Demand Forecasting for Controlled Substances

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Transcript

Welcome

Susan C. Winckler, RPh, Esq, CEO, Reagan-Udall Foundation for the FDA

Susan Winckler: [00:00:30] Hello and welcome. Thank you for joining us here in person and online. If those of you in person are wondering why is she wearing a microphone, it's for the people who are online and that is why we will do the microphone just to make sure that you can all hear us. But we have a couple of folks who are joining us online as well. I'm Susan Winckler and I serve as Chief Executive Officer for the Reagan-Udall Foundation for the FDA. And we are pleased to be convening [00:01:00] this public meeting today in collaboration with FDA on demand forecasting for controlled substances. For those of you who are new to the Foundation's work, we are the nonprofit non-government organization created by Congress to help FDA do more to protect and promote the public's health. One way we do that is by convening meetings like this one to help the agency gather information and hear from a range of stakeholders about important issues.

We are [00:01:30] pleased to be talking about demand forecasting today, but let me address a couple of housekeeping issues first. So our speakers and some attendees are gathered here in our room in Washington DC, and as I noted, we have a significant number of virtual participants. Because of the size of the virtual meeting, virtual attendees, cameras and microphones will remain off for the event with one exception. We have a public comment period, and during that public comment period, we [00:02:00] will be calling on each of you who we confirmed to provide stakeholder comment. At that time, we'll grant you access to unmute and to turn on your camera, and I will have very specific instructions about that in just a moment. We are recording this event and we will be posting the recording, the transcript, and the slide decks to our website, which is reaganudall.org next week.

And for our virtual participants, there [00:02:30] should be a link coming up in the chat to the meeting materials. And those of you in the room should have received meeting materials when you checked in. So let's talk about our agenda, and as we do that, I will thank those of you who have joined us today who will be speaking as well as those who are providing public comment. We are going

to be taking a journey through the various factors that are considered when determining the scientific and medical [00:03:00] and reserve stock needs for Schedule I and Schedule II controlled substances including opioids and stimulants. In a moment, we will hear opening remarks from FDA Deputy Commissioner Lowell Zeta. Then we'll hear perspective from FDA's Center for Drug Evaluation and Research in a fireside chat with Deputy Center Director Dr. Marta Sokolowska. We'll hear a background presentation from my colleague at the foundation, Amar Bhat, and then we will move to stakeholder comment.

[00:03:30] We're going to close out our discussion with a panel review of many perspectives in this space. So let me talk about the public comment period. We have 25 individuals confirmed to provide public comment and each of those public commenters has up to three minutes to speak. Public comment is organized by topic area and we will begin with our one in-person public commenter. When we get [00:04:00] to that topic, we will begin with that in-person and otherwise we will move through the virtual commenters. We are proceeding primarily alphabetically by last name. I will give you advanced notice to the fact that you are speaking. So I'll give a rolling list of three speakers. If you're paying attention, you'll hear your name twice before I call on you to unmute and to speak, for example, I will begin public comment by announcing that our first three commenters are Jane A, Jane B, and Jane C.

[00:04:30] All of the Janes should be paying attention at that point. And when you first hear your name, you'll be prompted to join the webinar as a panelist. Please do so when the commenter immediately before you concludes their remarks, unmute yourself and turn on your camera. Our producers will then highlight you when you are introduced to speak. At the end of your three minutes, and you will have a countdown clock that helps you monitor that time, your audiovisual support will cease. So you have three minutes to provide [00:05:00] the remarks and we welcome you doing so within those time parameters. I will note that no one from the foundation, nor from the agency, nor any of our speakers will be responding to public comment. Our objective here is to gather the public comment and to be sure that we understand the perspectives shared by members of the public.

And so with that, I think I'm done with all of the things that we have to do before we get to the substance, but it's important that we cover some of that. [00:05:30] So I want to turn the podium over to our first speaker of the day. Lowell Zeta is Deputy Commissioner for Strategic Initiatives at the US FDA, as well as special counsel for the agency in the office of the Chief Council, which is the Food and Drug Division of HHS. With that, Lowell, I will turn that over to you to provide a few remarks.

Opening Remarks

Lowell Zeta, JD, Deputy Commissioner for Strategic Initiatives and Special Counsel, U.S. Food and Drug Administration

Lowell Zeta: Great. Hi everyone. Thanks, Susan. Good afternoon everyone. And I want to thank you all for [00:06:00] taking the time to join us today on this very important topic. I'd like to thank the Reagan-Udall Foundation for their efforts to convene and host this meeting. One of FDA's most important, but to some degree less visible responsibilities is our collaboration, our partnership with DEA specifically to help set annual production quotas and limits of controlled substances. We're here today as Susan outlined, because FDA is required to prepare an annual [00:06:30] estimate of medical, scientific, and reserve stock needs for specifically Schedule I and II substances. FDA submits this annual estimate to DEA and then DEA uses these estimates along with other data sets to set an overall quota or limit for these substances. And while this process sounds technical, as you all know, being here, the impact is profound. It determines whether patients have timely access to prescription [00:07:00] controlled drugs they rely on from treatments for breakthrough pain to therapies for substance use disorder to medications that support mental health.

The stakes are high, and we need to ensure that Americans have sufficient medication to treat their legitimate medical needs. But as you know, controlled substances are by design tightly regulated. We also limit the potential for [00:07:30] misuse and diversion through these limits. Some have raised the risk of oversupply and misuse to worsening the overdose crisis by having too many of these substances on the market. And this is a topic specifically that I'm looking forward to hearing from you. To what extent should these risks and effects be considered in demand forecasting and what are the potential impacts of underestimation and overestimation of these numbers? Now, drug manufacturing [00:08:00] and supply chain issues are near and dear to me, an area that I enjoy talking about and learning about. It's where I'm spending a lot of my time at FDA where we're really focused on safeguarding and strengthening the US drug supply chain from streamlining manufacturing assessments related to applications to shoring up and strengthening the foreign inspection program.

It's also an area where [00:08:30] prior to rejoining the agency where my practice focused on working with drug manufacturers across the globe and helping them to try to navigate the FDA DEA paradigms, it's not easy. And as you all know, the supply chain for these types of products is very rigid, less flexible than others, and that means it's often susceptible to shortages. But at the same time, it also demands heightened [00:09:00] vigilance to prevent misuse, diversion, security risks. And that's why FDA's role here is critical. It's critical to provide accurate and timely data, and our estimates must reflect the real needs of patients while providing adequate flexibility for ideally near real-time actionable steps to ensure sustained access to current medications while also creating opportunities space for new market entrants.

[00:09:30] While these factors and causes of shortages we know are primarily or historically manufacturing and quality control-related issues, an increasing number are attributed to increased or spikes in demand. Specifically, for example, the shortages we ran into during and after the pandemic, and even over the last few years as we saw innovative breakthrough therapies reached the market for [00:10:00] radiopharmaceuticals, for GLPs, and while not scheduled examples of what could be down the path unless or until we take some action. So the stakes are incredibly high. And today, we're looking forward to exploring the important question of how to improve demand forecasting. And in line with FDA's commitment to radical transparency, my colleague, Marta [00:10:30] Sokolowska, will provide some insight in our current efforts to estimate medical need. There are some fields and opportunities where I'm particularly interested in hearing from you all how to increase AI integration to enable more accurate nuanced demand predictions.

How can we be more process-focused, analyze data in real time? How can we adapt our regulatory framework towards agile and flexible processes? And also, now these are not new or [00:11:00] novel topics. So what have the rate-limiting factors been from folks on the ground and what you're seeing? What can we do to unlock those barriers? I'm grateful for you all here today in the room and online, your rich and deep perspectives from patients, advocates, clinicians, academics, and industry members who are taking the time to share their experiences and expertise today. We encourage your engagement both in the public comment section and in our demand forecasting panel. And [00:11:30] by sharing information with each other, we hope to shed light on the many factors that affect the accuracy of demand forecasting and potentially sharpen FDA's best practices. With that, I'd like to thank you all for joining us and being part of this thoughtful discussion. Back to you.

CDER Fireside Chat

Marta Sokolowska, PhD, Deputy Center Director for Substance Use and Behavioral Health, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Susan C. Winckler, RPh, Esq.

Susan Winckler: Great, thanks so much, Deputy Commissioner Zeta, we know there are many demands on your time, so appreciate you being here. So let's turn then to the second part [00:12:00] of our conversation and I will join Dr. Marta Sokolowska on stage here and we'll have... I'm glad we don't have a fireside for our fireside chat, but we will have a conversation about the work that's done at the agency as it relates to demand forecasting. So I'll remind folks your title is not as long as the Deputy Commissioners, but reflects your responsibilities within the Center for Drug Evaluation [00:12:30] and Research where you serve as Deputy Center Director for Substance Use and Behavioral Health. So within that, I think you have some of the responsibility that the Deputy Commissioner mentioned related to FDA developing that, should we call it a proposal or you transmit to the DEA an estimate of medical need for Schedule I and Schedule [00:13:00] II

controlled substances, and that helps inform DEA's quota allocation process. Can you tell us a little bit more about the process for developing that estimate?

Marta Sokolowska: Happy to do that. And again, thank you very much for hosting this event and giving us an opportunity to hear from others regarding this very important issue because we hear a lot when things go wrong and we want to make sure that we can have proper assessment of a [00:13:30] demand so we can avoid that. That's the purpose of this meeting. So again, thank you very much. But to your question, I think it's important to clarify that assessment or the publication and allocation of quota is part of DEA responsibility. This is per statute, that's what DEA does, and they take into consideration domestic and international quota and other factors as part of that. However, per statute, [00:14:00] also HHS and through HHS, FDA is asked to provide information regarding domestic quota, domestic medical science needs and research needs for these substances. So how do we do that? Ideally would get information from all the prescribers across the country regarding how much of a product do they need. And so we would be able to collate it all together and submit [00:14:30] it to DEA.

Well, unfortunately, it's not that easy. The data sources are somewhat more limited. So we are trying to figure out what are the best assessments that we can use? What are the best data sources that can be utilized in order for us to make the evaluation of the domestic need for the next years to come? And typically, we look at the past performances, but one aspect that is important to know is that [00:15:00] the data sources are limited. So as [inaudible 00:15:02] typically look at factual dispensing of the products in the past, and we use that to approximate what would be the potential need in the future. Also take into consideration what are the potential policy changes that might be impacting increasing or decreasing need for a given substance. So we take it all together, we summarize it, use for forecasting methodology, which we are hoping to hear more [00:15:30] about the best practices that are currently available. And we use that in collating that information, sending it to DEA for the evaluation and consideration as they're assessing and publishing the final quota for the years.

Susan Winckler: Okay. So if I hear you correctly, then you're right, it would be one thing to ask people what is needed, but that's a little... Even that would be [00:16:00] a thought process and an exercise. So you look at existing data sources, develop that estimate and then hand that to the DEA.

Marta Sokolowska: That is accurate.

Susan Winckler: Okay. I would imagine though that that's not just a handoff, but perhaps there's a collaboration with the DEA. Can you talk about... Because one does... There is the ability to collaborate between agencies and how does [00:16:30] that happen?

Marta Sokolowska: Absolutely, and that's part of our work is to make sure that we have an opportunity to speak with DEA throughout the year, not only regarding the quota letter that we provide, but also ongoing assessment. Also, when there are

challenges to the system, we make sure that we are signaling it to DEA early on as soon as the signals are identified to us. And there is a very strong collaboration between drug shortage [00:17:00] staff at FDA within the CDER. Now, with DEA regarding any signals that they hear from manufacturers and sponsors, if there are potential problems, that we make sure that the DEA is aware of those signals. And frequently, DEA also hears similar signals from the manufacturer. So we make sure that we have open lines of communication throughout. And importantly, if they're on a [inaudible 00:17:26] system, we have opportunities to make it both [00:17:30] informal as well as formal requests. And one of the formal requests that actually many of you might be aware of was the Federal Register notice that was published in September of last year regarding increasing lisdexamfetamine quota.

So essentially in July of '24, FDA sent a letter to DEA stating that, first of all, that we determined that lisdexamfetamine [00:18:00] is intended for use in the prevention and treatment of debilitating disease or condition, and therefore falls under the statutory notification requirement. And as such, we also determined that active ingredient was a reason for shortage that we have observed. So with our estimate of what should be the increase in the quota, we sent the given letter to DEA, and DEA acted on it by publishing the Federal Register notice that led [00:18:30] to increase in the quota. So this is one of the examples of formal engagement that led to action that we believe hopefully helped a number of patients to get access to the important medication.

Susan Winckler: So that, I guess that's a good reminder that there's a... And maybe in framing us and reminding us that the quota is set so that we can say what should be available for patients, what [00:19:00] should be there, and that's set on an annual basis. And then the example you just gave is that it's also not one and done, that there's some monitoring that occurs and then you have the opportunity to provide that information to DEA.

Marta Sokolowska: Absolutely. And that's why having the engagement, ongoing engagement is so critical on this and other issues with our sister agencies including DEA.

Susan Winckler: Yeah. Yeah. So what are you hoping to get out of the meeting today? It might be the [00:19:30] wonkiest meeting that's being held in late August here in Washington DC or anywhere in the country, but wonky and yet incredibly important when we think about the processes that are necessary to assure that medications are available to patients. But what does success look like at the end of today's meeting?

Marta Sokolowska: If everything goes [00:20:00] right, nobody should ever hear about the issue of quota. This should be a problem that nobody's hearing about because there's no extra abundance of controlled substances that people might use inappropriately and misuse, fueling potentially another overdose crisis. And at the same time, all patients who need the medication get the medication and they don't have to go to five, 10 different pharmacies to [00:20:30] get the drug that they need. So that would be the success. The problem is that how do we get there and

understanding the limitations. I think it's really critical to understand a couple things, we need to hear loud and clear, and we've heard on numerous occasions the impact on patients when we get it wrong. And as public health agency, it is really critical that everybody knows that, A, we do hear you. We do want to make sure that we [00:21:00] address those issues. So how do we do it and what can we get out of this meeting is to have a better understanding what are the different sources of information that we can utilize and should utilize to get it right.

At the same time, demand forecasting is not a new area of science. This is something that is utilized across different industries on regular basis. So we are not trying to reinvent the wheel. We want to make sure that we understand the best practices from industry and across different industries [00:21:30] that will help us to inform our demand forecasting. So that's the other thing that I'm hoping to get out of this meeting, is to make sure to level check that the methodology that we are utilizing, the data sources that we are utilizing, the assumptions that we are making, they are appropriate and they're fitting the current age. And as Lowell mentioned, there are a lot of innovations right now in a lot of the spaces. So how can we look forward to make [00:22:00] sure that we integrate the novel technologies and novel methodologies to our process? So I'm looking forward to hearing from you all. This is not one and done, this is ongoing, and we are looking forward to the next steps.

Susan Winckler: Excellent. Well, so I hear you say you want to hear about the impacts of the work that we all do, as well as potential innovations about how to do it better and [00:22:30] just some real world dynamics of the process. So we will see if we can deliver on that in the rest of the component, the rest of the meeting. Let's then turn to our next section, but first, we'll thank you, Marta, for bringing us here. I'll let you go that way. And now, I guess, Dr. Bhat, I'm going to bring you up with the label of, we do need some slides about [00:23:00] the wonky topic. And so if you would give us some background. I know you've been leading a lot of the work really we've done here at the foundation to think about this. And so if you'd provide that overview, that would be very helpful. I'll step out of the way so you can do it.

