

Speaker 1: Welcome to the Cancer Aware podcast, where we'll discuss cancer prevention, treatments, the latest in research, and important news around cancer. Brought to you by the University of Michigan Health Rogel Cancer Center.

Eric Olsen: Hello, I'm Eric Olsen, and today we're talking about cancer drug shortages with Dr. Andrew Shuman, Rogel Cancer Center head and neck oncologist, and chief of the Clinical Ethics Service in the Center for Bioethics and Social Sciences in Medicine at Michigan Medicine. A recent statistic estimates that drug shortages in the U.S. have increased by as much as 30% in recent years, putting the shortfall at an all-time high. Dr. Shuman has testified about the current cancer drug shortage before the U.S. Senate Committee on Homeland Security & Government Affairs. Welcome, Dr. Shuman.

Dr. Andrew Shum...: It's a pleasure to be here. Thanks for having me.

Eric Olsen: So my first question for you is, how did we get to this point?

Dr. Andrew Shum...: So drug shortages have been a plague affecting our country for many decades. So while this has been in the recent press and has made a number of patients, families, and clinicians quite anxious over the course of the last number of months, this is a much more long-standing problem. This is a problem that's also quite multifactorial and has been exacerbated by many things, both from a public health, public policy, and economic standpoint for many, many years. Broadly speaking, drug shortages are a manifestation of a fundamentally flawed healthcare system in which we work. Many of the medications that are not available are tried and true generic sterile injectable drugs, including cancer drugs that have been around for many, many decades and generally are not the drugs that are generating large profit margins for pharmaceutical industries or frankly anyone else.

One of the challenges is that the production of these drugs is not incentivized in a way to keep up with the necessary demand for them, which means that when the prices are low, there's not an incentive to maintain a large supply. There's not an incentive to ensure that the quality product is being produced in newer factories with increased quality assurance and also that many of these drugs are being produced abroad in parts of the world where our country doesn't necessarily have the same degree of control of the quality and the supply of the products themselves.

Eric Olsen: So is it that those drugs from those areas, we just don't trust them as much or we're concerned about their quality and efficacy?

Dr. Andrew Shum...: So somewhere on the order of 90% of drugs and their derivative chemicals come from abroad. Many of these come from places in the world such as India and China. The drugs that are sold in the United States, even when they originate in those nations, are still being vetted and approved by the Food and Drug Administration of the U.S. federal government. So the U.S. is still vouching

for them, but the challenge is that their production, their supply, their quality is somewhat tenuous, especially when we're dealing with drugs that are not the ones that pharmaceutical companies are paying their shareholders with.

Eric Olsen: In addition to the points you made about financial incentive as well as some of the supply issues around the world, are there any other obstacles in finding a solution to this drug supply shortage?

Dr. Andrew Shum...: There are many. Part of the issue relates to how drugs are bought and sold in the country today. The more typical capitalist approach of supply and demand simply does not apply for many of the generic sterile injectable drugs that we're talking about. Doctors, patients, hospitals don't necessarily buy these drugs on demand but rather purchase them in large group purchase orders through contracts that last for many, many years, meaning that prices and supply are not as malleable and flexible with ebbs and flows over time. As a result, we're quite vulnerable to shortages of drugs where, for example, the price won't necessarily increase in a way that will keep up with demand or vice versa because of the system in which we're working.

Eric Olsen: So if there's no financial incentive, there is a distinct possibility that many of these drugs will simply stop production. Is that a concern for you?

Dr. Andrew Shum...: And even if they don't necessarily stop production, the number of companies who are making them and the redundancy in the supply chain will disappear in a way that makes us much more reliant upon single producers and single factories. When that happens, all it takes is one quality issue at one factory somewhere in the world related to either a COVID surge or a contamination issue or anything else to dramatically impact the supply of drug available on very short notice across our country. And that's exactly what has happened with a number of the recent drug shortages that have made national news.

Eric Olsen: So what do you think the solution is for that?

Dr. Andrew Shum...: So the solution has to be multifactorial. This requires us to thoughtfully reconsider how we prioritize and incentivize the production of the drugs that we so desperately need in this nation. Many of these drugs, as stated, don't have the financial incentive necessarily behind them in terms of sticker price, but there are other ways that the federal government, pharma, FDA, and other stakeholders can work together to ensure quality products here in this country. I am quite optimistic that the U.S. Congress can and will take the necessary steps to address this issue. This is something that I have focused upon and have spoken with members of Congress about over the last number of years. And currently, in this Congress, there are quite a number of proposals both in the House as well as in the Senate that have the potential to move the needle in the correct direction on this issue.

