

Mayo Clinic Q&A - Dr. Eric Tichy - Dr. Mary Gilmer - Combati...

Wed, 7/13 11:50AM 12:29

SUMMARY KEYWORDS

drug shortages, shortages, mayo clinic, medications, gilmer, rx, supply, pandemic, drug, patients, generic drug, proactive approach, insulin, manage, supply chain, joining, delays, manufacturers, result, needed

SPEAKERS

Dr. Mary Gilmer, Dr. Eric Tichy, Narrator, Jason Howland

N Narrator 00:01
Coming up on Mayo Clinic Q&A,

D Dr. Eric Tichy 00:04
The number one reason for drug shortages is actually unknown. And this speaks to the lack of transparency in the drug supply chain. And that's one of the things that we aim to work on.

N Narrator 00:14
Drug shortages can pose a significant threat to public health as they can result in delayed treatment for patients, medication rationing, and in some cases, treatment being denied because of the lack of important drugs. Addressing these shortages remains a top priority for Mayo Clinic.

D Dr. Eric Tichy 00:31
We have created a more organized and structured process and with the collaboration with our external partners to help end and prevent drug shortages, we hope that this really best prepares us to manage drug shortages that we see in the future.

J Jason Howland 00:48
Welcome, everyone to Mayo Clinic Q&A. I'm Jason Howland sitting in for Dr. Halena Gazelka. Drug shortages continue to be a major healthcare issue in the U.S. with more than 200 ongoing

and active shortages per year since 2018. Mayo Clinic has taken a leadership role in combating drug shortages, including joining the End Drug Shortages Alliance. That's a coalition that seeks to prevent drug shortages in the U.S. Mayo was also a founding member of Civica RX, a nonprofit generic drug company, whose goal is to reduce shortages of essential medications that hospitals use. Civica RX recently announced plans to manufacture and distribute affordable insulin. Joining us today to discuss combating drug shortages are pharmacists Dr. Eric Tichy, Division Chair of Pharmacy Supply Solutions at Mayo Clinic, and Dr. Mary Gilmer, Director of Pharmaceutical Supply and Procurement from Mayo Midwest. Welcome both of you to the program.

D

Dr. Mary Gilmer 01:51

Thank you.

J

Jason Howland 01:53

So, first off Dr. Gilmer, why are there drug shortages right now in the U.S.?

D

Dr. Mary Gilmer 01:58

That's a great question, Jason. Well, let me just start by saying that drug shortages are not new to healthcare. But really over the last two years with the COVID-19 pandemic, the shortages have really exposed the vulnerability of our global drug supply chain. And these drug shortages continued to remain high, despite decades of continued and increased awareness, effort and significant resource investment in these drug shortage programs at the highest level. And so, you know, I just want to touch on a few reasons for drug shortages, or rationales, and there are a variety of them. They include the supply and demand considerations and challenges, as mentioned, that we've seen with COVID, natural disasters like hurricanes, even including issues with manufacturing. So, this could be the raw materials shortage, or even the staffing challenges that manufacturing plants are experiencing as a result of the pandemic. And then certainly, we can't ignore any kind of business and regulatory changes as a result of profit or market analysis where manufacturers may decide to end a product line completely because it's not profitable for them.

D

Dr. Eric Tichy 02:30

So, one of the frustrating things about drug shortages is that the number one reason for drug shortages is actually unknown. And this speaks to the lack of transparency in the drug supply chain. And that's one of the things that we aim to work on.

J

Jason Howland 03:37

So, which medications are affected. We mentioned insulin earlier in the intro to the program, is insulin one of them, and what are some of the others?

D

Dr. Eric Tichy 03:46

Absolutely, Jason. And really, let's level set and say any medication can be on shortage. But the biggest challenges with shortages is when we are in short supply of our life-saving medications like insulin. These medications may include the insulin antidotes, any kind of reversal agents, and certainly our common injectable medications that are needed to sustain life. So, that's really what you're speaking to. And when these shortages affect these types of medications, that's when our patients are most negatively impacted.

J

Jason Howland 04:20

How is Mayo Clinic managing drug shortages?

D

Dr. Eric Tichy 04:24

Well, there's high levels of stress and frustration for everyone involved when it deals with shortages. And so, Mayo Clinic has really acknowledged that there's a critical need to create an organized and structured approach to how we manage medication shortages across our entire enterprise. So, this is involving all sites. We have necessitated a coordination and collaboration of teams, and this is internal and external to all of our inter disciplinary team members. And we've developed under the direction of the Mayo Clinic Pharmacy and Therapeutics Committee, so our most overarching practice committee, the Medication Shortage Management Oversight Subcommittee we call MSMOS, and this group seeks to take a proactive approach to ensure the effective and timely management of medication and shortage supply concerns.

J

Jason Howland 05:22

And what is that proactive approach?

D

Dr. Eric Tichy 05:25

Absolutely. So, right down to the frontline team members when we're experiencing, when we go at the point of ordering any kind of supply shortage or simply when supply doesn't meet demand. So, when we place an order for a medication, and we do not get in sufficient quantities of what we're needing to take care of our patients, that's when we start escalating it and really developing the collaboration and coordination around how we understand and identify shortages so that we can best proactively manage them. So, that's getting everybody on board for awareness, and any changes in our electronic health system that we need or engaging our formulary colleagues to understand what alternatives or substitutes we can use. So, this is just a few of the strategies that we use when we're talking with this MSMOS group about creating a structured and organized approach to managing each and every shortage we encounter.

