STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

IN RE: DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL

______________________________________________/

COUNCIL MEETING

DATE: August 17, 2017
TIME: 9:30 a.m. - 11:31 a.m.
LOCATION: Homewood Suites
2987 Apalachee Parkway
Tallahassee, Florida 32301

Reported by:

JESSICA RENCHEN, Court Reporter
For the Record Reporting, Inc.
1500 Mahan Drive, Suite 140
Tallahassee, Florida, 32308

ORIGINAL

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
Council Members:

STEVE MAYS, CHAIR
BRIAN FILES
MICHAEL MONE
DEAN ELLIS
PATRICK BARNES
JEENU PHILLIPS
ARLENE ELLIOTT
JEFFREY TULLER
PETER HART
JENNIFER GOLDMAN

DBPR Staff:

DINAH GREENE
REBECCA BURNETT
RENEE ALSOBROOK

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
PROCEDINGS

MR. MAYS: Okay. Good -- good morning, everyone. This is Steve Mays. I would like to call this meeting of the Drug Wholesale Distributor Advisory Council to order. And we have a court reporter present.

I just want to remind everyone to identify yourself before you speak so the court reporter will know who is speaking for the record.

For anyone on the phone, please make sure you mute your line when not speaking, and please do not put us on hold so we don't have to listen to any music or anything like that during the meeting.

And also for everyone in the room, we don't have microphones around the room, so if you're going to speak up, you're going to speak -- make sure you speak up loud enough where the people on the phone can hear you.

Ms. Greene, I think we're ready for roll call.

Ms. GREENE: Jeenu Phillips?

MR. PHILLIPS: Present.

Ms. GREENE: Brian Files?

MR. FILES: Present.
MS. GREENE: Michael Mone?

MR. MONE: Present.

MS. GREENE: Scott Brock is not going to be here.

Arlene Elliott? Dean Ellis?

MR. ELLIS: Present.

MS. ELLIOTT: Attending on the phone.

MS. GREENE: Jeffrey Tuller?

MR. TULLER: Present.

MS. GREENE: Patrick Barnes?

MR. BARNES: Present.

MS. GREENE: Peter Hart?

MR. HART: Present.

MS. GREENE: And Jennifer Goldman?

MS. GOLDMAN: Present.

MR. MAY: Okay. All right.

As usual, I want to start the meeting off by reading the goals of the council as stated in Chapter 499 of the Florida Statutes.

The council shall review this part and the rules adopted to administer this part annually, provide input to the department regarding all proposed rules to administer this part, make recommendations to the department to improve protection of the prescription drugs and public
health, make recommendations to improve coordination with other state's regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to minimize the impact of regulation of the wholesale drug distribution industry while ensuring protection of the public health.

So we'll get on into the agenda. Under tab one, you'll -- we have one topic. Liz Gallenagh from HDA, formerly HDMA, is here to provide the council an update on the Drug Supply Chain Security Act. As you recall, Heather Zink (phonetic) gave us an update back in February, and I know there have been a few developments since then. So I'm going to read a brief bio, and then we'll let Liz get started.

Elizabeth Gallenagh, Esquire, is a senior vice-president, government affairs, and general counsel for HDA, which is Health Care Distribution Alliance. She is responsible for overseeing federal and state advocacy on behalf of HDA member companies, and is the organization's chief in-house attorney.

Additionally, she serves as HDA's primary
expert on prescription drug traceability, distributor licensure and tax issues. Since joining HDA in 2003, Ms. Gallenagh led the association's industry-wide efforts to replace a 50 state patchwork pedigree laws with one national traceability solution which became a reality through the enactment of Title 2 of the Drug Quality and Security Act in November of 2003.

In 2014, she was the recipient of the distribution management award for industry leadership, which honors an individual who has exhibited the highest standards of honesty and integrity working to enhance industry relations and knowledge as well as supply chain efficiency and security.

Liz holds a JD from George Mason University School of Law, and a BA from George Washington University.

So Liz, at this point, we'll turn it over to you.

MS. GALLENAGH: Thank you, Steve. It's a pleasure to be here today. I was telling a few of you, I've been with HDA now for 14 years -- oh.

MR. MAYS: Can you guys on the phone hear okay?

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
MS. ELLIOTT: Not very well.

MR. MAYS: Okay. All right.

MS. GALLENAGH: We're just waiting. Hang on.

MR. MAYS: We're having a few technical difficulties here in the room. Just bear with us.

That's always a good sign, at least you can see something on the screen, right?

There we go. There we go.

MS. GALLENAGH: Very good. We're going to add IT to your job title.

MR. MAYS: We got IT support in the room, and we didn't know we had it.

MS. GALLENAGH: Well, thank you, again, everyone. Again, my name is Liz Gallenagh, and thanks Steve for the invitation to speak here today and for that very nice introduction.

One of the things when you were talking, it made me chuckle a little bit was the -- was the statement I think in my bio that the DSCSA makes this sort of uniformity across the country a reality. And I guess it's a reality on paper in terms of the statute, but not necessarily, as you all know, particularly dealing, you know, from the regulatory side, and from the state side, that that has not necessarily come to fruition yet. So
we are working through all of that.

If you don't know or are not familiar with HDA, we're the health care distribution alliance. We used to be HDMA. We rebranded I guess last year. And we represent 35 primary wholesale distributors by predominantly directly from the manufacturers of pharmaceutical and health care products and then sell predominantly directly to the pharmacies and all the other providers across the country.

Our members move about 15 million products a day across the country and account for about 94 percent of the distribution market in the US.

So we have a very large company, as some of you know. And very small companies. But they all do the same thing and try and achieve the most efficient supply chain and most secured and safest supply chain that we can have.

So with that, I'll get into my presentation. We wanted to talk about DSCSA (inaudible), and this really an update, sort of a follow on to Heather Zink's presentation last time around. She and I talked, so I try to sort of pick up where she left off. I won't follow out of the nuts and bolts of the DSCSA in this presentation, but
really more of a what's the current state of affairs, and what's the industry doing, and then some things that HDA has been working on as well.

In terms of traceability implementation, this is our -- DSCSA time line, just for everybody's recollection, these are sort of the main milestones that are in the law at the federal level. 2017, in November, this is the date in the statute where the manufacturers are essentially supposed to be affixing or imprinting a product identifier. Product identifier is defined in the law, as you know, and includes a serial number essentially for every product package that is going to -- through to the pharmacy customer.

There is also a requirement to put a product identifier on each homogeneous case. Essentially, a case full of the same product.

And then 2018, 2019, 2020, we have various milestones for repackagers, wholesalers, and distributors with 2023 being the ultimate goal of -- for full unit level traceability across the supply chain.