Eric Olsen: In addition to these long-standing issues that you discussed, how did the COVID-19 global pandemic affect the drug supply issue?

Dr. Andrew Shum...: So COVID did not cause drug shortages, but it exacerbated a problem that already existed. Many of the tenuous supply chain challenges that we experienced through COVID really were manifestations of much more long-standing problems, but ones that really became clear in crisis. In addition, COVID impacted supply and demand in concert. So for example, when factories were unable to produce a certain amount of, for example, drugs used to keep people asleep or sedated, there was also an increased need to have those drugs in intensive care units around the world in order to take care of critically ill patients with COVID and of course all of the other patients with critical illness and needs that were long-standing.

So both demand increased and supply became more tenuous at the same time, which was a pretty terrifying situation with regard to supply as well as demand and impacted patients, clinicians, and everyone else during that period. I will say that some of those supply and demand issues improved over time as we've come out on the other end of the pandemic, but others have not. And in fact, many of the drug shortages that we are experiencing right now are even worse than they were at the height of COVID for a number of different reasons.

Eric Olsen: What are some of those reasons? Why do you think that is?

Dr. Andrew Shum...: One relates to the fact that the generic sterile injectable supply is reliant upon many outdated factories that quite frankly don't keep up as well as they could with quality assurance. And FDA's role in ensuring quality product means that some of those suppliers are unable to keep up with the demand of a quality product. In addition, the financial challenges that have long existed, but that COVID exacerbated have become even more problematic. And the global supply chain in general has been strained by the COVID pandemic and its aftermath in a way that has continued to impact drug supplies around our country.

Eric Olsen: Are you seeing any positive reaction to the stresses that were caused by the pandemic in the supply chain? In other words, are you seeing any evidence that some of these suppliers are shifting and adapting in response to that pandemic?

Dr. Andrew Shum...: So I think the pandemic has made the public more aware of the importance of scarce resource utilization and prioritization. So the idea that we simply do not have everything we need is better understood and appreciated by the general public as well as policymakers at every level. I do not think that we are in a better place with regard to the supply chain itself or where the complex interactions between FDA, pharma, and institutions using this medication are coexisting right now. That is going to require a larger sea change and frankly, legislative action. There have been some laws passed over the past number of years that have addressed this issue, but they have not made the type of systematic change that we so desperately need.

Eric Olsen: Okay. So what does all of this mean for patients not only at Rogel Cancer Center but at cancer centers across the country?

Dr. Andrew Shum...: One of the major challenges of this situation is that patients are in the tragic situation, especially patients with cancer where there may be a drug available that could literally save their life that costs less than a tank of gas that was developed 50 years ago that we simply don't have or may run out of. That is the type of situation that is truly unimaginable to patients and families and of course also to the doctors and other clinicians providing that care who are so desperately trying to save those people's lives. At Rogel and at Michigan Medicine more broadly, we are privileged to have a large team of individuals focused upon ensuring that our supply to drugs, even those that are scarce, will be maintained to the best of our ability. And as a result of that, generally speaking, our supply has been more steady than it has been at other institutions.

That's not to say we're not feeling the brunt of this, and in fact, we have a large team of people not only focusing on maintaining our supply, but also making sure that when we are in a shortage situation, that those drugs are being thoughtfully allocated to the patients most in need, who will most benefit, and that we are conserving that supply as best as we are able. Other hospitals and systems that are not as well-resourced as we are certainly suffer the burden and the brunt of those shortages more so than us. And part of our job as stewards of resources, not just for our own patients, but also more broadly, is to work with neighbors around the region, around the state, and around the country to more thoughtfully think about how we can maximize reserves and supplies that become tenuous.

Eric Olsen: Are there alternatives to preferred drugs that can come into play that might not be as effective, but would be effective enough? Is this an option in a lot of treatment situations or are we looking at one or two primary drugs that are really the things that are needed for treatment?

Dr. Andrew Shum...: It really depends upon the situation. One of the challenges of shortages of, for example, old-school generic injectable cancer drugs, is that they're often used for many different types of cancer. So for example, we have a recent shortage of carboplatin and cisplatin, which again fit into that cheap tried and true cancer drug that is actually part of somewhere between 10 and 20% of all cancer treatment courses for everyone around the country. It is used for everything from blood cancers to head and neck cancers that I take care of to cancers of the genitourinary tract and gynecologic disease. So when we run short on these medications, it's incredibly complicated to determine who and how best to allocate them to the patients who are most in need.

