

Q&A with FDA: Drug Shortages with CDR Emily Thakur

Dr. Roach: Welcome to “Q&A with FDA”, from the FDA’s Division of Drug Information. In this podcast series, we answer some of the most frequently asked questions we’ve received from the public.

My name is Dr. Sara Roach, and today we are discussing drug shortages, a topic that impacts both consumers and health care professionals. Drug shortages have been frequently in the news lately, as well as the subject of Congressional testimony. Our Division has received hundreds of inquiries from concerned patients and their families.

Today we are joined by Commander Emily Thakur to discuss this important topic. CDR Thakur is an active duty Pharmacist officer serving in the United States Public Health Service Commissioned Corps. She serves as a Team Leader with the FDA’s Drug Shortage Staff and is with us today to discuss recent drug supply challenges, new FDA guidance, and solutions to mitigate drug shortages. Welcome Commander Thakur, thank you for being here!

CDR Thakur: My pleasure!

Dr. Roach: We know that drug shortages can occur for many reasons, such as manufacturing and quality problems, production delays, and product discontinuations. But there are many other contributing factors. What are some of the main causes of drug shortages that you want consumers and health care professionals to know and understand?

CDR Thakur: Great question. Manufacturing quality issues are the primary reason for drug shortages. However, as you mentioned there are other reasons, like manufacturing production delays, when companies experience delays in receiving raw materials and components from suppliers.

Another reason that is important to know about is when a drug product is discontinued, FDA does not have the authority to require a firm to continue manufacturing or marketing a drug that it wants to discontinue. Sometimes companies discontinue older drugs in favor of newer versions.

To illustrate this point, let’s consider sterile injectable drugs, such as Total Parenteral Nutrition, or TPN products. There are few firms making TPN products, and a limited number of production lines. Suppliers are also limited in the amount of components they can make due to capacity constraints at their facilities. This small number of manufacturers and limited production capacity, combined with long lead times and complexity of the manufacturing process, make these drugs vulnerable to shortage. When one company has a problem or discontinues the drug, it is difficult for the remaining firms to increase production quickly, and a shortage can occur.

Dr. Roach: We are often asked what FDA is doing to resolve drug shortages. Will you describe how FDA's Drug Shortage Staff help manufacturers reduce the impact or avoid drug supply and shortage situations?

CDR Thakur: As an Agency we take great effort to address and prevent drug shortages and supply issues. Our Staff uses a variety of tools within our legal authority to monitor the supply chain.

As you know, the FDA does not manufacture drugs and we cannot require a pharmaceutical company to make a drug, make more of a drug, or change the distribution of a drug. But we can help encourage companies to do so.

For example, due to the COVID-19 pandemic, the Drug Shortage Staff asked manufacturers to evaluate their entire supply chain, including active pharmaceutical ingredients and finished dosage forms, in an effort to understand the vulnerabilities in the supply chain and prevent drug shortages.

Dr. Roach: During what was termed the tripledemic of COVID-19, flu, and RSV infections, our Division responded to many inquiries from parents and pharmacists concerned about the availability of pediatric ibuprofen and acetaminophen. Can you talk us through how FDA was able to intervene in this situation and help alleviate the shortage?

CDR Thakur: Yes, that's a great example for us to talk through. The triple threat of COVID-19, RSV, and influenza was beyond what anyone could have predicted.

In general, supply issues are more common in winter — we've experienced seasonal shortages for more than a decade.

In the fall of 2022, due to the increase in respiratory illnesses, ibuprofen and acetaminophen oral suspension supplies could not keep up with the increased demand.

To address this, we successfully worked closely with the manufacturers on their efforts to further increase supply to meet the increased demand.

In addition to working with manufacturers of existing products, in January 2023, we issued guidance to help increase the supply of ibuprofen oral suspension products in hospitals and health systems by allowing certain products to be compounded.

Dr. Roach: I know how many of those with whom we spoke, pharmacists in particular, appreciated the guidance FDA provided during that difficult time. More recently, we have been receiving many questions about the shortage of Amphetamine and Dextroamphetamine salts.

CDR Thakur: The shortage of Amphetamine and Dextroamphetamine salts, as described in our Drug Shortage database, is due to both an increase in demand and a shortage of the active ingredient. However, some companies do have product available. Although the majority of shortages are caused by manufacturing issues, we have also

seen some shortages due to increases in demand. While manufacturers are required to notify FDA of permanent discontinuances and certain interruptions in manufacturing, they do not have to notify FDA when they are seeing an increase in demand. That gap in knowledge can sometimes lead to shortages that the agency can't address preventively.