So currently, we are across the supply chain engaging in transactions between trading partners. Every trading partner has to be an authorized
trading partner. Essentially, again, defined in the law. Really it means that they are properly licensed by the State or FDA.

And then they are exchanging what we call the three Ts. So transaction history, information, and statement for every product. This is right now at the lot level. So we're not yet at that sort of individual product ID situation.

And that's, I think, very important to remember when sometimes we're talking to folks outside, and you know, sort of the day-to-day, and experience on implementation, and I think that they forget that we are dealing with lot level right now.

Supply chain partners are working towards the next milestones, which include electronic requirements and the serialization by manufacturers, which will really, we think, will really change the operations of the entire supply chain.

And return to verification, which there's --

I'll talk a little bit about that in my presentation, but return to verification in 2019 is a requirement for wholesalers.

Supply chain organizations are also looking
more closely at 2023. We've just started at HDA and along with some of our fellow trade associations, looking at the broader picture, what 2023 requirements really are in the statute, but what that system can really look like. And I think there are two -- two viewpoints. There is sort of the forward looking, what does 2023 look like in a perfect world, and what is the most efficient and most sort of advanced technological system that we can put in place. And then there's also, if you dial it back a little bit, there's also just what are these -- the basic requirements of the statute that have to be met. And somewhere in between is probably the perfect answer. We don't probably have that yet.

But there is pilot activity going on, and then just recently FDA issued a draft guidance talking about enforcement discretion for manufacturers' next deadline. So I'll talk about that in depth.

Before I get to the enforcement discretion piece, in terms of recent FDA activities on the DSCSA, there was a listening section in April where the FDA collected information from various sectors of the industry to see where the industry
is and where the supply chain is on implementation progress.

These are just some snapshots that a colleague of mine took from the presentations that were given to the manufacturers. What we heard was many could not meet the November 27th, '17 serialization deadline, and for various reasons, and some of them requested enforcement discretion or a delay for that deadline.

There were challenges cited with contract manufacturing organizations, challenges cited with trying to incorporate aggregation into their -- into their serialization plan, and some other operational difficulties with data exchange, et cetera.

From distributors, I think they heard from us in particular that we urgently needed FDA state licensure regulations released. This was a part of the law which calls for a new standard at the federal level for 3PL, from third-party logistics providers, and wholesalers. And that has not yet been released by FDA.

Also described, distributors implementation challenges like think practical things, there's barcodes that are already on packages, scanning
problems, data integrity problem. And then HDA and our members, as well as some of our sister organizations are proceeding on several projects examining or supporting implementation. I'll get into a couple of those in a minute.

And dispensers, we heard mostly that there is this cascading effect. If the manufacturer deadlines were delayed, then dispensers' dates must also be delayed. And that goes for the entire supply chain. And I think we see -- we'll see FDA's attempt at that in their recent guidance, but it gets very complicated once you move one deadline, it sort of creates this chain effect for all of the other trading partners.

And then barcode readability issues, and at the time, although this is changing, I think, dispensers at that time -- let me pull up these -- had not yet been involved in the piloting. And across the board, and potentially because they are in an unique situation for their businesses in dealing with patients and dispensing activities but also because they are at the end of the implementation dates. So they are really, in my view, looking toward upstream to see what happens before they can know how to implement at their
level.

So the draft guidance that was just recently released on DSCSA's product identify requirements, what this really was, is a -- is an important discretion piece. And I'll get into some of the details as well. Because again, it's rather complicated.

Comments are due September 1st, so I encourage all of you if you have -- if you have comments or thoughts on this piece, to weigh in with FDA on that. And this is just a couple of links to the official federal register announcement, that the guidance that was originally released. And then the FDA has also updated their website with that announcement. They posted other information that you can get there, too.

So the draft guidance is a compliance policy. It sets out their enforcement discretion for products and homogeneous pieces that are introduced in a transaction into commerce by manufacturers between November 27th of this year and November 27th of 2018 that do not have the required product identifiers. Essentially, sort of at the very basic level, it extends the
manufacturer deadline by a year. That is probably an oversimplification of the entire guidance, though. So bear with me if I go through some of the details.

The compliance policy also addresses verification requirements and how downstream supply chain partners may transact with the product in homogeneous cases that do not have product identifiers.

In discussing their scope, FDA states that we consider products be introduced in a transaction into commerce where the manufacturer first engages in a transaction involving that product.

This is important, because FDA has sort of drawn that, at least in this draft. Remember, this is a draft guidance, it's not binding, and it could potentially be revised based on the comments they receive. So I just wanted to make sure everyone, you know, understood that caveat.

But this is sort of a line in the sand indicating what FDA used as the ultimate deadline for manufacturers to serialize.

The industry, we believe the manufacturers have taken a slightly different view. The statute talks about a product intended to be introduced in
a transaction into commerce. And so the industry collectively has supported -- and this has been for the last couple of years -- has supported the concept about when a product is packaged, essentially, that that is when it is intended to enter into a transaction.

So the timeline changes slightly, I think, for -- for the manufacturers when they're dealing with this sort of statement by FDA. It also changes when you're talking about product that is in the supply chain already, or sitting on a -- in a manufacturer's inventory where it hasn't been sold yet, and may not be serialized. And it also has implications for grandfathering, which has also still yet to be issued by the FDA.

So for manufacturers, which is really the -- the big focus of this guidance, FDA does not intend to take action against them if they don't meet that November 27th, 2017 requirement. And it does go on to specify they also don't intend to take enforcement action against their manufacturer who cannot verify product without a product identifier at the package level. For instance, in suspect or illegitimate product investigations. It will not take action against a manufacturer who
does not verify a product without a product identifier upon a request from an authorized trading partner, and also one who does not verify a product -- a package or sealed homogeneous case without a product ID that is intended for further distribution as a saleable return product.

So that really addresses sort of the corresponding requirements in the statute that go along with the serialization requirements for verification upon suspect and illegitimate, or on request by a trading partner, or the 2019 saleable returns verification requirement for wholesalers.

It also goes on to talk about, again, I mentioned before, this idea of when it is first engaging in a transaction involving that product. So it does not apply to other product out there, but that is slightly unclear, again, because in the absence of a grandfathering policy, we're not really sure how yet to treat that -- that un-serialized product that may not fall into the November deadline category.

If a -- and this is a new one, really, this next piece. It's sort of a new concept. If a product has a product identifier, FDA expects manufacturers and downstream trading partners to
use it in verification. On its face, that sounds logical. And it also indicates that FDA is trying to keep things moving in terms of implementation and towards the ultimate goal of unit level traceability in 2023.

However, I think it also creates a new hurdle for downstream supply chain partners, how do you know if data is going to be there associated with that product identifier? How do you know which products are going to have product identifiers, and which products are not? And how do you know which products may be grandfathered or not?

