantages of implementing CM technologies and capabilities, there are also labor, sterility, and other logistical factors to take into consideration. With additional equipment in facilities, more staff time and resources need to be dedicated for operating the equipment and maintaining it when not-in-use. Sterility and clean room requirements can also limit what facilities CM equipment can be placed in. If CM equipment is implemented in existing facilities, it can reduce the amount of space for other purposes or impose on current operations; if housed within a mobile unit, the equipment must be safely stored and transported without sustaining damage or contaminating sterile areas. Lastly, while CM technologies available in Connecticut can be adapted and changed according to the desired end drug product, it has not yet been tested for purposes other than its current use. This recommendation may have fiscal implications if the state were to invest in such technologies.

- Implement an information-sharing platform that tracks data from pharmacies and health systems—such as current inventory of specific drugs, drugs that are no longer available for order, activation of contingency plans—to monitor and predict drug shortages. A Connecticut hospital shared that with the resources currently available, information on drug shortages is difficult to assess; for example, they would like to know if a shortage will be short-term or last for months. Although ASHP and the University of Utah’s Drug Information Services tracks drug shortages nationally, they do not track shortages regionally and cannot always distinguish differences between a limited supply or complete absence of a drug (Whitledge et al., 2023). Sharing timely, localized data on drug shortages would be invaluable for hospitals and other stakeholders’ decision-making on prevention or mitigation strategies. This recommendation may also have fiscal implications if the state were to invest in such technologies.
- To help inform controlled substance quotas, DCP has provided DEA with aggregate data on controlled substance dispensations from CPMRS. As part of establishing and reviewing their quotas, DEA routinely solicits DEA-registered manufacturers to provide data on controlled substances (DEA, n.d.). To complement such data on inventory, procurement, and distribution/sales, DEA also plans to identify “new” data—which may include CPMRS dispensations (Strait, 2024). Further, the data provided by the Department aligns with DEA’s intent to move towards real-time data collection, as the CPMRS data is currently published quarterly on the DCP Prescription Monitoring Program webpage (Strait, 2024). The DCP will continue to support DEA’s efforts around its controlled substance quotas.
- Invest in stakeholders for their research and development to improve redundancy in the drug supply chain, ramp up production during drug shortages, or implement pilot programs. For example, in-state 503B outsourcing facilities already have manufacturing equipment and sterility and quality systems in place that, if there were a shortage in a drug of the same drug class that

the facility currently produces, they could respond quicker to market needs. However, if the facility were asked to produce drugs in other drug classes, this would increase the time and expense needed to implement the new drug product in their portfolio. One 503B outsourcing facility in Connecticut reported that it takes at least six months from the time they decide to create a new product to when they ship the final product to hospitals and health systems—and possibly more time and expense if they need to acquire new equipment or develop new processes. 503B outsourcing facilities also take into consideration the amount of time they can legally sell the compounded drug—once the FDA removes a drug from its drug shortage list, facilities only have 60 additional days to fill orders of the compounded drug (FDA, 2018). To minimize the time required to start compounding and optimize the time period during which facilities can fill orders, state funding can incentivize 503B outsourcing facilities to develop manufacturing and quality processes for drugs prone to shortage. However, because this would involve predicting future drug shortages that might not transpire, a cost analysis could be performed to explore the types and extent of state funding.

We thank you for the opportunity to discuss this important issue. The Department of Consumer Protection looks forward to working with the legislature to provide further guidance and advice upon request.

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