Overview

Amar Bhat, PhD, COO, Reagan-Udall Foundation for the FDA

Amar Bhat: All right, thank you. Thank you, Susan. And thank you to Dr. Sokolowska and Deputy Commissioner Zeta for being here. My name is Amar Bhat and I'm the Chief Operating Officer for the foundation. I also had the pleasure of being the project lead [00:23:30] for this particular activity. So in my presentation today, I hope to provide a little bit more context for this conversation and explain what demand forecasting is. Before I forget, sorry, yeah. Before I begin, I wanted to acknowledge the contributions of the many people that we spoke to as part of this project, as well as our sister project on prescription stimulant availability. In conducting the research, we heard from many people throughout the controlled

substances supply chain, [00:24:00] including manufacturers, distributors, pharmacists, and of course patients and their family members. We also had assistance of those at FDA and other federal agencies. And finally, I want to acknowledge the assistance of my fellow team members, including Joy Linda and our consultant Jim Wu.

Do we have this... Oh, I need to do these slides, don't I? Okay. Okay. All right. Project origins. So starting in 2022 and 2023, [00:24:30] during the pandemic, pharmacies, patients and parents started reporting shortages of prescription stimulants. FDA asked the foundation to explore and explain for the public the drivers of ongoing shortages of prescription stimulants. This led us into a deep dive into the supply chain for controlled substances. Controlled substances are drugs... As Dr. Sokolowska said, controlled substances are drugs that have a high potential for abuse and [00:25:00] dependency. Production of controlled substances is governed by the Controlled Substances Act, administered by the Drug Enforcement Administration. The goal of CSA is to prevent diversion of controlled substances to the non-medical supply, otherwise known as the illicit market.

Okay. So the Foundation's early work led to the development of this interactive infographic you see on the screen outlining the steps taken by various [00:25:30] players in the drug supply chain, including checkpoints and approvals performed by the regulatory and law enforcement agencies i.e. FDA and DEA. For our virtual participants, you can see a link to this infographic in the chat, and I urge you to take a look offline or online, I'm sorry. Of course, you can also get it off the screen here. Each red and yellow icon has a different pop-up with an explanation of what is taken at each [00:26:00] step. So you can see from all the numbers of red approvals or yellow limitations that there are many points at which the supply chain can easily get disrupted. For example, you can't make medicine if you don't have the necessary raw materials.

Okay. I want to zero in on a little bit on one component of that infographic, and that is the quota system. Dr. Sokolowska [00:26:30] referenced this earlier under the CSA, DEA establishes annual quotas on how much manufacturers can make or import. DEA grants quota on a semi-annual basis or depending on the product, but semi-annual basis to each individual manufacturer of active pharmaceutical ingredients, otherwise known as API or finished dose formulations, the finished product that you see. Quotas are generally [00:27:00] granted on historical sales and overall estimation of domestic medical need provided by FDA. FDA has asked the foundation to look at industry best practices in pharmaceutical demand forecasting to improve their estimate of medical need.

Okay. So what is demand forecasting? At its most general level, demand forecasting is the process of predicting quantity of product required to be manufactured [00:27:30] to meet the needs of consumers at a future point in time. Demand forecasting helps us to ensure that supply meets demand, avoiding overproduction or waste, or in the case of controlled substances,

avoiding diversion, illegal diversion, and underproduction or shortages. On your right is a picture of the classic supply versus demand curve. Unfortunately, for pharmaceuticals, particularly controlled substances, the [00:28:00] situation is far more complex than this simple diagram. So why do demand forecasting? Demand forecasting can help companies plan and allocate resources efficiently. The accurately predicting future demand can also help businesses prepare for potential disruptions such as sudden changes in market conditions or manufacturing disruptions, problems in the supply chain, et cetera. [00:28:30] Manufacturers take in data from multiple sources. They also put their forecast of multiple uses resulting in different types of forecasts developed for different purposes.

Pharmaceutical demand, there's different reasons for doing forecasting. Pharmaceutical demand forecasting plays an important role for any entity along the drug supply chain. So not just manufacturers, but wholesalers, pharmacies, they all need to predict customer orders, maximize [00:29:00] profit and efficiency, and minimize risks and waste. DEA and FDA also need to do forecasting and in order to ensure legitimate medical need while minimizing risk of diversion. All right. So on the screen here, a few different types of statistical modeling techniques have been evolved over the last 100 years. These are becoming more [00:29:30] and more sophisticated, but it should be noted that for the pharmaceutical industry at least, those that we talk to, most of them rely on the more simpler early techniques and moving averages, exponential smoothing, et cetera, which are easier to work with and are more agile, easier to kind of change the parameters, et cetera.

Okay. On market products versus new product launches. So when you think of the pharmaceutical [00:30:00] market, most of you think or are already aware of the distinction between branded drugs and generic drugs. But in pharmaceutical demand forecasting, the key distinction is from a manufacturer perspective, is whether a drug is already on market that is already in the marketplace, or a new product being launched for the first time, whether that product is branded or generic, it doesn't really matter from the manufacturer's perspective. So how you craft and use the demand [00:30:30] forecast depends on whether your product is on the market and thus has a sales track record to base your forecast. Or if your product is entering the market for the first time and thus has no sales track record. On market products generally can include both generic and branded products, and as I said, new products can be both branded or generic.

Okay. So oh, that should be what do you [00:31:00] trust? Sorry. Pharma companies use a number of different data sources to craft their forecast. There's internal sales data, which is the most reliable from a manufacturer's perspective because it's their own data and it's also the one that they rely on the most. It can include or indicate seasonal fluctuations such as cold and allergy medicines, which peak [00:31:30] in the spring and fall and lower in the summer. Commercial data sets are another important source of data. Those are purchased from trusted sources, but they are supplemental to internal sales

data and to help understand how your competitors are doing in the market, especially specific market segments. No one external data set is perfect. There is no one that can be entirely relied on, [00:32:00] so you have to use it with judgment. Experience and judgment are needed to apply and validate information from whatever data sets that you have.

Okay. Exogenous factors in demand sensing, so these are my $2 words here. Exogenous factors are real time factors that impact pharmaceutical demand but are not reflected in historical data. For example, sales data. In other words, you cannot [00:32:30] predict the impact of these factors. Exogenous factors by looking backwards in time, your sales data, past sales data will not show you what you need about what the future is going to look like. Demand sensing focuses on identifying and incorporating these various exogenous factors into the forecast. For pharmaceutical industry, that could be... That's why they use these more simpler models and then kind of [00:33:00] work in their using experience and judgment, some of these exogenous factors.

Speaker 1: [Inaudible 00:33:06].

Speaker 2: [Inaudible 00:33:09].

Amar Bhat: Yeah. Okay. All right.

Speaker 1: [Inaudible 00:33:15] I'm trying to turn my phone off and instead [inaudible 00:33:19].

Amar Bhat: Sorry. That's okay. So these are some typical exogenous factors. Unfortunately, I don't have enough time to go through these in detail. That would take up my [00:33:30] entire time, to be frank, maybe more. But these are important factors that can impact demand. They can [inaudible 00:33:41] from pandemics to increases in patient populations, new regulations and laws, supply disruptions, et cetera, all of these are factors that can impact demand in the market and are really hard to predict by looking backwards. [00:34:00] Social media trends is another one that I want to mention where that can also influence demand. All right, estimating medical need. So as I noted previously, there are different types of forecasts for different purposes, and so far we've been discussing how industry forecast demands.

Now, I want to just take a look at how FDA forecast demands. There are key differences in how industry uses these forecasts rather than FDA or DEA. [00:34:30] FDA as Dr. Sokolowska mentioned uses best available market data to formulate its annual estimates of medical need. In doing so, it relies on sales data from prior years. For example, an estimate submitted to DEA in the estimate that FDA would've submitted to DEA this summer, FDA would've used sales data from 2024 and before. That makes sense since 2025 data is not yet available. DEA will then use these estimates to [00:35:00] formulate its quota

allocations this fall and and ideally provide these quotas to companies before the end of the year. Sometimes that slips to the early part of next year.

Companies need time. They need 9-12 months to source the raw materials. Once they have the quota allocations, they need time to source the materials, schedule the manufacturing runs, and transport the finished product to warehouses. So in reality, based on the quota [00:35:30] allocations granted this year, the product doesn't hit the market until 2027. And as we saw in the previous slide, there's a lot that can happen in two years.

And this is the last graph, I promise you. Once a shortage occurs, it can be hard to catch up. In typical markets, if a shortage occurs for whatever reason, manufacturers are allowed to increase production to meet [00:36:00] demand. With controlled substances, manufacturers must stick to the quotas given. In a shortage situation, sales that are recorded do not reflect true market demand. Pharmacies cannot sell more or cannot dispense more than what they have in stock. In other words, recorded sales are less than true need in a drug shortage situation.

The recorded sales data are then used to formulate the next year's estimate of medical need and quota allocations. In other words, [00:36:30] while demand is rising, manufacturers must stick with the quotas based on the prior year's recorded sales data. Depending on the reasons behind the shortage, the gap between true need and recorded sales can grow over time, creating even greater shortages of need in medication.

Note, this slide here on the screen is a hypothetical situation, and in reality, there is room for limited growth in the quota year over year. Nonetheless, [00:37:00] the market signals are muted. In other words, what demands in the market are not always able to reach the manufacturers, and it can take years for manufacturers to catch up to demand.

That's my last slide. I want to thank you, and I'll note that some of the issues I brought up here and some of the solutions that we've been thinking about, or at least ways to alleviate the situation, will be discussed, I hope, by [00:37:30] our panelists after the public comment section. So, we look forward to hearing more from them. Thank you.

Susan Winckler: Great. Thank you so much, Dr. Bhat, for giving us the important grounding that we needed as we think about the situation.

We will turn now to the public comment portion of today's meeting, and this is for those of you who pre-registered to provide public comment. [00:38:00] I'll remind you that there will be no response to the comment. This is about gathering the comment and capturing that insight.

We're going to proceed through each of three predetermined topics. Those are, the first is methods and processes used in forecasting demand and considerations for the unique circumstances of estimating demand for controlled substances. The second topic is the effects of misuse and diversion on controlled substances and how they should be considered in demand [00:38:30] forecasting. And the third, potential impacts of underestimation or overestimation of demand on patients who are prescribed Schedule II substances.

As I introduce each commenter, I will then list the next three commenters who are in the queue. The first three virtual commenters for our first section are Sally Balsamo, Bill Grubb, and Pat Irving.

As those first three commenters prepare, I'll recap the logistics. [00:39:00] When I first announce your name, that's your cue to look for the Zoom prompt to join as a panelist. The second time you hear your name, turn on your camera and prepare to unmute your microphone. When the speaker before you completes their remarks, unmute your microphone and wait for my introduction. Our producers will bring you on screen as you are introduced, and you will have up to three minutes to comment.

If you do not begin speaking within 10 seconds of my turning the virtual stage over to you, we will move to the [00:39:30] next commenter. If time allows, we will circle back to you at the end of the section's virtual commenters. A countdown clock will display showing the time that you have remaining. I'll come back on screen when you have about 15 seconds left, and at the three-minute mark, we will end your audio-visual support and move to the next public commenter.

So, now we are turning, our queue is Sally Balsamo, Bill Grubb, Pat Irving and Mark Wagner. [00:40:00] I will turn first to Sally Balsamo. If you're with us, please proceed.

Public Comment

Topic 1: Methods and processes used in forecasting demand and considerations for the unique circumstances of estimating demand for controlled substances
Topic 2: The effects of misuse/diversion on controlled substances and how they should be considered in demand forecasting
Topic 3: Potential impacts of underestimation or overestimation of demand on patients who are prescribed Schedule II substances

Sally Balsamo: I am. Thank you. I am Sally Balsamo. I am an advocate for social equity in the treatment of chronic pain in Illinois. I've been doing so since 2016. I serve on Governor Pritzker's overdose advisory board, but he doesn't know me, don't ask him about me. There's a lot of us. Prior to him becoming disabled myself, I ran a $5 billion [00:40:30] PNL for a Fortune 100 consumer finance company in

Chicago. So, forecasting was my life, so a lot of what you're talking about is very familiar to me.

In the April, 2018 issue of the American Journal of Public Health, CDC scientists disclosed for the first and only time that they had been significantly inflating the deaths from Rx opioids because they had been counting illicit fentanyl in the same bucket. In addition, it is known that many ME's offices don't use sophisticated [00:41:00] enough equipment to determine a heroin death versus an Rx opioid death over time.

All this means is that the 2016 guidelines for opioid prescribing were based on bad data, and they never.... they waited until 2022 for an update. This should have been vastly announced to the government and the media. I've seen forecasts and what really happened, and I've done some myself, and it is staggering, but none from the CDC.

The most [00:41:30] foremost expert in the opioid epidemic now states fentanyl took over in 2015. The result of this error and the stealthy way in which it was announced caused an overdose epidemic whereby chronic pain patients took the hit, and everyday Americans weren't being warned that illicit fentanyl was everywhere. Pain patients were forced off opioid medications, often cold turkey, by doctors with whom they have built relationships for years. Clinics closed and there aren't enough doctors to take the [00:42:00] patients that are orphaned. We are now facing an older population, as well as the implications from chronic COVID, that we only now understand. There are already shortages of pain management and mental health meds.

We should be taking a humane approach to the treatment of medicine once again and allow doctors to treat each patient as an individual. We should be kinder to our veterans, for as a recent study shows, the absence of pain medication does lead to suicide. It's not about being [00:42:30] kinder, it's actually about telling the truth. Are you using corrected CDC data ,and what can you do now for the chronic pain community to help us get out of this rut that we're all stuck in due to this misinformation?

One last issue. Buprenorphine is considered the third-strongest opioid by the DEA, and it is being sold and abused. It is prison currency. People are put on MAT by the government, with the expectation they will be on [00:43:00] it for years. Please tell me how this differs from long-term opioid therapy for chronic pain patients. Tell me if the government will continue to put the onus on people in pain, instead of where it belongs.

Susan Winckler: Thank you. Our next queue in the public comment, we have Bill Grubb, Pat Irving and Mark Wagner. Bill, if you are present, we will turn to you now for comment.

Bill Grubb: Good afternoon. My name is Bill Grubb, Vice President of Compliance and Corporate Development [00:43:30] at Noramco. Noramco is a controlled substance API manufacturer based in Wilmington, Delaware. Nine of the 21 APIs that we supply are on the essential medicines list.

The previous DEA administrator's abrupt change to a quarterly and then semi-annual quota allocation process, combined with a reduction in inventory limits, continues to severely disrupt manufacturing supply chains today. When we begin the year with low inventory, insufficient quota or delayed quota awards, [00:44:00] it can result in months of supply delays to our customers due to equipment constraints and manufacturing lead times.

A specific recent example is our inability to supply Lisdexamfetamine dimesylate, which is on the drug shortage list due to API shortages. We entered 2025 this year with virtually no inventory based on insufficient quota grants in 2024. Then the DEA didn't grant us manufacturing quota until February 21st. The DEA knows that it takes Noramco 55 days [00:44:30] to manufacture Lisdex. Hence, we didn't have product available to supply the marketplace, our customers, until May, despite our customers having procurement quota.

And the story doesn't stop there. Our June request for additional quota was totally denied due to the DEA exhausting the aggregate by giving out all the manufacturing quota to other suppliers. Our customers who receive procurement quota are left without supply today. Without the additional quota request in June that we submitted, we will end [00:45:00] 2025 with zero inventory, which is obviously below the DEA's stated expectation of 40%.