J

Jason Howland 06:22

Jason Howland 06:22

So, Dr. Tichy, how do drug shortages affect patients?

D

Dr. Eric Tichy 06:25

Well, because of the work that Dr. Gilmer's team does, and so many of our clinicians at Mayo Clinic, we like to think that the impact on the patient's themselves is minimized. So, we really do a great job of finding alternative therapies, we do things to conserve the products that we have to make sure that we are taking care of those that are sort of most urgently needed. When the shortages are severe, it can actually lead to delays in appointments. So, when the COVID pandemic first occurred, one of the reasons why the entire economy locked down was that they wanted to give the health system time to sort of prepare for what they expected was a big influx of patients. So, I would say that 99% of the time, these never affect the patients themselves. There are some rare instances, though, where it could lead to delays of therapy or using alternative medications.

J

Jason Howland 07:22

So, what alliances or partnerships is Mayo Clinic involved in to best prevent or end these drug shortages?

D

Dr. Eric Tichy 07:30

So, I'm glad you emphasize the end drug shortages, because I think a lot of what we've talked about thus far is really sort of mitigating the impact of a shortage. And our goal is really to get further upstream and actually end them and stop them from happening. So, we do a lot of advocacy with the government and different regulatory agencies. Anytime someone says they want to, you know, help end or manage drug shortages, we're always interested in what that opportunity is. So, Mayo Clinic has made a couple of big investments. One is that we were a founding member and investor in Civica RX, which is a generic manufacturing company that is focused on critical medications, mainly used by hospitals. And our goal there is really to turn these critical drugs into a very highly reliable supply, similar to what you see with like basic utilities like water and electricity, that you can rely on them, and that if they go down, it's for a very short period of time, and we have strategies to replace them. And then most recently, we've joined the End Drug Shortage Alliance, which is a coalition of many different stakeholders. So, there's patient advocacy groups, there's manufacturers, distributors, and health systems similar to ours that are all participating in this to sort of, so we can speak with one message to end drug shortages.

J

Jason Howland 08:56

Can you talk a little bit more about Civica RX and the work that's underway? So, you mentioned it's a generic drug manufacturer?

D

Dr. Eric Tichy 09:03

Correct. So, Civica is a generic drug manufacturing company. It's based in the U.S. So, part of the strategy is actually onshoring production of these medications, because of the national security issue that that actually brings up. And I think the country really understood that at the beginning of the pandemic when so much of our medical supplies were produced offshore, and we actually had seen some countries doing sort of protectionist measures to make sure that their populations had access to some of these medical supplies, including drugs. And it was a big wake up for the United States that we really strategically needed to onshore production of these products. So, Mayo Clinic had actually helped start Civica, about two years before the pandemic. And then as a result of the Cares Act, Civica RX received about \$200 billion of funding from the U.S. government to build a manufacturing facility in the United States and Civica will start rolling products off of their manufacturing lines sometime in 2024. So, it is a bit of an involved process, but it's, you know, something that really will make a materially significant impact towards ending drug shortages.

J Jason Howland 10:17

Well, we're just about out of time. But my last question to both of you, how long do you think these drug shortages will continue to persist?

D Dr. Eric Tichy 10:29

Well, drug shortages were uncommon 20 years ago, and in the last 20 years they have become increasingly common. And my hope is that we could get back to where we were 20 years ago, where drug shortages were rare, similar to what we see with utilities. And I think that the pandemic has created a unique opportunity for us because of the attention it's brought to the importance of supply chains. And a lot of organizations are really recognizing this as a problem and making investments to prevent drug shortages. So, do I think you can 100% eliminate them? I think that might not be realistic. But I do think we can get to where we were 20 years ago, where drug shortages were very uncommon and drug supply was very reliable. Dr. Gilmer, what are your thoughts on this? Just to speak to what Dr. Tichy had shared, we absolutely hope that we have created a more organized and structured process, and with the collaboration, as Dr. Tichy had mentioned, with our external partners to help end and prevent drug shortages. We hope that this really best prepares us to manage drug shortages that we see in the future.

J Jason Howland 11:42

Fantastic. Unfortunately, we're all out of time. But I'd like to thank our guests today, Mayo Clinic pharmacists, Dr. Eric Tichy, and Dr. Mary Gilmer. Thank you both for joining us.

D Dr. Eric Tichy 11:53

Our pleasure.

D Dr. Mary Gilmer 11:54

Thank you.



Narrator 11:54

Mayo Clinic Q&A is a production of the Mayo Clinic News Network and is available wherever you get and subscribe to your favorite podcasts. To see a list of all Mayo Clinic podcasts, visit newsnetwork.mayoclinic.org. Then click on podcasts. Thanks for listening and be well. We hope you'll offer a review of this and other episodes when the option is available. Comments and questions can also be sent to mayoclinicnewsnetwork@mayo.edu.