Drug Shortages Near an All-Time High, Leading to Rationing

A worrisome scarcity of cancer drugs has heightened concerns about the troubled generic drug industry. Congress and the White House are seeking ways to address widespread supply problems.

By Christina Jewett

May 17, 2023  Updated 9:31 a.m. ET

Thousands of patients are facing delays in getting treatments for cancer and other life-threatening diseases, with drug shortages in the United States approaching record levels.

Hospitals are scouring shelves for supplies of a drug that reverses lead poisoning and for a sterile fluid needed to stop the heart for bypass surgery. Some antibiotics are still scarce following the winter flu season when doctors and patients frantically chased medicines for ailments like strep throat. Even children's Tylenol was hard to find.

Hundreds of drugs are on the list of medications in short supply in the United States, as officials grapple with an opaque and sometimes interrupted supply chain, quality and financial issues that are leading to manufacturing shutdowns.

The shortages are so acute that they are commanding the attention of the White House and Congress, which are examining the underlying causes of the faltering generic drug market, which accounts for about 90 percent of domestic prescriptions.

The Biden administration has assembled a team to find long-term solutions for shoring up the pharmaceutical supply chain, at a time when the United States remains heavily reliant on medicines and drug ingredients from India and China. And in recent weeks, generic drug makers, supply-chain experts and patient advocates have appeared before lawmakers to discuss the problems.

The scarcity of generic forms of chemotherapy to treat lung, breast, bladder and ovarian cancers has only heightened concerns.

“This is, in my opinion, a public health emergency,” said Dr. Amanda Fader, a professor at the Johns Hopkins School of Medicine and a president-elect of the Society of Gynecologic Oncology, “because of the breadth of the individuals it affects and the number of chemotherapy agents that are in shortage right now.”

The American Cancer Society last week warned that delays caused by the shortages could result in worse outcomes for patients.

“If these drugs are not available, people are going to get inferior care,” Dr. William Dahut, the society’s chief medical officer, said. “That’s the bottom line. These aren’t third- or fourth-line drugs where there are multiple other agents around. These are used up front for people you are trying to cure.”

Ryan Dwars beat pancreatic cancer in 2021, but late last year a scan showed cancerous spots on his liver. Mr. Dwars, 39 and a father of two young children, had hoped to receive his final four doses of chemotherapy in April.

Then his doctor delivered stunning news: He didn’t make the cut of those given priority for the treatment.

“The light at the end of the tunnel was within sight,” Mr. Dwars, a special education teacher in Iowa City, said. “It made it even worse to be so close — and now this.”

Laura Bray, who founded a nonprofit called Angels for Change, works as a liaison among patients, health systems and drug companies to “micro-source,” as she calls it, hard-to-find medications.
“Will we have the resolve and sense of urgency to fix this?” asked Ms. Bray, an adjunct business professor who has been providing information to the White House and Congress. “It’s possible. It can be done. It happens in other supply chains. But we have to focus on it and have to think about ending it — instead of mitigating it. I think the jury’s out on that.”

For Mr. Dwars, Ms. Bray contacted a maker of cisplatin, the chemo drug he needed and arranged for a supply to be sent within days and for others at his hospital. Some in states around the country have not been as fortunate, encountering frightening gaps between treatments.

The White House team working on the broader issue of longstanding drug supply breakdowns includes national security, economic and health officials, according to James McKinney, a spokesman for the Food and Drug Administration. Bloomberg reported earlier on the White House involvement.

Officials have been debating possible measures like tax incentives for generic drugmakers and greater transparency around generic drug quality. The current incentives favor drugmakers with the lowest prices, which includes those that might cut corners — leading to disruptive plant shutdowns if the F.D.A. demands a fix. (Some shortages, like those of weight-loss drugs, are the result of sky-high demand, while others have been attributed to overprescribing, including for antibiotics, or a lack of investment in potential alternatives.)

The F.D.A., which employs a team of about 10 people who do the day-to-day work of mitigating and reporting drug shortages, has said it is seeking authority from Congress to get additional information about the drug manufacturing and supply chain.

But the agency has also expressed its concerns to the White House about severe financial strain in the generic drug industry — an economic problem that F.D.A. officials say they are not suited to address.

Dr. Robert Califf, the F.D.A. commissioner, highlighted the agency’s views during recent appearances before Congress, saying officials can only plug so many holes.

“We have got to fix the core economics if we’re going to get this situation fixed,” Dr. Califf told a House panel on May 11.

David Gaugh, the interim chief executive of the Association for Accessible Medicines, which represents generic drugmakers, recalled warning F.D.A. officials in an April meeting that the recent bankruptcy and shutdown of Akorn Pharmaceuticals would likely be followed by others.