We have some specific recommendations. One, return to the previous quota system, restoring the 50% year in inventory allowance for API suppliers. Two, award manufacturing quotas at least 90 days in advance of procurement quotas. Three, award 75 to 80% of our quota at the beginning of the year to allow us to utilize our multipurpose plants in an efficient [00:45:30] manner. Four, find a way to process quota requests faster. It shouldn't take six to eight weeks to get an answer.

And finally, and most important, the DEA needs a forward-looking, not retrospective view of the market for C-IIs. The quota process today doesn't consider share shifts or suppliers who are able and willing to supply the market, resulting in a lack of supplier diversification and higher drug costs to patients. Numerous executive orders underscore the importance of securing domestic supply chains. We are a domestic [00:46:00] manufacturer whose business is being negatively impacted by the lack of timely quota awards and lack of inventory. We would like to invite this committee and the DEA administrator to visit our Wilmington Delaware facility to see firsthand the challenges that we face. Thank you for your time.

Susan Winckler: Thank you. Our next public comment will come from Pat Irving. In the queue, we have Mark Wagner and Terry Lyle Wilson. Then we will turn to topic two. So,

commenter Irving, if you are present [00:46:30] and ready to present, please proceed.

We will return to commenter Irving, as he chooses. So, let's go now to Mark Wagner. In the queue, we have Terry Lyle Wilson, and then turning to topic two, we'll have Lucas Gerler and then Paul Giacinto. Mark Wagner, we'll turn to you now.

Mark Wagner: [00:47:00] Thank you. I'm a pharmacist attorney with Baker Hostetler. Today I'm speaking on behalf of the Outsourcing Facilities Association, also known as OFA. OFA is the trade association representing FDA registered outsourcing facilities operating pursuant to Section 503B of the Federal Food Drug and Cosmetic Act. OFA's members provide compounding and repackaging services to patients, healthcare providers and healthcare facilities, and strive [00:47:30] to ensure the specific needs of both providers and patients are met with safe and effective compounded and/or repackaged medications under current good manufacturing practices.

OFA comments today on demand forecasting for controlled substances, specifically methods and processes used in forecasting demand, and considerations for the unique circumstances of estimating demand for controlled substances. 503B outsourcing facilities are subject to the same DEA quota as drug [00:48:00] manufacturers. However, many 503B outsourcing facilities are compounding and repackaging, with FDA-approved finished products as the starting material, rather than from bulk drug substances or active pharmaceutical ingredients.

By requiring outsourcing facilities who compound or repackage from FDA-approved finished products to obtain quota, DEA may think there are two products in the market instead of one. This is because the original manufacturer had quota [00:48:30] that was used to manufacture the original FDA-approved product, and the 503B outsourcing facility who compounds or repackages that original product is also required to have quota, despite the fact that 503B outsourcing facilities do not manufacture any additional product. This may lead DEA to believe more product is in the market than is actually available.

On August 21st, 2023, DEA published a final rule, in which [00:49:00] it stated there would be an addition of subcategories for quotas, including quota for repackaging and packaging, labeling and relabeling to prevent this double counting issue and artificially low quota. Based on a survey of OFA members, they have not noticed the addition of the subcategory for repackaging.

If the DEA and the drug shortage calculations, including FDA's drug shortage database, want to be accurate, the subcategory for repackaging must be put into use, [00:49:30] or alternatively, those entities who are repackaging or compounding from FDA-approved finished products should not be required to obtain quota from the DEA.

Additionally, OFA members have experienced delays in requests for additional quota. This is harming patients and healthcare providers, and hampering their to adequately treat patients. Thank you for your time and attention to this important matter.

Susan Winckler: Thank you. We'll now [00:50:00] turn to our next public commenter, Terry Lyle Wilson. In the queue, we'll move to topic two, where we have Lucas Gerler, Paul Giacinto, and Richard Lawhern. So, Terry Lyle Wilson, if you're present, please proceed.

We are not hearing you. Could you unmute? [00:50:30] We cannot yet hear you, so I'm going to move to the next public commenter. We will come back to you, commenter Lyle Wilson, when we've had time to troubleshoot that AV issue. So let me turn to topic two. Lucas Gerler, Paul Giacinto, Richard Lawhern. Commenter Gerler, if you are present, we are ready to hear your input.

Lucas Gerler: Thank you.

Susan Winckler: Please [00:51:00] proceed.

Lucas Gerler: So, thank you to the Reagan-Udall Foundation, the FDA, the FDA members and other speakers, for having this meeting and taking public comment on the matter of demand forecasting for controlled substances. My name is Lucas Gerler. Today I'm representing myself, both as a patient on behalf of my companies, Liquid Gold Consulting and Panacea plant Sciences. And lastly, I humbly speak on behalf of friends, family, and the community affected who already lost their battles and couldn't be here today because they were victims of demand forecasting in one way or another.

My [00:51:30] companies sit at the intersection of legal and health, and I have the unique perspectives and experience of seeing things from both sides as they relate to the development and then the impact of new drugs that have a wide-reaching impact potential, as well as the impact they have when things go wrong. Aside from being involved in fighting the opioid epidemic on behalf of the victims, we've also been involved in conversations in the past around legalization of things like hemp, cannabis and other psychedelic class of drugs. As well as we current have a stay in court concerning scheduling of [00:52:00] certain tryptamines, as well as the rescheduling of cannabis, which if that were to happen, would obviously change things immediately and there would be allotments and things that would need to be done.

Onto the topic at hand, though. History shows us that when diversion concerns are weighted too heavily, the result is often underestimation of the true demand, and it's the patients who pay the price. So, when supply is underestimated, patients face the shortages, and then most patients, then desperate for relief, [00:52:30] turn to the illicit market, where substances are

unregulated, unpredictable and far more dangerous. But it's a market that moves that light speed to meet the demands of the market.

And we've seen this before when access to prescription opioids was restricted, many turn to the illicit market, fueling a devastating wave of overdoses, but its overdoses not due to them wanting to take a legitimate drug. It's due to the things that are mixed inside of those drugs, like fentanyl. And so, things like fentanyl, when they're mixed [00:53:00] in, it's not that somebody is looking to take that, it's that that is mixed in, unfortunately, to their supply, because it's a cost-cutting saving measure.

And so things like methadone, as an example, while it can absolutely reduce risk, there are upcoming class of drugs that may make it obsolete, and that the upcoming media coverage and things like that may fast-track getting approval for these different drugs and into the hands of the public.

And so, the need for [00:53:30] y'all to really understand the true demand and to make sure that the forecasting is balanced and really patient-centered and grounded in public health realities is now more than ever important. Mental health is a new crisis, and patients are looking for all sorts of alternatives for that. And so, the quicker that we can find those things and replace current things in the market with better alternatives that lead to healing, I think it'll be an easier job for all, because we won't have [00:54:00] to be continuing to treat. Thank you for your time.

Susan Winckler: Thank you. Our next commenter will be Paul Giacinto. In the queue, we have Richard Lawhern, Stacey McKenna, and Rachel Robinson. To commenters Irving and Lyle Wilson, we'll turn to you at the end of topic two. So, commenter Giacinto, if you're present, we are ready to hear your input.

Paul Giacinto: Thank you. I live in Bayonne, New Jersey. I was diagnosed with AIDS, spinal damage and stage three kidney disease. [00:54:30] For almost 27 years, I was taking Oxycontin 80 milligrams and 800 milligrams of Gabapentin three times a day. No history of abuse or misuse. Totally coherent, as I am now. Doctors were amazed, yet always saw my pain medicine and not the person. I was almost killed three times because of my medical complaints were not taken seriously until I returned in critical condition each time.

The Oxycontin stoppage was poorly done. [00:55:00] No system by the medical establishment was in place for those cut off. Did anyone track overdose and suicide rates attributed to the cut off of the Oxycontin? I only found out after asking my pharmacist what options I now had. Naproxen wasn't recommended for kidney issues. Tylenol was ineffective. By luck, he heard about Journavx. My neurologist wasn't even aware of the drug. I begged for the prescription and appealed for the approval of the drug on my own.

I [00:55:30] also contacted the rehab Department of Christ Hospital in Jersey City. They weren't aware of the drug. That's not part of their approved treatment plan. As told by staff, a person at my level of pain medicine and length of time, they normally would refuse because the patient would normally leave in the middle of detox because they couldn't handle the withdrawal and pain. They said that the patient would typically seek a pain management doctor or turn to other means to manage their pain.

[00:56:00] I visited a pain management doctor, was offered Journavx, Suboxone, spinal injections, fusion, and the internal TENS unit, all imperfect or failed history, as options. I wound up detoxing at home alone, not knowing if Journavx would work.

I've had some success with Journavx and with the Gabapentin for now, but my activity is now limited. I still have back and neck pain. We don't know if [00:56:30] long-term usage is even safe of Journavx. Suboxone and methadone is just switching to a more acceptable drug and possibly creating addiction itself.

In college, I worked for the State Department of higher education under a grant for alcohol and substance abuse outreach and education in 1990 through '92. Methadone was outed as a way to wean people off of opioids back then. People I know who went on it are [00:57:00] still taking it or dead from overdose, abusing that drug with alcohol or other street drugs. Suboxone seems to have a similar success rate, in my opinion.

Humans, if intent on altering their conscience, will always find a way. Many countries have tackled the addiction issue with consumption centers that offer a safe space to use and prevent overdose, offer help if needed, or...

Susan Winckler: Thank you. Our next comment will be from Richard Lawhern. In the queue, we have Stacey [00:57:30] McKenna, Rachel Robinson, and David Smith. Commenter Lawhern, please proceed.

Richard Lawhern: Hopefully I am on.

Susan Winckler: Yes, we can hear you.

Richard Lawhern: Thank you. I'm Richard Lawhern, PhD. As a healthcare educator and nationally known subject matter expert on public policy for regulation and pain medicine, I have 28 years experience and over 300 published papers in this field. I teach guideline-informed best practices [00:58:00] to clinicians in courses accredited by the postgraduate of medicine. From this background, I will support and expand on themes sounded here by several others, and go substantially further.

I would as assert that the members of our FDA panel are in fact accessories to one of the largest healthcare frauds in US history. They're also entirely aware of what I'm about to say because I and my colleagues briefed them a year ago.

[00:58:30] As I wrote last December on KevinMD, America's most widely read and cited healthcare newsletter, the FDA is talking when they should be listening. It is time to challenge the entire concept of risk estimation and mitigation strategies that incorporate draconian limitations on patient access to safe and effective pain relief.

We know beyond any possible contradiction that opioid analgesics prescribed in an ongoing doctor-patient relationship are both safe [00:59:00] and effective. Specific support for this reality is as follows. One, risk of treatment-related substance use disorder or overdose is less than one patient per thousand patients who are treated by a doctor with prescription opioid analgesics. This is based on a paper treating 34 million-plus patients, by Gabriel Bratt and his colleagues in 2018.

Two, in rare instances where a drug [00:59:30] overdose, suicide attempt or successful suicide occurred in over a million patients treated with prescription opioids, mental health factors are six to 24 times more significant as predictors of short-term risk, versus prescription of opioid pain relievers as such.

Three, 40 years of data published by CDC and the Veterans Administration demonstrates beyond any doubt that there is no relationship between rates of opioid prescribing and either accidental drug overdose [01:00:00] deaths or hospital admissions for overdose treatment. That is Hawre Jalal et al in Science, 2018, and Aubrey and Carr in Frontiers of Pain Medicine in 2021.

Four, overprescribing of pain relievers to pain patients has never been a dominant accidental drug... Excuse me, a dominant cause of accidental drug overdose, and it isn't now. Our crisis is caused by illegal drugs circulating in street markets. [01:00:30] FDA bureaucrats live in glass houses. It is time to break the glass and let in the light. Thank you for your time.

Susan Winckler: Thank you. Our next public comment will be provided by Stacey McKenna. In the queue, we have Rachel Robinson, David Smith, and then we will return to our topic one to hear from Pat Irving and Terry Lyle Wilson. But I'll turn now to Stacey McKenna. Commenter McKenna, please proceed.

Stacey McKenna: Thank you for taking public comments on this matter, [01:01:00] and thank you for having me here to present. So, my name is Stacey McKenna. I'm speaking today on behalf of the Integrated Harm Reduction Department at the R Street Institute. R Street is a nonprofit, nonpartisan public policy think tank. We're committed to supporting policies that balance free market, limited government ideals with pragmatic solutions that prioritize public health and safety. So that's why we're interested in this.

Given the fact that [01:01:30] others have spoken so eloquently on the harms that come from underestimating the need, I want to focus a bit more on what happens when we overestimate diversion. Or misunderstand why diversion is

happening and what's going on with it. We do get good examples of this from the opioid situation. We know that [01:02:00] increasing the barriers to accessing opioids, whether it's for pain or whether it's for treatment for medications for opioid use disorder or something like that, we have seen that this is associated with increases in overdose rates, and we've seen that it's associated with increases in transitioning to the illicit market.

So for example, we saw in 2014, when the DEA rescheduled hydrocodone from Schedule III to more restrictive Schedule II, there was an increase [01:02:30] in illicit opioid use. Because illicit market substances are unregulated and highly variable, it dramatically increases in turn the risk of overdose and other health complications. In fact, crackdowns on prescription opioid prescribing were a major driver of the second wave of the opioid crisis, beginning around 2007.

And then, in addition, we want to talk not just about the weight that's given to this, but really the underlying causes. And methadone is an amazing example [01:03:00] of what happens when people don't have access to their medications and how that relates to diversion. So opioids, methadone is Schedule II. It's used to treat both pain and in the treatment of opioid use disorder. When it's used to treat opioid use disorder, methadone reduces overdose risk by as much as 80%. It improves quality of life, it reduces criminal activity. However, it's hugely restricted.

So, what we've learned is that when a lot of people who [01:03:30] have an opioid use disorder, and they want access to methadone but they don't have it, or they miss a dose because of the restrictive situation, those are the folks that are most likely to access diverted methadone, not people looking for recreation. So the point of all of this, I think just to sort of double down on what others have said, is that we need to leave these decisions to healthcare providers and their patients, not to law enforcement.

Susan Winckler: Thank you. Our next comment will be [01:04:00] from Rachel Robinson. In the queue, I have David Smith, Pat Irving, and Terry Lyle Wilson. Commenter Robinson, please proceed. We cannot hear you if you are speaking.

Rachel Robinson: My name is Rachel Robinson. I am a registered nurse of more than 30 years. I'm also a chronic pain patient. I have [01:04:30] not had any access to medication for over eight months, and partly because of all these regulations. They have curtailed the doctors prescribing, they have curtailed the manufacturing of these medications. You don't understand what it's like [01:05:00] to need medication to be a functional person and not being able to have access to that. It is making me choose between continuing to work and filing for disability.

Right now, my life consists of working and bed rotting. I have no social life. I don't enjoy [01:05:30] anything. And just doing bare minimum takes everything I've got in me. I just want you to know what is going on. If this much effort was put into the illicit drug market, we wouldn't have an issue. It's not your chronic pain patients that [01:06:00] are causing this.

Susan Winckler: Thank you. We'll turn next to David Smith, and then follow that with Pat Irving and Terry Lyle Wilson, and then we will turn to topic three. Commenter Smith, please proceed.

David Smith: [01:06:30] Thank you. Let me First apologize for going fast and furious. My name is David Smith, age 62, disabled scoliosis patient with 18 levels spinal fusion bulked it into the back of my pelvis. Intractable pain patient who suffers harm for the ongoing drug shortages. I'd like to state the following eight facts that I know to be true from my litigation efforts and my work as a pain patient advocate.

