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LedgerDomain Webinar - DSCSA Exemptions and You with Tish Pahl.mp3

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2 SPEAKERS

Speaker1
Speaker2

START OF TRANSCRIPT

[00:00:00] Speaker1
Today we're going to be talking about Dscsa. At a high level and the upcoming exemption period and what it means for everybody as we navigate this all together in particular. So I'm Alex Colgan. I head up partnerships and marketing at legerdemain. Today I'm going to be joined with Tish Paul, who, um, almost doesn't need an introduction at this point, but I'm going to ask her to give herself one anyway.

[00:00:30] Speaker2
Um. Thanks, Alex. Um, I'm Tish Paul, and I am a principal at the law firm of Olson, Frank Terman. Matz. Um, I consider myself both a late arrival to the Drug Supply Chain Security Act and an early arrival in that. The first time I really cracked it was in January of 2014. Uh, and but so in that sense, I had not been intensely involved in the things which preceded it, such as the pdma and the patchwork of state licensure laws that we were dealing with at the time. However, I have been dealing with the DSA daily since January 2014, so in that sense, I am an old hand at it. But like so many, always learning something new and it's always a pleasure to come together with new and old friends to talk about it again.

[00:01:29] Speaker1
Thanks, Tish. So today we're going to be covering a general update on where we are with DSA, with Tish talking about the exemptions and moving into some of the nuts and bolts of authorized training, partner credentialing, tracing, verification and confirmation, and moving on to, uh, general feedback and thoughts on your action plan over the next few weeks and the next few months. And Q&A tea time with Tish. So I'll just touch on Dscsa at a very, very broad level, and Tish will sort of narrow in on a lot of the specifics. Um, you know, we're now into almost, you know, sudden death overtime as of November 27th, it was initially a ten year rollout on this federal law, followed by a stabilization period and now followed by a cascading series of exemptions that FDA issued actually earlier this month. So dscsa is, um, as a law, uh, rather interesting. It creates a, a community. It creates a, a boundary around that community who's in and who's out. It mandates certain activities between different members of that community trading partners. Um, you know, defines what different roles in the supply chain are, and a lot of those.

[00:02:58] Speaker1
Activities involve, you know, direct interoperability between trading partners for purchasing and selling of prescription drugs. Some of those activities actually involve, uh, mandated interactions between what are called indirect trading partners. These are commonly known as verification and trace. So a little bit of a unique law in that sense. Another another element of the law is that it mandates electronic interoperability for these activities. But um, to a greater or lesser extent really did, um, you know, throw the ball over to the industry with a couple of exceptions, um, in terms of defining exactly what that electronic interoperability would look like. Um, but, you know, Tish is the expert here. She'll be able to talk to that at a more detail. Uh, Tish, over to you. Oh, actually. Sorry. Even before that, um, I think, um, I think the other development that we've seen over the past few months is that enforcement and inspection activities have been ramping up. Um, up until earlier this year, the only 483 inspection letters that we had seen, um, related to DSA, were levied at wholesalers. Um, a a FOIA request submitted earlier this year. Uh.

[00:04:25] Speaker2
That was me.

[00:04:26] Speaker1
Exactly. Uh.

[00:04:28] Speaker2
So I the only thing that annoys me about that is that I didn't do it sooner.

[00:04:34] Speaker1
So it's and again, Tish can talk a little bit about what, uh, about what she observed in some of these, um, letters that had come out. But it it does seem that FDA is ramping up. Um, questions and evaluations around Specific requirements under Dscsa, in particular around verification, suspect and illegitimate product notifications, and really sort of tuning up, um, SOPs and examining SOPs. The two big questions in all of these cases seem to be is a given trading partners SOPs. Are they in line with the requirements of the law? And are is the trading partner following those SOPs? Um, and I think we're, by all indications, going to see more of these as time goes on. Uh, but now I will toss it over to Trish or Tish.

[00:05:35] Speaker2
Great. Thanks, Alex. And I'll be happy to talk a little bit more about the enforcement that we're we've been seeing. Um, and the enforcement that we expect to see in the next year or so. Um, During questions. Um, so, you know, for a lot of you and I see a lot of familiar names in the in the chat and among the attendees, this is all you all know this, and you've been living with it, as I have since November 27th, 2013. Um, however, I have also found, as I've been speaking over the last, really more intensely in the last year during the FDA stabilization period, is that frequently, a full 25% of the people who come into the webinar, in the session that I'm giving, they have no idea what the Dscsa is. No. No clue. They have nothing in place. So on the chance that we're dealing with that level of baseline ignorance here, um, I want to talk about some of the basic requirements of it. And it's also useful as a refresher for those of you who are more up to speed on it, because it helps to explain what the stabilization period and the FDA, the recently granted FDA exemptions what those do and do not do. However, if you feel you're pretty confident with all of this, go ahead and just put me on mute and go back to carving your pumpkin and we'll move on.