And so there are -- and I think across the board, what we've been hearing from the distributor side, is that there are various states among the manufacturers of readiness in terms of some that have ruled out serialization, but not necessarily data accompanying that serialized product. It's still the data. The data is still being exchanged at the lot level. And that is still the requirement until 2023.

So this statement, as well, I think indicates kind of where FDA's headed, but also I think raises a lot of questions in terms of how this is going to work.
FDA also invites comments on the compliant policy including how manufacturers can indicate the date they initially introduced a product in a transaction into commerce, and how downstream trading partners can determine that product was initially introduced by manufacturers in a transaction during that time period.

Again, this is challenging. I don't know what the manufacturers are going to say on this. Again, I think, it probably differs across the board. But this is something that was not necessarily contemplated when companies are moving toward implementation and designing their serialization and compliance plans.

MR. PHILLIPS: Elizabeth?

MS. GALLENAGH: Yes.

MR. PHILLIPS: So -- and the term "downstream trading partners," does that include dispensers?

MS. GALLENAGH: Yes, it does. Yeah, so when I say "downstream trading partners," I mean everybody after the manufacturer. So repackagers, wholesalers, dispensers, any kind of provider where the -- that's going to be receiving a product before it gets to the patient.

MR. PHILLIPS: So from a technology
standpoint, dispensers should be, I guess, by 20 -- November 2018 involving that process?

MS. GALLENAGH: So dispensers have to -- under the statute, dispensers' deadline currently, which hasn't changed, I don't think, in this, is 2020 for receiving all product, having basically engaging in transaction with product that has to have product identifiers on it. For wholesalers, that is 2019.

MR. PHILLIPS: So I guess that's why I don't understand the guidance document. If -- if they're -- if the deadline is 2020, then how are they requiring if the manufacturer hasn't --

MS. GALLENAGH: That's exactly my point. That's exactly the confusion, is that there isn't -- in the statute, there is no requirement for downstream trading partners, you know, particularly dispensers, to use that product ID in their verification activity. The manufacturers, I don't think, are certainly counting on that either, because they are just trying to get product serialized, and sort of roll that out. I don't think they are thinking about also -- well, they are probably thinking about it, but they are not counting on having to field those verification
requests that early and that early on in the stream of things.

So, that's -- I mean, it's a great question. I think it's very much unanswered. And I think this statement from FDA raises many, many more questions.

MR. PHILLIPS: Okay.

MS. GALLENAGH: Okay. So there was also some guidance included in the draft document for the packagers, distributors and dispensers regarding product identifiers that states basically for products without identifiers, introduced by manufacturer, which mean this November and 2018, FDA does not intend to take any action against a repackager who on or after November 27th, 2018, accepts ownership of such product in a transaction, even though it does not have a product identifier. And a wholesale distributor who on or after 2019 engaged in the transaction, and a dispenser who on or after 2020.

So those are basically the statutory deadlines for receiving product will be with product identifiers that are laid out. So FDA has done a good job in recognizing that they have to sort of, you know, take into account this
cascading effect when they are extending -- in
essence, extending the deadline for many
packagers.

And when I say "extending the deadline," I
also want to point out, and as many of you are
aware, they haven't come out and said this is a
new deadline, because it's a statutory deadline.
So they can't change that statutory deadline. But
they can, you know -- they can exercise, of
course, with discretion, and essentially that's
what they are trying to do here.

In terms of repackagers and product
identifiers, it states that the compliance policy
does not affect the requirement that begins
November 27th, 2018, for repackagers to affix or
imprint a product identifier on each package, or a
homogeneous case. This may have implications,
some serious implications for repackagers making
(inaudible). And part of that reason is because
repackagers were staggered in implementation in
the statute for the very reason that they are
taking previously manufactured product from the
original manufacturer, and now they have to
serialize -- basically put their own product
identifier on that package for sale.
It also requires the repackager to essentially link their new product identifier somehow in their records and whatnot to the original product identifier from the manufacturer. So if the manufacturer -- the original manufacturer isn't going to be putting out product identifiers on their products, this is going to delay the time the repackager has to fulfill that system or to work with that -- with that process. So that could have implications.

Michael?

MR. MONE: This is Michael Mone. Liz, would it not make logical sense to try and read the paragraph that you're dealing with on the top regarding product identifiers and the repackager date to 2018 with the sentence that causes the problem in the prior slide to say that what the FDA is intending, reading both of those together is, we recognize in bullets two and three that you have different dates. But to the extent that we're expecting repackagers to comply, that manufacturers must communicate that information to repackagers?

MS. GALLENAGH: That would make a lot of sense, yeah.
MR. MONE: Okay.

MS. GALLENAGH: Yeah, I think so. And again, I haven't spoken to repackers directly on this. But I think that they are looking at --

MR. MONE: This is Michael Mone again.

I would suggest that to those individuals that may, in fact, respond to the FDA draft guidance, that they seek clarification of the application of that sentence to these three types of characteristics or components of the supply chain. Because in my interpretation of reading all of this (inaudible) is correct, then I think we have a more clear answer as to what that -- the intent of that sentence was. And in fact, if that is correct, it ultimately limits the scope of what that is and clarifies to the industry what FDA intends.

MR. MAYS: Excuse me, for those of you on the phone, if you're not speaking to the council, could you please mute your line, please? Thank you.

Thank you, Mr. Mone.

MS. GALLENAGH: Thanks. And then the last piece for repackaging, also this is really for wholesalers and dispensers to be aware of, is they
state at the beginning of 2017 -- 2018, distributors and dispensers who have to purchase from a repackager should ensure that they verify the identifier.

So it's also contradicting what we just talked about essentially.

So, again, this is just another example of some confusion I think that is out there as a result of the draft guidance.

You know, whether -- and again, this is a very -- it's a very complex undertaking, but (inaudible) by issuing this enforcement discretion, and I think that -- you know, sort of it seems like their heart is in the right place in terms of recognizing the downstream effects of moving any, you know, enforcement discretion, or in that sense, moving any deadlines. But I think there's some work that needs to be done here. And so we'll see what those comments are back to FDA.

And then the same on verification. This talks about verification and repackaging. Again, repackagers and wholesale distributors and dispensers, and what essentially those requirements are also not going to reap any enforcement discretion if the product does not
have a product identifier and sort of falls into this draft guidance scope.

Again, when product does have a product identifier, FDA states that they expect trading partners to use it in verifying product. So they restate that, and we just talked about the implications there.

And then for saleable returns, a wholesaler -- a wholesaler repackager may receive but not does have to verify or return product without a product identifier if the return product is introduced into a transaction into commerce by a manufacturer prior to the 2018 date.

