



AS THE NATIONAL DRUG SHORTAGE PERSISTS, NO QUICK FIX IN SIGHT

Written By Kate MacDonald

Picture this: You walk into your local pharmacy to refill a crucial mental health medication, only to be told that it is unavailable, and they do not know when it will be back on their shelves. Or imagine this nightmare scenario: You bring your child into a nearby hospital for chemotherapy, where a receptionist tells you that, after this treatment, you are going to have to reschedule every other appointment because they must start rationing their life-saving chemo drugs – they are going to run out soon. People across the country are facing situations exactly like these, and a plethora of others, as the national drug shortage climbs into unprecedented territory.

While Americans encounter this kind of trouble at pharmacies, hospitals, clinics, urgent care facilities, and other places they receive medical services, they're strategizing about thinking outside the box to get the medicine they desperately need until things get back to normal. However, as industry insiders know, that might be easier said than done—there is no magic bullet, and it will not be a quick fix.



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BRAD-6503-z

#1293927791 02/24 (exp. 02/26)

HOW DID WE GET HERE?

While drug shortages may seem particularly acute lately, and the recent situation has been repeatedly in the news, unfortunately, this is not new. There have been several notable years of drug shortages. For instance, 2014 was a particularly bad year; in the third quarter of 2014, there were 320 active drug shortages. More recently, in the second quarter of 2023, there were 309 active shortages. When there is a significant shortage, it can be hard to right the ship, and a snowball effect can easily happen.

Still, there was a national record set in the first quarter this year, when March ended with a total of 323 drugs officially in shortage. The question remains, though: how did the situation become so dismal? There is no easy answer to that either. Here are just some of the biggest culprits we can identify:

1. Production issues (which can include anything from natural disasters to plant shutdowns);
2. Rising rates of sickness (think supply and demand);
3. Reduced ordering capacity (necessary legislation against opioid abuse begets smaller dosage amounts); and
4. Middlemen pricing and competition (a common industry complaint, which can lead to finger-pointing).

A PERFECT STORM

Production issues will always be an intangible problem that the pharmaceutical industry will have to deal with and something they can rarely plan. For instance, Puerto Rico is a significant manufacturing base for Big Pharma, and its infrastructure is still reeling from the after-effects of Hurricane Maria, which severely damaged a large saline bag factory. Saline is often used to clean wounds and in intravenous bags to provide fluids, and the bags were compromised. And then there was last summer's tornado that destroyed a North Carolina Pfizer plant, affecting that production line for years to come. But this is not just caused by natural disasters – the Food and Drug Administration (“FDA”) also performs routine inspections of drug manufacturing facilities and is currently working through a pandemic-caused backlog.





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When facilities fail or otherwise have deficiencies, those plants halt production, often leading to material or drug shortages.

There is also a simple economics theory at play – sometimes, the demand for a drug (or piece of equipment – there is also a rising medical equipment shortage) outpaces what is currently available. That issue is manifesting rapidly across the country in numerous ways. Perhaps most prominently, thanks to social media platforms, people are sharing experiences and encouraging others to seek mental health treatment, which has lent itself, in part, to a years-long ADHD drug shortage.

Similarly, a celebrity concentration on weight loss medications has also cropped up. Furthermore, a national syphilis outbreak is significantly affecting a low injectable antibiotic supply. On top of that, a national fight against opioid abuse and settlement rules has meant that pharmacies are limited to a certain number of narcotics when stocking their shelves. As such, manufacturers will not over-produce.

Finally, because many of the poor-quality problems that cause shortages involve generic drugs (the most commonly used and cheapest), generic manufacturers are often priced out. Since companies make much less money and pharmacy benefit managers (“PBMs”), or middlemen, get a cut when there is a scarcity, it often makes more sense for pharmaceutical companies to either stop making generics or upgrade to producing higher quality drugs. Generic lines are the most vulnerable to shutdowns – because they are so heavily used, they are going to affect the most people.

LET’S RUN THE NUMBERS

According to the two most recent United States Census Bureau Household Pulse Surveys, Louisiana, West Virginia, and Alaska residents are having a particularly hard time finding the drugs and



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equipment they need. Meanwhile, 14.6 percent of Americans overall are suffering from prescription drug shortages.

So, how are they coping? Overall, 49 percent are either delaying or completely stop using their medications and 24 percent are rationing where possible. The survey indicated Missourians are the most likely to stop taking medications (three in five), while Washington residents are paying more for pricier substitutes (nearly one in four).

This reality has forced some to go out of their health plan's network. On the other hand, this has empowered others to be more engaged with their health plan benefits. In fact, some PBMs have experienced exceptionally high engagement during this stressful period, as individuals have prudently started calling their insurance carriers to see what they can do to find their prescriptions.

As for hospitals, a second quarter 2023 National Comprehensive Cancer Network report showed that 93 percent of cancer centers experienced a carboplatin shortage, while 73 percent faced a cisplatin shortfall – both are used in combination in chemotherapy treatments. Only 40 percent of providers received an indication of a timeline from manufacturers.

THE GOVERNMENT GETS INVOLVED

In March 2023, the Senate Committee on Homeland Security and Governmental Affairs published a report on the threat drug shortages can pose to national security; If our drugs are unreliable, shortages persist, Americans become sick, and our nation becomes vulnerable. This February, the House Committee on Ways and Means held a hearing, including expert testimony on the risks drug shortages pose and possible congressional solutions.



Things came to a head in April when the Biden administration, with the Department of Health and Human Services (“HHS”), released a plan to create two non-governmental organizations to upkeep a rating system and incentivize manufacturers and hospitals that maintain supply chains and avoid shortages. This may counter the risk of a shortfall, as the strategy is to buy drugs in large quantities instead of at the last minute. Despite this approach, some industry leaders believe the plan does not adequately address quality issues and may adversely affect smaller hospital systems that lack the resources to keep up.

While it is promising that steps are being taken at a government and industry level, significant progress is still to be made. Certainly, consumers should check the FDA's shortage list (on its website) to see if their prescriptions are included and call their doctors and insurers for further guidance. Thankfully, though, the government and the industry are starting to listen. ■

As a Health Benefits Consultant for The Phia Group, LLC, Kate MacDonald drafts, edits, and analyzes self-insured health plans to ensure compliance with industry standards. She is a regular contributor to the company's newsletter. She previously wrote for The Cape Cod Times.