[00:06:58] Speaker2
Um, and then you can come back in when we start talking exemptions. Uh, but in any event, um, for those of you who are new to all of this, um, the dscsa, of course, applies to trading partners. And that means manufacturers and repackagers wholesale distributors and three plus and then dispensers, which includes, among others, pharmacies, hospitals, health systems and healthcare practitioners. The Dscsa applies to products and it applies to transactions of products between trading partners. And we'll move through each of these different definitions because the Dscsa is a very definitional, driven law, and what it particularly focuses on is not what you yourself characterized yourself as, but what you are doing in the supply chain. If you are acting as a manufacturer, you are regulated as a manufacturer. If you are acting as a wholesale distributor, you are regulated as a wholesale distributor. And it doesn't matter if you're saying, oh well, I'm a dispenser. If you're engaged in wholesale distribution, you need to comply with the requirements that are applicable to a wholesale distributor, among others. So next slide, Alex. We're just talking about trading partners. And all trading partners have to be authorized in order to engage in transactions of covered products. And we'll talk about what transactions and covered products mean. But for manufacturers and repackagers, that means you have to have a valid FDA registration. And for everybody else, you need a valid license under state law.

[00:08:16] Speaker2
Now, in February 2022, FDA issued its long awaited and long overdue national standards for wholesale distributors, and we are not expecting to see a final version of that rule until probably March of 2026 at the earliest. And it's these national standards that are then presumably going to be adopted by the states and which will govern, uh, the licensure of wholesale distributors in three place at a national level. And of course, these are current requirements. You can only be doing business with authorised trading partners and you yourself have to be authorised. Um, and then the Dscsa applies to products and that's finished prescription drugs for human use intended for administration to patient. I still get a lot of questions about whether or not a particular product is covered by the dscsa. And you know, what I say in the first instance is unless it's a manufacturer who's asking the question is, is that, you know, what did the manufacturer tell you? Because the manufacturer knows its product best, and it's the one who's responsible for determining if the dscsa covers its product or not. Something that was interesting, um, that I discovered when I started diving into these 483 that FDA had issued, is that I'd found a number of warning letters, involving, among other things, the dscsa that FDA had issued to outsourcing facilities and compounding pharmacies.

[00:09:50] Speaker2
So establishments that were compounding drugs now compounded drugs are outside the dscsa. They are exempted from the definition of product. However, if a compounding facility so an outsourcing facility or a compounding pharmacy is not complying with the applicable part of the food, drug and Cosmetic Act, which is for a compounding pharmacy is 503 A and for an outsourcing facility is 503 B. If that establishment is not complying with 503 A or 503 B is applicable. Among other things, it loses its dscsa exemption. So the products that it's making then become subject to the Dscsa. So you can go on from there. Alex. Um, product identifiers, all those products need to at this point have an identifier on them. That's, you know, as I say, emphasize it. It's a current requirement. And trading partners should have systems in place in order to be sure that the products that they're transacting all have an identifier. Um, unless the product is grandfathered. We know that while this requirement has been in place since November 27th, 2018, that there are some products in the supply chain that have really long, um, expiration dating. And so some of those products might have entered before that date and don't have identifiers. But at this point, um, that number should be small and decreasing. Next, um, which is uh, transaction. And of course a transaction means the transfer of a product between persons in which a change of ownership occurs, not possession.

[00:11:25] Speaker2
Um, and so one of the most important exemptions to that very broad definition is dispensing to a patient is not, um, a transaction under the law. And then there are numerous other instances where product is moving within an entity, but there's no change of ownership, it's just a change of possession. And so the dscsa doesn't apply. So things like, you know, you get product into your DC and then you move it to another of your DCS, or you move it from a DC to one of your stores. This is all, um, outside the, um, uh, outside the Dscsa, um, something that I am continuing to hear a lot about are pharmacies that are engaged in sales to other pharmacies where there is not a specific patient, specific identified patient. So a pharmacy A is selling to pharmacy B and there's no identified patient. These are very likely dscsa transactions, which means among other things, you need to be providing transaction data. And you may and the entity may need to be licensed as a wholesale distributor. Um, and this includes borrowers and loans. The practice continues to be rampant. And it is, um, it is in fact subject to the dscsa. Um, although some people continue to not be aware of that. Um, and of course, an ATP can only transact covered products with other atps.

[00:12:50] Speaker1
Tish um, is it is it fair to say that trading partners need to regularly check the ATP status of their trading partners and and log this activity?

[00:13:01] Speaker2
Great question that I get a lot, which is how often do I need to check? And the FDA has not provided any guidance in that area. What the FDA says and what I tell my clients in the first instance, is that if you transact product, if you purchase from or sell to a covered product to someone who is not authorized, you are in violation of the law. That's that, that's that's the plain and simple. And we have seen warning letters and 483 should address this. So that's that's your baseline, which is that if you engage in a transaction with someone who is not authorized, you are violating the law. So then the question is, well, what do I do in order to be in compliance with the law? And what I typically tell clients is that in the first instance, you need a standard operating procedure for how you are going to confirm that all of your trading partners are authorized. How often you check that becomes a business decision based in part upon, among other things, how well you know, your trading partners. Um, and again, absent any FDA guidance on this and the requirement of the law that everybody be authorized, people have come up with different ways to do this.