And this is also confusing. I think we are all looking at verifying saleable returns beginning in 2019. So there's some question over whether there were some errors in this draft, or whether they truly are intending to move that saleable returns deadline up, which --

MR. MAYS: Other enforcement discretion.

MS. GALLENAGH: Exactly.

MR. MAYS: So -- so, Liz, this is Steve, I -- if I -- and I don't want to get too technical here, so for a wholesaler, that verification date for returns, they can't just assume because of
product that's being returned has a 2D barcode, that it's going to have -- that it's going to be serialized, correct?

MS. GALLENAUGH: Correct.

MR. MAYS: So they are not -- they basically would have to scan everything with a 2D barcode to make sure they are catching -- because otherwise they are not going to know.

MS. GALLENAUGH: Right. And I think for -- for wholesale distributors, especially for our numbers, the challenge is because while the -- you know, we've grappled with this a lot. The volume of product is still very, very large. And so when you're talking about scan -- you know, one, just scanning every return, or however you're verifying the sale or returns is a challenge anyway. But then when you're talking about scanning all of your returns, not knowing which have product identifiers, which have 2D barcodes but that are not product identifiers, which don't have any product identifier. I think you have different categories of product.

And that's also why it -- in addition, certain compound that with a lack of a grandfathering policy, because wholesalers, I
think, we were expecting to probably have -- not beginning in 2019, having more product come back that's -- that has product identifiers, or serialized to actually verify.

But there was also a thought that there would still be product that is sort of bleeding its way out of the system because it, you know, was grandfathered, or it wasn't serialized prior to that manufacturer deadline. So now you're adding more unserialized product to that -- you know, to that bucket.

MR. MAYS: And I think to put it in perspective, isn't -- I think the industry average for returns runs about three, three and a half percent? Something like that.

MS. GALLENAGH: Yeah, somebody -- yeah, I've heard like somewhere between two and three, somewhere around there. But -- and I have the number in here. I want to say it's something like 60 million products. It's something -- and again, honestly, when we were going through the drafting phase of the law and working on behalf of our members in that process, I think even our members thought, oh, it's two or three percent, we can handle this verification and return -- it was
looked at -- honestly, that 2019 process was
looked at as two things, one, another safeguard
against that product or counterfeits, or you know,
suspect product getting in through the returns
process, which has always been sort of a challenge
for distributors and others in the supply chain.

But then, two, sort of a mid milestone before
we got to 2023, for distributors to be able to
learn how to work with serialized product, for
manufacturers to learn how to really nail down and
perfect their verification systems and things like
that. So it -- it was -- I also thought that
because the wholesalers were -- their deadline for
receiving product identifiers was 2018, that was a
two-year period where you would have manufacturers
serializing product, and how they all got
serialized product out in the marketplace.

Food for thought was that most of the
unserialized product would have gone out with the
system by then. You know, not all, probably, but
the vast majority.

So when you sort of -- when you inch up on
those other deadlines, you sort of change that
scenario of it. So that -- that may or may not be
a challenge. I think it will be.
Sorry, I'm just catching up on my slides here.

So this is just more on repackaging, same -- similar. They kind of laid it out very similarly for each of the sectors. And then they talk about -- they essentially instruct trading partners. This -- this section is critical for us, I think. And this goes back to the question before about dispensers and when their requirements are, versus what the FDA's putting in their guidance. And this is a call by FDA in the draft guidance to document that manufacturer introduced product without an identifier into commerce between November 27th this year, and 2018.

Essentially, instructing trading partners to take steps to determine that the product is introduced into commerce by the manufacturer in this time frame, and that recommending the trading partner make this determination based on the following: At least one of the transaction information documents that compose the transaction history for the product, describes an initial transaction date from the manufacturer that occurs between those dates, or if there's documentary
evidence created by trading partner in the course of business containing a product description that matches the product, the package, or homogeneous case of product that is not labeled with a product identifier. And this evidence should contain a date from which it can be determined that the product is introduced in a transaction into commerce by the manufacturer between those dates.

Examples of these documents may include but are not limited to bills of lading, commercial invoices, and shipping invoices. And FDA invites comments specifically on this issue.

Just on its face, this in itself presents a new requirement for all the downstream trading partners, predominantly for the wholesale distributors. But this is not -- none of this, whether it's the documentation about the status of a manufacturer and their placing a product identifier, and whether a product has that product identifier, that -- that documentation is not required by the statute.

In addition, there's some practical hurdles with the way that they suggest to take these steps, in particularly, there are not initial -- initial transaction dates and the like. It's not
included in transaction information or history or statements currently. And that is -- those elements are very specifically laid out in the statute.

And then the other piece is that these -- there is no requirement to match your three T information with the product identifier at this time. So the manufacturers may -- they will continue to send the three Ts with product exchanging of transactions. However, even though they are serializing product, there was not an expectation that that -- that those three Ts would match the serial number until 2023. So there's a couple of practical hurdles here that don't make a whole lot of practical sense. And if FDA decides to pursue this route, create some new requirements that are not outlined in the statute.

So in terms of industry response, had, as well as others are busy working on formal comments. They are due September 1st on this draft guidance. It's a work in progress. I think based on my comments, you know, you probably can gather some of the direction that EPA's comments will take. Mostly more questions than answers. And you know, we need further -- some further
clarification. But also a need following further discussion with FDA about some of these, what we see as new requirements that are outside the scope of the statute, or things that are not necessarily practical. So more, you know, stay tuned, and we'll have those available once they are filed on September 1st.

In addition, you know, there is very much always, as we continue through implementation, there is always this recognition -- need for recognition of practical effects and the downstream impact. And we know something that our members and us at staff at had are always constantly kind of going through it. You know, we start with the statute, but then it's always sort of what happens, and what does this mean, once you start to implement for every single requirement that we go through.

And then essentially, we also are really calling or urging FDA to issue something on grandfathering, because they are addressing non-serialized product, and they are issuing -- or exercising enforcement discretion, it becomes, I think in our opinion, even more critical that grandfathering guidance of some kind be released.

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
In addition to this draft guidance, FDA has also, not to be overshadowed by it, but FDA has also released a couple of other notices just recently. There's been an announcement for a pilot project program under DSCSA, and a request for comments. And FDA has announced its intention to establish a pilot under DSCSA to assist in development of the electronic interoperable system that would identify and trace certain prescription drugs as they are distributed within the US.

They do not intend to begin the proposed pilot project or accept requests to participate until OMB has approved the -- OMB is office of management and budget, has approved the proposed collection of information. And it's a very sort of curious, and FDA, I think, is challenged. They are required by statute to launch a pilot program, at least one, and really focusing on sort of the 2023 vision, I think. That said, FDA does not have a lot of resources, and I think that they are probably hoping that industry and others submit projects that -- that are under way or that can be carried out by industry using industry resources, essentially. But sort of including FDA in that process, whether it's sharing information or
having them at the table in some way.

