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WHEN MEDICINES ARE CONTROLLED: HOW DRUG ENFORCEMENT ADMINISTRATION RULES EXACERBATE DRUG SHORTAGES

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PANEL DISCUSSION:

MARTA E. WOSIŃSKA
Senior Fellow, Center on Health Policy, The Brookings Institution

MICHAEL GANIO
Senior Director, Pharmacy Practice and Quality, ASHP

JOHN A. GILBERT, JR.
Director, Hyman, Phelps & McNamara, P.C.

BILL GRUBB
Vice President, Business Development and Innovation, Noramco

MODERATOR: AMY GOLDSTEIN
Visiting Fellow, Economic Studies, The Brookings Institution

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GOLDSTEIN: Okay, I think we'll get started. Good afternoon and thank you all for joining us. Those of you who are here in Saul Auditorium and what I understand are a few hundred of you who are watching from near and far online. My name is Amy Goldstein and I'm a visiting fellow in Brookings Economic Studies program, which means that I'm part of the Center on Health Policy and the Center for Economic Security and Opportunity, and I'll be moderating today's discussion. But the heart of this event is my colleague Marta Wosińska, a senior fellow in Brookings Center on Health Policy. Marta came to Brookings from roles in government and academia, including as director of the Bureau of Economics at the Federal Trade Commission, chief healthcare economist in the US Department of Health and Human Services, Office of Inspector General and director of the economic staff at the US Food and Drug Administration's Center for Drug Evaluation and Research.

And as you might glean from all that, Marta has for much of her career focused on pharmaceuticals and in particular the supply of prescription drugs, which is to say often shortages. Today's event marks the unveiling of Marta's newest work, a paper that examines a subset of drugs that are under the eye of a different federal agency than the FDA, which regulates most medications. This subset is called Schedule Two drugs, and they have a double identity. There are controlled substances that can be abused in illicit ways, but they also have important legitimate clinical uses. Think opioids, which sparked an overdose crisis, but also are important for controlling patient's pain. This class of drugs is regulated by the Drug Enforcement Administration, and we will hear from Marta how the mindset of this agency, which is situated within the Department of Justice, can get in the way of giving patients proper access to medicines that they need.

Following Marta's remarks, we'll hear from a panel of three people. Whoops, I wasn't counting on the microphone in my hand. Three people who have, three people who have expertise in these issues from different vantage points. Seated next to me, Michael Ganio brings a pharmacy point of view. He is senior director of pharmacy practice and quality for ASHP, the nation's largest trade group of pharmacy professionals, and it represents tens of thousands of pharmacists who work in hospitals, clinics, and other patient care settings. Next is Bill Grubb at Noramco, where he has held a variety of roles for nearly three decades, and currently is vice president for business development and innovation. Noramco is the leader in the production of controls substances for the pharmaceutical industry. So, Bill brings a deep manufacturing perspective to our conversation.

And then we have John Gilbert. He's a lawyer with decades of experience in the law and regulation of pharmaceuticals. John is a director at the law firm Hyman, Phelps and McNamara, and he's especially well versed in the US government's handling of controlled substances and international drug control agreements. And just so you know, near the end of our time together, we'll leave room for some audience questions. So allegedly, you were offered index cards when you got here. I see it. Evidence of index card. And a couple times during the session somebody will be coming around to collect them if you have a question. So, Marta, you ready to begin?

WOSIŃSKA: Yes, I am. Thank you.

GOLDSTEIN: Maybe you can just start by telling us why you wrote this paper.

WOSIŃSKA: So why did I write this paper? I have been as, as Amy you have in indicated. I have been studying drug supply chains for probably 15 years. I first stumbled on drug shortage issues when I worked at the at the FDA. At, in 2011, we had a major crisis with just unprecedented number of shortages and on and off I have been doing work in this space. A lot of it has been around generic sterile injectable drugs that tend to be much more likely to be in shortage. And even though fentanyl IV fentanyl, morphine and hydromorphone are in that group I'm never really truly paid attention to them until about 2023.

In 2023. This is as you many of you might know, this is when we started to experience major shortages of drugs to treat attention deficit disorders. So, ADHD drugs and. I had a number of people approach me and say, what's going on here? Why do we have a shortage? And my answer was initially there's solid oral dose products. Those supply chains are much more resilient. I am, I'm thinking about sterile injectables and. The issue wasn't going away. And then in August of 2023, the DEA and FDA issued a joint, dear American letter where they basically tried to explain what's going on. And one of the things that they said is that we give quota to manufacturers and a quota is basically how much the manufacturer is allowed to make or use of a controlled substance.

So, we give quota to manufacturers, and we give them the quota and 70% of the quota sit there unused. It's their fault. It's the manufacturer's fault. And I read this, I'm like, this makes absolutely no

sense. You have a shortage, meaning there is demand, and manufacturers are not using the quota. There must be something structural going on. And so that's really what caught my attention at first. But the idea set around for about a year because for me to be able to do a research study, I actually need to find a grant. So, then a year later I had a conversation with Dr. Tracy Koehlmoos, who is a professor at Uniform Services University, which is part of the Department of Defense, Department of War.

And she was tasked to oversee a body of research around drug supply chains. She is a health services researcher, so drugs are not a, an issue that she knew too much about. So, she started reaching out to experts. And so, we met over lunch and I was telling her some of the things that were on my radar screen that I thought really could inform how we think about supply chains and what the vulnerabilities are. And a couple of weeks later, she comes back and she says, Marta, in this big grant that I have a bucket of money. And what you told me about the vulnerability that we have with morphine is so critical for to war fighters and morphine uses the same supply chains that all the other American patients for that use morphine would be also using. Can you work on this? So, this is how the whole story began. It has to be two pieces. You have to have the funding and the idea.

GOLDSTEIN: So, once you had the funding and the idea or the idea and then the funding how did you conduct this research? What did this project consist of?

WOSIŃSKA: So, I would say that there's two pieces to this. One. I could not have done this work without my co-author, Ben Graham, who is sitting here in the first row. He's a senior research assistant here at Brookings. And he dug into every regulation that da has done federal registered notices, stakeholder comments. Did we could write a book on the history of controlled substance regulations on the supply side. And it's actually a fascinating history. So, a lot of this was basically really diving in and reading a lot of these documents. And then I guess the other piece is I was trying to leverage my expertise in what I know about drug supply chains and what kind of, what makes supply chains work well versus what makes them vulnerable. So, trying to map what we learned about DA's system with what I know about drug supply chains in general, and in a sense that's what the paper does. It tries to marry those two pieces.

GOLDSTEIN: And can you tell us what you've learned?

WOSIŃSKA: What I have learned is that the system that's designed by the DA, the quota system, is incredibly complex. I would use the word bewildering.

GOLDSTEIN: I'm sorry, you said quota system. Can you just explain what that means?

WOSIŃSKA: Yes. So let me just very briefly described this it, so the, there is a in 1970, I believe Congress signed or the President Nixon at the time signed into a law, the Controlled Substances Act. And as part of that act the basically gave da the responsibility to assign. Quota to, for production and for use of certain controlled substances, and especially the ones that are designated as schedule two. So again, ADHD drugs fit under that solid oral dose. Opioids fit under that. And also, the ones that are used in with patients with trauma, during surgeries and so on. So, some of the IV opioids. The idea with the quota is that there's three parts. One is that by law there needs to be a ceiling, in a sense, a quota for the aggregate production of the of the substance in the United States. That's called the aggregate production quota. Then DEA is supposed to be under the law, actually didn't da didn't actually exist until a couple of years later. But the law basically says that then the aggregate production quota, you there are manufacturer quota of those who make the controlled substances that also are going to limit how much they themselves can produce. And then so that's basically in a sense, you cannot make more than a certain amount.

What was really fascinating for me as an economist, actually an economist coming to Brookings, straight from being director of the Bureau of Economics at the Federal Trade Commission, is that in a sense, what DA is doing is assigning market shares to manufacturers. They basically say, you can, make this much, which means you cannot have more than this market share, and you can have this market share. So that alone was pretty stunning to me that we actually have a centrally planned market that it basically a setting like that. And what I learned is that there's incredible complexity with this. So, there's probably a couple of dozen-controlled substances scheduled to control substances overall.