[00:14:16] Speaker2
You know, they establish a process and then they check periodically. And what that periodic check is just depends upon the the trading partner. Some have, of course, um, elected to purchase a solution from a solution provider that automates or partially automates that process. And, you know, which is where we get into the credentialing discussion and the law does not require credentialing. And FDA would never say that you must have a credential, but it is a it is an efficient business option for some trading partners. Whether or not someone elects to do that is is up to them and their trading partners. Um, so, you know, that's really the best I can answer on it. It's it's a very idiosyncratic decision that each business needs to make. The key is you need to establish an SOP and then you need to follow it. And that actually goes to Alex to a point that I also continually make, which is that don't make yourself the low hanging fruit in that once you have that SOP, follow it, because if you don't follow it, you become a very easy target for an inspector or an auditor.

[00:15:23] Speaker1
And what do we get? Do we have a sense of what the consequences of non-compliance for this particular policy looks like.

[00:15:31] Speaker2
Well, um, so far, what we've seen most commonly is a 483, um, or a warning letter. However, we have the example of safe chain solutions, um, which was really a catastrophic situation of purchasing counterfeit product from trading partners who were not authorized. Um, and then, um, so, among other things, these were fraudulent transactions of counterfeit product, where it is very fortunate that patients were not injured as a result of it. And in that case, you know, we saw not only an extensive 483 issued by the FDA and a warning letter, but we have now seen criminal indictments, um, for the violations of, among other things, um, the dscsa. So, yeah, you know, I mean, that's an extreme example, but the every violation of the food, drug and Cosmetic Act is potentially criminal. So yeah, take take that for what it's worth. That's again, I want to emphasize that was an extreme example where they, you know, took not know your customer or supplier to the next level. Uh, but um, trading partners be warned that, you know, that option does always exist for the agency.

[00:16:54] Speaker1
And are there, um, are there sort of additional or nuanced requirements for manufacturers and repackagers in particular?

[00:17:03] Speaker2
Um, I don't know what, you know. Um, I mean, I'd be curious if you think of particular things that the law doesn't require anything in particular other than know your know your customer. And I would say that that applies to a wholesale distributor selling to a dispenser as much as it does to a manufacturer selling to a, um, a wholesale distributor or direct to a dispenser, you have to know your customer, and confirming that your customer is authorized is a part of the diligence that any trading partner should engage in when they're onboarding someone.

[00:17:42] Speaker1
Great. Thank you. Um, that covers me. On to the next.

[00:17:48] Speaker2
Um, on the product tracing data, which is that Atps have to be providing, receiving and maintaining product tracing data. Um, that was originally what we were calling the three TS, T, th and TS. Um, on November 27th, 2023. The three TS became the two TS because t h uh said did what's called sunsetting by operation of law. The the law eliminated t the th requirement. Um, so otherwise this is a current requirement. You've got to keep that data for at least six years. Next, which is that before November 27th, 2023, when we were in the three T's world. Um, those three T's were typically being exchanged in an ASN, or the supplier was posting it to a portal that it was maintaining for the customer. Um, and that was Lotte level product tracing data. Um, after November 27th, 2023, we moved to the package level world. Um, and these are requirements that you'll hear referred to as package level data exchange, or EDS in standing for Enhanced Drug Distribution Security Requirements, or where these requirements exist in the food, drug, Cosmetic Act in section 580 2G1, so you'll hear it referred to by various things. 580 2G1 package level serialized data. Eds requirements. It all means the same thing, which is package level data exchange. Um, and what that means is that the product identifiers must be in T for each package in a transaction. No, you cannot provide just the identifier on the case.

[00:19:30] Speaker2
If you are selling a sealed case to a customer, you have to be able to tell that customer the serial number that's on each package in that sealed case. It's typically being provided in an epcis file, of course, or the information is being posted to a portal. Now, of course, the compliance with these package level requirements have been delayed. And we'll come back to that. And it's the providing, receiving and maintaining of this package level data which will enable tracing regulators and Atps can request product tracing data under certain circumstances. And you know, I'm happy to take some questions on that, because the package level tracing requirements are pretty complex in terms of who can ask and what they get. Um, but something that's real important, and it was by no means clearly understood over the years that we've been engaged in dscsa development. And that's at a responding, a trading partner responding to a tracing request provides the data that it has. Um, so if a wholesale distributor is responding to a valid trading request, they provide what, what it has and it's not expected to go up to the manufacturer who we purchase from and obtain that manufacturer's data. Nor is it if it's, say, it's sold to another wholesale distributor or to a dispenser, to go to that downstream trading partner and provide their data. You provide the data that are within your four walls. Uh, next.

