



NATIONAL JOURNAL

Does this mean I die?': A lack of key drugs has families worried, Congress on alert

From Tylenol to chemotherapy treatments, shortages in the U.S. increased 30 percent between 2021 and 2022.



(AP Photo/Jenny Kane, File)

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A few months after Laura Bray's daughter, Abby, was diagnosed with leukemia, a shortage of her chemotherapy drug delayed treatment in the spring of 2019.

"Does this mean I die?" Abby asked her mother, in an emotional exchange Bray recounted during a House subcommittee hearing Thursday.

Bray set out to find the treatment herself, and she succeeded. Abby would encounter two more drug shortages in her regimen between the fall of 2019 and early 2020. By that time, Bray had founded the group Angels for Change, which

she now heads as “chief change maker” to help other patients encountering similar issues.

“All of [the shortages] were crises; all of them were medically necessary for her survival; all of them were really knowable,” Bray told *National Journal*. “We generally know how many kids are going to get leukemia each year; we generally know what they need to be using. It was quite startling for me that there wouldn’t be additional or extra supply, or things in place for these medicines.”

The good news: Bray told lawmakers that 13-year-old Abby is doing well.

While the issue has been a concern for a long time, new drug shortages in the U.S. increased 30 percent from 2021 to 2022, according to a [March report](https://www.peters.senate.gov/newsroom/press-releases/peters-report-finds-continued-shortages-of-medications-present-significant-health-and-national-security-risk) (<https://www.peters.senate.gov/newsroom/press-releases/peters-report-finds-continued-shortages-of-medications-present-significant-health-and-national-security-risk>), from the majority staff of the Senate Homeland Security and Governmental Affairs Committee. By the end of 2022, shortages had hit a five-year high.

The issues underlying drug shortages are complex and multifaceted, and there is some disagreement around best solutions.

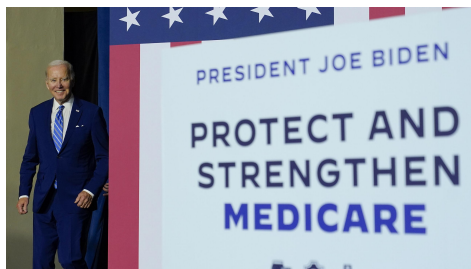
Homeland Security Committee Chair Gary Peters wants to first examine the supply chain to determine where the issues are. “The most important thing out of the box is just having more transparency as to where the actual gaps are when it comes to the supply chain,” he said.

The Senate report recommends the federal government better coordinate between agencies and industry partners to map the entire pharmaceutical supply chain. Neither the federal government nor the industry has “end-to-end visibility.”

David Gaugh, interim CEO of the Association for Accessible Medicines, a generic-drug trade group, told *National Journal* that companies are already required to disclose certain information to the Food and Drug Administration under the CARES Act, enacted in 2020.

Any entity that registers with the FDA for finished drug products, active pharmaceutical ingredients (APIs), and other types of listed drugs is required to disclose to FDA annually the amount that was manufactured, prepared, propagated, compounded, or processed.

Gaugh raised concerns over confidentiality when asked about greater transparency: “In our industry, these are trade-secret pieces of information—where I get my API from—because I don’t necessarily want other competitors getting involved and getting that same product. ... Brand companies could use that as another avenue for restricting us.”



DAILY

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An unprecedented default could lead to delayed payments to medical providers and force states to pick up the entire tab.

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House Energy and Commerce Committee ranking member Frank Pallone said the CARES Act was not enough to address drug shortages, partly because FDA’s current reporting requirements don’t allow the agency to determine which suppliers of active pharmaceutical ingredients manufacturers rely on.

“FDA has repeatedly told us that with its limited tools, it’s simply not capable of using its existing authorities to directly prevent or mitigate a shortage,” Pallone said at the Thursday hearing.

Providing more information to other stakeholders in the supply chain can help them make decisions, said Vimala Raghavendran, vice president of informatics product development at the U.S. Pharmacopeia.

“Most of the time the organizations and people that are responsible for getting drugs to patients when they need it are not within the federal government. ... They don’t have that full view of the supply chain in order to be able to make informed decisions that would protect patients,” Raghavendran told *National Journal*.

Todd Ebert, president and CEO of the Healthcare Supply Chain Association, said that the more “the manufacturers know that we’re looking for that information and we’re looking for a strong supply chain, that is their incentive to really build on a strong supply chain.”

“No one wants to go through what we did with the pandemic,” Ebert said.

The Healthcare Supply Chain Association represents health care group purchasing organizations, also known as GPOs, which negotiate the purchase of supplies for providers.