But DEA assigns four over 4,000 different quotas each year. And some of this is because DEA also added a level of procurement quota. There's also now it's broken down into exports versus imports. A manufacturer like bill for example, represents a manufacturing facility that makes active ingredients, not the final product he has to get both procurement quota and the finished dosage quota. What I've also learned is not only that there's so many different quota that sometimes don't line up, but they're given really late in the year. And Bill can tell you a lot more about this. The way demand is being estimated, and the aggregate quota are being set is backwards looking. It assumes that, for example, when there's a disruption in the system and one manufacturer cannot produce.

What happens is that it's not that other manufacturers can pick up the slack because they don't have the quota to do this. They have to go and apply former quota. DA is very reluctant to give quota to somebody else when they've already given the quota to somebody. In the meantime, clinicians start prescribing the alternatives. So, demand basically gets spilled over to those other molecules. But those were given quota medications, right? Other medications those were designed, those, they have their own quota that were designed under the assumption that there will be no demand spillovers. And then when DA projects forward what kind of quota they should set for next year, they very heavily rely on historical data.

Which is basically going to reflect not the actual demand, but the quota and the inability of manufacturers to potentially use the quota when there was a disruption. So, it's a perpetuating, self-perpetuating system that just in a sense what we basically have is, coming from an era from a field where I look at drug supply chain resilience, how much do we talk right now about drug supply chain resilience and having resilience supply chains, especially for essential medicines. And fentanyl, morphine and hydromorphone in IV version very much are that resilience means the ability to absorb shocks and recover from shocks the way the system is designed, there is no slack. There's absolutely no slack. It's tried, it's so tight to try to make sure that. There is no diversion into inappropriate channels, into illegal channels, that it's designed to have no resilience. And so that, that was resilience, meaning flexibility, ability to absorb shocks, recover from shocks.

So, it's, if you wanted to design the most non resilient supply chain I think I could point to the way the system operates really. So that, that really was just so striking for me, for someone who both has

looked at the, where markets are efficient and also not just efficient, but also what creates resilience in supply chains. And just to see really none of that.

GOLDSTEIN: So, was this all a big surprise to you, or not so much, or?

WOSIŃSKA: So, I guess, what I just said was a surprise, but when you, when I take a step back. In a sense, maybe it shouldn't. If you look at my work, I frequently talk about, at the end of the day, we really need to be thinking about incentives. And I really do think that this shouldn't be a surprise When you think about, what is the word DEA sits, that it sits in Department of Justice and not in HHS, which is by the way, how a lot of other countries have set it up. They put it in Ministry of Health. Their job is to really prevent diversion and misuse and the access for appropriate patients.

That's not their objective. Their objective is to prevent illegal use and misuse. And so, in a sense, that's what you would expect. You would expect a system that does that. And also, I'm not just saying that this is just da I would say Congress has had a lot to do with this, because of the opioid epidemic and because DA earlier on was increasing the aggregate quota a lot. What you saw Congress doing is basically going after DA and say, what are you doing? You need to cut the quota you need to, you, you should undo what you were doing. The problem is that it sounds like a good idea, but it's a really blunt tool. Quotas are a really blunt tool.

Think about this. Let's say that we really don't like shoplifting, right? So, you basically have a government policy that says we're going to eliminate shoplifting by basically putting a lot less on, on shelves in the stores. And we're not set going to put some, like you go to CVS in DC and there are things behind a shelf. We're not gonna do that. We're just not going to have it in the store. That's basically what we have, it affects, there's less to shoplift, but the paying customers are also going to be folded into this. And in a sense, that's exactly what's happening here. If you're focused only on shoplifting, your solutions are going to be very different if you're also thinking about the paying customers.

GOLDSTEIN: Okay. So, the bottom-line metaphor is schedule two drug regulation as shoplifting. Okay. Okay. Mike, of the three of you on this panel with Marta you have a pretty strong ground level

view of what this all means. As I understand it, your organization tracks shortages. So could you perhaps just talk a little bit about. What shortages exist, how severe they are, how long they persisted, what should we know about what these shortages actually look like?

GANIO: Sure. So, as you mentioned, we have a drug shortages database, and some of you may be familiar with that database, or you may be familiar with the Food and Drug Administration. So, the FDA also has a drug shortage database, similar, slightly different nuanced detail. Happy to talk about it in depth sometime if anyone's interested. But through this partnership with the University of Utah Drug Information Service, A SHP posts drug shortages, and we track the metrics. So, where we sit currently about two years ago, we hit an all-time high. We were tracking 323 ongoing active drug shortages.

GOLDSTEIN: And that's for all types of drugs. Non...

GANIO: For all types of drugs.

GOLDSTEIN: Scheduled two ones, right?

GANIO: Correct. For all types of drugs. Currently we are down to about 216, which sounds great when you compare it to 323, but if you think about the American public as having some sort of challenge accessing 216 medications, it's not really something they get that excited about the reason for optimism. But there's still some challenges. Now, as Marta mentioned, most at any given time, most of our shortages are generic sterile injectables for many reasons. Again, different discussion. Happy to have that conversation. But included in those drugs are IV fentanyl, IV morphine, IV hydromorphone drugs that are the backbone of pain control and sedation, procedural sedation, ICU sedation in our hospitals and health systems, drugs that are on essential medicines lists. And so, if you look at the history of these drugs, for many reasons, they have been on our shortage list. For about 10 years. If you,

GOLDSTEIN: And those are, just so I understand, those are all drugs that are subject to the kind of DEA regulation Marta was describing, right?

GANIO: Correct. They're schedule two controlled substances, and they've also been on FDA shortage list, at least going back to 2017, I believe Fentanyl is back to 2012.

GOLDSTEIN: So that's a lot of shortage.

GANIO: It's a lot of shortage. And then when you think about the impact of that shortage, so on the front lines in a pharmacy, I like to categorize into two buckets. We have operational management of shortages, and we have clinical management of shortages. The operational management is basically inventory management. It's optimizing your inventory through procurement strategies. Maybe you're buying labels you don't normally buy, concentrations you don't normally buy. You're building up supplies, so the, there's labor expense here, but at the end of the day, typically the patient still gets the drug of choice, which is great, right? That's our outcome. Unfortunately, that starts to introduce some risks. So, we'll take hydromorphone for an example, comes in a prefilled syringe of two milligrams per ml, one milligram per one ml, four milligrams per one ml.

If that's stocked in a dispensing cabinet or in an anesthesia tray or something, in a procedure where that clinician is just used to routinely grabbing a syringe and not checking the label, and maybe barcode systems aren't in place, you now risk an overdose or an overdose depending on the setting, depending on which drug is administered and which concentration. While the patient in theory should still get the same drug, we've introduced risk. Now, on the clinical side, we're talking about things like therapeutic alternatives. Drug of choice is a drug of choice for a reason. It's either more effective. It has fewer or less severe side effects, or it's more cost effective, cheaper.

So, if I'm not giving a drug of choice, I'm sacrificing one of those things, sometimes more than one. And you can look at a drug like morphine or hydromorphone here, morphine. If a patient has poor kidney function, there's a metabolite that can build up. And so, you have a pronounced effect or the morphine in a patient that may have poor kidneys. So, there's a drug of choice for a reason, is my point. On the extreme end here, you start looking at canceling procedures, delaying procedures, switching patients to medications. In the ICU, imagine maybe some of you have had a loved one with, they're on a mechanical ventilator, they have a breathing tube in their throat, and one of the regimens of choice is a fentanyl infusion.

Something we just administer to keep them sedated and calm. Sometimes it's hydromorphone if that drug's not available. Now I'm reaching for alternatives that have different side effects. Clinician clinicians may be less familiar with them, and all of this sounds scary and it should be scary. About 15 years ago, there were about 12 to 15 patient deaths associated with errors due to opioid shortages. Fortunately, today, electronic health records, barcode scanning, et cetera, have modernized, and we've been able to catch a lot of that type of error, prevent it. But it still introduces risks to our patients.

GOLDSTEIN: Do you have a way of giving us a sense of how prevalent these problematic events are today? Cancel procedures, substituted not quite as good treatments? Is that something at the margins today? Is it pretty common today? How should we think about it?