[00:20:59] Speaker1
Question in the chat. Oh, yeah. Um, yeah. Uh, Ray asks why was transaction history sunsetted?

[00:21:08] Speaker2
Um, it's in the law. Yeah, I mean that I there were, I think negotiations around that. And the feeling was, is that when we moved to package level requirements that the importance of th, um, uh, diminished, but that would involve me getting in the heads of the people who negotiated this law over ten years from, you know, 20, you know, from 2000 to 2013. And I wasn't in the room for that, but it's it's in the law. And so FDA could not by law, um, mandate that it continue because it sunset as a matter of law. So it's just that's what Congress decided. That's a good question though.

[00:21:57] Speaker1
All right. On to verification systems.

[00:22:01] Speaker2
Um, yeah. So this is going back to the excerpts of those 483 that Alex was showing is that if you do nothing else, you must have verification systems, which are your systems for the management of suspect and illegitimate product, like your tracing data. This needs to be maintained for six years, and it's a really high enforcement priority for FDA. And this is where I go back to my point about don't be the low hanging fruit. Is it? First, have your verification systems in place. Um, and make sure that the SOP that you have in place comports with what the FDA has set forth in law and guidance. I mean, you need to compare them and make sure that everything that's in the FDA verification guidances and in the statute are in your SOP, and then you need to follow it. Um, because if either of those two things are not true, you have made yourself into an easy target. And this is a really high enforcement priority for the agency. For FDA, this is how, um, illegitimate product is entering the supply chain. Um, and moreover, we're looking at Increased interest by states. States know about this requirement too. And so it's a current requirement. And we can expect um, and we can expect continued enforcement, um, that everybody have systems for verification.

[00:23:34] Speaker2
And Scott, um, so someone has added about the th requirement from 2015. Yeah. And as I said, it's the the reason why it dropped out of the law, um, is because of the increased confidence that comes from, um, from being able to interoperably exchange transaction data with that, um, with product identifiers. So, you know, we are able to trace packages, um, in the supply chain in a way that we weren't able to do and only a lot level world. Um, so the next is the verification of product identifiers. Really important current requirement. And in fact, had a question a couple of weeks ago from a manufacturer who wasn't aware that they needed to be able to do this. Manufacturers and repackagers have to respond to a request to verify a product identifier, um, from an ATP that's in possession or control of the product. Current requirement. They've been doing it for years. Um, and manufacturers, repackagers and wholesalers also have to be able to verify product identifiers and suspect product investigations. Regulators can and are making these verification requests. Um, so that's current state future. Um, although these requirements went into effect in 2019 and 2020 is that wholesale distributors have to be able to verify product identifiers on returns before resale. And if a suspect product investigation, a dispenser has to verify the product identifiers on at least three packages or 10% of the suspect product, whichever is greater.

[00:25:06] Speaker2
Um. Uh, or all packages of fewer than three and FDA has delayed this requirement several times. And we'll come back to this point as well. Um, and then we're into the world of what was effective November 27th, 2023. Um, which are these package level requirements, the 580 2G1 requirements or the enhanced requirements? Um, and that unique product identifier that's on all packages becomes embedded in the existing Dscsa requirements. So this means that trading partners have to exchange product data, tracing data securely electronically, and interoperably that product tracing data needs to include the product identifiers in T for each package in a transaction. Um, trading partners have to be able to verify and trace at the package level based upon that identifier, and to accept a return from a customer. The manufacturer Repackager has to associate the product and its identifier with the outbound um transaction information. Um current requirements continue, But of course, given the state of readiness in August of 2023 last year, the FDA issued its stabilization policy and it said that it wasn't going to enforce these package level requirements until later, um, next month. Uh, November 27th, 2024. Alex, I can't hear you if you're talking.

[00:26:36] Speaker1
Oh, there we go. Sorry. Yeah. So? So both verification and tracing often happen between indirect trading partners. Um, and the latter especially needs to be, um, at least doable in a secure, electronic and interoperable way. Um, you know, what methods exist for trading partners to, to meet those requirements as, as they come in for the 2023, uh, 583 G.

[00:27:01] Speaker2
2023 2024 requirements. Yeah. Um, so That's a complicated question with a number of complicated responses. And so first is that tracing at the package level, um, will exist when trading partners are interoperably exchanging package level data. And we're not quite there yet. Um, you know, that's that's a part of what the stabilization period was for. And then of course, the, um, the extent the FDA exemptions that have been recently granted, which we'll talk about in a minute. Um, so, you know, first is that tracing at the package level presupposes that trading partners are providing, receiving, maintaining package level data. Then in the 580 2G1 requirements, these enhanced requirements, you have to be able to verify at the package level, which you know, in a way, doesn't make a whole lot of sense because you're always verifying that product identifier. Um, but Depending upon the the nature of that that verification how trading partners are opting to do that depends for indirect trading partners. One way that they are going to be verifying product identifiers, meaning contacting the manufacturer to confirm that that identifier is one that the manufacturer assigned, is that they're using the verification router service in order to to make that verification. And moreover, in a suspect or illegitimate product situation, that's what trading partners might be doing. Or they might just be picking up the phone and contacting a manufacturer to confirm it. Now, I will say that as a general matter, there are plenty of manufacturers who aren't thrilled at the prospect of having to handle, um, a lot of telephone calls from people trying to verify product identifiers.