So whether it's the recent triple threat, increases in demand, or another issue, our team's strategy is the same: we work closely with drug manufacturers to communicate issues and to help restore availability.

Dr. Roach: Each year, the Drug Enforcement Administration, or DEA, establishes quotas for schedule I and schedule II controlled substances. Are these quotas ever the cause of drug shortages?

CDR Thakur: If a drug at risk of shortage is a controlled substance, FDA works closely with DEA in efforts to prevent or mitigate the shortage. Among other duties, DEA is responsible both for setting aggregate limits on the amount of certain controlled substances that may be manufactured and for allocating to each manufacturer a specific percentage of the aggregate limit (or a quota). This tight control over controlled-substance products requires FDA and DEA to coordinate when a shortage of a controlled substance is looming. For example, FDA may work with DEA to enable a manufacturer to increase its allotted quota of controlled substance if this step would help avoid a shortage of the product.

Dr. Roach: You mentioned that manufacturers are required to notify FDA of permanent discontinuations and certain disruptions in manufacturing. Can you expand upon that?

CDR Thakur: Yes. It is the drug manufacturers' responsibility to provide FDA with certain information related to potential supply disruptions, which helps in our efforts to prevent and mitigate shortages. We then work closely with manufacturers to prevent or reduce the impact of shortage that may result.

Recent legislation has helped to enhance FDA's ability to identify, prevent, and mitigate possible shortages of drugs, including for example:

- notifying FDA of permanent discontinuances and interruptions in manufacturing of active pharmaceutical ingredients;
- creating risk management plans for establishments in which certain drugs are manufactured; and
- annually reporting the amount of listed drugs and biological products manufactured.

This all ultimately enhances FDA's visibility into the drug and medical product supply chains and helps us prevent and alleviate shortages here in the United States.

Dr. Roach: Speaking of visibility and transparency, the Drug Shortages Database is publicly available on the FDA website. When and how are drugs added to this database by your team?

CDR Thakur: The Drug Shortages Database is a great resource and is available on FDA's website at www.fda.gov/drug-shortages. When our team confirms that a drug shortage exists, we post this information to the Drug Shortages Database. We make updates daily with new and resolved shortages, as well as additional information we receive from suppliers on their manufacturing capacity.

The majority of the information in the database is provided by drug manufacturers, but we encourage everyone to notify FDA for drug shortage or supply issues. The database focuses on shortages of medically necessary products since those shortages have the greatest impact on public health. Shortages that are expected to be resolved quickly, shortages that involve only a particular strength or package size, and shortages where a substitute strength or package size is available are not usually the focus of FDA's program.

The American Society of Health-System Pharmacists (or ASHP) also has a drug shortages database that lists drug shortages and provides suggested alternative therapies. A link to this database is provided on our Drug Shortages webpage navigation pane for "Additional News and Information."

Dr. Roach: In our final minute together I'd like to invite you to share your thoughts on whether there is a way to resolve drug shortage and supply issues and prevent drug shortages from happening altogether.

CDR Thakur: Sure, I wish there was an answer to this right now that would prevent all future drug shortage and supply issues. While we do all that we can within our authority, that authority has its limitations. Our team responds to potential drug shortages by taking action to address their underlying causes and to enhance product availability. Using all the tools available to us, we determine how best to address each shortage situation based on its cause and the public health risk associated with the shortage.

While we can't require other firms making a drug in shortage to increase production, we do work closely with these firms to ask for their help with ramping up production if they are willing and able to do so. Often, they need new production lines or new raw material sources approved to help increase supplies. We expedite this review and approval to help resolve shortages as quickly as possible.

Dr. Roach: Thank you again Commander Thakur for providing your insights on drug shortages!

Thanks for listening to "Q&A with FDA". The full podcast and transcript of this recording is available at fda.gov/QAwithFDA. If you have questions about this episode, or anything drug-related, email us at druginfo@fda.hhs.gov.

Resources:

[CDER Conversation – The Latest in Drug Shortages | FDA](#)

[Drug Shortages Database](#)

[Drug Enforcement Agency Quota Applications](#)

[Drug Shortages: Root Causes and Potential Solutions](#)