GANIO: It ebbs and flows, and I'd say right now it's fairly common for substituting hydromorphone. This has been hydromorphone intravenous. The injection form is really a challenge for our health systems at this moment. Now, as use might switch to morphine or fentanyl. Then that becomes a problem. And so, you play this game of whack-a-mole of which drug is coming in, which one, do I have enough days on hand? Because if I make a wholesale change, it's a lot of work to go through that in electronic health record to educate the staff about which drug or choices. So that whack-a-mole right now is shifting away from hydromorphone. But at any given time it, it can vary by health system based on their inventory.

GOLDSTEIN: Now, I think a couple years ago there was a morphine shortage and there was some efforts to try to interact with the government to do something about that. Can you describe what happened as a case study of what you've been talking about?

GANIO: Absolutely. And Marta queued this up beautifully when she talked about the inability to withstand shocks. So, in McPherson, Kansas in 2019, one of the one of the manufacturers that produces most of our country's supply of morphine and hydromorphone went down unexpectedly. They planned to take the plant. To reduce output while they worked on some maintenance issues.

And it turned into an issue where they had to cut off production completely 70% of morphine and hydromorphone. And so, through advocacy, through FDA has a drug shortage staff. They do a phenomenal job. Through interactions with other stakeholders, health systems, policymakers, we had been advocating for that additional quota to be reallocated to other manufacturers who could step in and begin production. And the feedback that we received was not one of a clinical perspective, it was one of a law enforcement perspective. And so, while eventually the quotas were reallocated and adjusted, the mindset was one of defensive protecting the public, which is a, an important mission in charge. But you have to consider protecting the public from harm, from not having appropriate medical treatment.

GOLDSTEIN: Okay. So, what I hear you saying in essence is that the kind of regulatory complexity, which I think a word that you used that Marta talked about has real life consequences in in terms of the provision of care.

GANIO: Absolutely, yes. Both in labor expense, in patient pain and suffering, and unfortunately patient illness.

GOLDSTEIN: Thank you for that perspective. So, Bill, Marta has already talked a fair amount about different forms of quota. And from the perspective, a company that makes ingredients for drugs, can you give us a sense of how these quotas affect the manufacturing process?

GRUBB: Sure, I'll try to. So as far as quotas in our world, again we're an ingredient manufacturer, so our product is a white powder and a drum. It's a long way from a prescription or even from the formulation. That's our customer. We're shipping it to a formulator that's making a pill, an injectable or a liquid. From my standpoint. In the world that we live in just our company making ingredients, we're making around 12 basic ingredients. There are different forms of them, but around 12 basic ingredients that are controlled substances-controlled substances for ADHD, methylphenidate, lix, amphetamine pain, morphine, codeine, oxycodone, hydromorphone, et cetera.

GOLDSTEIN: And can you just explain what those are used for?

GRUBB: Yeah. ADHD, from a medicines and methylphenidate would be in, in different ADHD medicines. Lex Vyvanse ...

GOLDSTEIN: Is the brain episode hyperactivity disorder, right?

GRUBB: Yes. Just hyper. A yes. Pain, the pain management drugs, a lot of which you just talked about. We manufacture the ingredient. We also make drugs like naloxone that are used for overdose and buprenorphine that's used for managing addiction. They all have one common thread is they're controlled substances and you have to have quota. So, in quota, for us, there's two different kinds that we deal with. One is manufacturing quota, the quota that's needed and granted by the DEA for us to make a certain quantity of active ingredient. The other quota that we deal with is procurement quota. We have to have quota to. Procure the majority of our raw materials that we use. When we get, once we've finished manufacturing and we want to sell the drug, our customer, the formulator also has to have procurement quota.

So, to use the example of hydromorphone that was mentioned by Mike earlier; in order to make that, we actually have three different quotas. We have to get procurement quota to get the raw material. In our case from Australia, we have to have manufacturing quota to make the intermediate, which is a quota called, or Paven quota. And then we have to have hydromorphone quota. So, to make one simple active ingredient, we're actually dealing with three different quotas. And unfortunately, those don't always line up. So, we may get manufacturing quota for the final API, but not the quota for the intermediate. So, we're done, we're stuck.

GOLDSTEIN: When you say they don't always line up, was that kind of understatement or is it like occasionally they don't line up?

GRUBB: I it's more often than you would think. I will say that it's definitely getting better. It. And this year is a good after the changes at the end of 2023 and 2024 with the administrate, the past administration it, it became quite challenging. But things are getting better.

GOLDSTEIN: And could you extend from, your company's role to what happens to the companies that are waiting to receive what you're making?

GRUBB: Yes. So, one of the things that happens routinely is in our world, quota expires on December 31st and is regranted ideally on January 1st. So that means that everything you were doing at the end of the year, you wipe off the table, and you start over. And so, what ends up happening is we're doing a man, a chemical manufacturing process. And typically for us that means 60 to 90 days to make something. We get our new quota on January 1st, and so does our customer. So automatically on January 1st, our customer is saying, ship US material. And we're saying we've got X amount in inventory, but we've gotta start over and make more.

And maybe when we talk about potential improvements, we'll. We'll come back to that. But we, there is the ability to manage through inventory. The DEA does understand that the changes that were made at the end of 2023 into 2024 reduced our inventory. So that made it even harder for us. But in practice, what happens is our customer, and we routinely get quota on the same day. And so, we're already starting off from arrears after we've depleted the inventory that we have on hand. So, there's not just a mismatch in the quotas that you need, but there's a mismatch between when your customers, the manufacturers are gonna make the finished drugs, need them, and when you can supply them. At any point during the process, if we don't get procurement quota for raw materials or quota for the intermediates or quota for the final, we can't supply. And then if all those things do line up and we can make the API and more customers

GOLDSTEIN: API, meaning?

GRUBB: The active ingredient if they get, if our customers receive more quota than we have inventory, then they're going to be waiting at least 90 days until we can supply.

GOLDSTEIN: Okay. I've got a nitty gritty question for you. Okay. I'm hoping you can explain, I understand that sometimes there are large percentages of quotas that go unused even when there are shortages. How can that be?

GRUBB: Yeah, that's a really good question. And really, if you think of a chemical manufacturing plant it's a multipurpose plant. So, it's not like that there's dedicated equipment for each of the active ingredients. It's a multipurpose plant. And just by way of analogy to say that we make 12 products

we've got four or five basic manufacturing lines. And so, we do what are called campaigns. We run a bunch of. The same product all at one time so that we can stop clean out so that we don't get chocolate in the peanut butter and switch to the next product. What ends up happening, and one of the reasons that quota can be unused is that if you don't receive enough of your quota for all of the different products at the beginning of the year, it makes it very hard to schedule that equipment. And once you exhaust the quota, we can go for 30, 60, sometimes even 90 days, not using equipment because we don't have the quota to run.

So, one reason for not using it is that we don't get the quota at the right time. A second reason for not using it may be that we get quota too late in the year one year. 2024, we received very large percentages of our quota on December 13th. If we have a 90-day manufacturing process and we get quota on December 13th and it expires December 31st, there's just no way we're going to use all of that. And then there's, like any chemical manufacturing operation, there's maintenance and shutdowns and trying to manage all of that complexity in a quota constrained world. Those are all reasons that quota may go unused, but it certainly is not. As the D-E-A-F-D-A paper made it sound like, because we didn't wanna make it. We are a business and we do exist to manufacture and supply customers.

GOLDSTEIN: Okay, so you've talked a fair amount about. The timing of quotas. What about the amount of quotas that you're given? Is that something predictable or unpredictable or it, can you just ask for what you want? Like how does that part work?

GRUBB: So, we ask for what is the legitimate need based on our customer forecasts and our history of selling. Unfortunately, it is not super predictable. I would say that there's a perception that we get all of the quota that we need at one time in the year. If you read what's. Out in the news and that's not true. Across, across the 12 products that I mentioned in 2024, we made 75 quota app, 74 quota applications. In 2025, we made 65 quota applications. So, we have to apply for more quota repeatedly during the year. It takes six to seven weeks to get an answer back. And during that time, we're saying do I use this piece of equipment or do I use this piece of equipment?

GOLDSTEIN: And you're making these appeals or applications to DEA or who's the...