Number one, sudden discontinuation of opioid medications and benzodiazepines create known [01:07:00] increased risks of death from very high blood pressure, heart attack, stroke, and suicide.

Number two, shortages of pain meds began in 2018 and continue through today after DEA cuts in production and distribution due to legal action demanding that DEA change its method for estimating misuse and diversion when setting annual production quotas.

Number three, DEA has been notified that these cuts have caused drug shortages and harm to patients by the comments published in the Federal Register each year after [01:07:30] the proposal for the cuts.

Number four, Memorandum of Understanding number 225-15-11 created a framework for FDA and DEA to share information to prevent drug shortages needed to fill legitimate prescriptions, but the sharing of information is still not happening.

Number five, DEA maintains that it "Is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet legitimate medical, scientific and export needs of the United States." [01:08:00] However, the ongoing shortages have placed the United States in violation of the 1961 United Nations single Convention on Narcotic drugs, to which the U.S is a signatory.

Number six, there is no factual scientific evidence to show that current overdose crisis is in any way related to prescription opioid medications. I have petitioned the Department of Health and Human Services with a 44-page notice outlining all of the research and data to support that statement, and have requested a complete [01:08:30] review of the public health emergency declaration in the opioid crisis, which has not yet been answered.

Number seven, DEA published in the Federal Register that "Quotas are being set by DEA to prevent misuse and diversion of pharmaceutical controlled substances, and thus to reduce the occurrence of overdose and death from the

use of legitimate controlled substances," without clarification concerning methodology nor proof of actual misuse or diversion by any individual patient.

Number eight, whatever the [01:09:00] methodology for estimating misuse and diversion, that process is obviously an abject failure, since we continue to experience life-threatening drug shortages nationwide. We need to wait for patients to be able to quickly and easily report shortages online in real time. And thank you for your attention.

Susan Winckler: Thank you. We'll now return to the final two commenters from topic one, and then we will turn to topic three. I'll turn to Pat Irving, followed by Terri Lyle Wilson, and [01:09:30] then we will turn to our in-person commenter, Giuseppe Rendazzo, for topic three. Commenter Irving, please proceed.

Pat Irving: Yes. Can you hear me?

Susan Winckler: Yes, we can.

Pat Irving: Okay. My name is Pat Irving, and I'm an RN with over 35 years of healthcare administration experience. I am here to talk about a significant flaw in demand forecasting. No current method takes into effect the restrictions being caused by the [01:10:00] state's attorney general Nationwide Opioid Settlement Injunctive Relief. The settlements created thresholds or ordering limits for each type of drug type or DEA base code. The thresholds were implemented in 2023. Can you still hear me? Uh-oh.

Susan Winckler: Yes, we can.

Pat Irving: Okay, and we're put in place for 10 years. These are beyond the DEA quota. This is not the DEA [01:10:30] quota. These are thresholds. Why do thresholds matter to demand forecasting? Thresholds are acting to artificially lower the demand for controlled substances. In the simplest terms, thresholds block the pharmacist from ordering more than a given amount in a set period. The threshold is calculated by an algorithm that have been purposely hidden from the pharmacist. The pharmacist threshold amount is also secret.

It is well documented that toward the end of the month [01:11:00] when the pharmacist goes to order a controlled substance for a legitimate prescription, they are blocked from putting in that order. This unfilled demand for the medication remains high for the rest of the month, but it's invisible to everybody above that. You cannot see it on purpose. How do we know? Although no one can know what the threshold limits are, verification of this mechanism has come from high level officials in both the HHS [01:11:30] and the DEA.

In addition, a letter dated May 10th, 2024, from the AMA, the American Pharmacist Association, the American Society of Addiction Medicine, and the

American Society of Health System Pharmacists specifically stated thresholds were, and I quote, "Frustrating the nation's pharmacists and physicians, and they are exacerbating the nation's overdose and death toll. The negative [01:12:00] effect of thresholds have also been widely reported in legitimate news sources."

Outcome. As many have mentioned, patient complaints about shortages have risen dramatically. In 2024, Pain News Network reported that 90% of patients have trouble filling opioid prescriptions. What is the solution? At the bare minimum, you must take thresholds into account when doing demand forecasting for all controlled substances. Ideally, [01:12:30] the thresholds will be analyzed and this harmful government overreach will be removed in its entirety. It is critical that solutions cannot be discriminatory and favor one controlled substance as the American Society of Addiction-

Susan Winckler: Thank you. We'll turn now to Terri Lyle Wilson, then to Giuseppe Randazzo, then Rose Bigham. Terri Lyle Wilson, please proceed.

Terri Lyle Wilson: Good afternoon. Thank you for the [01:13:00] opportunity to provide comment. My name is Terri Lyle Wilson. Today I am speaking on behalf of the End Drug Shortages Alliance, or EDSA. Our organization brings together stakeholders across the industry to ensure reliable access to essential medications for all patients. Today, the quota system is being asked to do something that it cannot accomplish. Quotas do not stop diversion or abuse. That is an enforcement matter. What quotas do impact is patient access, and right now the system too often leaves patients behind. [01:13:30] Patients suffer when there is inadequate access to critical medications.

A major challenge is that the forecasting model equates sales with demand, but sales cannot reflect true clinical needs. They only reflect what is available at one point in time. This creates a cycle where shortages mask true demand. To move forward, we need forecasting that integrates clinical need, prescribing trends and shortage signals, not just historical utilization.

I also want to highlight an [01:14:00] issue with the way 503Bs are counted within the quota rules. Many 503Bs compound or repackage from FDA approved finished product, but under current policy, they are required to obtain DEA quota as if they were producing from bulk API. This means the system counts the manufacturer's quota and the 503Bs quota creating the picture that two separate supplies exist when only one does. The double counting inflates DEA's numbers, making shortages look less severe [01:14:30] than they truly are, and ultimately obscures the fact that patients do not have access to needed medications.

By addressing this error, DEA would improve accuracy in its supply calculations and reveal the true impact shortages have on patients. We also encourage flexibility in quota management, allowing a modest 10 to 15% increase under strict oversight would provide a safety valve for manufacturers to respond to

shortages or unexpected spikes in patient need. This does not weaken controls. [01:15:00] It strengthens patient access while maintaining accountability.

In addition, API manufacturing has long lead times, six to nine months. DEA responses can take up to two months creating delays that cascade into shortages. Faster reviews, better alignment of timing and quantity between API manufacturing quota and the data procurement quota and permitting higher year-end inventory for API manufacturers would reduce these risks. Establishing quotas further in advance would also improve predictability in production [01:15:30] planning and better match supply with demand.

In addition, we encourage DEA to follow its own regulations by permitting injectable manufacturers to carry up over 50% supply into the next year. This would provide a critical buffer to prevent future shortages. At the end of the day, this is about people. People with cancer, chronic pain or in palliative care deserve access to the medications that their doctors prescribe. Thank you.

Susan Winckler: Thank you. We'll turn now to topic three, potential impacts of underestimation [01:16:00] or overestimation of demand on patients who are prescribed Schedule II substances. I'll turn to our singular in-person commenter, Giuseppe Randazzo.

Guiseppe Randazzo: Good afternoon and thank you to Regan Udall for convening this meeting. My name is Giuseppe Randazzo and I am here on behalf of the Association for Accessible Medicines, AAM. AAM represents manufacturers of finished generic medicines and biosimilars. Generics and biosimilars supply 90% of all prescriptions dispensed [01:16:30] in the US, while only accounting for 13% of prescription drug spending, saving $3 trillion in the last decade alone.

Today due to limited time, I'll focus on underestimation of quotas. Quotas set too low translate into back orders, pharmacy stock outs and treatment delays. Patients may be pushed to less appropriate alternatives or high-potency options simply because the right strength or route isn't available. Before talking more about the impact to patients, I'd like to mention some of the practical challenges generic manufacturers face when quotas [01:17:00] are underestimated.

One challenge is the inconsistent application of injectable allowances. Regulations recognize that liquid injectables require high inventory allowances and different suspension thresholds. Yet in practice adjustment requests are often denied or only partially granted with limited transparency. Underestimation also creates logistical, structural, and economic challenges for generic manufacturers. Generics serve high-volume, low-margin markets and rely on predictable schedules and [01:17:30] timely in-year adjustments to plan accordingly.

Inconsistent application of injectable allowances, for example, and opaque decision-making often results in start-stop campaigns, idle lines and preventable shortages. Without correct quotas and timely quota adjustments, firms may not be able to meet demand, leading to penalties or even production discontinuation, which can worsen shortages and increase patient costs. At the center of this, of course, are the patients. Patients deserve [01:18:00] a continuity of care. This care is threatened when quotas are too rigid or opaque, resulting in canceled procedures for substitutions or destabilized treatment.

Formable populations such as pediatrics, geriatrics, those with chronic pain or ADHD are a particular risk when appropriate strengths or routes aren't available. Healthcare providers are also impacted. They may have to resort to workarounds such as splitting vials or compounding on the fly. These practices may increase waste and complicate diversion controls [01:18:30] while consuming critical pharmacy and nursing time.

There are solutions we can offer. One, apply injectable allowances consistently and transparently. Two, create a rapid adjustment pathway for shortage signals with clearer timelines. Three, synchronize API and finished dosage quotas, so increases translate into actual production, not just paperwork. Four, build in pre-decision touch points to reconcile inventory and avoid preventable denials or partials. [01:19:00] Five, differentiate diversion risk. Oh my gosh, six, publish performance metrics to build trust and enable continuous improvement. In closing, inappropriate quotas and delays in adjustments in the end harm patients.

Susan Winckler: It's all right. Thank you. The time does proceed quickly. We'll turn to the next tour in the queue. Thank you, Rose Bigham, Jessica Collier and Toni [01:19:30] Collins. Commenter Crowder Blanigan, you are present, please alert our producers so that we can turn to you in the queue, but I'll turn next to commenter Rose Bigham, please proceed.

Rose Bigham: Hi there. Can you hear me?

Susan Winckler: We can.

Rose Bigham: Great. I'm a disabled person and patient advocate in Washington State who has been on stable non-escalating dose of prescription opioids for nearly 20 years. I feel pain every moment of every day due to multiple [01:20:00] progressive incurable pain conditions. Over the past two or more years, the consistent drug shortage of extended release and immediate release opioids has meant that every single month has become a race to find a local pharmacy who can fill or order medications that I rely on daily, which used to be relatively effortless.

I cannot request that my prescription be filled until the 30th day since it was last filled, and if pharmacies are out of stock on that day, which they routinely are, then I go without pain relief or start cold calling pharmacies within 50 miles to

try to find it. [01:20:30] Yet, the FDA drug shortage list routinely reflect no shortages. Somehow those control medications are not available consistently, and at the same time, the [inaudible 01:20:42] shift drug shortage lists reflect far more accuracy in details about the shortages from multiple manufacturers, and it's ongoing.

This places an undue burden on prescribers who have to resend prescriptions all over, patients and pharmacies who have to accept partial fills in desperation, and just untreated pain by people disabled [01:21:00] by pain. The focus all these years has been on saving people with substance use disorders, and those people do deserve appropriate care, but those of us disabled by pain have been left by the wayside. No one tracks what's happened to patients without substance use disorders, who have been consistently taking RX opioids as written to apply it with treatment. Why? There are something like five times the number of people with high impact chronic pain in those with substance use disorders, yet people disabled by pain are ignored.

The potential impacts of underestimation [01:21:30] means people like me and 10 million more suffer. The potential impacts of overestimation? There are still dozens of checks and balances to prevent diversion or misuse. Leaving millions in agony is no solution to the overdose crisis. I can't help but notice that when the quantity of stimulants became a nationwide crisis back in 2023 that the DEA took immediate steps to address those issues.

Where is the concern about people with untreated pain? The rate [01:22:00] of opioids dispensed in my state has decreased 60% since the peak year of 2008, and there are still just as many people who have pain here than ever, sometimes more. I cannot believe in this day and age that our FDA is not aware, not paying attention, not collecting the data on just how many people are suffering all the time now because they can't get medications [01:22:30] that are prescribed appropriately for everyone. Thank you.

Susan Winckler: Thank you. Our next public comment will come from Jessica Collier. In the queue I have Toni Collins, Tandy Crowder Blanigan, and Jeanette French. Commenter Collier, please proceed.

Jessica Collier: Hello, my name is Jessica Collier and I'm a harm reductionist based out of Cleveland, Ohio. I work for two harm reduction organizations serving people who use drugs, [01:23:00] people who are in recovery from using drugs, and I also have parents who use drugs and I myself use drugs. I also am a person whose life is infinitely better today due to more than one Schedule II drug. We will never eliminate drug use. People have used drugs since the dawn of time and they will always continue to.

However, having a safe, stable supply of drugs to utilize for the innumerable symptoms, symptoms that humans will continue [01:23:30] to face no matter what the FDA, the DEA or any other agency tries to do, they will always be there. I'm going to quickly go over the overestimating, because honestly, every

symptom that I read in that was just drug war rhetoric. We have answers for that. Other countries are doing things that we know work. A safe supply of drugs given to people who wanted to use them does work, [01:24:00] and then they can transfer to the drugs that you all are already comfortable with, like Suboxone and Methadone, and the drugs on their way out for stimulants just the same. So I wouldn't even like to focus on that, but I do know lots of folks suffering from these underestimation symptoms.

People cannot get the meds that they need and they end up turning to street supply. People can't get their symptoms addressed and they end up with worsening mental health symptoms, mental health crisis that are completely [01:24:30] avoidable. The stresses on the healthcare system are already immeasurable due to the overdose crisis that we're not handling properly. I know tons of people that are struggling every month to fill prescriptions or cannot get their prescriptions anymore and are told they should take something like Suboxone or methadone that just isn't going to adequately treat their pain.

We are making people suffer and there is [01:25:00] no reason for it. The US is a country that is capable of just about anything that we want to do, and with so many other countries doing things that are working, the data and the evidence to support that those things do work, there's no reason that we can't take steps towards better working measures and stop making our people suffer and die. Y'all are killing people. Thank you.

Susan Winckler: Thank you. Our next public comment will come from Toni Collins. Then [01:25:30] if present, we'll hear from Tandy Crowder Blanigan and Jeanette French. So Commenter Collins, please proceed.

Toni Collins: Hello and thank you for the opportunity to speak. My name is Toni Collins. I'm a 43-year-old mom of two living with end-stage chronic spine pain after injuries and failed surgeries. I've tried nearly every non-opioid and interventional option over 28 years. In California, a carefully [01:26:00] prescribed opioid regimen let me function and be the mother that I am and live with dignity, but after moving to Indiana, I went four years without any treatment, saw seven doctors with no help.

It's only the past four months that I have been prescribed opioid medication again and I'm still undertreated, I'm still mostly bedridden. The difference between access and no access is the difference between functioning [01:26:30] and barely surviving. When demand is underestimated, patients like me pay the price. It means out of stock at pharmacies, forced tapers, withdrawals, ER visits, lost jobs, depression, and even suicide. Families are strained and treatable pain becomes a lifelong disability.

