STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DRUG WHOLESALE DISTRIBUTION ADVISORY COUNCIL

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2987 Apalachee Parkway
Tallahassee, Florida

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REGGIE DIXON, DIVISION DIRECTOR
DREW WINTERS
RENEE ALSOBROOK
DINAH GREENE

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P R O C E E D I N G S

CHAIRMAN MAYS: Good morning, everyone. This is Steve Mays. I would like to call this meeting of the Drug Wholesale Distributor Advisory Council to order.

I see we have a court reporter. 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 those of you on the phone, please mute your Line when you're not speaking, and whatever you do, please do not put us on hold so we don't have to listen to your background music and so forth.

Ms. Greene, you want to do a roll call?

MS. GREENE: Yes, sir.

Jeenu Phillips.

MR. PHILLIPS: Here.

MS. GREENE: Brian Files.

MR. FILES: Here.

MS. GREENE: Michael Mone.

(No response.)

MS. GREENE: Scott Brock.

MR. BROCK: Here.

MS. GREENE: Arlene Elliott.

(No response.)

MS. GREENE: Dean Ellis.

MR. ELLIS: Here.

MS. GREENE: Jeffrey Tuller.

MR. TULLER: Here.

MS. GREENE: Patrick Barnes.

MR. BARNES: Here.

MS. GREENE: Peter Hart.

MR. HART: Here.

MS. GREENE: Jennifer Goldman.

DR. GOLDMAN: Here.

MS. GREENE: And Steve Mays.

CHAIRMAN MAYS: Here.

MS. GREENE: You have a quorum, sir.

CHAIRMAN MAYS: All right. A couple of things I would like to start with before we get to the agenda. First, I want to welcome our new physician member to the Council, Dr. Jennifer Goldman.

Dr. Goldman, would you like to tell us a little bit about yourself.

DR. GOLDMAN: Sure. Good morning. Thank you all so much for inviting me here.

I am a family physician and I'm the Medical Director of South Broward Community Health

Services, which is the primary care arm of Memorial Healthcare System in the Fort Lauderdale/Hollywood Florida, area.

CHAIRMAN MAYS: Great. Well, we look forward to your contributions to the Council.

DR. GOLDMAN: Thank you.

CHAIRMAN MAYS: Second, I want to share some news that we're losing Reggie Dixon as the Director of the Department. And he's been announced as the new Chief of Staff.

Reggie, would you like to say a few words?

MR. DIXON: No. I just thank you for everything. I think you guys are in good hands. My replacement is Drew Winters. You will find that he is an exceptional Director. We've already started working on a bunch of things and I think you guys will be definitely pleased with his leadership.

CHAIRMAN MAYS: Drew, welcome.

MR. WINTERS: Thank you. I appreciate it and look forward to working with everybody.

CHAIRMAN MAYS: We look forward to working with you.

Finally, as has been practiced in past meetings, I will start the meeting off by reading

the goals of the Council as stated in Chapter 499.01211 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 the protection of prescription drugs and public health, make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health."

So we'll get on into the agenda. Under Tab 1 in the Chair's report, Heather Zenk is here from AmerisourceBergen to provide the Council with a Drug Supply Chain Security Act update.

As some of you will recall, Heather gave us an update back in August of 2015, and I know there's been a lot of developments since then. So what I'll do, before Heather gets started, I'll read a brief bio.

Those of us that are blocking the screen may

have to move over to the side a little bit.

Heather Zenk is a registered pharmacist, PharmD, is Vice-President of Global Secure Supply Chain operations of AmerisourceBergen Corporation. In this role, Heather has responsibilities for developing and implementing traceability business processes and technology that will enhance patient safety, further secure the pharmaceutical supply chain and create broader service offerings to the manufacturer partners and AmerisourceBergen's customers. In addition, Heather manages manufacturer programs and data.

Heather has over 15 years of pharmacy procurement and supply chain experience which she has utilized through her career in AmerisourceBergen, including that of Vice-President and Distribution Center Manager at the Chicago Distribution Center, SAP Business Liaison and running operations at the Canada Distribution Network.

Prior to joining AmerisourceBergen Corporation in 2007, Heather worked in Walgreens as a pharmacist and Manager of Generic Procurement and Strategic Solutions. As part of her dedication to patient safety and advocacy, she

continues to maintain her license to practice pharmacy in Minnesota as well as in Illinois.

Heather received a Bachelor of Arts degree from College of Saint Benedict's in Saint Joseph, Minnesota and a Doctorate of Pharmacy degree from the University of Minnesota.