[00:28:58] Speaker2
So, um, some, maybe many manufacturers are very interested in seeing trading partners using the verification Router service in order to initiate these verification requests. In the case of wholesale distributors who have to verify a saleable the product identifier and a saleable return before that product goes back into inventory, what many of them are intending to do, although again, not all this is an individual business decision, is that they will be verifying against the what's referred to as replicate data. They'll be verifying product identifiers on their returns against the data that they receive from the manufacturer. So that's the verification part of it from a tracing standpoint. Um, well, and actually this is true for, for verification as well, insofar as regulators are concerned, is that the FDA is looking to use its next gen portal to initiate tracing requests and verification requests. And state regulators are understand and are moving towards. Although I don't know that this is uniform towards potentially using the Nabbp pulse system in a similar way. So then what we're left with is what does a trading partner do when it's trying to initiate a trade request to another trading partner? And that's a very nuanced part of the law.

[00:30:25] Speaker2
In 582 G, one E and an authorized trading partner may initiate a trade request to another trading partner. However, the responding trading partner, um, is required to evaluate the extent to which it and is entitled to protect any confidential commercial information that might be, um, that it might otherwise have to provide in response to a request. It's entitled to protect that confidential commercial information. So these are going to be Nuanced, and I think one on one situations that do not currently have and I don't think in play. Um, an assumption that this is going to be automated or that you'll be able to send a request out into the world, um, and send a request out into the world, uh, for, for tracing information and get something back without, uh, the ability to evaluate and respond to it. I know that if I were representing a client who had received a tracing request, that I would want to advise that client on what they were providing and how they were providing it. Um, so, you know, that's that's an area that is still under development. So kind of a long answer, but it's complicated because there are a lot of different pieces to it. Um, and I see a question in the chat is what does FDA using the next gen portal mean for for industry? Are we expected to integrate electronically or on board.

[00:31:59] Speaker2
The way that the next gen portal works is that you establish an account with FDA voluntarily. They know that they can't make you do it, although if you are a manufacturer or repackager, you are already in the FDA system so they know who you are and how to find you. Um, and, uh, for other trading partners, they're encouraging trading partners to establish accounts in the next gen portal. And then, should the agency wish to initiate a trace or verification request, it will use the next gen portal to communicate with you. Um, it's optional, but there are numerous advantages to in theory, in theory, to using the next gen portal. Among them being with clients that I've had who have been trying to respond to a tracing request. They've been very concerned with whether or not it actually is FDA. Um, and then there also are concerns with the amount of data that are being provided. And often this, you know, may be highly confidential information and really big files. And so how to be able to facilitate the exchange of that information in a secure way with the agency is is important. And the next gen portal is intended to be a step forward in that process. It's not without some problems. Um, but it's a, it's a, it's a right step in the right direction for purposes of responding to FDA initiated tracing requests.

[00:33:28] Speaker1
Thanks. Um, should we move on to exemptions? Yeah.

[00:33:31] Speaker2
Exemptions. Um, so on July 12th, FDA exempted small business dispensers from these package level 582 G1 requirements. Um, and they're exempt until November 27th, 2026. A small business dispenser is someone who has 25 or fewer, um, full time licensed pharmacists and qualified pharmacy techs. And then on October 9th, FDA issued an exemption for certain trading partners. Um, and this exemption is intended to cover the movement of product after November 27th, 2024, with the expiration of the stabilization policy. Um, and so what it does is that for certain eligible trading partners and we'll talk about who's eligible for it. Um, it extends um, compliance with those final package level requirements. It rolls it rolls them out in um, in phases, which is really just key. And we're so grateful to FDA for doing this. Um, so for manufacturers and Repackagers, they have until May 27th, 2025 to comply with all requirements. Um, those package level requirements for wholesale distributors have until August 27th, 2025. So it's six months, nine months and then 12 months for dispensers with 26 or more full time, uh, pharmacy, uh, full time licensed pharmacists and qualified pharmacy techs. The exemption. What it's intended to do is to keep products moving to patients, while eligible trading partners can keep coming back to it because only certain people are eligible for it. Continue to work on the data quality problems. In a way, the stabilization policy, although it was intended to deal with all of this, it it was kind of a blunt tool and, uh, industry just wasn't ready. We were still working on establishing these all important connections to enable that, um, uh, the business to business connections, uh, for the provision of these files.