The association has called on Congress, as it reauthorizes the [Pandemic and All-Hazards Preparedness Act](https://supplychainassociation.org/wp-content/uploads/2023/03/HSCA-Senate-HELP-Committee-PAHPA-Response-3.29.23-FINAL.pdf) (<https://supplychainassociation.org/wp-content/uploads/2023/03/HSCA-Senate-HELP-Committee-PAHPA-Response-3.29.23-FINAL.pdf>), to grant the federal government authority to require manufacturers and providers of raw materials and active pharmaceutical ingredients to disclose information about quantity, location, and predictable shortages. They request that some or all of that information be shared with other supply-chain stakeholders.

GPOs also get their share of attention from lawmakers as potential sources of drug shortages. “Manufacturers blamed GPOs’ and distributors’ contracting practices for driving prices down and eliminating manufacturers from the

market, pointing to 'low price clauses' and 'most favored nation clauses' as problematic," the Senate report stated. "The GPOs interviewed by Majority Committee staff denied contributing to drug shortages and 'race to the bottom prices.'"

Rep. Morgan Griffith, who chairs the Energy and Commerce Oversight and Investigations Subcommittee, said in his opening remarks for the hearing Thursday that "the root cause of drug shortages is a profound market failure caused by economic forces unique to the drug market. Middlemen, such as pharmaceutical benefit managers (PBMs) or group purchasing organizations (GPOs), do not care to look for ways to mitigate shortages."

Ebert told *National Journal* that "GPOs don't go out and say, 'Give us the best price or you go out of business in three months.' Our approach is, we want to develop a competitive, fair price so that we can have a long-term, valuable, sustainable supply chain."



DAILY

Code Blue: Overcrowded emergency rooms hurting patient care

Hospitals warn that a lack of long-term beds means patients often face lengthy waits, inadequate care

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Lawmakers are also looking for ways to address drug shortages caused by sudden spikes in demand. A bill introduced last month by Reps. Sara Jacobs and Cory Mills would require manufacturers to notify FDA within 48 hours after there was a sustained increase in demand for a drug for six weeks. The pair introduced the bill in response to shortages of children's Tylenol and Motrin; [news](https://www.washingtonpost.com/dc-md-va/2022/12/01/childrens-tylenol-ibuprofen-shortages/) (<https://www.washingtonpost.com/dc-md-va/2022/12/01/childrens-tylenol-ibuprofen-shortages/>), [outlets](https://www.axios.com/2023/01/05/why-childrens-tylenol-shortage/) (<https://www.axios.com/2023/01/05/why-childrens-tylenol-shortage/>), over the winter reported empty shelves as parents looked to treat their sick kids.

“It would give FDA a little bit more notice so that they can start implementing some of their mitigating strategies to prevent a shortage or to mitigate the impact of a shortage,” said Michael Ganio, senior director of pharmacy practice and quality at ASHP, which represents pharmacists and distributes its own drug-shortage list.

Craig Burton, senior vice president of policy and strategic alliances at the Association for Accessible Medicines, questioned the utility of this information. “If I get a significant increase in orders, does that mean that there’s a massive spike in demand? Or does that simply mean that I did a heck of a job stealing market share?” Burton said. “I as a manufacturer don’t know that, so that data is literally meaningless.”

Until solutions are developed to address and prevent drug shortages, losing access to needed treatments can impact patient care and put physicians in a bind.

Shortages disproportionately impact pediatric hospitals, according to [research \(https://www.childrenshospitals.org/content/supply-chain-services/case-study/pediatric-drug-shortage-trends-and-best-practices-for-mitigation-strategies\)](https://www.childrenshospitals.org/content/supply-chain-services/case-study/pediatric-drug-shortage-trends-and-best-practices-for-mitigation-strategies), from the Children’s Hospital Association and Vizient, a health care consulting firm and group purchasing organization.

“What we know is that there are way more sick grownups in the world than there are sick kids,” said Terri Lyle Wilson, director of pharmacy and supply-chain services at the Children’s Hospital Association. “So anytime we use data to project risk or to direct our efforts towards what we should focus on, the children will fall out of the data. ... A drug that is uniquely and disproportionately pediatric won't be on the radar if we don’t call specific attention to it.”

José Cabañas, president of the National Association of EMS Physicians, said drug shortages can lead to medication errors as paramedics have to quickly adapt to a different drug or a different concentration.

“The medications used in EMS are critical to saving lives before and during transport,” Cabañas said in a statement to *National Journal*. “We lack the buying power of large hospital systems, especially among smaller and volunteer EMS agencies in rural areas, to receive priority in the distribution of limited drugs. We need different concentrations than hospitals, and we need them consistently to avoid switching medications and doses to prevent medical errors.”

Jeffrey Davis, director of regulatory and external affairs at the American College of Emergency Physicians, said emergency physicians need warnings and guidance in best practices when there is a shortage. He noted that the problem of handling drug shortages comes on top of other challenges emergency departments are facing.

“We’re already overwhelmed, and this just adds to the chaos that’s going on right now,” Davis said. “That’s going to lead to poor patient outcomes and also increased burnout by physicians, which is going to exacerbate the staffing shortages.”