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

MS. ZENK: Thanks. I said it sounds a little bit like my mother and father. But thank you all for the time today. I know many of you, I've been here before, or I have other colleagues in this space that do equal amounts of work around the federal implementation of DSCSA.

I'll try to stick to some highlights. There's a lot of slides, I apologize. But I think we'll try to say, you know, how did we get here as a reminder? So we did end up here because we had, I think, at one point about --

MS. GREENE: Can everybody see that?

(Affirmative response.)

MS. ZENK: And, please, interact. If there's a question or there's an acronym or a term that you're not aware of, it's not going to hurt my feelings to ask. I kind of live, eat and breathe

this every day, as does Mr. Files and a few others in the room, so we tend to talk in code and we don't even know it's code anymore, so please ask a question.

Some of the reason, just so we remember how we got here, is that we did have 28 to 32 states that have some type of record-keeping requirement, licensure requirement or pedigree requirement, and we did actually as an industry -- and by "the industry," I mean the pharmaceutical industry, so even a bit more than just the wholesaling industry. We actually petitioned Congress and worked with the FDA and worked with yourself and other agencies that had stakeholder share in the pedigree law and said we really do need to have one manner in which to secure the pharmaceutical supply chain in the US.

So at times where I think there's frustration that, you know, not many states are changing their requirements to align with federal, et cetera, I try to remind everybody you actually wanted this. This is something as an industry that we felt would add additional protection to patients and to patient safety and to the pharmaceutical supply chain if we were all under one federal regulation.

The other reasons that we got here are to do with -- particularly here in Florida and also in California -- there was serialization requirements that were going to go into place and we were really struggling as an industry to say we can't have 50 different flavors -- I say of ice cream -- we needed one manner in which to do this because this is a very complicated process for the pharmaceutical supply chain to undertake and we needed one way to go about doing that.

We've also seen this start to happen globally. So not only just is the US implementing this requirement, we have 40-plus countries throughout the globe. And from our manufacturer trading partners, they stated we're going to struggle to comply globally, we can't possibly comply with an Indiana requirement, a New York requirement, a Florida requirement and a California requirement all being different, we really need to have one manner in how to handle and secure the US supply chain in a harmonized way.

So that was kind of how we got here. I won't go into the details. We just kind of put these in as background. I think everyone is aware.

This is, you know, a federal requirement that had two sections, it was passed in 2013. Jokingly it was passed the day after Thanksgiving so my pharmacy humor -- and I apologize if there are actually funny pharmacists out in the world, I am not one of them -- but we say we don't know if President Obama pardoned the turkey then the signed or signed the law, then pardoned the turkey. But it was signed the day after Thanksgiving in 2013.

Interestingly enough, the first part of the bill was about compounding and the second part is around pedigree or the Drug Supply Chain Security Act. Pictorially this is just a timeline to outline. So for those on the phone, I'm on slide four.

So pictorially we've attempted to try -- and believe it or not, this is what I use actually internally and when we talk at any event we tend to use this timeline so people understand that this was a lengthy federal law that took -- that is taking place over the course of ten years so there are various requirements that go into place over the course of time.

And the intent of that was to allow the

industry to work together to solve any concerns or operational impacts that might take place and allow us enough time to work through that versus there being undue burden on regulatory agencies or the FDA to mandate a significant amount of activity that just might not be the most optimal way for the supply chain to advance the security.

So moving on to slide five, which, again, is a bit of background. These are just the data elements. So you'll hear reference frequently to the three T's or TI, TH, TS. We just wanted to include what those were. I think everyone in the room is well aware of what those are.

So I'm going to take a little bit of time and go through what's upcoming now. So we've kind of gotten to a point where on the timeline slide we have implemented anything to the left clearly before '17. So mostly what that was was that there were some procedural changes around making sure the industry knew who was authorized treating partners, whoever is to do business with. There is some updates around identifying suspect and illegitimate product and what are those processes and procedures. And then there's also been this exchange of information, and that's the TI, TH,

TS.

So the bulk of the industry has spent a significant amount of time working through how we exchange those datasets. But there are things coming up. And I won't go through ad nauseam each of these. We've tried to extract these out and re-standardize, if you will, the need to talk about requirements that are on that timeline.

So I'll spend today mostly talking about what's coming up in '17 at the end of this year. So on November 27th of 2017, the manufacturers are required to place a serialized 2D DataMatrix barcode on the smallest saleable unit in the US market.

So what does that mean? We'll show you some examples. I'll show you what we're seeing. We'll show you on both good and bad. I say we kind of protect the innocent and the guilty in this example. And then I'll spend a little bit more time focusing on 2019, which is the next requirement that is the big requirement in the statute, and that has to do with wholesalers and returns that would be saleable in the marketplace that would come back from pharmacies that they're servicing.