GRUBB: Yes.

GOLDSTEIN: Receiving end of this?

GRUBB: It is to the DEA, but to go back to your original question, January 1st, we typically will get between 30 and 50% of what we ask for. Alright? Un unfortunately, in 2024 out of our 12 molecules, for three of them, we got zero. So, it's really hard to recover from zero.

GOLDSTEIN: Why was that?

GRUBB: And, because I think that, I don't really know, which is a little frustrating. But I would say that based on the calculus that the DEA was using and based on the data that they had they, in their judgment in adjudicating our application, they said that we had enough. And I think when we get to improvements, that's one of the problems is that the data is very lagging. If it, if I make an application and it takes six weeks to get an answer, think about what happens in six weeks when you're buying and selling materials. So, the data's quite lagging but I think. The truth is, I don't know why we got zero, but I do know that there's, there are smart people at the DEA who try very hard. They were using data, the data they had, and in their judgment we didn't need it. But in fact, we did need it or we wouldn't have asked for it.

WOSIŃSKA: Amy, if I could just chime in. It's interesting to contrast DEA as regulator and FDA as regulator. Just imagine, if Bill goes to FDA and says, I want to start making this new active ingredient and here's my application, FDA might actually tell you what might be wrong with this application. And you submit it and it turns out that FDA had issues, they will tell you exactly what the problem was. Just such a stark contrast with DA as a regulator, you ask for something and then you get an answer. This is how much we're gonna give you, why there's no answer to that. So, it's just really fascinating to compare, this two regulators that act in a very different way.

GRUBB: And then, when we got the zeros two of those were on the drug shortage list. That's frustrating. 2025, I think we had two that were zero, 0%, but it's really for us to say that we're doing 60 to 70 quota applications a year. That also means that someone at the DEA has to be there to process those and look at 'em, and they're using the best data they have available which I believe is to be

lagging, which is why there's this hamster wheel and we're one registrant and I, you introduced it and I've heard the DEA say this, they're doing over 4,000 app quota adjudications a year, probably more than that.

That's just the initial ones. So, it's quite a, it's quite a complex morass and I'm just one manufacturer. And I'm recognizing that, but I do think that there's opportunities with data transparency, data accuracy, and in using more recent data, John and I were talking about it until five years ago when we were using a form to order quota, or our customer was using a form to order quota. It was like a six-carbon form. It wasn't electronic. This was on paper. And in five years things have really changed, and I think that presents an opportunity. Maybe we'll get to that later.

GOLDSTEIN: Okay. Thank you. John, you're our lawyer on the panel, but I hope you don't mind if I also ask you to serve as our resident historian...

GILBERT: Certainly.

GOLDSTEIN: Can you explain how the system became the system that we've got?

GILBERT: Sure. Without boring everybody for a couple of hours, but I think, the way to look at this is that if and the way I've tried to summarize is that, so if you look at before 1960 and you go back through the 19 hundreds is when the world started worrying about opium and coca and Right. These were natural, raw materials that were finding their way, and the world started to realize that these were being abused, and they were very much unregulated. So, there was a series of international treaties throughout the 19 hundreds trying to get at the problem and trying to address just by trying to limit the amount of production right.

In some of the countries that produced the raw materials. But then when you get to around 1960 and generalizing very much there then was this issue about the fact that you then started to see not just raw materials, but the ability to synthesize drugs, right? The ability to develop synthetic medicines, that, that obviously expanded the use of these raw materials. Both for good and as we've talked about, obviously for bad as well.

So what you saw happen around 1960 was the un the commission on narcotic drugs get together and they created the first international treaty, the 1961 treat single convention, which really tried to put some context around signatories to the international treaty, would abide by certain rules and regulations regarding production, regarding record keeping, regarding and join together to try to as a world to try to potentially be able to regulate. And a key part of that single convention was. Language related to the country should take action to limit word quota doesn't exist in those treaties. It's the word limit. And that continually in some of the laws and...

GOLDSTEIN: Limit what? I just wanna make sure...

GILBERT: Excuse me. To limit the production, to limit the manufacturer to limit the manufacturer, limit the production of these to only for legitimate medical use. So, it was a part of the treaties that was trying to say to the member countries, look, you need to take some steps to try to limit the production and manufacturer only for legitimate me medical use. And in the US there was a law passed in 1960 under...

GOLDSTEIN: Can I ask you something before you go into the next step in your good narration of the history of this at the time, was there a sensitivity to the possibility of abuse or it was all about what's needed for clinical real uses.

GILBERT: There was definitely a sensitivity to, to abuse and because they were fairly unregulated the aspect of them being used in medicines didn't really come into play. And it was only when the focus began on abuse that you then started to see if we're gonna focus on abuse, we still have to have some provisions in place to make sure we don't affect medical use. And that was the goal. So the goal was in, in the treaties, was to try to say, if we limit product, if we limit and we regulate and we require companies to get licenses and we require companies to keep records, we can create this chain of distribution manufacturer and manufacturer that will be able to make sure that the only amount of drugs that are being produced are for legitimate reasons.

The concept was to control it to that extent. And as I mentioned in the US there was an early law called the Narcotics Manufacturing Act of 1960, which was the, which really took the treaties, the US

being a signatory to the international treaties and tried it to begin to implement. Some of these requirements. And in that law, the first time mentions of things like quotas and quotas related to production. And interestingly, it was assigned to the Department of Treasury, and the Department of Treasury was responsible for implementing that law. And it was also with the help of HEW at the time.

So, there was a recognition at that time that they're really looking at this more from an economic standpoint, Marta, to, to your field than it was in terms of law enforcement. You then fast forward to, as Marta introduced as now we get to 1970 and under the Nixon administration and there's now a much more of a concern about what's happening and the fact that you're still having concerns about drug abuse and increased abuse of illicit substances. So, we have the formation of the Controlled Substance Act, which build on the Narcotics Manufacturing Act. But when even a little further, as far as some of the requirements that we're gonna be in, in regard to regulating and at that time. The term we use is creating a close in the US a closed system of distribution.

So, account for everything from the time that Bill's company makes the API to the time that the drug is being dispensed in a pharmacy, right? So, account for it entirely throughout that process. And in doing so, in creating this law, building on some of the treaty requirements as well as the early laws in the United States, they also then create this format, the structure in which they create the Drug Enforcement Administration. And so, this is a new agency, and it's placed under the Department of Justice. So, there was debate and talk at the time about what do we do about some of these requirements, like limitations, quotas, like scheduling, how do we schedule drugs, what drugs should go into which schedule. And there was a deb debate about where that should go.

Should it go to HHS, should it go to HEW or FDA. And in the end. The decision was made, no, we're gonna put it in the drug enforce administration under the Department of Justice, but we're gonna create this administrative body within the DEA to carry out these functions. And again, on the purpose of limitations, built into that process, of course, was the establishment of a quota system. And primarily at that point the function was that was gonna be assigned to the DEA. And as Bill has mentioned, when people go to get quotas, if they're trying to determine what their medical needs are, it's an application to the DEA and the DEA has since 1970, been the government body that's regulated controlled substances.

GOLDSTEIN: Okay, so that's a good history lesson. Now I wanna ask you an international comparative question. Is the way things are done here in the United States the way that most countries handle these regulations?

GILBERT: Yeah. Generally, no, it's different. And I go back to the word limit because that's the word that you find in all the international treaties that you find it in a lot of the early earlier work; you still find it listed. If you read any of the international un treaty documents, we talk about limitations. So, the countries who are signatories to the conventions, which are pretty much most of the world they just have to figure out a way to abide by the treaties by creating limits that limits for medical use.

And as Mardo alluded to, in a lot of countries, this is placed under a ministry of health or a what you would consider to be a health. Agency in terms of making these determinations as to what the amount should be. And in terms of quotas, the countries do them very differently in terms of the way that they, they implement it, whether they, whether they even, they don't even use the word quotas in some countries. So, the way they apply, how they create, how they ensure the goal of only of production only being limited to legitimate medical use. They approach it from very different ways. And I have to say, in some cases it's a black hole because I think even the UN has trouble figuring out how some countries get to the amounts.