FDA also announced three public meetings, the first of which is next week on supply chain security for 2023. And enhanced drug distribution security needs. And then December and February on sort of the next steps interoperability, standard for data exchange, data architecture, aggregation and imprints, and then further refinement of security needs and building capacity for 2023.

Again, these are -- they are required by law to have public meetings, and these topics come straight out of -- many of them come straight out of the statute.

So FDA is doing -- is doing their job in terms of, you know, having those forums, and putting out these announcements and inviting collaboration among the industry. So we'll see what the results of them are. Like I said, the next one is on August 23rd. So we'll see more after that meeting, I think. And then also more as industry comments on the draft guidance.

In terms of State activity, and I know this is very important for -- for you all here in Florida, FDA has not promulgated standards yet for wholesalers and 3PL licensure. I've lost track of
how overdue they are. I think it's two years potentially. And then once they do promulgate those standards, which is assumed, would be via regulation. The states have two -- I think two years to adopt them. And this is meant to be sort of a new standard to raise the bar and to get more uniform across the country.

For a state like Florida, the thought is probably that much of what you already have in place would be, you know, in compliance or apply, and that essentially the categories that are laid out in statute are a -- are in place here.

The details of what they will include in these standards at the federal level, and also the details on how they are going to direct states to implement or to not, have yet to be released.

So what we're seeing, and I was talking about this earlier, the states across the country, what we see, it's not a -- it's not a flurry of activity right now. But there is still ongoing activity across the states either on the legislative front or on the regulatory front, or even on the enforcement authority front. And sometimes in conflict with DSCSA provisions, sometimes in conflict with preemption provisions,
and sometimes really there's just a large degree of confusion out there about what they are supposed to do. I think states are sort of clamoring. You know, I can't speak for any one of them, obviously. And you all know better than I do, but I think they are clamoring for direction from FDA, and you know, a release of these standards so that -- so that this piece of the law can move forward as well.

When the statute was enacted, the thought was that the licensure focus in that portion of the law would -- would really supplement the traceability portion. And it was also designed to create a uniformity to eliminate this 50 state patchwork that we had so that there wouldn't be any gaps across the country in terms of, you know, letting bad actors in, or not having authorized trading partners be in the legitimate supply chain.

And the other piece was that, the thought was if you streamlined licensure regulation for the entities involved in the supply chain, that they could devote other resources toward fulfilling the traceability portions of the law.

MR. PHILLIPS: Elizabeth?
MS. GALLENAGH: Uh-huh.

MR. PHILLIPS: So I guess from a state activity standpoint, do you see where roles for the Board of Pharmacy would come into play at a certain point? I guess especially around dispensers?

MS. GALLENAGH: Potentially. And I think -- I mean, Well, and Florida is unique, because the Board of Pharmacy doesn't regulate wholesalers --

MR. PHILLIPS: Right.

MS. GALLENAGH: -- or make -- or you know, supply chain other than the dispenser community. In other states, as you know, a lot of the board of pharmacies regulate us as well. So it's a little bit different here.

But I do think it would be important to -- for the Board of Pharmacy to at least be aware of what's coming down the pike, and then to potentially engage whether it's in the pilot activities or those discussions, you know, as well as if there are any -- I don't think there will be, but if there are any implications in like, for instance, the wholesaler of 3PL standards on the licensure side for dispensers.

I don't think that there would be. It really

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
be more just of a, you know, an informational
thing for dispensers to be aware of and to know,
you know, whether there's anything in there that
would impact.

MR. PHILLIPS: I guess -- I'm not sure of the
exact process, come 2020 or so, from an
enforcement standpoint, is it FDA that would
enforce dispensers, or would it be the -- the
board inspectors? Would it be DBPR? I don't
know. I'm just curious.

MS. GALLENAGH: I -- that is unclear.

MR. PHILLIPS: Okay.

MS. GALLENAGH: Unclear.

MR. MAYS: It's going to depend on the state,
right?

MS. GALLENAGH: Well, it would -- yeah, and I
would -- and Drew, I don't know if you have any
insight into that.

MR. WINTERS: Well, actually, it was more of
a question, because what we're seeing is that some
of the confusion that's been created is we have
preemption, but there's no licensure to allow for
that. And I was wondering, because of the
preemption, the way it's set up, is to allow
states to kind of step in or step out of
regulation, to defer. Are you seeing a lot of the states coming whether adopting new licensure programs or kind of the opposite, just --

MS. GALLENAGH: So what we're seeing is, states trying to -- I would say on whole -- on whole, states are trying to maintain the status quo as much as they can, and sort of keep an even keel waiting to see what guidance comes from FDA on any new standards.

The one piece where that differs is on the 3PL side, because the statute has very -- a very complicated section on 3PL licensure, and essentially states that the state can no longer license a 3PL as a wholesaler. It also goes on to essentially put this whole new construct in at the federal level for 3PL licensure, but none of that has been done yet.

So the states are grappling. I've seen some states not -- you basically strike 3PL from their books and not -- and essentially rescind licensure from 3PL, just not doing anything. And sort of holding fast. And I think that they are -- that is one tactic that I think the -- there is an organization representing some of the 3PLs that has -- that has advocated for that, essentially
stop licensing 3PLs, and they should be licensed at the federal level. That's been their view.

Our view at HDA has been -- there is a policy gap that was unintended by the law. And these entities should be licensed if they are going to be participating in the supply chain.

So it's not perfect, but what we have seen a lot of states do is go ahead and implement basically by statute or by regulation, put in a 3PL licensure category, so they are no longer -- they are no longer a wholesaler and then basically apply the same wholesaler licensures standards that they have been using all along for those entities in the interim.

The 3PL association has not been fond of that approach. At HDA, we do have some members who have 3PLs that are private -- that have slightly different than sort of a typical 3PL, in that they are only focused on pharmaceutical distribution. And they are -- have been long regulated similarly to wholesalers. They operate, you know, in tandem with their wholesale operations, and so they are very comfortable with that approach.

And I think as an organization, from a state safety standpoint, we would -- we support that,
because we don't think that these entities should be just unlicensed and out there, you know, unregulated.

MR. FILES: Good morning, Brian Files.

The only thing I'm going to add to that, and I -- and I know Liz mentioned this earlier in regards to states amending whether -- they are regulatory policy, the statutes, is that the definitions. I know that we discussed states trying to stay status quo. But the federal law prompts states to redefine or categorize the different entities in regards to the supply chain or the distribution of pharmaceuticals. And that's probably the biggest grapple with some states, we're just trying to comply -- with some business entity that are just trying to comply.