[00:35:33] Speaker2
And, and now what we're working on is the quality of the data in those files. So that's what we're doing in this new exemption period. Next, Alex. So what this means is that eligible trading partners and I'll get to who's eligible in a minute are temporarily exempt from those enhanced requirements, those package level requirements. So that means that if you're eligible, you don't have to be providing and receiving product identifiers in T, you can continue um, lot level. Um, and you don't have to do this in a secure, electronic and interoperable manner. You don't have to be able to trace and verify at the package level, and you don't have to associate a saleable return with its outbound T, um, and it also delays those enhanced verification requirements for wholesale distributors, so they don't have to start verifying those saleable returns until August 27th. And for dispensers, they don't have to verify the three packages 10%, um, until November 27th, um, and other requirements continue. And something that's very important about this exemption is, is that because it is by operation of statute rather than FDA merely saying we're not going to enforce this. This is a statutory provision Um, in the law that allows them to issue this exemption is that it's probably going to preempt a state from taking enforcement action of these package level requirements. Um, so that's that's a that's a big win.

[00:37:02] Speaker1
Um, Tish, we've heard that some trading partners are moving ahead on requirements like salable return t reconciliation. Um, even if they're claiming exemption from other elements such as the the 100% saleable returns verification. Um, what would be your advice to trading partners who are working to navigate the gray area between, say, FDA's requirements and the business decisions of their trading partners?

[00:37:28] Speaker2
So, um, first is that this is, you know, the the exemption is optional. Um, what it's intending to allow is for good product to continue to move while trading partners work on data quality issues. Um, but with Whispering with regard to when a trading partner elects to make itself fully compliant with the 582 G1 requirements, the sooner the better, because you know that that deadline is going to hit, you know, faster than you think, and we don't want to be put in the position of scrambling and being non-compliant or having to submit another exemption request and whatever. So, you know, you need to get compliant as soon as possible. So that's number one. And so that means moving toward compliance with the full 582 G1 enhanced package level requirements as soon as possible. But there's there's a special issue with regard to the, um, the association requirement. And this is something that I think I had glossed over, but a part of the 582 G1 requirements is that, um, wholesale distributors and manufacturers, when they receive a product back that is supposed to be a return from a customer. They have to be able to match the identifier on that product to the T that they provided to that customer. So there has to be that 1 to 1 match. And I would caution that the definition of return in the law has been there from the very beginning. And a return, by definition, in the law is a product that's only going back to the entity that sold it. So if a dispenser is trying to make what they think is a return to someone who didn't sell them the product, that supplier cannot accept the product that becomes a brand new transaction under the law.

[00:39:21] Speaker2
The dispenser may have to be licensed as a wholesale distributor. They certainly need to be providing transaction data. So this is a requirement in the law that trading partners have been doing the best they can to comply in a lot level world. But now that we are moving into a package level world, you don't have trading partners, don't have that flexibility anymore. Um, a wholesale distributor has to be able to match their outbound tea with the package that came back from that customer. And if they if there isn't the match, if they can't demonstrate that they actually sold that product to the customer, then it's not a return. It's a brand new transaction and they can't accept it. Um, you know, it becomes a sale. Um, so that's why we're seeing, um, trading partners move toward compliance as quickly as possible. And in this case, it's actually, um, coming into compliance with something that package level data exchanges is making possible. Uh, and another thing with regard to returns, which I think is important to to keep in mind, is that, yes, it is more difficult and more burdensome for all trading partners to handle this, because a return can only go back to the entity that sold it. But that's what the law was intended to do. Congress looked at the practices with regard to returns, and saw that there was a vector for the introduction of counterfeit product into the supply chain. This was this was a part of a gray market. It was a problem in certain states and in certain practices. And so the fact that it's more difficult to send product back, that's intentional in the law.

[00:41:06] Speaker2
It's it's an artifact of the law. And if you don't like it, you're going to have to take it up with Congress, because this is what the law requires. And to not comply would be a violation of the act. Um, so a little bit more about who it covers, uh, this is really important. And that's that, um, the exemption that FDA issued in October is very clear that the only entities that are eligible are those that have initiated systems and processes for successfully completing data connections with their immediate trading partner, um, or they've documented their efforts to establish those connections. If you're still in the Uber slacker, um, category, if you haven't initiated that process for successfully completing the data connections or documented your efforts to do so, you are not eligible for this exemption and you need to get an exemption from FTA really, really fast. Um, the agency also says that the exemption follows products and trading partners downstream. So the manufacturer enters, takes advantage of this exemption and introduces the product, sells it. Um, the the exemption will follow that product and cover all of the subsequent trading partners. Um, and the agency doesn't need to know if you're intending to avail yourself of the exemption. Um, but you are expected to notify your trading partners, um, through a readily accessible resource or communication that's in the exemption. Um, and you should include a mechanism for trading partners to confirm what I'm seeing. Most trading partners doing is posting something on their website and then also sending a Dear Customer or Dear Supplier letter. And I think that's it for me.