But the other part of this, which I should mention is that the other thing that the US has to be, very concerned about and comply with is the treaties also said to all the countries that are signatories. You also have to report to us. So, what you find happening, and it happens here in the US is that while they're trying to regulate what's happening in this country, they also in the back of their mind say we've gotta report all this stuff to the un. We gotta tell the UN how much we've allowed to be produced, how much we allowed to be imported, how much we allowed to be exported, what happened to it. So not just the us but I found a in my experience in going to some of these international meetings, I find the countries are very much concerned about for lack of a better way of saying it, looking good, right?

Looking that they're doing the right job, that they're doing things. And that I think affects and this is my opinion, obviously, that I think it affects the way countries do it. They want to be able to be seen as

being good regulators. Of ensuring that they're limiting the abuse of the drug. So, in, in some ways that affects being able to really take, in some cases, very hard lines to be able to show that, as a country, let's take the us we're trying to do our best to solve this worldwide problem. 'cause that's what it is, right? We tend to look at our borders, but the fact is drug abuse and the way drugs move around the world. Drug abuse is a worldwide problem in terms of trying to stop the abuse of illicit substances.

GOLDSTEIN: So, I wanna ask you a question to which I don't know the answer, which can be dangerous, so forgive me. Is there any way of comparing internationally whether countries that use a framework that relies more on the health agencies in that country have less problem with shortages than we do here in the United States?

GILBERT: That's a good question. To be honest. I've, I don't know the answer to that. I don't know if they have the same issues as the US does in terms of shortages. I guess the only way, the other way I would answer that though, which is why it's particularly an issue in the US is that we are the largest consumer. The US is the largest consumer of medicines in terms of potentially pain drugs. We are we far from what I understand from the statistics, we far out use medicines for these types of treatments than a lot of other countries. And you can look at that from the standpoint is the benefit cost to the US is having them available.

A lot of countries, the drugs just aren't available. So that plays into shortages. The real shortages in a lot of countries from my experience in this is that they just can't get access to the medicine. And even in some countries there are laws as such that really make it very restrictive to get ahold of this medicine. Attending the UN conference every year, you hear stories from some countries, and it really is heartbreaking to hear the practitioners talk about how well, I'm treating things with drugs that I have no business treating pain with, but that's all I can get.

GOLDSTEIN: So, focusing back on the framework in this country, as you were tracing that evolution, you talked about both congressional action and regulatory decisions. How should we think about. Which is the predominant controlling influence? Is it more decisions that DEA has made along the way, or is it more all emanating from Congress's law quite a few decades ago?

GILBERT: Yeah, I think it it's obviously a combination of both, right? And as DEA has tried to carry out its function in terms of maintaining and limiting that, that the quota system has evolved. As Marta and Bill both alluded to, it's evolved over the years and what you've seen even since the passage of the most recent law was that, and it's continually trying to get to a more granular level, right? More data, the DEA is looking for more information to try to make some of these decisions. But unfortunately, in my opinion, the impact has been that in doing that. As it was alluded to earlier, it's potentially slowing down a process or creating situations where there are delays being created by all this search for data to pro to ensure that you're only giving out quotas that are for legitimate purposes.

And I think that's an issue. One of the things about the most recent change in the law that that congress approved, again, in my opinion, again as a result of the opioid crisis, right? There was an outcry of Congress, you need to do something. So, Congress came up and made some amendments to the quota provision.

GOLDSTEIN: When was this? I'm sorry.

GILBERT: This was in 2018. And what happened was Congress had talked about, okay, now we have to look at this diversion, right? The opioid crisis was all these drugs being diverted and people were dying and we have to do something about this. So, they put in the quota provision. In the quota law. Now, which the DEA has to look at in their signing quotas a diversion factor. And this gets back to Mar's example, a bit of the shoplift.

GOLDSTEIN: Explain what you mean by diversion factor.

GILBERT: Sure. Of its, they have to look at, in, in looking at the quotas, the DEA is supposed to analyze for a given drug, how much of that is being abused or diverted. And by diverted I mean it's being used not for legitimate medical purpose, right? So, it's being stolen from a pharmacy. It's a doctor writing a bad script to a patient who shouldn't get it. It's somebody stealing a case of oxycodone out of a distributor. It's anything that, that's showing its way into the black market. So, the law was changed to say, okay, stock factoring in diversion, and start looking at quotas in terms of diversion.

And again, tomorrow's example, I was looking at it, and I was thinking when I saw this being passed, I said wait a minute. So, if a given city in a given state is seeing a 10% increase in, in hydrocodone abuse, so you just give them. 10% less, and that takes care of the bad guys. If you take away 10% of the quota, you're probably dramatically affecting the legitimate use of it. So, you can't isolate, quotas can't be used. And I think my concern with that change in the law was that it was trying to use diversion and trying to use the quotas to directly affect, abuse or bad use of the drug, when in fact I think to the point Bill made, it's a blunt instrument.

It doesn't, it shouldn't be used for that purposes. And I think when we talk about it, I think there's some things that can be done because the quote is, do serve a purpose and the US is obligated to, to limit the amount of drugs being used for a legitimate medical purpose within the context of the regulated industry. But being able to do that in such a way that doesn't cause the shortages, that doesn't limit the legitimate use of the drug is the thing that, that, I think that particularly in light of the opioid crisis that this country's really struggling with now.

GANIO: I, if I can, I'd like to make a comment on the diversion too, just given what I mentioned, the injectables that are used in hospitals and health systems. If you think of the opioid crisis and the examples you even used, so fraudulent prescriptions, theft, most of that is not happening in hospitals and health systems are, controls for inventory are very strict. The traceability of where products are, the accountability of who's touched them, and yet it's patients everywhere will suffer because of the limitations from the quotas.

But it, again, it's these critical patients. It's the sickle cell patient that's coming in with severe pain. It's the patient that's in an intensive care unit with a tube down their throat, helping them breathe, then maybe isn't getting that drug of choice. And so, this unintended consequence of using this blood instrument to control all opioids is having a very serious unintended effect in an area where the diversion really is not much of a factor.

GOLDSTEIN: Okay. A couple of you have been clearly itching to talk about what we should do about all this. So why don't we just put that on the table and have a little free for all. What do you think should happen to improve what you've been describing?

GRUBB: I'm pretty passionate about this, so I'll go. I do think that, as I said they're very good people at the DEA making decisions for, on applications and requests. But they're using data that's old and in a lot of cases flawed. And I think there's a huge opportunity there. Again, five years ago, a lot of this was on carbon forms. And what happens in practice right now is that our January allocation of manufacturing quota and procurement quota is actually based on data.

That's from the third quarter of the prior year because we're only required to report ARCOS data through four times a year and. They're using old data and even though in our applications we try to give current data and say, here's where we are, here's what our inventories are. That's not the way the system's set up that they have to follow an SOP that says, go look at this data and do the estimate. So, I, I think that just giving. Real time inventory data. Right now, using SAP and using modern inventory systems, you can get very crisp inventories very quickly that are quite accurate and shortening that time that the decision is made at the DEA through staffing and technology and using more current data I think would be a, it would be shocking. It would be a transformational change.

GANIO: So, Amy was reading questions. I'm gonna play Amy for a second. What you said Arcos, what Is Arcos?

GOLDSTEIN: Nicely done.

GANIO: Yeah. Arcos is the, I can't remember what the acronym stands for, but it's the basic database that in the closed system tracks where inventory is at every point in the system. And so, it, as a manufacturer, I put in what I made and what I shipped as a finished dose producer. They put in what they received and what they shipped. And along the way we put in what was lost in chemical synthesis and went, was waste and things like that. So, it's an automated system. Or data warehouse.

GILBERT: And I think picking up on, on bill's topic about, about, what could be done and, and the DEA is having to try to look at a lot of data to try to make some of these decisions. And it's coming at them from all angles and they have a lot of registrants. But one of the things that, that I would like to see and some of this has to do with, I think when I went back to talking about where they put this quota function right over in a law enforcement agency as opposed to maybe HHS, it's transparency.

Marta alluded to the different ways that, that a, the agencies approach things and Department of Justice approaches things much different than DA or EPA where they're transparent by nature. But I think transparency is critical. Because I do think, and Bill alluded to this when he was asked the question about do you know why you're going to get zero? And he said I don't know. I've experienced this with a lot of, I get these calls usually right about the end of December where they say, John, we just got our quota letter, and it says they maybe they asked for a hundred.