Overestimation has consequences too, stigma and tighter restrictions, but the daily immediate harm comes [01:27:00] from under supply. For people like me, medications are a lifeline. They're not a moral failing. We're not asking for a free for all prescribing. We're asking for accurate forecasting that reflects real

medical need so legitimate patients are not collateral damage, including patient advocate groups will give a better picture of current issues patients are actually facing. Inaccurate demand forecasting is about access with accountability. Please center patient's [01:27:30] lived reality in your models, because every miscalculation has a face, a family, and a future. Thank you again for the honor of speaking.

Susan Winckler: We have in the queue Tandy Crowder Blanigan, Jeanette French and Monty Goddard. Commenter Crowder Blanigan, if you are present. Please proceed. [01:28:00] We'll turn then to commenter Jeanette French. In the queue we have Monty Goddard, Brandy Hoerauf, and Danita Marrs. Commenter French, please proceed.

Jeanette French: Okay. I'm focused more on underestimation and has led to many increased costs, medication errors, new barriers to care with lost trust between doctors and patients, [01:28:30] stricter regulations in doctors fearing arrest and being imprisoned, law deciding medical necessity and medical use, promoting forced tapering, severe medication shortage, patients severely stigmatized and shames, and added [inaudible 01:28:47] pain control, more suffering deterioration, multiple treatment delays, increased medication errors, ER hospital visits, increased mental and psychological distress [01:29:00] on doctors and patients.

What it didn't do. It did not lower illegal drug use or availability, improve or treatment care, provide equal access to pain management, create better medications to actually treat chronic pain or solve long-term solutions that it never will. Well, what to do? Since reducing opioids is not working, establish a drug shortage management team totally independent of the DEA, [01:29:30] the CDC, the FDA, with no political affiliation, working with patient advocates, doctors on evidence-based unbiased information and studies that reports directly to the public. Bring the production up 20%. Continue doing this yearly until the saturation point is reached. When all patients have access, that's your saturation point.

Assess yearly. It does not mean over-prescribing like before. It means [01:30:00] proper prescribing, to ask in all harm reduction strategies like Portugal to bring overdoses to almost zero. Is the United States saying they aren't capable of doing this? Or they saying they don't want to give up overdoses as a political football? Education program starting in grades three and four, like [inaudible 01:30:28]. The perfect practice fallacy. [01:30:30] Legal advocates have noted the immense pressure on doctors who treat pain and addiction, and that they can be unfairly prosecuted for making a small number of mistakes among thousands of patient encounters. 95% of imprisoned doctors do not belong there for treating patients in good faith.

[01:31:00] The harm reduction is just not the whole point isn't keeping people alive the objective? Harm reduction keeps people alive and gives them a chance

to make better option choices. If they are dead, there's no hope. Addicts must choose to stop. You can't force them. It is proven-

Susan Winckler: Thank you. Our next comment will come from Monty Goddard. Then in our queue we have Brandy Hoerauf, Danita Marrs, and Claudia [01:31:30] Merandi. Commenter Goddard, please proceed.

Monty Goddard: Good afternoon. My name is Monty Goddard. I'm a licensed civil engineer. I became a pain patient advocate for my wife's quality of life in our golden years were destroyed by our government's mischarging war on the opioid epidemic. I got interrupted there by the host asking me to start my video. Let me begin by stating the obvious. Underestimation [01:32:00] of demand results in harm to patients. Simple as that. I have two related issues.

First of all, for all of 2023 and 2024, the FDA listed zero shortages of fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone. In 2025, the FDA lists shortage of only fentanyl and hydromorphone. The SHP listed shortages of all five analgesics in 2024 and '25, and listed three of the five [01:32:30] in 2023. This dichotomy is a major problem. If the FDA does not even acknowledge there's a shortage of these essential medicines, the FDA will certainly take no related remedial action, as you did in concert with the DEA to address the ADHD medication shortages last fall.

The FDA must modify its methodology for collecting and reporting drug shortages to better reflect the reality experienced by patients whose legitimate prescriptions go unfulfilled due [01:33:00] to shortages on pharmacy shelves. These all too real shortages frustrate physicians and pharmacists and harm patients. Second, for the DEA's annual controlled substance and production quote announcements in the Federal Register, the FDA for the last four years has predicted the levels of medical need for Schedule II opioids in the United States would decline on average on a year-over-year basis by 18.9, 5.3, 7.9, and 6.6% from each [01:33:30] prior calendar year levels.

As evidenced by the factual information I presented, these FDA predictions are irrational. They can only be defended by ignoring the reality experienced by physicians, pharmacists and needlessly suffering patients. In a recent DEA production quota setting exercise, a commenter mentioned the ASHP's warning of shortages of pain medications, noting the shortages have not been publicly acknowledged by the DEA or FDA. The DEA responded [01:34:00] in part, "If the drug manufacturer notifies the FDA drug shortage staff, FDA will coordinate with the DEA to address and minimize the impact of shortage of both agencies." Currently, FDA has not issued any nationwide shortage of oxycodone and hydrocodone. My takeaway from this, neither the FDA nor the DEA are responsible for paying patient harm. It's those damn manufacturers. The ASHP [01:34:30] captures the reality. The FDA must do the same. Thank you.

Susan Winckler: Thank you. Our next comment will be provided by Brandy Hoerauf. Then we'll turn to Danita Marrs and Claudia Merandi. Commenter Hoerauf, please proceed.

Brandy Hoerauf: Hi, thank you very much. My name is Brandy Hoerauf and I work for the Doctor-Patient Forum. I am a lifelong pain patient and I was born with spina bifida and scoliosis and had my first spinal fusion at 12 years [01:35:00] old. I represent the millions of pain patients who were negatively impacted by the DEA oversight. My medicine has been out of stock twice now, longest for four months. I was told that I could only switch pharmacies three times due to NARC score.

Months back, the Doctor-Patient Forum had a docket asking the FDA to claim NARC score as [01:35:30] a medical device, as that is negatively used against us. Unfortunately, when our medications are out of stock, we cannot just pharmacy hop, as it's a listed red flag per the DEA. My father had a complete rotator cuff surgery done a couple of years ago. His oxycodone script was not anywhere in the city. He proceeded to have to go to five pharmacies, [01:36:00] which obviously he couldn't drive, and he looked at me and asked me, "Is this what you deal with?" And I said, "Yes."

The problem is, is that every year we go on regulations.gov and we submit our comments telling the DEA to stop cutting production. This is harming and hurting patients. Unfortunately, the DEA keeps doing what they do. We want the DEA out of healthcare. They have only caused harm. [01:36:30] ODs continue to skyrocket while the RX opioids continue to go down. So I appreciate your time and we would like something to be fixed, as this is now a decade of this harm against people who suffer in pain.

Susan Winckler: Thank you. Our next comment will be from Danita Marrs. Then we'll turn to Claudia Merandi, Kate Nicholson and Jeffrey Rosenberg. Commenter [01:37:00] Marrs, please proceed.

Danita Marrs: Hello. Thank you for this opportunity. Everything's been said. I would just, first of all, I guess I would say thank you for taking time to listen to public comments and I appreciate that you look into ADD medication shortages and [01:37:30] SUD medication shortages. I really wish you would all listen to the people in the pain community who have been struggling with trying to get medications for years now.

I don't know. I probably shouldn't just tell you specifically what medications we've had trouble with getting, and also a lot of the medications don't seem to work like they used to. I thought maybe it was my imagination, but [01:38:00] then I found an old one and I took it and it was night and day. There's something going on, but here's another problem. I've noticed that when you go to the pharmacy and you can't fill your prescription, then you're ping pong back to the doctor. Often you have to get a medication that may be stronger than what you had before, and if you're really looking into less harm, then you want to make

[01:38:30] sure that the medication is there in all doses and all forms so that people don't have to change their medication unnecessarily.

I was born with congenital hip dysplasia. It wasn't diagnosed till I was over 17 months old, so the regular braces didn't work. I ended up having to have surgery starting about the age of seven and then total hip. I won't go into all [01:39:00] that. It's been a lifetime of braces and casts and surgeries, and after everything else had been done and tried, I was finally sent to pain management where I actually had a good quality of life until the CDC guidelines came out. Medications were cut back basically under 50 MME, and other than that, you live in bed.

That's not the way I expected to spend my retirement. I taught for 23 [01:39:30] years and I'd like to be volunteering in schools. I'd like to be useful in society. I just wish we would be. I wish we had that option, and for some people, when nothing else works, it's that medication that actually gives us a chance to live our life productively. Thank you.

Susan Winckler: Thank [01:40:00] you. Our next comment will be from Claudia Merandi, followed by Kate Nicholson, Jeffrey Rosenberg and Bev Shechtman. Commenter Merandi, if you are present, please proceed.

Claudia Merandi: Good afternoon. My name is Claudia Merandi. I'm the founder of the Doctor Patient Forum, a nonprofit that advocates for patients living with pain. We have chapters in all 50 states. We have about a half a million who follow our efforts on social media. We've heard from thousands of patients [01:40:30] over the past few years who have been harmed by medication shortages, most commonly morphine, oxycodone, and hydrocodone. These are people with cancer, post-surgical pain, rare diseases and hospice needs, and they're often left scrambling to find any pharmacy that can fill their prescription.

Dr. Chad Kolus, a hospice and palliative care physician, recently told us that his patients with cancer are still being affected by the morphine shortage. That alone should be enough to rethink how these [01:41:00] forecasts are built. But there's another layer of harm that never seems to get addressed. Every time a patient is forced to visit multiple pharmacies due to shortages, they get flagged in the prescription drug monitoring program. Risk algorithms like NARCs care treat this as doctor shopping or pharmacy shopping, even when the only thing the patient did wrong was try to access their medication during a shortage.

We've seen patients flagged for simply having used more than one pharmacy over two years [01:41:30] or for driving 25 to 50 miles out of town because their local pharmacy was out of stock. These same forecasting errors that caused the shortage now lead to patients being reprimanded, red-flagged, or they lose their medication entirely and are dismissed and medically abandoned by their providers. So we're not just talking about inconvenience. These shortages are causing algorithmic punishment. You asked for public comment on how forecasting should work, so let's say this [01:42:00] plainly. If your models

prioritize diversion data over clinical reality, they are creating harm. If you exclude palliative care, hospice and surgical care specialists, the forecast will never reflect true need, and if the system punishes patients for trying to access legal prescriptions while claiming it's keeping them safe, then we've lost entirely. Thank you for [01:42:30] having us speak.

Susan Winckler: Thank you. Our next comment will be from Kate Nicholson. We'll then turn to Jeffrey Rosenberg and close out with comment from Bev Shechtman. Commenter Nicholson, if you're present, please proceed.

Kate Nicholson: Thank you. I think I can't turn my camera on, but I will go ahead and proceed. Oh, now I can. Okay. Good afternoon. My name is Kate Nicholson. I am [01:43:00] the executive director of the National Pain Advocacy Center, a nonprofit that takes no industry funding, and works to advance the health and rights of people with conditions causing significant pain. 2025 marks the ninth consecutive year that the DEA in consultation with the FDA has reduced the medical supply of opioids, following on further reductions going back to the 2010s.

But over the past few years, NPAC has seen a dramatic uptick in complaints from patients who aren't able to access their [01:43:30] medication at pharmacies and from providers reporting supply barriers at both pharmacies and hospitals. These reports come to us via email from all over the country, Washington, Minnesota, Florida, Ohio, et cetera. Moreover, members of NPAC's community, people I know and work with daily, have been directly impacted.

A board member, who is a power wheelchair user with multiple sclerosis, also the executive director of an organization and a professor was repeatedly [01:44:00] unable to access the medications she uses for occasional flare-ups, impeding her ability to perform her job. A community leader at NPAC, who is a retired hospital pharmacist, experienced numerous supply side barriers in accessing his medication. "I can't do anything," he said. "I can't even go shopping for food." Our clinician advisors have received notices from institutional pharmacies or patients that the opioids were simply not available.

Others in tertiary care hospitals [01:44:30] experience notices that basic medications like Oxycodone, acetaminophen 5325 are down to a one-day supply or entirely unavailable. Losing access to medication doesn't just increase patient suffering. It can result in sudden opioid stoppage or dose destabilization, which numerous studies show cause harms, such as destabilizing care relationships, undermining chronic disease management, mental health crises, increased hospitalizations [01:45:00] and emergency room visits, and importantly increased risks of overdose and suicide. To put these studies in a human context, another NPAC member, a wheelchair user with quadriplegia recently suffered a heart attack when his medication was suddenly reduced. His son was present when it occurred and he was fortunate to wake up on a ventilator, but he suffered stage 4 pressure sores that took months to recover from. This was due to a reduction by a provider, but the practical impact of

unavailable [01:45:30] medications on patient harm is the same. We know of course, that FDA is aware of these harms, given actions it has taken previously regarding opioid cessation such as its 2019 drug safety communication on the issue. IQVIA studies on medication usage in the US over the last three years show that drug shortages are concentrated in pain and anesthesia therapeutics. So we would ask that frontline harms to patients be strongly considered as part of supply as...

Susan Winckler: [01:46:00] Thank you. Our next comment will be from Geoffrey Rosenberg, and then we'll turn to Bev Schechtman. Commenter Rosenberg, please proceed.

Geoffrey Rosenberg: All right. So I just wanted to start with the fact that the United States is one of the most rural countries. California is the size of Canada, [01:46:30] so when we talk about healthcare, OTPs aren't even existent. They don't exist in all the states. That's a challenge. There are supposed to be billions of dollars in settlements. And actually, after COVID, the methadone reforms went great and the trust in the greater take homes was perfect. There was less diversion, and actually, it's getting better there. So we need more options there, [01:47:00] like the NHS who they all have more options there, but we also need access. Access again, is mitigated by stock and it's always been a problem because we had 30,000 FTC comments, mainly ADHD patients that could not get their medicine. They were completely disabled. They couldn't go to work, provide for their families for weeks. Some of them got fired.

But the DOJ [01:47:30] nonetheless, seems to be the gatekeeper because I thought for always that FDA was the oversight and the FTC would order. Why everything is outsourced when we can insource things, like better protections with fentanyl patches. Or a lot of EDS patients and complex patients such as like CRPS, they have to have the morphones. So they need hydromorphone, they need oxymorphone, but we [01:48:00] need to be able to use technology and start progressing forward so that the doctor-patient relationships can excel and their advocates in the hospital systems. And of course, the DOJ can look at transnational organized crime, which we were promised.

I just haven't seen that yet, but again, when you're talking about under ordering, it's better to have it and not need it, than to need it and not have it. Because [01:48:30] there are many people, and I know some, it's some of my friends, almost everyone knows someone that has gone out and OD'd either because of a true SUD. But now and for the last three or four years, I've heard it specifically has to do with the DEA, not just continuously cutting medications down and innocent doctors in my opinion, being put [01:49:00] in prisons. So hopefully, we can change that around. Thank you for you guys' time. We can do this.

Susan Winckler: Thank you. Our final public comment will be from Bev Schechtman. Commenter Schechtman, we'll turn to you now.

Bev Schechtman: I'm sorry. I couldn't hear you.

Susan Winckler: That's all right. Commenter Bev Bev Schechtman, go ahead.

Bev Schechtman: Okay. Thank you. Hi, my name is Bev Schechtman. I'm vice president of [01:49:30] the Doctor Patient Forum. And I am here today because pain patients are being harmed not just by shortages, but by what those shortages set in motion. Every day I wake up to emails from patients who are out of their Schedule II opioids because the pharmacy is out of stock with no estimate of when it will be available. We've heard from thousands of patients who are stable on long-term opioid therapy, only to be suddenly cut off due to shortages. Some of it stems from DEA quota decisions, some from opioid settlement agreements, but whatever the cause, the impact is the same. These [01:50:00] patients are repeatedly destabilized, unable to work, care for their grandchildren or manage daily responsibilities not because of misuse, but because their pain is unmanaged due to medication shortages.