[00:42:47] Speaker1
All right. Thanks, Tish. So I'll cover how we tackle some of these challenges. And then we'll pick it up at the Q&A portion. So I think what we we've learned is that, you know, authorized trading partner is this sort of foundational prerequisite in the law. And it underpins a lot of different types of activities. Uh, if you're buying or selling prescription drugs, your trading partner has to be an authorized trading partner. If you're engaging in in tracing, uh, activity, then you need to protect confidential business information and be communicating with authorized trading partners for verification. Manufacturers are only required to respond to verification requests from authorized trading partners and federal regulators. So the way that we've been tackling this in practice is with ATP credentials. It's sort of like a passport. It allows you to sign a message, send it over a secure network or even a network like email. And the party on the other side can unpack it and determine that you are who you say you are. You're an authorized trading partner, and we can sort of move ahead. So this is a sort of digital driver's license or passport. It unlocks sort of the three key applications for compliance and really maps out from what the requirements are to what the applications are that perform these activities. And they all run on ATP credentials tracing, verification and the address book. So our solution manages the credential as your passport and AR control tower manages some of these enhanced workflows. Tracing. Um, this is, you know, enhanced drug distribution, security, um, sending trace requests and receiving responses from, in many cases, indirect trading partners. Um, as Tish pointed out, there are many different ways to potentially meet this requirement.

[00:44:58] Speaker1
Um, there are there's probably nobody who wants to fully and entirely end to end, automate every part of tracing. Um, but in terms of being able to check that a trace request that you got is legitimate and, you know, be able to pass it over and investigate and stand up and provide a response in a timely manner. Um, the the tracing standard developed by the partnership for Dscsa governance and the signing mechanism provided by the ATP credentials are the only components that really meet this from a solution standpoint. Today, for verification, um, the credentials work by adding an authentication layer to the verification router service. Um, manufacturers can know who's asking. And requesters, whether those are wholesalers or pharmacies, can indicate that they are in fact authorized trading partners. They are, in fact, entitled to get a response. Um, we have our own bridges into the network, uh, a standalone service, integrations and some secure fallback mechanisms as well for ATP confirmation. As, you know, as we sort of move over into this all electronic mode, um, you know, trading partners are looking to make sure that when they're performing authorized trading partner validation, um, either for their directs or in those sort of one off activities, trace and verification with their indirects that they're logging these activities, they're logging the checks that are being done in a way that is, you know, secure and auditable. You can electronic, you can go back and check it several years down the road. Um, in a lot of cases, we see that a lot of folks are falling back on email validation to sort of back and forth manual process, emails, electronic.

[00:46:55] Speaker1
It's interoperable. Um, but it's not a great system if you have to dig things up for auditability purposes later on. Um, one of the things that credentials do is, um, if you share out your credential with somebody else, um, they can hook into that and determine that you are an authorized trading partner because it relies on one of the licenses that they have under their control, and it provides a measure of automatic monitoring so that you don't have to keep cycling back to it. So with 27 days to go, I think we're seeing that, you know, most of the key requirements of the Dscsa are already in place. And there is this sort of staggered, uh, you know, phased approach rollout that we're going to be seeing over the next little while. Some trading partners are availing themselves of the exemptions. Many are not. Um, compliance means having full and complete SOPs that meet all of the requirements of the law that apply to you, and making sure that you follow those SOPs faithfully and that you're documenting that you're following those SOPs. Um, and with credentials, you can close the gaps, support your verification trace and ATP confirmation policies. Uh, so with eight minutes to go, we'll pass it back over. Tea time with Tish, I think, um, I want to circle back to an earlier question that Galvin had, um, which is, I think one that we, you know, we get very often. It's sort of a foundational question how does how do we verify atps. I think we've touched on that in a number of different places.

[00:48:35] Speaker2
Yeah. Um, so first is that, you know, to be clear, I'm, I don't endorse any particular solution. I'm agnostic as to solutions in the while. I'm not FDA, but it's in the same way that FDA is. What the law requires is that you only transact covered product with authorized trading partners. And what I have advised clients typically is, is that, you know, you you need to develop an SOP around that. You need to be confident in it and you need to follow it. Um, and some trading partners have opted to use something that automates or partially automates that process through their solution provider. Um, so, you know, that's that's really the, the the key is, is that, you know, you need to have a process that works for your organization and that allows you to, um, to be able to explain what you're doing. Should an auditor or inspector come in?

[00:49:37] Speaker1
I'm going to drop a link in the chat. By the way, to some example SOPs that we have that can be used in conjunction with, uh, ATP credentials, provided that you adapt the SOP to the needs of your particular organization.

