Alliance for Pharmacy Compounding
Compounding the Joy of Living®

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Anticipating and Alleviating Drug Shortages

A 503A pharmacy is a traditional pharmacy that dispenses compounded medications **one patient at a time** (and only when those patients have prescriptions for a specific compounded medication).

503B outsourcing facilities operate on a larger scale, and are also required to follow federal sterility and manufacturing regulations. They typically **distribute larger quantities** of medications for use in healthcare facilities including hospitals, clinics, and veterinary offices.

When the supply chain fails, pharmacy compounders are there…

We've seen how fragile the pharmaceutical supply chain can be for so many reasons, causing FDA-approved drugs to disappear from hospital and pharmacy inventory. 503B outsourcing facilities were created in part to help provide a reliable and high quality alternative when FDA approved drugs — always the first choice for treatment — are "currently in shortage."

503Bs were established by federal law in 2013 to allow (highly regulated) bulk compounding for hospitals and healthcare facilities and to supply needed medications when there is no FDA-approved alternative. The 80 or so in the country are registered directly with the FDA and adhere to robust production standards similar to those required of major drug manufacturers.

That's why, when the FDA determines that the supply of a drug can't meet demand, the law allows 503B compounding facilities to prepare a copy. They are able to — and expected to — fill gaps in the supply chain.

You don't have to look far for a perfect example: In 2023, compounding pharmacies and outsourcing facilities literally saved children's lives by compounding amoxicillin suspension when it was in severe shortage and parents were frantic.

Point is, we have at our fingertips a way to reduce the impact of drug shortages, whether caused by manufacturing issues, supply-chain bottlenecks, or even tornadoes.

… but they need time, and incentive, to prepare

As critical as outsourcing facilities are to alleviating shortages, they can't turn-on production of a drug at the drop of a hat.

Just like drug manufacturers, outsourcing facilities must adhere to FDA's Current Good Manufacturing Practice (cGMP) regulations. But that means it can take 3 to 9 months for a 503B to accomplish the necessary testing and other requirements that will allow them to begin production of a drug that goes into shortage. And that's not taking into account the lag between when hospitals notice a shortage and drug makers report it to the FDA.

Worse, too often there's little financial incentive for a 503B to put in the time and expense to prepare a shortage drug if it may come back into supply the moment it begins distribution.

The bottom line is that there's a gap between when hospitals are hit by a shortage and when 503Bs can step in to help. In the meantime, patients may have to be administered a second-choice drug or even postpone treatment.

We can — we must — do better for patients. Here are two relatively easy policy changes that would go a long way to ensure patients' access to necessary medications:

1. **Better anticipate drug shortages.** Equip the FDA to take into account more and better information about shortages will allow it to recruit and prepare outsourcing facilities to produce shortage drugs.

2. **Reduce risk.** Incentivize 503Bs to produce shortage drugs by reducing their risk of losing a large investment if those drugs come off shortage sooner than expected.

Two easy fixes

Ensuring continuity of care while maintaining quality and safety isn't difficult when we take advantage of the nimble, flexible nature of compounding pharmacies and outsourcing facilities. Here are two ways to mitigate the effect of drug shortages, no matter what the cause:

Anticipating the shortages

The first people to notice drug shortages are often pharmacies and prescribers. Unfortunately, when determining whether a drug is actually accessible to patients, the FDA is limited by federal law to a single source of information: the drug manufacturers themselves. The result is an FDA drug shortage list that lags the market. Shortages seen by pharmacists and prescribers may not be noted by the FDA for months.

A more realistic process would include feedback from health systems, providers, pharmacists, and other stakeholders. By including that information, the FDA can better forecast when a drug will no longer be accessible to patients, allowing it to mobilize 503Bs to begin their production ramp-up. The lag may not be eliminated, but it's certainly reduced.

Reducing 503Bs' risk

Today, even after a potentially huge investment in production, once a drug comes off the FDA's shortage list, 503B outsourcing facilities must stop distributing the drug within 60 days. That short cut-off is one reason some outsourcers are reluctant to fill shortage gaps. Further, even when a drug is officially off the shortage list, it can take more than 60 days to actually reach hospitals and patients.

The solution is simple: **Extend that "tail" from 60 days to 180 days.** That will give 503Bs more incentive to step in, knowing they're guaranteed at least six months to recoup their investment, while also ensuring continuity of care for patients.

Of course there is still that gap between when a drug goes into shortage and when 503Bs can begin production. But by getting ahead of the curve — and providing an incentive to compounders — that gap can be reduced and the effect on patients reduced without introducing any additional expense or risk.

What we're asking

Senator Tim Kaine of Virginia's soon-to-be-introduced bi-partisan bill, the End Drug Shortages Act, would go a long way toward solving these issues by helping the FDA anticipate shortages sooner. He's working to identify a Republican co-sponsor, and is expecting to introduce a bill this session. With the current record number of drug shortages, we urge Senators to join in co-sponsoring and supporting it. Contact Samantha Koehler in Sen. Kaine's office (samantha_koehler@kaine.senate.gov) office for details.

In the House, Rep. Abigail Spanberger (D) of Virginia and Rep Adrian Smith (R plan to introduce an identical companion bill. For details, contact Lucy Schwartz on Rep. Spanberger's staff (Lucy.Schwartz@mail.house.gov) or Joel Keralis (joel.keralis@mail.house.gov) in Rep. Smith's office.

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