But they are asking states to be very clear in their definitions, because from a retail perspective, some dispensers have positive roles even within their organization or external to their customers where they are a partial mix of wholesalers. They are truly dispensers.

Now, under the rule -- under the DSCSA, if your main function is dispensers, you're in a separate category. States are not clear with that
definition. Hence, every time that there's a --

some type of state mechanism, whether it's
regulatory or statutory, you know, their begs
clarity on that part.

And there's been some rulings by states as
early as 2015 that were either clear or unclear,
but it's just an ongoing saga, versus a
state-by-state situation.

So I just wanted to add a little bit of
clarity, which is, you know, she was discussing
amendments. You know, as they amend their laws or
their practices, you know, it's really about
clarity. And everybody is fine with the status
quo, or change, whichever it is, but just be clear
about it.

What we're uncovering is that the initial
idea was that, you know, this could potentially be
rendered neutral or nobody else gets caught in any
type of grab, and that's really not the concern
the business entities have. I speak on behalf of
CVS as well, just clarity. So we know what we can

and cannot do, how would we comply, how do we
apply for a different status, if that's
operationally important to us?

There are a new crop of, you know, specialty
pharmacies, or a new crop of virtual
manufacturers. You know, these definitions are
cascading across the country. And it's forcing
states to grapple with it. And my virtual
manufacturer and manufacturer, my virtual
wholesaler, and my dispenser are not a wholesaler.

So you know, not to belabor the point, but
clarity is probably the most important thing that
works in conjunction with the federal law.

MR. MAYS: Mr. Mone?

MR. MONE: This is Michael Mone. I would
like to respond in part to Dr. Phillip as it
relates to boards of pharmacy.

For those boards of pharmacy that actually
have jurisdiction, or in the case here in Florida,
where the jurisdiction is vested with another
agency, it's probably a reasonable expectation to
see as that timeline goes further on, that the FDA
will at some point probably draft an MOU with the
jurisdictions to clarify in terms of what the
expectation is between the communications, state
regulatory agency, and the federal government in
terms of the FDA.

While I think, and at least I could look at
the law in a manner to suggest that the FDA has
primary jurisdiction in certain aspects of what we're talking about, they don't have the manpower to exercise that regulatory jurisdiction, and therefore, their natural inclination is to find a state partner to be able to do that on their behalf.

So I would anticipate in the 2020s that at some point, there will be a draft guidance on a draft MOU that's going to go to the jurisdictions that have regulatory jurisdictions in the states for consideration of that information sharing and that regulatory oversight. That would be my expectation.

So -- I don't know if that's within their plan, but that's what I can sort of would expect to see.

MR. MAYS: Mr. Phillips?

MR. PHILLIPS: If -- Jeenu Phillips.

So the question, I think, would be around authority, so the Board of Pharmacy, if we're going to write any rules, it's done via statute.

So our statutes in Florida need to be formed around this piece in order for the Board of Pharmacy to actually have the statutory authority to write the rules? I don't think the FDA could
provide the authority to the boards to do that.

MS. ALSOBROOK: It's not exactly accurate.
You can be commissioned by the federal government
and have the authority that the federal -- the FDA
actually has, if you're commissioned as an agent
of the FDA, you would be acting under -- you would
be acting as an FDA agent and have all the
authority that the FDA has. So The Board of
Pharmacy wouldn't have to do anything.

MR. PHILLIPS: Okay.

MS. ALSOBROOK: But you also, under the Board
of Pharmacy Law, you have the responsibility to
comply with both state and federal law so you
would have that requirement already there. Now,
whether you could propose rules that would set up
that you would have to require specific things, I
would have to defer to your assistant attorney
general on that. But you know, there is
responsibility for almost every profession to
apply to comply with state and federal rules and
law.

MR. PHILLIPS: I think the point I'm bringing
up now, is if statutes need to be written, now
would be the time to get those proposed.

MS. ALSOBROOK: Well, I think that that's the
two-year mark between the licensure provision that's set forth by the federal government in the two years they give the states to implement their state laws for licensure. That's the whole reason they gave us those two years, is to get those legislative packages together and get them implemented before the Legislature.

MR. PHILLIPS: Right. Thank you.

MS. GOLDMAN: This is Jennifer Goldman. Are there plans in the future for any kind of educational effort directed at patients to inform them of these changes, and what to look for on their prescription bottles?

MS. GALLENAGH: Not that I know of. And part of the reason for that -- I mean, that's -- it's something that maybe we can ask FDA. Part of the reason for that, though, is that the -- there's not a great -- it depends on how the product is packaged. But there's not a great likelihood that the patient will see any difference in their operation -- you know, in how they receive their product or in what the product looks like, other than this product identifier, which is a 2D barcode, and then -- and also in human readable form has four elements essentially. That would be
on -- essentially a stock bottle.

So unless the patient is receiving that sort of stock bottle that comes directly through the supply chain, and then the pharmacist puts the patient label on that. If they are getting a regular prescription, like in a -- you know, in a vial, in an amber vial, they are not going to ever see that at all.

In addition, the -- sort of the cutoff of the -- of the chain of information is when it gets to the dispenser. So that never goes down to the -- the patient level. There's no patient information involved, there's no -- there's nothing like that. And I don't know if Brian, if you had anything else to add to that.

MR. FILES: Actually, to your point, there's going to be a conversation about that at some point, because the law depicts in 2023 that it will be not only a secured -- a security enhancement to the system, but there will be realtime information that will travel all the way down to the dispenser.

So the question begs what access to that information does the patient have? Because this whole project, this whole implementation is about
the patient.

So will the patient have access to data through their last dispensing point to check to see if their product was safe throughout the supply chain?

MR. MAYS: I don't think FDA -- this is Steve. I don't think there was any FDA having any intent for this statute to --

MS. GALLENAGH: No.

MR. MAYS: -- to bring patients into the scope. You know, once it gets to that dispenser, that's the end of it, unless it's going back up the chain.

Mr. Barnes?

MR. BARNES: Patrick Barnes.

So when this law is fully implemented, help clarify this for me, is that for the dispenser, will they be required to know which lot number it was dispensed to the patient? Do you know?

MR. MAYS: I don't believe so.

MR. BARNES: No?

MS. GALLENAGH: No.

MR. MAYS: I don't believe so.

MS. GALLENAGH: No. Because once that -- they will need to know in their records what they...
received from their distributor, or the
manufacturer in their pharmacy, essentially.

MR. MAYS: And I think --

MS. GALLENAGH: What was checked in, and did
they have the appropriate documentation, you know,
the 3T documentation that accompanied that
transaction. And it's all transaction based.