For some of these patients, there very well may be alternatives, and of course, we will pursue that here at Rogel and elsewhere, but one challenge is that we don't necessarily know that those alternatives work as well as the drug that is tried and true and the one that we've done the original research with. So as a

result, clinicians and institutions are often put in the very difficult situation of making the best decisions that we can with limited information and sometimes even on short notice.

Eric Olsen: Extrapolating this a little bit, are there any other drugs for other critical diseases that could sever the same sort of situation? Are we aware of any of that happening right now? Is that a potential?

Dr. Andrew Shum...: It's not a potential, it's a right reality, and this is a massive issue around the country, both here as well as elsewhere. Some of the medications that are on shortage that are not cancer drugs as of right now and today include things as simple as lidocaine, the medication that we use for basically every surgical procedure in order to provide local anesthetics. That's not to say that we are out of lidocaine, but what it means is that we may not have the specific dose, the specific preparation, the specific type of agent that we would use, and that creates challenges in terms of an increased risk of errors, increased time and workflow, complexity in providing that care and so on. So that is one example of a drug shortage that is not necessarily life-threatening, but one that dramatically changes and complicates the delivery of care that we are providing. Another similar shortage relates to steroids. Again, dirt-cheap drugs that have been around forever, but when companies don't necessarily have the incentive financially to make them, we are at the mercy of shortages that dramatically impact patient care.

Eric Olsen: What is the long-term outlook for the current drug shortages? How do you see this unfolding in the future?

Dr. Andrew Shum...: So, unfortunately, I left my crystal ball at home. I will say that I worry that we are in some ways reinventing the wheel and experiencing similar challenges and problems that we have for more than a decade. Until we have significant legislative change that can address this issue in terms of its root causes, we will be doing this over and over again and patients and clinicians will be suffering the consequences. With that said, I am optimistic that we can and will make strides in the correct direction. For example, the FDA in 2019 put out a report detailing the root causes and the necessary solutions to address this problem. The U.S. Senate Committee on Homeland Security & Government Affairs came out with two reports over the past number of years as well that similarly articulate a legislative path forward. Both of those, in addition to other pieces put forth by multiple stakeholders and think tanks have recognized what we need to do.

Eric Olsen: So another way of thinking about this is this could be similar to when we talk about energy security, some of the laws that are being talked about, that this would be maintaining a sort of drug security, pharmaceutical security for our patients in this country. Is that...

Dr. Andrew Shum...: That's exactly right. So just as we need reliable water supply and we need reliable electricity, we need cancer drugs that are cheap, effective, proven to

actually be on the shelf when patients in need are diagnosed and need that treatment. That is at least in my opinion, something that our government needs to ensure. Another key is ensuring that companies actually have an incentive to make quality product. For example, if the production of a quality product will improve their ability to sell drug, make a profit, and ensure that the people who are buying it can know that they are going to have a stable supply of a quality drug, everybody wins. Those are other components of legislative changes that will move the needle on this issue.

Eric Olsen: Dr. Shuman, is there anything we didn't ask today, any other aspect of this that you'd like to address before we leave today?

Dr. Andrew Shum...: The only other perspective that I think is worth recognizing is the human one, that the patients who are experiencing this desperate search for drugs is horrific, and that for the clinicians who are taking care of them, it is similarly horrific. Part of our job as clinicians here at Rogel is to partner with our patients and families as well as with the clinicians with whom we work, to be honest, to collaborate, to work together, and to recognize that drug shortages are a reality that we need to face in a way that is thoughtful, evidence-based, fair, and measured. That is what we strive to do every day here, and part of the reason why the care that we provide is at a higher level. With that said, cancer drug shortages are an ongoing scourge in the provision of oncology care and one that Rogel is not immune from, but one that we continue to address on a daily basis.

Eric Olsen: That's all the time we have for today. I'd like to thank Dr. Andrew Shuman for joining us today and speaking to the topic.

Dr. Andrew Shum...: It's my pleasure. Thanks so much for having me.

Eric Olsen: For the Rogel Cancer Center, I'm Eric Olsen, and thanks for listening.

Speaker 1: Thank you for listening and tell us what you think of this podcast by rating and reviewing us. To stay up to date on what's happening in the cancer world, follow us on X @UMRogelCancer. You can explore additional episodes at www.rogelcancercenter.org/podcasts. Cancer Aware is part of the Michigan Medicine Podcast Network.