And the quota letter says, we're giving you 50. Thank you very much. And the question is, why did you give us 50? Did our math not add up? Is there something else you're looking at? And my sense is that if the DEA could be more transparent, like an administrative agency and explain why they only gave you 50, the company could say, okay, that's fair. We get it. You've given out to other, or they could say, wait a minute, you added, you didn't carry the one we actually showed you. Let us supply more information. And I think that's critical. I think, and I think again, the problem with that, or the difficulty for both DEA and the agency is that. We're running on this calendar year system.

One of the thing I'll mention just from a standpoint being an attorney, 'cause I've had this happen when clients ask me, what do I do now? I said there's a procedure in the law and the regulations; you can request a hearing. If the DEA either totally denies or partially denies your quota, you have a right to go before an administrative law judge and make the agency tell you why they didn't do it. But guess what? So now it's December or January, they get their quota. We say, I'm gonna apply for a hearing. I might get that hearing, get through the A LJ process. It's now May or June. Half the year's gone. And quite honestly, most clients will say to me, John, we can't afford that. We can't afford to wait six months for an answer. So, the cycle, so if we're talking about things that aren't working, in my opinion it's the, if we can get more transparency so people know this hearing process, just doesn't make is it's in the law, it's been in the regs. I've used it once in 30 years of practice because it's just unworkable for most companies.

GRUBB: I think, one other thing from a data standpoint is it's lagging data. And I have to emphasize this, hydromorphone has been on shortage for 10 years, so that means that what's being seen in the data is artificially suppressed. It's on shortage, it's on back order. And so, in the adjudication process,

the DEA is looking at historical data, not necessarily accounting for what is the back order or what's the prospective demand. And that's another way that more real time data could be helpful.

WOSIŃSKA: So, if I could chime in. I think you guys I would like to blow it up a bit more. This seems to be a lot on the margin, and I'll tell you I'll tell you why. Again. What is the problem that we're trying to solve? We're trying to address diversion into illicit channels, where does this diversion happen? It does not happen at the hospital, and it does not happen really at the manufacturer level. So, we're using this incredibly blunt tool. We're basically saying, let's deal with shoplifting by not putting on the shelves.

Now, if this was the only option that DA would have, but DA has a lot of other tools. So, in, in the report you'll see that I mentioned an office of office of Inspector General Report for the Department of Justice back in 2019. They issued a report looking back at DA's role in the opioid epidemic. The very first finding is that as the opioid epidemic was evolving, DEA kept on increasing aggregate quota. This is what Congress saw and they say, you can't do that. What is really interesting about DoD's report is that not a single of their recommendations had to do with use the quota system.

Every one of their recommendations was, look, diversion is what you should be going after. You have so much information you're sitting on, you need to use that data better. You need to improve your data systems. Again, going back to, for how long did they have, carbon copies of data and everything was done on paper. I'll actually tell you an interesting story. So, the ARCOS data that we mentioned is not publicly available. And DA doesn't even share it with, I was at the inspector office of Inspector General at HHS, and I was also at the FDA and DD and DA does not share these data, but the data were shared historical data were shared publicly under by a judge that was, that oversaw the opioid settlements.

And so there was some publicly available historical data done, and a colleague of mine David Bradford at University of Georgia used these data to, he started playing around with these data to see what he could find and what did he stumbled upon? Is this what looked like a massive diversion incident? And it was blatant, he actually ended up talking to some folks at DOJ, not a DA, and say look at this. It just seems there's something really big going on. And they basically, something said

something along the lines of oh, they, oh hell, they really look guilty. But there, there seems to be really a major problem.

But this is past the statute of limitations. We can't do anything about it anymore. So, the Office of Inspector General actually said, really utilize your data do data analytics and then go where the problem is because you can actually see where the problem is. And improving the data systems and DA has been improving their data systems. There's no doubt about it. They're moving in the right direction. But what that also means is that they're leaning into more of this. They could be doing less of that really incredibly blunt tool because they now have more of a capability. So, as they're switching towards being more risk-based and getting closer to actually where the problem is, they really should be backing off of this system.

And this goes back again to what's in the law and what's regulatory. The quota system in the Controlled Substances Act is like barely over a page. There's very little in it. It mentions aggregate quota and it ma mentions manufacturer quota, which only applied to API manufacturers for how much to make. The procurement quota are entirely an invention of DEA, and we have, this sort of this alignment misalignment problem that happens. There's, it's not in the law. You don't need Congress to step in on that, in the last few years we had a division into procurement quota for import and export and for domestic, for manufacturing versus for procurement versus for transfer, versus for, there's these sub quotas, just the incredible complexity that got created.

That's fully DA's sort of decision to do. And I just think that there's an incredible opportunity to really just pull back on using that blunt tool and lean in much more on, so for example, I would expect both DA and FDA are very concerned about, a manufacturer suddenly dumping a lot of product on the market, right? But if Bill. As an API manufacturer we're to send it to, some unusual order to a downstream manufacturer before that manufacturer makes it. It's going to be weeks, if not months. If you have good data. And actually, there is a reporting even monthly now DA will know that Bill sent it to that other manufacturer and they can go in and start asking questions and say, what are you guys doing?

What's your plan here? So, there's definitely ways for them to step in and say, we're gonna take your DA's license if you, because you seem to be doing something wrong. And the same thing with pharmacies. ARCAS data again. Even if you were to dump a lot of product on the market, let's say that a manufacturer were to put out a lot of product on the market, wholesalers now have all these data systems under the opioid settlement that if any pharmacy were to try to order an unusual amount, they will get blocked. So, this sort of ability to just dump a lot of product on the market is more of a theoretical thing at this stage because of the systems that got set up. So again, really no reason not to pull back on something that really has constrained the markets and made them so non resilient.

GOLDSTEIN: Let me just ask something. I'm sorry. You can be next. In addition to the imperfections of data, which I hear you all saying loud and clearly one thread that I've heard through all of your remarks is that there's an imbalance between the emphasis on preventing misuse of these. Substances versus making sure there's enough for legitimate uses. How would you go about rebalancing that?

GANIO: Blow it up.

Speaker: But how would you do it?

GANIO: And I wanna underscore something that Mar has said with data by adding one more layer that I don't think we've talked about. And in the absence of any other tool, it's still a blunt instrument. It's still not ideal, but it layered even a beyond the opioid settlement and the wholesaler scrutinizing orders. Every state has a prescription drug monitoring database, and more and more they communicate with each other. And so that, even the pill mill, the pro, the prototypical pill mill that you might think of patients who are just filling prescription after prescription or physicians that are all, that's now recorded also.

And so there, so that's how you find the abuse and the diversion not starting at the top. You go to the level where the diversion is happening and I don't want to imply that's not happening, it is happening,

but that should be the primary instrument for making sure that use is appropriate. Not by making sure there's no use, but by finding where the inappropriate use is and going after it there.

WOSIŃSKA: So, it's basically demand side interventions rather than supply side interventions. If you look how we got out of the opioid. Crisis, the prescription drug monitoring programs where you go to a pharmacy and basically, there's data that feeds into it. Are you doctor shopping? Are you prescribed? So, a patient will not get it prescribed. So that played a role. The insurers started to basically deny coverage of certain drugs and looking for patterns as well. You had CDC issue guidelines for providers. Dentists stop prescribing it for, pulling wisdom teeth.

So and so those are demand site interventions and also really targeted, interventions on the law enforcement side. So, I actually was at H-H-S-O-I-G of Office Inspector General. And OIG worked very closely with DEA on a number of take downs where they would basically analyze, look for apparent patterns and look at prescribers that were, basically pill mills and then arresting them. So again, it's really on the demand side interventions and not supply-side interventions that really made a difference. And we really, that's what we should be leaning in on rather than the very, very blunt instrument that we have.

GILBERT: Yeah, I'd agree with that and I think as I was alluding to, I think one of the issues with the change in the law and creating more data for requiring DEA to look at more data and DE has also broken down categories of, in looking at quotas and asking companies to not just give them one number, but give them a breakdown of how much is in development and how much is production. And that providing, breaking down those numbers even more also means the DA analyzes it more. And to Bill's point, it, it reduces the flexibility of a company to say look I'm giving DA estimates six months in advance, so maybe we don't need as much for production.