“Shortages are on the rise. We’ve all seen that,” Mr. Gaugh said in an interview. “And it is likely going to get worse, not better, very soon.”

Mr. Gaugh cited data underscoring pressure facing the generic industry. Although the number of generic drugmakers has increased, a review by IQVIA, a health care analytics company, showed that the market has consolidated such that three buyers account for about 90 percent of generic drug purchases. The intermediaries are combined major drug distributors and retail chains, like Red Oak Sourcing, which includes CVS Health and Cardinal Health and ClarusONE, which includes Walmart and McKesson. Walgreens also has distribution agreements with AmerisourceBergen. The companies did not reply to requests for comment.

The competition for the contracts with those intermediaries pits U.S. manufacturers against those in India, where labor costs are far lower. When a generic drug company can’t get a contract for a medication, it tends to stop making it and might see already-slim profits shrink.

“The opportunity to get it wrong is much narrower if you’re a generic manufacturer,” Mr. Gaugh said.

Hospital pharmacists and supply-chain experts were stunned in February by the abrupt shutdown of Akorn, whose products were then recalled since there was no staff remaining to address potential quality concerns.

That added “insult to injury,” said Eric Tichy, a supply chain division chair at the Mayo Clinic and the board chairman of the End Drug Shortages Alliance.

Akorn made roughly 100 medications, including cylinders of albuterol that children’s hospitals had relied on to ease their breathing difficulties. And it was the only company that made an antidote to lead poisoning, Dr. Tichy said.

“Health is so foundational to our country functioning well,” Dr. Tichy said. “And then we have a domestic manufacturer that just goes under and there’s not a lot of action.”
Four Senate bills with bipartisan sponsorship could help get generic drugs to market more quickly by addressing tactics or loopholes that cause delays. During a House hearing on the shortages Thursday, Anthony Sardella, a business research adviser at Washington University in St. Louis, said generic drug prices had fallen by about 50 percent since 2016.

“But there is a high cost to low prices,” Mr. Sardella said, noting that they may lead to cost cutting that can result in quality problems.

A recent case in point was Intas Pharmaceuticals, a company in India that makes three key chemotherapy drugs that are difficult to find: methotrexate, carboplatin and cisplatin, the drug Mr. Dwars needed. Intas temporarily suspended manufacturing of the drugs after the F.D.A. found serious quality-control violations.

During an unannounced visit to the Intas plant, F.D.A. inspectors discovered a “truck full of” hundreds of plastic bags filled with torn and shredded documents, according to a report issued in December. One quality-control worker poured acid on torn records and stuffed them in a garbage bag, the report said.

F.D.A. inspectors pieced papers together and found quality control records for products bound for the United States, the report said. The agency cited a raft of other problems as well.

To ease the supply disruption, the U.S. distributor for Intas, Accord Pharmaceuticals, said a handful of lots were tested by a third party, certified and released to the U.S. market. The treatments arranged by Ms. Bray that reached patients in Iowa were among them.

The companies were working with the F.D.A. to restart manufacturing for U.S. customers, a statement from Accord said, adding that it found the shredding to be an “isolated incident.”

The Society of Gynecologic Oncology sent out a nationwide survey in recent weeks. In response, doctors in 35 states said they had little to no supply of key chemotherapy drugs, even at large cancer centers and teaching hospitals.

Dr. Patrick Timmins, a partner of Women's Cancer Care Associates in Albany, N.Y., said his practice ran out of some chemotherapy drugs on May 9, but still has 25 patients who need them.

“Our patients are in a war, and what we’re doing is we’re taking their weapons away,” Dr. Timmins said. “It’s completely ridiculous that we can’t figure out a way, at least in the short run, to get our patients treated, and in the long run to solve these recurring problems.”

When Ms. Bray met with White House staff members in late April, she said that she recommended creating an exchange, to get drugs where they were needed most, and increasing the production of small-batch medicines, often referred to as compounding.

Dr. Kevin Schulman, a professor at Stanford Medicine who has studied the generic drug industry, said he had urged the White House team to examine how much power the intermediary companies have in contracting with generic drug makers. He said they demand rock-bottom prices, but unlike a customer-facing company like Apple that contracts with suppliers worldwide, the drug intermediaries face no accountability when shortages arise.

Dr. Schulman said he had recommended expanded government contracting with the nonprofit Civica, which sells generic drugs at slightly inflated prices, which can help generic makers run a stable business.

“The intermediaries are driving people out of the market,” Dr. Schulman said. “I think it’s a market problem and we need market-level solutions.”