[00:49:50] Speaker2
Um, yeah. Something I would caution on is that we we saw this a bit in the 480 threes that FDA issued to manufacturers is that it appeared from the way that the one of the 40 threes was written is that somebody had bought some sort of an off the shelf solution and then probably put it on the shelf and never looked at it again. Um, and so not only did they not confirm that that off the shelf solution actually complied with their requirements under the law, but they weren't that they they didn't do anything with it. They didn't apply it or use it. So, you know, those are those are important components of your compliance program.

[00:50:33] Speaker1
Tisha, was there anything else that had jumped out at you from the the 483 that, um, might give folks an indication as far as what FDA is looking to is looking for or going to be focusing on over the coming year.

[00:50:49] Speaker2
Um, so I have now heard from several people who have met with FDA after the exemptions came out and they all said more or less the same thing, which is that, uh, we had, uh, you know, my my rule of thumb continues to be that don't don't be the low hanging fruit. Um, get into compliance to the best extent you can. I don't think FDA is particularly interested in going after the good faith. Uh, the the companies that are undertaking good faith efforts. Um, but they are interested in the Uber slackers, and, uh, FDA now knows who they are because they've been, you know, they've been identified in the exemptions that trading partners made, um, to the agency. So they know who, um, who the companies are, who are behind the eight ball, who are behind, who are those Uber slackers? And so, um, the the feeling that people are getting is, is that some of those companies could get an FDA inspection. They would not be surprised if that happened. Um, in particular, because the agency is very clear that the only people who are entitled to that, you know, October 9th exemption are those who are connected trading partners or those who are making good faith efforts. Um, so I think that's that's something that we could start to see as a is a broader enforcement. Also, I read something this week, although I haven't found it yet that FDA has apparently added some sort of a dscsa verification systems module to its inspector training or, you know, to what inspectors should be looking for. Um, and that apparently wasn't there before, or if it was there, somebody only recently noticed it. So I would expect that inspectors are armed in a way that they haven't been before and motivated.

[00:52:53] Speaker1
Wow. Um, are there what are the sort of relative advantages or drawbacks, um, for folks who, um, maybe still on the fence about whether they want to claim the the October 9th exemption?

[00:53:10] Speaker2
I mean, why not, you know, why not take advantage of it? And the example that I give is, is, I think a really good one. Um, that is helpful to understand what it applies to. So let's assume that you're a manufacturer and wholesale distributor. And you've got a connection. And the data are flowing really regularly between the two of you. You know, shipment one in week one is fine. Shipment two in week two is fine. Three fine. And then the fourth week, something happens. The product arrives before the data do, or there's something causes the file to fail. There's an error. Something happens. What? The exemption allows those two trading partners to do, who are connected and who have been working in good faith to comply with the law, is that it allows the wholesaler to receive that product and to continue to move it through the supply chain to patients who need it, while it works with its wholesale distributor supplier on that problem. That's what it does. And so there is every reason to take advantage of this to the extent you can. You know, you you continue to get as close to perfect as you can, but it allows a little bit of give a little more flexibility to begin to fill the supply chain with, you know, good quality data from the manufacturer to the wholesale distributor and then from the wholesale distributor to the dispenser. It creates that phased approach rather than having to flip a switch for everybody at the same time. So these are the reasons why it's very useful to avail yourself of it. You don't have to tell FDA anything. You just tell your trading partner to make it available, and then it gives you the flexibility to continue to meet patient need while you work through these problems.

[00:55:01] Speaker1
We've got a great question in the chat from Sharath. Um, with regards to enforcement, would FDA utilize remote audit processes? Check for DACA compliance as part of establishment inspections or both.

[00:55:15] Speaker2
Um, what we've been seeing is that it's been a part of establishment inspections. You know, there's somebody on site which I recall from the 480 threes, whether they would use the remote process. You know, so often what they're doing is that they're asking for, you know, like, you know, send us your SOPs. So I think it could be a part of that. I'm not aware of it. Um, maybe some others have had to deal with that. I've not seen that yet, but I would not be surprised, because sometimes what FDA can do is if somebody doesn't have them, then, you know, you've you've made yourself into, as I said, that low hanging fruit. Or if they look at the SOP and it's off the shelf and it doesn't comply with the law, then I think that again, it would, you know, the agency could proceed, um, with, uh, issuance of a 483 without even having to go to the, to the facility. But, you know, I think we'll have to see either way, um, some of this is.

[00:56:12] Speaker1
I think Boris has a comment, which I think is I think it's true. Um, there's a lot of shaking down that has yet to be done. Um, when it comes to the alignment between the physical and the data supply chain.

[00:56:29] Speaker2
It's hard, you know? I mean, there's no real answer there. Yeah, I agree. Boris, you put it in the chat that some of the issues is created is from a is a shipment of product being rejected because the data arrived late and you know so the and sometimes it's that, you know, the supplier and the customer are like within a block of each other or, you know, within a mile. And it can take time for that really big data file to move. And it moves faster than the than the truck does even in, you know, say city traffic. Um, so these are um, these are issues that the exemption is going to allow trading partners to work out and perfect.

END OF TRANSCRIPT