Maybe we need more for testing. But because they've told, already told the DEA, that they're hesitant to try to say I can't just shift some of that quota over here because the DA's gonna come and say, oh, you, you missed, you, you misled us. And so that's the part if we're just talking about the shortage, that you're right, and trying to get people to get their quotas quicker and get them more accurately. It has to be transparency in terms of the data. I agree entirely that the focus of the balance of trying to

attack and balancing this between availability of medicines and abuse has gotta be done on the demand side primarily. It, you can't look at it from a supply side and say, okay, if we just reduce the supply, that's gonna take care of it because it's, as we've all been talking about, it's just, it hasn't worked. We're still here. And it hasn't shown a dramatic effect.

GOLDSTEIN: What's the political climate like for thinking about making any of these changes? You all are aligned but I don't know whether there are influences...

WOSIŃSKA: Yeah.

GOLDSTEIN: That either just haven't thought about it or have an interest in not having these changes made.

WOSIŃSKA: So, it depends on what changes we're talking about. We talked a lot about DA being part of DOJI cannot, that would require legislation. The, in a sense, good news is that so much of this can be done administratively and without involving Congress. So that's a, that's good news because I think it's challenging the sort of the legislative landscape is very challenging. What I think is important to flag here is that we have so much discussion right now about drug supply chain resilience, and we think we're thinking about how to protect the supply of essential medicines. A lot of it is about China, but then again, remember how I, the story that that I described of how this project started, morphine is incredibly important for department of war, department of defense for war fighters.

So, I am hoping that sort of the fact that three essential medicines are part of this would open up some doors here. I will also say that, again, part because the department of, because Congress was pushing DA so hard, but I will say that, under the previous administrator DA really leaned in and tried to make it as complicated as it could possibly be. I recommend you read my paper because we provide a lot of detail. And so, the amount of complexity in the quota system that was introduced during the previous administration was just incredible. And there's, there, there's a lot that the Trump administration can do to, in a sense revise and reform this system. So, a lot of flexibility for this administration to do things. And then the question is, what will be their willingness to do it?

GANIO: I think there's a perception issue too that needs to be addressed. And for some things we have a very short attention span and short memory. But when you say opioid crisis, I think that resonates for a lot of people. Still, I think there's a lot of rural communities that are still hurting from the opioid epidemic and you could argue that it's actually not completely resolved. So, I think it's education. It's forums like this where we can state the facts and why are there problems and where there's opportunities to fix them.

But in a vacuum, if you just were to go back to your constituents, if you're a member of Congress and say, we're gonna make the opioid production more lax, how do you think that would land? And so, I think there's a perception that has to be addressed as well in all these other layers that we've talked about today that you have all heard about, that maybe the general public isn't aware of.

WOSIŃSKA: Yeah. And I just would add, Congress might not need to change laws, but Congress would have to be okay with changes, right? Again, they will be the ones they've been scrutinizing the opioid epidemic quite a bit. And they were part of, the big push on DEA to do something about it using quota. And so, I think it's also important to communicate with Congress on this so that they really fully understand that. Talk about a blunt tool. This is not a store deciding that they're gonna limit shoplifting. This is the government telling us in all the, in all the stores out here, we're gonna deal with shoplifting. All of you are supposed to carry less of the product. And I think that realization of just how blunt of a tool it is. I think the public needs to understand it and I think Congress needs to understand it, and then it gives room for the administration to act on it.

GILBERT: Yeah. And I think the other focus, and it alludes to the point Mike was making is that when you look at the perception here and look at the issue it struck me as I was obviously involved in a lot what was going on during the opioid litigation and issues when I was looking at a lot of this is that, and again, I'm very much generalizing, but when you look at where fundamentally the issue was, as Mike said, not so much in the hospitals, but in the pill mills in the, so the doctors prescribing bad doctors prescribing more than they should and pharmacies dispensing more than they should.

The amount of action that I saw being taken against doctors, for example, by state medical boards was almost non-existent. And the boards of pharmacy were having trouble keeping up with some of

the issues they were having with bad pharmacies. But that's where a lot of the problems was. It wasn't with the manufacturers. It might've been some oversupply down the chain, but at the end of the day, if the doctor's not prescribing it. The people aren't getting it right, because no matter how much the distributor or manufacturer was putting out there it wasn't, it wouldn't get there unless there was somebody prescribing it or somebody dispensing it. And I think to Mike's point about the PMPs, I think a lot of this is at the state level. A lot of this needs to be, I think a real focus on what is going on with practitioners holding their feet to the fire, which then will ensure appropriate availability when you get up to bill's level of trying to make sure the medicines are available for the legitimacy.

WOSIŃSKA: John, are you suggesting PMPs for ADHD drugs.

GILBERT: I'm yeah, I'm just suggesting there be more accountability at that level, because I think that's where some of the issues were. And there was a lot of blame to go around but the one area, and again, I'm speaking for myself, I just was surprised at the level of a lack of enforcement against at the demand side, which I would put the doctors and the pharmacies and some of the some of the patients in that box.

GOLDSTEIN: Okay. I think that your point about public perception and how that reverberates is a great segue to start asking questions that. Audience has. So, this one I think starts by addressing you, Marta. It says your report, so you're the author of the report. Make some very interesting points about the way that Congress views the role of DE's quota program, especially in the lead up to the opioid epidemic, which we've just been talking about. Can you expand on that and help us understand how they may feel now as a result of widespread ADHD drug shortages?

WOSIŃSKA: It's interesting. I testified with the Senate Finance Committee in December of 2023, so that was really still at the height of the shortage. And I can tell you that every member of Congress. Has heard from their constituents about this. And I, it was about, ADHD medications. The hearing was really about generic sterile injectable drugs. But I did get some questions about this. There's clear awareness of this. Again, all congress members have heard about this.

I don't think they really have been appreciating just how blunt of a tool it is. I remember getting a question about, what do we do with this? And I basically said, look, quota is such a blunt instrument. We basically say there are appropriate and inappropriate patients. We're gonna cap it and now let the appropriate and inappropriate patients somehow sort each other out. And the senator pause and he says. Oh yeah, that, that is a really blunt tool. I'm not sure if I'm exactly answering your question. I think there's a lot of room for education here.

GOLDSTEIN: Next question. We often talk about how quality problems can exacerbate shortages. Does the relationship ever go the other way around? The FDA has reported an increase in med watch reports of ineffective. We've got a lot of ADHD minded questioners here of ineffective ADHD stimulants over the past few years, for example. So, what about the...

WOSIŃSKA: So, I'm not sure the other way, but a lot of drug shortages start with a manufacturing quality problem where a facility goes down. What is very unique about controlled substances scheduled to substances is what happens next, right? So even if there was a manufacturing quality problem that might have stopped the facility as in this case, right? FDA would probably go and look at med watch reports. They would go to the facility, they would, the manufacturer my pause production.

What happens next is that now that facility's down, they're sitting on unused quota. Patients still are getting prescriptions. They're going to alternative products. The manufacturers cannot make more of that because they don't have the quota. The manufacturers of therapeutic substitutes also don't have the quota. And so, the market, there's no resilience in the system and there's no ability to recover easily. So, it just sits there. And is it surprising for me to see that we have had 10 years? Of hydromorphone and morphine shortages. You, and again, you, it feeds back to, then we look at historical data to project next year's demand after we had a disruption.

Of course, the sales are gonna be lower this year because we had a shortage, right? So, we're basically looking at past shortages to forecast demand. And you have this sort of, in a sense, one of the problems with our data on shortages is that we say a drug is in shortage or not in shortage here. We just have drugs per perpetually in shortage. And it just bounces within a shortage. Right now, hydro MOFO is particularly bad because there was a disruption for a manufacturer that makes one of

the formulations. But again, it can bounce back, but I don't even know how you get out of these because of how the system is designed like the idea of recovery from some sort of other completely unrelated issue to the quota system. Just in a sense, it goes around in circles here.