So -- but then once it goes on their shelf
for, you know, dispensing -- you know, for filling
prescriptions, it's kind of cut off. There
wouldn't be a way -- again, unless you have that
stock bottle with that product, or you know, you
have to go through a recall situation, you know,
and some of the technology might enhance those
processes --

MR. BARNES: That's where I was going.

MS. GALLENAGH: -- down the road -- yeah.

MR. BARNES: Yeah, as it comes -- as it comes
in, you could can scan it, and boom, you know.

And then for every individual package has, down to
the lot number, when you -- as you go through the
system, you're scanning everything, you can pick
up that data and record it, from a federal
requirement, though.

MR. MAYS: And I believe some -- I guess in a
lot of hospital environments, there's some traceability of those drugs to the patient anyway. And in some cases, I guess, the technology allows they --

MR. BARNES: It just --

MR. MAYS: Not as robust as I might think.

MR. BARNES: Only at the NDC level.

MS. GALLENAGH: Okay.

MR. BARNES: Only at the NDC level currently.

MR. MAYS: Okay.

MS. GOLDMAN: NDC?

MR. BARNES: National Drug Co.

MS. ALSOBROOK: It would be nice if it facilitated a recall.

MR. BARNES: Right.

MS. GALLENAGH: Right.

MR. BARNES: Absolutely.

MR. MAYS: If it's down to the patient, yeah.

MR. BARNES: When you like to know all the way down to the lot number, and now --

MR. MAYS: Excuse me, Ms. Greene, are we okay for time? I just want to make sure. We're having a very good robust discussion here. I just want to make sure we're not going to get kicked out of the room before we get finished here.
MS. GREENE: We're fine, Steve.

MR. MAYS: Mr. Mone, did you have --

MR. MONE: I did want to -- this is Michael

Mone, I did want to add one other comment,

Dr. Barnes.

One of the things that I think is to be

thought about is precisely what you suggested.

While there is no statutory -- and Liz, you can

correct me if I am wrong, while there is no

statutory requirement that the information be

captured all the way down to the patient

dispensing level, if a system did that, it would,

in fact, facilitate if there were class one

recall, the ability to know the patient. But

there's no statutory requirement at this time.

MR. BARNES: That makes sense.

MR. MONE: So your system may choose or

voluntarily enhance your own systems to be able to

do that, but there's not a statutory requirement

in that process at this point to do that.

MS. GALLENAGH: Right. And in terms of just

regular, you know, sort of enhancing the current

recall process, I think there's always been this

hope that the -- you know, the traceability system

will enhance the ability to recall product in a
faster more efficient way. I think that's still a work -- you know, it's obviously still a work in progress.

MR. MAYS: Yeah, because right now, they are casting a pretty wide net, you know, for -- for -- especially for primary wholesalers and direct purchasers where were not lot tracking. You got to basically send out that recall notice to everyone you sold that NDC number to.

MS. GALLENAGH: Right.

MR. MAYS: And so that they can get to where they can do a lot more targeted recalls, it's going to be a whole lot more efficient for the supply chain.

MS. GALLENAGH: Exactly. Yeah, so I think that's the hope. And from the manufacturers too. I think they would hope that that is an enhancement that can be built into their systems.

But that's a while down the road.

And I think even -- and we talked about this when we were going through the legislative process with the statute, we think that those things are possible. How long it takes to sort of rely on the technologies to do that accurately, we don't know yet. So I think that'll be -- you'll
probably see some piloting and some other things going on as -- as the systems are built, is my thinking.

MR. MAYS: Okay.

MS. GALLENAGH: And then here's some resources for you, just, again, the draft guidance, the federal register announcement, the pilot's notice. I also included HDA's transaction scenarios. We went through a very painstaking process in the beginning of implementation just to kind of map out what transaction -- typical transactions look like, and what type of 3T documentation was required for those transactions. And that's all available on our website to look through if you're interested.

And then our traceability seminar is in November. This is our annual event that is becoming one of our largest events, and it's focused -- it's basically a day and a half focused all on traceability, and on DSCSA implementation. So it ranges from some of the policy discussions, but a lot of technical presentations and sort of real world case study type information as well.

And then I'm going to talk about a couple of things. Two initiatives that had has been working
on as a result of our implementation work. The first is the had verification router service initiative, or the VRS. Some key drivers in this were the 2019 milestone to verify serialized return -- saleable returns. And as we talked about before, there is a large amount of nearly 60 million units returned as saleable to distributors each year. You know, on average we say it's somewhere between two, three, four percent of -- for all product that's in the supply chain, which doesn't sound like a lot on its face, but when you're talking about units of product, and verifying every unit, that's a lot of product.

Had engaged in some pilot activities surrounding this requirement. Nine different methods were examined and tested. Some of those were sort of desktop tests, or white papers. And then two were identified as the most cost effective and viable to basically facilitate this 2019 verification requirement.

One was sort of the internal database option, which requires serialized data to be provided by the manufacturer. And then the other was an external verification router service. And the
thought was that this would — if there could be an external router service developed, that this could aid both distributors and the manufacturers that were responsible for this process.

There are a few basic elements that were contemplated. It would be cloud based. There would be lookup directories, for lack of a better term, for use in verifying product identifiers. And all of the — all four elements of the product identifier would be verified.

Individual companies could access it via a service provider participant or via its own system. So there would be multiple ways to basically link in to this router service.

Interoperability is key to making something like this work. All of the systems need to be able to talk to each other, so there's some standards that would have to be adopted there.

And ideally, this would be up and running by October a year from now. So October of 2018. In January, that was the first introductory workshop that we hosted on this. There were 90 attendees with 31 manufacturers, nine distributors, and 22 service providers. And then the output was taken back to our smaller work...
group internally.

In March, there's sort of the kickoff. We've hired a project manager from PPNG that's managing this whole process for us and really for the industry. And then there's two tasks force within this group, a business requirements group and a governance group. So one who really look at what the standards should be and -- and how entities and the like should be engaging, and then one to figure out, hey, if we put this all together, then how are we -- what are the rules of engagement, essentially.

There's a second industry workshop in May. We had 55 industry stakeholders there to review the business requirements document, and then they talked about next steps. So that we're now sort of in the phase two of this project.

And then the next steps through the end of 2017, they are currently developing a 18-month timeline for the design and build and testing of the system. They are developing guiding principles, they are developing a timeline, and then the architecture that would actually be the nuts and bolts of this.

There are some technical challenges, getting
service providers to talk to one another, connection standards, interoperability, design decisions, and then who runs it, who pays for it, and how is it organized.

The theory is also that there will be multiple vendors involved. Anybody could be part of this from a company perspective. Like I think I mentioned before, you could use a vendor, or you could use your own internal system if you so chose.