When an antibiotic is out of stock, no one bats an eye if the patient switches pharmacies or the doctor calls in a substitute. But let me walk you through what happens when a pain patient's opioid prescription is delayed due to shortage. They call their doctor to say the pharmacy is out, that alone can get them dismissed from care. They try another pharmacy, but that violates [01:50:30] most pain contracts and triggers a red flag in the PDMP. If the doctor calls in a second prescription, NarxCare, which others have commented on today, it leaves no room for context. And that alone will cause a red flag, raising the patient's overdose risk score. If they travel more than 25 miles to find a pharmacy, it's another red flag. If they go to the ER while waiting for the med to be in stock, they're seen as drug-seeking, and that ER visit alone could get them dismissed from care. We've seen patients cut off and labeled with OUD because the pharmacy was out [01:51:00] of their medication.

Pain patients on opioids are already viewed with intense suspicion and when a shortage happens, there's no plan, no backup, just blame. Pharmacies won't take new pain patients, ERs won't help, doctors won't send in a new prescription. The patient is left in pain, destabilized and completely abandoned. This harm starts with a shortage, but the harm doesn't end there. Too often, harm from losing access to opioids is overlooked, but pain management is a legitimate part of medical care and that includes access to medications patients have relied on safely and [01:51:30] appropriately.

There are 17 studies that show that forced tapers or sudden discontinuation can lead to overdose, hospitalization or suicide, and that's exactly what happens when a patient can't access their prescription due to a shortage. When it comes to shortages of Schedule II opioids, the ripple effect of harm cannot be overstated. While I understand the desire to reduce unnecessary opioid availability, cutting supply at the pharmacy level comes with dire consequences. And these consequences are falling hardest on the patients least equipped to navigate them. [01:52:00] It is time for the DEA to stop reducing the supply chain and instead, listen to patients who require these medications as part of a comprehensive pain management program. The focus on harms from opioids is

constant, but the harm from losing access is ignored. Nobody is measuring tracking or recording pain patients who lost their medication, nobody knows how many died. Please stop reducing supply and start measuring patient harm. Thank you.

Susan Winckler: Thank you. That concludes the public comment portion of our meeting. And [01:52:30] at this point, when we hold these, that I really must underscore how much we appreciate the investment of each individual who provided public comment. We know that it requires investment, often as you heard, vulnerability, as well as efficiency and proficiency in speaking quickly to deliver those remarks. But we appreciate everyone who took that step and chose to share [01:53:00] today. So that real-world perspective is really just essential. As we finish the stage setup here, I'm going to invite my panelists to come on up. The stairs are on that side and I will not ask you to step up without the stair, but we are going to close out our program today with the conversation among those who represent a range of individuals. They have a range of experience in demand [01:53:30] forecasting and the real-life tensions of getting it right. The font on the cards is very small, so I'll tell you, you'll find it. There we go.

Demand Forecasting Panel

Laura Bray, MBA, Chief Change Maker and Founder, Angels for Change
John A. Gilbert, JD, Director, Hyman, Phelps & McNamara
Nicolette Louissaint, PhD, Chief Policy Officer, Healthcare Distribution Alliance
Emily Tucker, PhD, Dean's Assistant Professor, Department of Industrial Engineering, Clemson University
Jillanne Schulte Wall, JD, Senior Director of Health and Regulatory Policy, American Society of Health System Pharmacists

So, we now have five additional individuals on the stage. Thanks to each of you for joining us, and I am anxious to jump into this conversation. We're just going to jump right in. So we're going to turn first to [01:54:00] my left. And here, Emily Tucker, you are an assistant professor in the Department of Industrial Engineering at Clemson University. I'll note that we don't usually have professors from engineering colleges here at the foundation, but I think it's important today that we tap your engineering and operations research perspective first. So would you frame up the conversations that we're about to have with a few observations? I guess give us that structure that comes from being an engineer.

Emily Tucker: I would be [01:54:30] happy to. And a little bit of context why an engineer is thinking about medications. Well, what goes from the raw materials to get to patients? There's a lot of engineering, there's a lot of math, there's a lot of decisions in that process. How you use data matters. And so I'm coming with about a decade of experience, thinking and studying about drug shortages and supply chain resilience. I am not in the system. I'm outside the system. And so I try to provide some context for how systems' best practices can inform [01:55:00] in particular, these topics. And so there's a couple of concepts I'd

love to highlight as we kick off this conversation. The first thing is when it comes to forecasting in pharma and also generally, having the right data and what you do with the forecast often goes further than having a really complicated model.

Advanced models are wonderful, but I think setting up, making sure we're using the right data and how we're using the forecast, kind of that handoff matters a lot. Thinking [01:55:30] about that handoff, I do want to split up a little bit. What is a forecast is different than what you actually choose to do. And I think when you muddy those two together, it can lead to really poor outcomes. So one example, in any industry when we think about forecasting, it's very important to predict demand or medical need, but then you have to add on a safety factor because things go wrong. And so what you choose to make that safety factor of, can [01:56:00] depend on a lot of things. A big thing is uncertainty. What do you expect to go wrong either on the supply side or in the demand side if demand might be increasing?

The second is confidence in your data. You need to have a higher safety factor if your data doesn't properly reflect demand. A couple other features here. If things do go wrong, how rigid is your supply chain? If your supply chain is really rigid, you need more of a safety factor. And then finally, the last [01:56:30] thing on that safety factor I want to note is how aggregated is your forecast? So if you're trying to predict national need, that's very different than predicting an individual pharmacy's patient need on a given day. And if you want to go from that national to that specific, and we really want to get to patient level access, you're going to need a lot more of a safety factor because there's a whole host of things that go down the supply chain.

A couple other just very brief things. When it comes to data, [01:57:00] different stakeholders forecast for different reasons. Non-FDA stakeholders care a lot about orders, which is appropriate. FDA is thinking about medical need. And that was brought up earlier, but really to highlight, medical need is patient need and the further you get away from patients, the harder that is to predict. And then finally, I want to note that patient use matters a lot. We often talk about forecasting for individual compounds [01:57:30] or individual products, but if a shortage happens, patient's demand will shift. We've talked about prescription flipping, we've talked about substitutability. And when it comes to forecasting, we need to forecast not just for when things go right, but making sure we forecast when things go wrong as well. And so those are a couple concepts maybe to kick us off.

Susan Winckler: Yeah, really helpful and I've already got the slogan that I'm sure someone will pull up, which is data matters. But then also, thinking about some important components [01:58:00] that you flagged about when you need more, I guess flexibility in the model and thinking about where you need that, whether the idea of the aggregation. And then in particular, I'm struck by this thought of the demand forecasting being at a step-up or considering there's individual product, but then the dynamics in stepping that up. So as we [01:58:30] have time, we should think about, are there other system fixes that we can consider there?

So I'm going to go one by one, but you all know you can jump in because you each have a microphone that I have no control over. So let me turn to my other side and we'll continue in the supply chain. I'm turning to John Gilbert, who is at the law firm of Hyman, Phelps & McNamara, and he's not actually in the supply chain, but you work with manufacturers as they navigate [01:59:00] those waters, and you have experience having served at the Drug Enforcement Administration. So, paint for us the picture about how manufacturers think about demand forecasting for controlled substances and the various factors that animate those processes. And if you want to, you can weave in a commentary on the structure that Dr. Tucker gave us, but I'll turn the microphone over.

John Gilbert: Absolutely. And [01:59:30] approach it also with, I do work, have worked for many years with a lot of manufacturers. I did start at DEA, so I understand the process. And you heard from some of the comments today, what we're dealing with here is an issue regarding where we're trying to estimate patient medical need in a construct that really wasn't totally thought out. Right? We're dealing with a law that was written in 1970 and we're dealing with regulations that have evolved somewhat, but as you heard [02:00:00] people say, some for the good, some for the bad. So we're dealing with a system which inherently, is attempting to try to limit the amount of availability of certain substances because of the concern that if there is oversupply, that means bad things happen, diversion, abuse. So by its nature, that causes conflict with the fact of trying to then forecast or demand in a capitalist market. Right? In the fact that what you're going to have by its nature, if you let [02:00:30] the drug supply do what any other market in the United States does, you're going to have people wanting to make more to market their product more.

And so you are going to have by nature, the people that are able to market their drug or make their drug more available are going to have greater sales. But yet, the quota system, as we've heard a lot of comments about, tends to try to restrict that. So part of the problem that I think has occurred over the years and continues to occur is, how do you balance that, [02:01:00] right? How does FDA and the DEA balance that, given the fact that it has been pointed out where you have the law in and of itself, put some responsibility on FDA, and yet, at the end, DEA makes the decisions. Right? DEA sets the quotas. More so, DEA is having to operate in a legal construct that says, "We got to establish an aggregate for the year, and then we have to establish individual quotas for the year and try to work within [02:01:30] those."

Well, of course, the supply of medicine to patients and the manufacturing of those drugs doesn't run on a yearly basis. You don't start in January 1 and end on December 31st. It's a continuing process, yet, that's what the constraints are. And so what you have is a system which is not nimble enough. And part of the issues, I think, are that it's not nimble enough to react to things, like a manufacturer goes down. And so you have to reallocate. How do you reallocate quickly? Well, for the DEA to do that, they have to redo [02:02:00] supply, redo quotas. And as someone had mentioned earlier, God forbid if we already have given out the aggregate for the year. Because if that happens, now the DEA has

to publish a new federal register notice and go through notice and comment, just to get that aggregate increased.

So turning a little bit more on where Susan was taking this, but I think it's important to understand the constraints that are necessary in order for us to be able to try to come up with some solutions here. And I think those solutions [02:02:30] relate to issues of, I think, in terms of transparency. Because one of the issues, I think, that I have in working with manufacturers is that they're trying to figure out what it is that the DEA or the FDA is looking for in the ways of data. So more transparency in what those issues are will allow the manufacturers and the other people on the supply chain to say, "Hey, here's what the data is telling us." And so hopefully, the regulators can understand the need, and then it's a timing issue. Right? [02:03:00] Because one of the issues particularly with ADHD that struck me was that the concern about the fact that there were shortage of ADHD and some comments about looking at the aggregate data for the year was that it didn't look like there was a shortage from the assignment of quotas, but there was because of timing. Right?

So if the quotas aren't given out until... Or increases, I should say, aren't provided until too late in the year, then manufacturers can't use them. So the quota goes unused. So [02:03:30] it looks like manufacturers didn't use the quota they were given, but it was really because of a timing. Right? They had a five-month lead time, I get my quota in September, I can't make it by the end of the year, so maybe I don't use it. And again, this isn't to be critical of the regulator because they're working within this system, but I think timing and transparency is really needed here to make sure that the supply continues and make sure that we're meeting patient demand.

Susan Winckler: So what I'm struck is that [02:04:00] we heard first from Dr. Tucker about the need, that in certain situations, you need more flexibility. And then you're observing that the regulatory structure itself, and at some level, the manufacturing process itself is not very flexible. I think we have a little bit of a collision course there. All right. Let's continue our journey on the supply chain. I want to turn to the end of the [02:04:30] panel here and think about the wholesale distributor role, which is different than how manufacturers are thinking about things. But I'm going to turn now to Dr. Nicolette Louissaint, who is chief policy officer for the Healthcare Distribution Alliance. I'm going to guess that you hear from your members just a bit about dynamics related to controlled substances.

Nicolette Louissaint: Never.

Susan Winckler: What's the unique role that distributors play in this space, and how do you think [02:05:00] about some of these tensions about needing flexibility, and yet, being about as flexible as I am in a yoga class, which is not at all?

Nicolette Louissaint: So first, I want to thank you for the work that you all are doing in this space. I think this is incredibly important. And one of the things that I know is true is

that as we have these conversations about models and thinking about forecasting, it is really important to also hear the patient voice. So I appreciate [02:05:30] the intention that you all put into the public comment as well. And I think as we were listening to the comments, we continued to hear patients say, "We want to make sure you're hearing us." And so I do want to offer that assurance that this conversation does have the patient at the center of it.

I think everything that Emily and John have laid out is true. I think the tension between the traditional nimbleness of the supply chain being [02:06:00] constrained in the necessary regulatory and legal construct is what we're wrestling with here. I really like Emily's framing of a safety factor because ultimately, really what we're dealing with is what level of tolerance do we have to build into a safety factor. It's really nice to also have another engineer on the panel, so thank you.

So for me, it's kind of, how do we think [02:06:30] about what is that safety factor and how do we apply it? From the distributor perspective, we are thinking about that national number, but it drills down very quickly into a local or regional number. And so when we're thinking about how a quota is applied, sure there is the conversation, the ongoing conversations, I should say, John, with the manufacturers about how we're thinking about this, what we're seeing, [02:07:00] what we're anticipating. The demand picture is really a daily activity for distributors. We're thinking about everything from the flu season, cold season, back to school, months in advance. Those are things that we know.

Then there are the things that we don't know that might shift that picture. That picture might shift not just based on how much, but also, where. And I think that's where that national picture drilling down to [02:07:30] the local picture becomes very important because just as an example, we are in peak hurricane season right now. If you have, God forbid, a population that is displaced as a result of a hurricane, it may not be the how much that changes, but it definitely will be the where.

And so now, when we're looking for those patients to get those refills in another county or possibly even another state, that's when we're going to start to see [02:08:00] the nimbleness that would allow for your statin or other products to be refilled may be constrained in that environment. So that's the other layer of demand forecasting that we're trying to contend with, is thinking about, how can we put in enough inputs and how can we be a partner and a contributor to this to say, "Here are the types of variables that we're considering," but also understanding that it's really in that unknown, that safety factor, that is going [02:08:30] to determine what the nimbleness of the system will be able to absorb.

Susan Winckler: Yeah. I think the hurricane example is a great one, where probably we were all like, "Oh yes, hurricane, that might affect the manufacturer." Oh, wait.

Nicolette Louissaint: Hi, we're here.

Susan Winckler: Exactly.

Nicolette Louissaint: Right.

Susan Winckler: Where people are, really interesting, and then they're accessing it through the pharmacies. So let me turn there. So we're joined by [02:09:00] Jillianne Schulte Wall. And you work with the members at the American Society of Health-System Pharmacists. Pharmacists are often the face that is here in the communication about whether-

Jillianne Schulte Wall: Pharmacists are the poster child for shortages.

Susan Winckler: Yeah.

Jillianne Schulte Wall: Pharmacists spend a lot of time managing shortages.

Susan Winckler: Yes.

Jillianne Schulte Wall: So it ends up being a huge drain on the system, but it's also, as Nicolette was saying, sorry, that patients are really kind of [02:09:30] centered here. And for pharmacists, that is the end goal, is to get your patient the medication. And I think what I want to magpie from everyone, is like different pieces of what you've said. One of the things that I think is really important here is the rigidity of the constructs we're working with.

Susan Winckler: Right.

Jillianne Schulte Wall: Really, we've had conversations, ongoing conversations with DEA. Many of you may remember when hurricane Maria wiped out so much of the manufacturing in Puerto Rico. And so we had ongoing injectable opioid shortages [02:10:00] for a long time. And I think we're still in some ways, seeing ramifications from that even today. And we had conversations with DEA about trying to make the regulations more supple, to find ways to move quota faster, to ensure that these things were getting to patients in a timely fashion. But as of today, we're still in the same timeline. So we're still not getting manufacturers what they need when they need it. I think wholesalers and distributors are dealing with some issues around the national [02:10:30] opioid settlements, which are creating new problems that we hadn't anticipated when we're thinking about quota, because pharmacists are kind of stuck using proxies for what they think is going to be demand.