GOLDSTEIN: Okay, this is a patient-centric question. Are there policy options to support hospice organizations? They rely on these medications and it's really disruptive to patients who are dying when a pain management solution is disruptive because of a shortage. And another drug, to your point, might not work as well.

GANIO: I think this is the perfect example of a legitimate medical need. And think about the dignity of the end of life and that patient is competing for that product on the shelf. I think that sums it up perfectly, as far as I know, no, there's no protections for supply that would be for that. In fact, a hospice, unless it's part of a larger system, may be disadvantaged actually because health systems with large resources may have a pharmacist dedicated to managing drug shortages and be able to juggle inventory between sites. No, as far as I know, no policy, but it's, it perfectly highlights the problem, the inequity that's caused by these quotas downstream.

WOSIŃSKA: If I could just add, remember my analogy with shoplifting, we're not setting aside what CVS does. Nobody sets aside supply for appropriate patients. It just doesn't exist. It's basically we cut supply and we cut supply and there is no we would have to break the system and change the system entirely so that there is some product available for hospice patients.

GOLDSTEIN: That's what I was curious. Should there be some kind of carve out for specific patients?

WOSIŃSKA: But how would you do the carve out if you're controlling it at the top? We have to walk away from the quota system and the way we're imagining at the very top, you need to be allow for a more supply and then make sure that it goes to the right places. But you have to allow for more supply first.

GILBERT: Yeah, and I think it's in, it's a process of trying to build in more, as we were talking earlier before the talk about resiliency. You have to figure out a way to, to be able to, to bill's point if, if the issue is that if one fi manufacturer goes down, so they're sitting on quota and so you have to have

someone else reapply for it. They have to give the quota back because if they don't give the quota back, then the DEA will exceed its aggregate for the year for that particular drug. And this just goes through notice and comment rulemaking or some of the assignment, now you're six weeks down the road and as Bill mentioned, six weeks in the manufacturing world is a lifetime.

And so, it does have to be Marta as you alluded to from a regulatory standpoint if you can't change the law's harder to change than the regs. You have to figure out a way for the process to create enough supply so that when we have situations. That we're talking about where a specific demand within a certain segment of the population or a certain segment of the healthcare industry that you can allude to that. You can't give quotas for hospitals versus quotas for pharmacies, right? That will never work, but the supply is gonna have to be sufficient and be able to pivot enough to address these healthcare issues as they come along.

WOSIŃSKA: I was just going to add, there is a lot more room to build in a buffer in aggregate quota. There is really no reason why the aggregate quota have to be so incredibly tight, especially that we are fully aware that some product is not going to be used up. There's going to be shocks to the system. Again, the aggregate quota. Do not allow for the do not com. The idea of demand spillover from one drug to another when there is a problem in supply just doesn't, it's not built in at all in the da quota system.

You can set and DA used to do this, that they actually built in a buffer at some point that they weren't allocating. But just in case, because if you are going to allocate all of the quota to manufacturing quota, then not only do you know the manufacturer has to apply, say, we actually need more because there's demand. Then DA will have to say, but wait, we are allocated the quota. We have to go through rulemaking. Not notice, we're not talking about six weeks, we're talking about several months, and they have to go through this process to increase it. If they had more of a buffer, it gives them more flexibility.

There's just and then you basically go with, trying to create the inefficiencies and the misalignment problems. Again, procurement quota are nowhere in the law, and you could get incredible insight into where the product is and who is manufacturing because of ARCOS data and all the reporting

requirements. We're basically using the quota as a monitoring tool to get data. It's I don't really see a purpose of procurement quota other than that. And it, so there's just there's so much you could eliminate so that you, right now the system is designed to like, think about it, supply chain as being, a factory line and you're basically throwing sand in the machine. That's really what we're doing. And so, let's just maybe not throw the sand in the machine.

GILBERT: Yeah, I think it's, I think it's, from my experience, it's also a coordinated effort. You, it, there has to be more coordination among an API manufacturer and what a, a dosage form manufacturer gets and the coordination in that aspect because, 'cause I've experienced times where one, a dosage form manufacturer has enough procurement quota, but their supplier, the DEA hasn't given 'em enough quota to send them the API or to send 'em the API. So, they're sitting there on quota and when we talk, go back to the point about 70% of quotas unused that statistic. Which again, my problem with that was that it was Bill's point, timing issue, right? If he gets quoted on December 15th, yeah, it's gonna go unused 'cause he can't make the product in the amount of time. It's the timing, it's also the function of I may have procurement quota, but I can't use it because my supplier hasn't gotten enough quota. So, it really needs to be a coordinated effort in order to address, each function of the supply chain.

GOLDSTEIN: Bill, I think this question fits best with the points you've made about the timing of when quota is announced and the suboptimal nature of that. From your perspective, how is the DEA being held accountable to timelines?

GRUBB: Yeah, again there's not, when you get a quota letter, it just says, here's what you got. It doesn't say why you got that. And then when it comes to timelines, I do believe that there's an internal metric at the DEA of around 53 days, and it, and generally speaking, we are getting answers within that timeframe. So, I...

GOLDSTEIN: So, it's not as if they're violating their own rules, it's just their own rules aren't all that practical in some cases.

GRUBB: That's right. So, it's managing the metric. Are you meeting your metric? Yes. Is the metric too long? Yes. So, I, and again, that, that number I've read that somewhere. I don't know that's fact, but I would say that they're pretty consistent. It's just a long time.

GOLDSTEIN: Okay. I think I'm gonna ask one more question and then maybe give each of you a chance to say a final thing if you'd like to. So, the last question is, can AI and more sophisticated models be leveraged to improve quoted decisions?

GRUBB: I believe the firm answer to that is yes. There's, my company was founded in 1979 to make codeine for Tylenol with codeine. And the fact that one of the drugs that we got 0% quota for was codeine. I, it blows my mind. That there's we've had established market shares for many products for decades, and so why wouldn't you say use that pattern to say, Noramco, my company needs to get this percentage of what they've gotten right off the bat versus making us go through five or six or seven applications per year. So yes, I think there's an opportunity for AI and data analytics.

GILBERT: Yeah. I think the more that it can marry the issue about the issue about what the demand really is, what the history has been, and be able to take out some of the noise, right? Because there was a shortage last year, doesn't mean that you're starting at that level. You're already behind the curve. So, if data analytics, AI can do that and so well really, they do need more. You need twice as much as last year because of all these other factors that happen in the industry. That would be helpful. I think it would be, yeah, extremely useful for the DEA, certainly.

GRUBB: And it could hopefully get some of the prospective nature too, as well as retrospective.

WOSIŃSKA: Where I would like to use data and data analytics is much more on the law enforcement side. And really use the data that you gather as part of the regulatory oversight to then target your investigations and target actions against DA registrants, be it on the manufacturer level, wholesaler level, pharmacy level. That's it. It's not all about how do we design quota better, which we should think about this process, because there are some constraints that are given by the law. But really lean in, again, I'm going back to the D-O-J-O-I-G report. You sit on so much data, you do have all these other

additional tools. That's what you need to be leaning in on. Again, DA is moving in that direction. I would like to see a lot more of that. While they're backing off using quota as a tool.

GOLDSTEIN: Okay. We've got about one minute left. So how about we just go down the line, and you each say briefly what you hope people will most take away from this conversation.

GANIO: Change is needed and I think if not now, when we have an administration that's in favor of deregulation. We're in a post Chevron Supreme Court ruling world. Now's the time.

GRUBB: Yeah, I agree. We're, you've got a bunch of good people on both sides of the fence. Working within a broken system, change is definitely needed to just start from a blank sheet of paper and say, how do you make this work better?

GILBERT: Yeah, and I think it, I think to get there it's from transparency and cooperation, between, DEA more involvement of FDA in some of these things. More of a health perspective in trying to accomplish this balance between, making sure medicines are available and trying to stop the bad guys from getting the drugs they shouldn't.

WOSIŃSKA: Completely agree. Probably what I would say is that just because something sounds like a good idea, it doesn't make it a good idea. And to me the quota system is a perfect example of that. It sounds like this would be the way for us to deal with diversion into illicit channels. It is just a really bad idea.

GOLDSTEIN: Okay. Thank you all the four of you, and especially Marta, for doing this work that spawned this conversation. And thank you all for being a good audience.