This is a very complicated diagram of how it worked. I'm not a technology person by design, so this is pretty -- sort of lays out, though, a general idea, which is you would have a sort of centralized router service with lookup directories. You would have requests for verification coming from the dispensers potentially and distributors for saleable returns. And then on the other side, would you have the manufacturers who would be responsible for originally essentially supplying that information somehow, and that would -- would be responsible for the verification responses.

Of course, all of this would have to be in a secure system, and would all be based on product
identifiers that were generated by the manufacturer.

So this is -- this is sort of, you know, the basic model that we're looking at for 2019 returns. Verification, I think also the hope is that -- and this is really been ongoing, but the hope is that anything we learn in this process, or by, you know, if we're successfully in setting the DRS up, that some of these things could be used, whether the lesson's learned, or some of the technologies, even, for 2023.

Any questions on the verification router service?

Okay. And then the last thing I want to share with you, this may -- we are very excited about, and this is Origin, it's our new had product data source. Again, this was really throughout of DSCSA discussions and implementation throughout the industry. The key drivers were the associated milestones with the law, the need for frequent and accurate data exchange.

GTIN is the required identifier for -- for GS12D Data Matrix 0S barcodes and for EPCIS messaging standards. So that's all -- DS1, as you know, is the standards body that it really kind of

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
stands behind a lot of these electronic requirements. The 2D Data Matrix barcode is essentially the product identifier that we'll be using. And then the EPCIS messaging standard is essentially the type of technology or system that we envision will be used to exchange that information at the unit level.

This is a complex network of manufacturers, distributors, dispensers, and products, and so there needed to be, I think the consensus was, and we heard this just not from our distributor members, but from -- from customer -- you know, from distributor customers, and from manufacturers, there needed to be sort of one source of what those -- what those standard product GTINs were. How are you going to, you know, arrive at where that information is without having to have each individual company go to each other individual company to get that information?

Had has taken this on. It's -- it's sort of an internal had service or product now. We're using Value Centric, which is a company that is our contracted service provider. They are building the system essentially. We've established an advisory committee of distributors
and manufacturers to develop it in terms of how this system should work. And also marketing strategy for rolling it out.

Essentially what it is, is a database of GTINs. So manufacturers will contribute the data, they will load their initial product catalogs, which will be the GTIN plus 13 data fields. They will update it with new products as they come out. They will update the database with new packaging configurations as they are developed. They will correct errors, and they will use either API flat file or web portal interface.

And then distributors, dispensers, any other downstream trading partners would be data users. So they would be able to go into this database and download that information and essentially population their master data files with accurate information. So this would be regularly updated. It would all be secure. And it's also open -- I should mention, it's open to everyone.

It is a subscription-based service. You do not have to be an had member to be part of it. It's really something that we were told by, you know, various sources in the industry that there was a need for this, and so we went out and -- and
commissioned Value Centric to build it, essentially.

There has been some talk of other systems out there. We don't know if they are up and running, or what their stages of development are. But hopefully, if there are, then they will all be, you know, compatible with each other. This is something that we had saw a need and hopefully it will -- it will serve the purposes it was designed to serve. Again, eliminating that one-to-one sort of business contact at every -- at every step of the way.

Right now, that beta testing I think is just concluding. And general availability should be this fall. And there's more information on had Origin web page in terms of details. Mostly I would say it's mostly sort of a description and also information for the users and contributors, for those that are interested in finding more about the service or more about, you know, how it works.

And then looking forward to just one part of how companies are working to implement DSCSA, you know, I worked with a host of our members and other industry partners, and there has not been a
week since the law has been active that there's not talk about this implementation on some level. This is sort of the -- the project that keeps on giving.

The focus is, you know, right now, is implementing Origin for the 2017 milestone, obviously that -- we still are moving ahead with that, even though the enforcement discretion has been released by FDA. We think there's still a need for it as manufacturers come to market with serialized product.

Long-term opportunities exist here too. Had has a new product form that the industry -- basically sort of an industry standard form. Every time a manufacturer launches a product, they use that for the distributors to be able to sort of get that product into their system. So there's a -- so the focus of this law will incorporate that. There's also hope that it will incorporate the verification router service and the information needed there. One day it may sync with global standards, and as it -- as it develops, or we kind of get used to using it, that potentially there could be other uses as we move towards 2023.
And that's it for my presentation. Any questions? I know that was a lot of information. And like I said, this is really sort of a work in progress. You know, we've been working on this at had since before the law was passed in 2013, and it just continues to be a great undertaking. But where there's a lot of collaboration across the industry and across supply chain partners, so it's a very unique process. Sometimes confusing and complex, but ongoing nevertheless.

So thank you, Steve.

MR. MAYS: Thank you.

MS. GALLENAGH: And any questions?

MR. MAYS: Any questions, further questions from council members? Are any other interested parties in the room or on the phone have any questions before we move on?

Okay. Yeah, it would be great if you could turn that thing off. I feel like deer in the headlights up here.

I'm sorry, you got a question in the back?

MS. PARMER: Christina Parmer.

Do you foresee any issues with the new executive order that -- essentially that there's only -- if you're going to promulgate a rule, you
have to eliminate two with this?

MS. GALLENAGH: You know, we haven't -- we haven't identified any specific issue right now with it. But that said, I think, you know -- and this goes for any change in administration, there's always sort of a slowdown for a little while at the agency. I think the fact that they've issued -- that the FDA has issued their, you know, public meetings notices and that plan, and the fact that they've rolled out the draft guidance for enforcement discretion is encouraging. But you know, obviously it's not formal regulations, so hard to say. But I think that's encouraging that they are -- they are still very much, you know, this is top of mind for them. You know, we haven't heard anything directly about the executive order affecting them specifically, but, you never know.

MR. MAYS: Any other questions? Okay.

Well, thanks, again, Liz. Appreciate it.

Okay. I just -- just the second part of Tab 1, I just want to direct your attention to the meeting transcript, just for informational purposes. So if you get a chance, feel free to review that from our last meeting.
So at this point, I'll turn it over to Mr. Winters for the division director's report under Tab 2.

MR. WINTERS: Thank you, Chairman Mays.

If you would allow me just a brief moment, I would like to one, say a few words just as -- one, thank you very much for all the help from every individual involved with this. As I've come on, I've reached just about the six month mark in my position here with the division. And it's been a great time and certainly something I have enjoyed the amount of learning, and the industry has been very great providing information and education as I come on board.

I did want to thank Renee and Dinah as well. They have been the best assets you could ever hope to come into in a position. So thank you to them.

And I also want to recognize Kathryn Price (phonetic) is in the back here, and we also have two very special individuals with FIR (phonetic), and if you would step up and just introduce them.

MS. PRICE: I'm Kathryn, I'm the chief attorney for DEC. This is Shoshana Silver (phonetic), senior attorney, and this is Andrew Butler, senior attorney. She's been here about a