You're going to look at your historic patterns from your prescribers, but you don't have access to everyone's prescribers, just your own prescribers. Maybe you're not going to have claims data necessarily. You're going to be looking at what you bought last year, but that can shift rapidly, depending on whether you have an influx of new patients. That's when you're going to be doing your big demand forecasting. [02:11:00] If you want to open a new oncology center, you

have to think about, what does that mean for what I'm going to be ordering? Is that going to flag me within that national opioid settlement? How am I going to do this in a way that makes sense? And none of these pieces work together right now. And at the bottom of all of it, is sort of this lack of supply where it needs to be.

And so I think we work with everyone in the chain, but we have very little control over any element of it, except trying to get the medications to patients. So [02:11:30] I think our main focus is, how do we continue to scream from the rooftops about shortages? Because anyone who has ever followed ASHP, knows that we talk about this all the time, and we have our own shortage list obviously. But I think that that's really where our members are focused. How can we get the right information to the right people so that they can help us get the meds to our patients?

Susan Winckler: Because that gets to the data component, right? Which actually, let me ask a data component on this kind of hurricane relocation [02:12:00] piece. So how do you know? Is it the new, and then you start to see it in the patient?

Jillianne Schulte Wall: I feel like Sophia in Golden Girls-

Susan Winckler: Yeah.

Nicolette Louissaint: ... but 2017, Puerto Rico. So it's interesting, because we often start the story with hurricane Maria, but I'll take you back. We had Harvey, and Harvey impacted Texas. There was actually so much water [02:12:30] that hit that landmass that the ground sunk. We then had Irma. The reason I say this is because we were at that point looking at Texas and Florida, a little bit of USVI. So there were patients that actually were moved from the USVI, some of whom actually needed controls to Florida, thinking that we're making them safer. So when Irma was [02:13:00] actually moving through Florida, there were not just the patients that would already have been in Florida. You also had patients from the USVI. When Maria moved, you then had those patients that were moved from the USVI, plus vulnerable Florida patients move to Georgia.

So when we're thinking about what happens in that event, it's easy to think about what happened to the people in Puerto Rico, because we're thinking about the devastation that was on that island, and we should. [02:13:30] But we also have to consider that there are often vulnerable patients that are moved. And when you have serial events, you're not just thinking, "Oh, okay, so they're here now." No, they're now in another state. So now, we also have to think about what products can move with them. And there were disruptions. A lot of those patients actually had to rely on the hospital systems to be able to get the products that they needed. And there were a lot [02:14:00] of calls and a lot of coordination with HHS and DEA. And even with that, it still took days.

So with that, and to Jillianne's point, there are these constructs that we operate in that create rigidity. So even when we're trying to be nimble, that lag... And we could say, "Oh, well, we got it from 10 days to seven days." If you are a patient, seven days is still a very long time.

Susan Winckler: [02:14:30] Indeed. And that's assuming that all of the pharmacies were still there.

Jillianne Schulte Wall: That's assuming everything is still operating and up and running. The other thing I would say is, when you get new influx of patients, you're also going to be trying to figure out playing whack-a-mole. You're going to run out of stuff. So then it's like, what's next on your list? And then can you backorder? And then everything is backordered. So even looking at backorders is not a very effective way to see like, what is actually where the demand is? There's no easy or really, perfect way for a pharmacist [02:15:00] to forecast what they're going to need in any situation.

Nicolette Louissaint: And that pharmacist is going to have to communicate with the distributor.

Jillianne Schulte Wall: Yes.

Nicolette Louissaint: That's the part that's different now. It can't just be in the system. There has to be direct communication to say, "X, Y, Z has changed." There is a process for that. But if let's say you're out of power, let's say your phone is not working because you are in a storm ravaged area, those are going to be challenges.

Susan Winckler: [02:15:30] And then I am going to turn to you now, Laura, because we've been having this conversation and saying, yes. And this is all for the flexibility that's needed, the rigidity that exists. Even when you think you know what might happen, something else will happen, and then you get to deal with it. At the end of the day, we're doing this all because we want to get the medications to the patient. So I'm going to turn to round out our [02:16:00] conversation. I'm going to turn to Laura Bray. You founded Angels for Change, and you have the best title ever in being the chief change maker.

Laura Bray: When you found something, you get to give yourself your own title.

Susan Winckler: That's the key, that's the key. But in your engagement, you often jump in when the forecasting has failed, and we've already started the conversation about shortages. But when you think about demand forecasting, so step back a little bit, what do you want to emphasize in that demand [02:16:30] forecasting landscape?

Laura Bray: Yeah. So first, thanks for having this important conversation. It is extremely important. And I hope that today is a beginning and not an end of that conversation, because patients are in desperate times and there really is no pathway right now to fix it. We've run a drug shortage hotline, the nation's only,

because there wasn't one [02:17:00] and anybody can call us in a drug shortage. There is a system that breaks a lot, not just when in this scenario. Right? But there are flexibilities and connectiveness that allow us to solve other shortages that we just don't have here. But from a big picture standpoint, one thing when we're looking at demand forecasting, is this is a unique market and [02:17:30] the question is, who are the demanders? Who is the demander? Is it the purchasers? Is it the pharmacists or prescribers? Is it the payer who decides who's going to actually reimburse what medicine and what formulary? Or is it the patient who's at the end, who can't decide any of it?

And when we're looking at just sales [02:18:00] demand, we're factoring in a very simplistic idea for a very complicated demand side. The reality is, the purchasers are a demander, and the prescribers and pharmacists, fillers, are a demand mechanism, and the payers are a demand mechanism. And in the end, patients have zero control [02:18:30] over any of it. We don't get to buy it. We don't get to decide who we even go to as our physician and pharmacist. That's all decided for us, either by location or by our insurance company. We don't even get to pay for it. So we have no power, in the same way that another supply chain that sells cheeseburgers does. And so, we have to not just have a flexible, nimble, connected signal. We have to recognize [02:19:00] that this is not a sales-based supply chain. It's a reimbursement purchasing prescriber supply chain. And all of those demand signals must be included, or we will automatically, not... Even in a non-quoted standpoint, we will not succeed because stable supply needs stable demand. Those metrics must be in it.

Susan Winckler: I [02:19:30] think probably the first time today that we've talked about that, just the payer or formulary dynamic. That is another kind of insertion into the decision-makers. So early on, we said, if only FDA could know what prescribers wanted to write for, I think you bring in the dynamic in that, even though that wouldn't-

Laura Bray: Yeah, that doesn't matter. And we saw that significantly during the ADHD challenge, which we still have today. It has lessened, but it is still ongoing. [02:20:00] It is not resolved. And while there was some flexibility, it was very minimal. The formularies decide what scripts patients can get, what scripts physicians can write, what medicine pharmacists buy. And if they're unsure, if you are going to get reimbursed for it, [02:20:30] they're not going to buy it in their pharmacy. They're not. And so the answer though will not be, "I won't buy this in the pharmacy." The answer is, "This drug's on shortage. Sorry."

And so this is why sometimes we can hear, "But there's supply, it's not short there is supply." Well what supply is there and was the largest prescriber not have supply? Because physicians [02:21:00] can't just write a new script. And even if they do at a certain point, they get tired of writing new scripts. Right. And pharmacists can't just buy a new medicine, a formula, if they don't know it's going to get reimbursed.

Susan: Well and in the schedule two environment it's also not as simple. Let me switch what it is should be dispensed. So that's a rigidity.

Laura Bray: That's right.

Susan Winckler: That exists because we recognize that there are benefits and [02:21:30] risks to these products. So there's some of the rigidity... Well, the rigidity is all by design, but driven by different factors.

So let's talk a little bit, we've delved into shortage and we've talked about shortage I think more broadly than controlled substances. So I want us to focus a little bit more on the, "Okay, so there's a shortage in a controlled substance." What is that rigidity, [02:22:00] let's use that word, what are the differences? What's some of that rigidity that we see in controlled substances shortages that we don't see elsewhere? And, Jill-Ann, can I start with you?

Jillianne Schulte Wall: Sure. So I think we talked a little bit about this. There are other layers of complexity once you get to a C-II. So you're talking about things like state and local requirements too, the things that impact what you can fill and can't fill, how you fill a prescription. So we have [02:22:30] members in hospitals and health systems and also in community pharmacies. What you're looking at is very different depending on whether you're looking at what you're ordering for your hospital or what you're filling at your community pharmacy.

I think that at the community pharmacy level, I think it's some ways it's even more complicated because you're in a situation as a pharmacist where a patient comes to you, you want to fill it, you don't have it. It's not necessarily going to be the simplest thing to say, "Go to your other pharmacy." You can call your other location, see if it's there. But you [02:23:00] know that you are potentially creating risk for a patient when you do that. Calling in the prescriber and raising the issue with them can also create a whole host of problems. So there's no easy way.

The other thing is when you're looking at your ordering, and this is true for hospitals and for community pharmacies, because of the new national settlement we don't know what those thresholds, the ordering thresholds are to flag and we're finding out on the fly. So what happens is you submit your orders and then you wait and [02:23:30] cross your fingers they're going to go through. And if they don't, all of your ordering is cut off, cold Turkey. It's not... that can be hugely problematic. It's usually restored very quickly from what we've seen, but there's no real communication mechanism between the pharmacies and the overseers in settlement.

And I think one of the things that I want to... I'd be curious what other panelists think about this is in working with DEA and talking to them about some of these issues, especially around red flags, [02:24:00] I get the distinct impression that DEA isn't particularly comfortable in this space. This is a much more clinical

space than where they want to be. And I think especially for folks who are watching this and who don't live in this world like we do, agencies are made up of people and they are human and they in most cases are just doing the best they can to get through the day.

And I think for DEA, when we had conversations with them, they wanted them to try to find solutions, but they feel hemmed in by the way the laws are written. And I also think they [02:24:30] feel hemmed in by the way that they are tared with the whole brush if things don't go their way. But anyway, I think for pharmacists, the C-IIs do create a whole host of additional potential minefields when they step into them.

Susan Winckler: Because by definition a schedule II controlled substance is treated differently, it simply is, and is available because [02:25:00] there is benefit to it. But then there's also just a heightened, "I'm going to pay attention to this more," which creates some challenges. Emily, did you weigh in here on when we're thinking about this and then we're in this really rigid system and...

Emily Tucker: I'd be happy to. And I think one thing that stands out in what you were saying is when we're in a controlled substance space, and the thing about schedule II in particular, there are different products under schedule II, and [02:25:30] I think it can be really dangerous to think about this conversation in aggregate. So maybe I keep pushing us to disaggregate, but it's important.

And in particular the differences when we talk about overage versus underage, I think at least from the clinical experts and public health experts, which is not me, I'm the math person, but that there is a real difference in having excess for different types of products under schedule II And there's a different risk of underage, of shortage, [02:26:00] for different products under schedule II. And that means we should be able to make different decisions and maybe not legally, but when it comes to what things are... I just want to bring that up as it can be a little dangerous that we're going to get it wrong one way or the other. If we're planning in a very risk averse or a very risk, we would call it risk seeking, but having more product available.

And so I do want to note if we can divide products, and maybe this is future, maybe [02:26:30] this is law, things like that. But in terms of best practices, I think matching choices to risk is going to go a long way. And then if I may, when it comes to rigidity, pulling what we can do now, perhaps. When you have things that are quite rigid, it's all the more important to have your plan set up well in advance. It's not inherently bad to be rigid if the plan goes well.

And so that means we want to make sure that we've put into [02:27:00] play a lot of backup options that have been well reviewed and that are well considered that if something goes wrong, we don't need to be hyper flexible, but rather we've defined a portfolio of options that we're comfortable with that isn't massively in excess, it isn't massively in shortage. And so I think that can help too, that there is a middle ground to some of this. Is that kind of what you're...

Susan Winckler: It is, and the visual I see is that if you [02:27:30] have these ways to address something, you don't necessarily have to, in our case because we're talking about demand forecasting, you don't have to necessarily have to fill it with API and allocate it, but rather you have a safety factor and then where it might need to be applied, yes.

Emily Tucker: Having quicker reviews and things like this, knowing that we exist in a rigid system, but can we move the system faster [02:28:00] and make sure it's well reviewed appropriately? The one other factor I do want to put in terms of controlled substances is unique to forecasting in this area, that patient behavior is affected by the quota and affected by shortage. We've alluded to this a little bit, but I do just want to point this out.

This is unique relative to forecasting in any non-controlled industry that, it's called demand censoring, if some of us are familiar with that term, that we're getting fewer orders, you alluded to this, [02:28:30] because there is a shortage. And so it's going to be this negative feedback loop. And just remembering in this space, we do have to take that into account.

Susan Winckler: That fewer tablets dispensed may not equate with a lower need. It's actually just fewer tablets dispensed.

Laura Bray: Well, and actually the Alliance for Safe Online Pharmacy and IQVIA have some really, really scary data about that, that when there is a shortage, people [02:29:00] move online, that 95% of online pharmacies are fraudulent, gray and illicit markets. That when they move that one prescription online and they get supply, they don't move back and they move other scripts online that weren't even short because it was so easy. And that has led to from 65 million to 85 [02:29:30] million doses being illicitly done online in just the last couple of years. So I think that's right. There is other risk here because patients don't just disappear.

Susan Winckler: Right. Well, where do we go to solve any other shortage? If I can't find the glue sticks I need for the kindergartner, I'm going online to see where I can find them.

Laura Bray: That's right. And that they don't realize that that pharmacy that seems reputable is not part of the traditional supply [02:30:00] chain that Nicolette is part of. So they don't realize that. And that is a tremendous amount of harm, not just for those shortage drugs, but for potential.

John A. Gilbert: And that's where the safety, as it's been defined, we call it a safety stock or allowing the quota system to be such that it realizes that there is these changes in dynamics or the nibbleness of the supply chain to be able to address it as you go down from the manufacturers to the distributors, to the pharmacies, and ultimately the doctors being able to feel like, " [02:30:30] I can prescribe this drug for this patient and know they can get it."

Because what the doctors are facing now is that, "I want to prescribe this, but they may not be able to get it." So then the person gets identified as maybe a drug seeker because of the behavior, because of the lack of that. And that's what the system needs to be able to be made to be done. And I think it's a transparency and I think it's an information flow from what I've seen to be able to get, whether it be FDA or the DEA, And Jill-Ann, I agree with you. I think from [02:31:00] the DEA's perspective, it's funny to say, I think they do feel a little squeezed here because their view is after this opioid settlement, they took a hit saying, "You guys increased the quotas, you let these drugs on the street."

So now, and this happened with the ADHD drugs, the DEA started pulling back saying, "Okay, we'll reduce the quotas and therefore we'll feel like we're doing our job." But it's hitting it with a blunt instrument. And I think you're right. I think we need to find a way to be able to work through the entire supply chain to be able to share information [02:31:30] so that gets addressed appropriately.

Nicolette Louissaint: So I want to chime in with two somewhat unrelated things. One, to Emily's point about when you think about the orders, I think it's actually really interesting to consider which orders do what in this type of a system, because while it is totally possible that we would see fewer pills prescribed because we're in shortage, I actually think the further upstream you go, you may see the opposite. [02:32:00] One of the reasons that... and I'll just take it out of the C-II space for a second.

One of the reasons that we use allocation processes is to control the fact that just because you can doesn't mean you should. Just because you can buy all of the atorvastatin that is available on the planet does not mean that you should, just as an example. And so I think what's true is that the further up you go, what you would actually see is the more [02:32:30] acute impact of the regulatory and legal pressures because the ordering won't change. The need is still there. The orders are still being placed.

What you're going to see is that there is no more product to be able to be sold to then be distributed. So I actually think you're onto something is my point in thinking about how to look at the various ways that we see the supply chain respond [02:33:00] and where we may be able to see that if nothing else changes, speed of review might be able to accelerate certain outcomes.

But I also want to think about the fact that as we're talking about the settlement, I think we should be careful, I'll say. The National Opioid Settlement does not mean that there is national operation of how some of these processes go. These are individual processes [02:33:30] that distributors have taken on and some of the things that have to happen now are a function of the settlement. So again, more legal constructs.

So if there are behaviors that are not communicated, having an order from a pharmacist stopped is a part of the requirement that distributors now have. So the nimbleness in being able to say, "Okay, I know who to call and I'm going to

call this person and I'm going to work through it." [02:34:00] The only thing you can change there is speed and the ability to know that you're going to have to explain what the swing is. So that's an example where the only change that can be made is the construct is the same, but the speed of review is the only thing that can change. And even then we may not be talking about a two-minute change. It may take a little bit of time, I think that is where the rigidity can be confronted with something other than more [02:34:30] product to potentially find a solution.

Jillianne Schulte Wall: And I think the wholesalers have been, what we've seen so far is that they've been very responsive. I think the frustration for pharmacies is simply that it's just this additional level of "We're not quite sure what..." It's also new. So anytime there's something new added to the system, there's that added level of stress to the system. So I do think that that's definitely rigidity and hopefully... I think you're right, I think there are ways to get around that that are maybe a little easier than some of the other pieces.

Nicolette Louissaint: Because it does put [02:35:00] an extra burden on pharmacists, there's an extra step, but there's also the frustration of just, "Tell us how much we can order." Legally we can't. And that's where when we talk about transparency, sometimes the legal constructs prevent us from being able to be transparent.

Laura Bray: Well, I also think it moves further than that. It's about not just transparency and it's not just about knowing information. It's about an inclusive [02:35:30] approach that can uncover unintended consequences before they happen. And that is a challenge right now, there isn't a multi-stakeholder, collaborative conversation that includes patients, supply chain experts, manufacturers that can uncover these challenges in any kind of adjustment and then there is no pathway to talk about them when we have incurred [02:36:00] unintended consequences. And honestly, by going it alone, there have been unintended consequences that made it even harder to navigate.

And so I think it's not just about transparency, it's about a multi-stakeholder approach that includes real-world, multi-demand factor forecasting, opportunities for public/private partnership, [02:36:30] engagement from experts in the supply chain and healthcare experts and even engineers. And then-

Susan Winckler: You're flanked there. So you're set.

Laura Bray: ... above all pathways to find solutions. Emily, you talked about how it's about having other mechanisms. Right now we have single sources of failure all over the place and then nothing to do with that [02:37:00] failure. And then everybody can just be, "Oh, it's short It's short." And instead of saying, "Okay, here is the next step," or "Here is the place that I call," or "Here's the body that we go to," or "Here are some solutions," there really is no space for that.

John A. Gilbert: Well, just listening to a lot of the patient advocates and some of this is the hangover from the opioid epidemic that's [02:37:30] happening and it is causing real problems. You look at the support act that was passed, and I think to your point, it put an emphasis on saying to the DEA and on the quota system, "Hey, you need to factor in diversion." How you do that? But it said you have to do that and you've got to go out to the states and ask them for diversion data and then try to factor that into the way you assign quotas.

I've read this law a million times, I still don't understand how you factor in diversion to assigning a legitimate industry, a manufacturer, [02:38:00] and ordering down the right amount of product. I don't how you do that and yet that's what the law is telling them to do.

Susan Winckler: Right. Because even if you said, "Oh, we were able to seize this amount of..." say there's a seizure of diverted product, if it's from outside the United States, that's really not relevant to the conversation.

John A. Gilbert: But I'll go one more. Part of the problem with it is if you look at some of the federal Register notices, the issue is not to get into a whole nother topic of suspicious auto monitoring, but [02:38:30] part of this is if you start reporting data that your drug is being diverted, well, what's the reaction going to be? The reaction could be is, "Well, we're going to assign less quotas."

Susan Winckler: Right. You get less.

John A. Gilbert: So am I going to start reporting more some of this anecdotal data? It just circles back.

Susan Winckler: That's a classic challenge in healthcare is how do we talk about problems, talk about whether it's medication errors or something else. The only way to do it better is to talk about [02:39:00] them, but you don't want to talk about it if you get penalized in the component.

We have time for what I think of as one other major question. You've already started to do this, but I would love you just to all think what are things that we should be thinking about in improving the processes and doing this better?

Laura, you just gave us this great list, including the multi-stakeholder [02:39:30] collaborative. Emily, earlier you had the comment about stepping above the individual product. I think, Nicolette, you've illuminated for us that it's yes, having transparency is good, but then also thinking about speeding up the conversation. And the John, I want you to fix the rigidity. Will you be ready if I turn to you for that?

But, John and Jill-Ann, you've shared thoughts as well, but I'd like each of you to think about what's [02:40:00] something that helps us move forward and have better demand forecasting that then would help with the establishment of the

quota and help us get medication to individual patients? I'll turn this way first, but you can say, "Susan, go in the other direction."

John A. Gilbert: No, what I was going to say, and I think it's a good point about the transparency. What I was trying to focus on with that is what I've seen is that is more of a sharing information, [02:40:30] which again, by its nature, some of this is confidential information, how much a company sells, how much a company... whether you're a manufacturer, how much you make. You're a wholesaler, how much you buy and what you charge for prices, pharmacies, how they sell.

But I think in terms of demand forecasting and focusing on quotas, it's understanding so what is the important information to the regulators for them to make those decisions? And I think that in my view, there's been a lack of understanding. And again, just from my [02:41:00] perspective, manufacturers keep providing all this information to DEA and they say, "Okay, one plus one equals two," DEA comes back and says, "No, it doesn't. It equals something else." They're like, "Well, why don't you see my math?" And the DEA is using maybe different math.

Not that they're right or wrong, but that's the problem, they're talking over each other. So I think the transparency is the regulators saying, "This is why we think that you're asking for a hundred. We only think you need 70,' but understand why they're saying 70. And then [02:41:30] the industry can say, "Okay, well now we get it. You're not looking at this factor, you're not looking at what the patients are saying. We can give you better information. Let's work together on that."

As opposed to a process now, which is, and this is just again, a factor of the rigidity, I apply for a quota, I get denied. What do I got to do? I either got to reapply again or I can appeal it. Well, the DEA appeal process of a quota, basically the year goes away before you could appeal it. So it's unworkable. So you just submit another quota request. [02:42:00] And so that's the process I think that needs to get done. More coordination among the groups, and I think including patient advocacy groups in that discussion somehow would be critical.

Susan Winckler: And what I hear you saying is that part of what the transparency needs to have is the context. You said why, and I don't know that we ever have enough conversation about the, "Why did I ask for this? Why did you say no?" in the more kind of full picture for that. [02:42:30] Jill-Ann, what do you think ASHP members would most like to see here?

Jillianne Schulte Wall: Well, I actually think John's said a lot of things that I would've said. I do think there's a lot of value in having a large group of stakeholders speak directly to DEA. When we went in with our members to have them speak directly to DEA staff, I think that did make a difference because they were using a lot... when we started out it was alleged shortages. Well, these are alleged shortages that we see literally as we are in our [02:43:00] hospitals and health systems. They're not alleged for us, they're real.

And I think ensuring that everyone feels heard and not gaslit, in any sense of the word, is probably a really important first step. And then I think a lot of us work together all the time, and that's something that happens outside of public view. And I think that is something that is extremely beneficial because it builds up trust and it helps our members build up trust. And I think as long as we continue that, [02:43:30] there's a lot to be said for that.

And the other thing I would think about is it's the speed, as Nicolette said, but also looking at how we are placing up the quota pie. What are the drugs that are really going to be diverted? Let's maybe focus on the most troublesome set of API and then make everything else much simpler. Is there a way to do that? I just think looking at different ways to make this a more streamlined process.

Susan Winckler: [02:44:00] And it strikes me that the idea of the multi-stakeholder, and it helps immediately with the context, but also lets you improve demand forecasting because you've got more of that information about who needs what when. Can I do Laura, Nicolette, Emily?

Laura Bray: All right, sure. So I said a little bit about it, what I think the answers are, but no one's actually said this out loud, but the current [02:44:30] forecasting system is based on sales data that is skewed by a quota-constrained market. So going back to the original question, what can we do about demand forecasting? Well, it needs to be multifactorial and I think the three big buckets are patient care, reimbursement realities and supply chain insight. Those are the things that are going to help us have a better forecasting model. [02:45:00] But none of it matters if we aren't working together when we uncover the unintended consequences or the realities of the market shifting.

Markets shift, they change, hurricanes... it's not just hurricanes, but there is better prescribing or there becomes healthcare deserts. We have a challenge not just in hurricanes, but in the steady state of these medicines. We can't think about being better in hurricanes if we can't even do steady state. [02:45:30] And so in the end, my perspective is it's not just about multi-stakeholder collaboration, it's that when law enforcement and the healthcare of American people are intersecting or colliding, agencies can't go it alone. They need us and we need them. And we have to be together in those solutions. And if we are, we can do better. We can help. We all want the same thing. We want patients to get care, [02:46:00] we want less crime. If we look at it in that way, we can actually solve it.

And to pull on what Jill-Ann just said, we do actually work together for the other 320 drug shortages that are happening right now. And we find solutions, ASHP and Angels for Change and HDA and AAM, we are working together for other drug shortages and there are solutions that we are able to [02:46:30] flex and put in place to help patient care. I think we can learn from those if we're allowed to work together in this space as well.

Susan Winckler: And seen as solution finding.

Laura Bray: That's right.

Susan Winckler: And not in any other light.

Nicolette Louissaint: As I think about demand forecasting, I find myself thinking we're leading with law enforcement and then talking about healthcare and then thinking about public health. And I wonder what happens if we reverse that. I also think [02:47:00] there may be different inputs to consider if we shifted that frame. And it's not to say that law enforcement is the least important, but it is to say that maybe there are some indicators in public health that even go beyond the supply chain insights, that go beyond anecdotal individual patient stories and experiences that give us a sense of what are we going to see at that local level.

I spend a lot of time talking [02:47:30] to state public health departments. They often have a different view of what the needs and potential demand of a supply chain might be.

Susan Winckler: Interesting.

Nicolette Louissaint: And so I find myself wondering, is there a space here where states are helpful and not to put more in the pharmacist, not to put more in states, but is there an opportunity to maybe pull in data and insights from individual states [02:48:00] that again, with demand forecasting can actually bubble up in some way that allows for us to have a different lens into how you take that national picture local.

Susan Winckler: Because those public health departments are seeing the other side where we have diversion in misuse, where we have been veered into abuse of the products or substance use disorder and see that, but then also see from the, ""Okay, so how do we help prevent that and then help those individuals?" [02:48:30] I'm struck by the opportunity to...

Nicolette Louissaint: I live in Baltimore and a few months ago there was a large overdose event in Baltimore. Those of us who are thinking about it from a supply chain perspective may think about are there additional products, are there additional supports that are needed to those systems? But the health department actually knows the story behind a lot of those overdose cases. And they actually are following and tracking [02:49:00] a lot of those individuals. They understand the intersection where it happened, they understand what the shifts are in the community. They're not just looking at illicit drug use, they're looking at the entire story for their community.

And so I'm thinking about what I just saw in my own city, and I'm thinking about just how we could bubble up some of this to be able to make those distinctions between legitimate product, illicit [02:49:30] product, but what we're going to see at that community level. And I think they're also sensing various fluctuations that might give us a different lens into what potential demand could be.

Susan Winckler: And help with that safety factor. All right, I'm coming back to you.

Emily Tucker: Thank you very much. And I agree with so much of what you all have said. I think a couple of things that I've been reflecting on. Where we can go from here, I want to tag on to what Nicolette is sharing. And we were talking a little bit before this conversation, and I'm just struck by this idea that [02:50:00] our current system is designed around products, it's not designed around patients.

And I think when it comes to regulating these supply chains, that is an important shift as you're alluding to this idea of we need to get to a point that we have resilient patient care more so even than resilient supply chains. And so when it comes to... I do want to recognize we're in a... it's a challenge. This is a challenging market, and we're almost asking, and maybe I'll just say this directly, we're asking regulators, [02:50:30] we're asking law enforcement agency and we're asking all the stakeholders to hit it exactly right all the time. And if it doesn't happen, we have shortage or if it doesn't happen, we have excess.

And so I think we need to shift the system, and we've talked about some ideas, and also we need to be sure we have plans in place when it does go wrong, because I do just want to share it is going to go wrong. And in order to care for patients, we need to be ready when that happens, like you are going through a medication [02:51:00] list, you have your first line and then you have your second line. We need our first line plan and then we need our second line so that we make sure we get drugs to the patients who need them and drugs don't go to the people who don't need them. And I think we can't lose that either. Do you mind if I-

Susan Winckler: Oh, please.

Emily Tucker: I think when it comes to where do we go from here, I think we can talk about short-term changes, but I also want to point to long-term changes. We've talked, which is some of what we've been talking about, [02:51:30] but when it comes to data sources-

Susan Winkler: Yes.

Emily Tucker: ... I think it's important that we use the data sources we have available well, we build in a correction factor, we know our limitations. But also I maybe want to challenge us that if we don't have a data source to get us the forecast we need, we should build that data source. And I think that comes from this multi-prong, multi-stakeholder approach, I think it comes from this local level, but I do want us not to be constrained on what we have now. We can build the data [02:52:00] set we need to make better forecasts.

Susan Winckler: Right. I think about a data set of, "Okay, so how could we capture those prescriptions that are issued that are abandoned?" It'll be very difficult to capture those that are never taken to a pharmacy, but those that get to a

pharmacy and maybe even get to a second pharmacy but are lost. That to me is a, how do we capture that information?

Laura Bray: One comment just as an outsider of the supply [02:52:30] chain who jumped into it five years ago, but I want to caution that we don't let perfection be the enemy of good.

Susan Winckler: Sure.

Laura Bray: There actual things that we can take on right now that will make this better. And if it makes it 10% better, 20% better, we can do that right now. We can evolve our current broken state into a future state over and over again until we hit the mark. And so I agree we should build what we need, but [02:53:00] we don't have to wait to build. We can build and act at the same time. And if we help five new patients because of that or 5,000 or 5 million, that's pretty okay too.

Susan Winckler: Laura, I can't think of a better way to say yes. Let's close on a point where we say... I think what you have illuminated is that there's some incremental change, there's some opportunity for building and an opportunity just to [02:53:30] perhaps do better with reflecting on the challenges that we've had and do better together.

So join me in thanking this fabulous panel. They know I could talk to them all day. And with that, I'll just note for everyone whose here, thank you for joining us. For those who are in the virtual audience, thank you as well. We will be capturing this recording, the slide deck from the earlier presentation [02:54:00] and a transcript that should be posted on our website later next week. So thank you for joining us. Have a great rest of your day.

Adjourn