I'm not going to go into a significant amount of detail on what's happening in 2020, and 2023, just because I think in the urgency of time and relevance.

So I am now, for those on the phone, on slide nine. You should see two pictures. And a little bit about what are we looking at. So on November 27, 2017, the Federal Statute says a manufacturer shall place this 2D DataMatrix barcode that you see on the bottle and on the case. So on a homogeneous case in the smallest saleable unit, which it's just easiest we said to talk in bottles, but if there's questions around, you know, vials, syringes, other things, we can talk about that afterwards.

With that said, each of that -- that 2D DataMatrix barcode will have four data elements contained within it by statute. Though four data elements are -- it's a product identifier. New acronym, GTIN, G-T-I-N, stands for global trade identification number. It will have the NDC code or the national drug code embedded within it, but it is a way uniquely to identify a product. After that will also come a serial number, the expiration date and the lot number. So all four

of those data elements will be encoded in that one barcode. And you can see examples of what they look like on physical packages today.

So not to pull a Facebook card, but you can see on the top of ten we kind have the thumbs down like wah, wah. Here's what we're actually seeing in the marketplace.

So slide nine was a bit of -- that would be the gold standard. Unfortunately, what we are seeing is not standardized barcodes today. We're not seeing ones that we can read, we're not seeing data elements that are encoded accurately or correctly, and we're seeing a bit of -- or a lot of people doing a lot of work and a lot of effort but maybe not doing it in an accurate, correct fashion. So just trying to show you what's out there for real.

I think, you know, we'll get there, we'll be optimistic, we'll work hard and we'll get there, but we are not seeing at this point in time even consistent linear barcodes which are in today's environment. So as we move forward to serialization, there is a bit of a concern on how do we get over this hurdle.

So going into what is the industry doing. So

in particular, we've been working with HDA, which is previously HDMA, so today it's the Healthcare Distribution Alliance, which is the federal organization that all of the primary wholesalers use as both a lobbying arm and also a standardization and guidelines arm and a supply chain and involvement arm. They have gone forward with best practices in barcoding. And it outlines more than I ever wanted to know, trust me, more than you ever wanted to know, about barcodes. It does go through how do you encode it, where's the placement, what do we do with duplicate. If I would pick up and want to start a manufacturing entity today and knew nothing about barcodes, this would be a good place to start.

So as we look ahead, we are learning things that, believe it or not, we hadn't learned before. So on the first time we had shown that -- if you can see on the top barcode here, that 2D barcode is on the interior of the corner. Well, what we were doing is we actually conducted a pilot where we just were trying to read barcodes that were coming into our warehouse. And what we found is that we've, unfortunately, placed that barcode in the most vulnerable place on the actual physical

case on that corner. And we were seeing then if you're stacking two or three high, that bottom one might have enough of a wrinkling on the case, couldn't read the barcode. So we went back to HDA to say we should put the 2D barcodes on the exterior of that corner wrap.

So I know this is just riveting stuff, trust me. But believe it or not, this will matter. And we were really trying to get out ahead of this so we could talk with our trading partners and manufacturer partners to say let's move it to the exterior now versus us having a requirement that we're looking at and then we can't read any barcodes and then potentially that product becomes suspect at that point in time.

So for those on the phone I am now on slide 13. So these are some more, unfortunately, not positive examples that we're seeing. And some of them, like I said, I know there's a lot of jargon in here, but we're seeing non-consistent terms used, we're seeing, you know, things that just aren't standard according to that, and we're really trying to identify these and have one-on-one conversations with the trading partners that are sending these to us, which we're fully

starting to understand it becomes more complicated the further we dig down.

So on slide 14, though, here are some positives in the marketplace. These are manufacturers that are doing things according to both the HDA standard and then also GS1 Global is also an entity that talks about data capturing and data sharing. GS1 Healthcare has really helped the whole industry globally understand how can I use the same standards to apply anything that I sell throughout the globe and use that same nomenclator and that same language and that same DataMatrix. If people aren't familiar with them, they are the same people that did the UPC. So when you think of a soup can or Wrigley's Gum, same companies, our same standards organization GS1 is helping us do this too.

So with the good comes the bad. So here are some of the bads that we're seeing on slide 15. Interestingly enough, the top one is we had a manufacturer that's like I'm going to put the 2D barcode on the bottom of the bottle, which sounds genius until you start to realize that it doesn't stick after a certain while because it's concave. So that little sticker -- the picture on the right

of that is supposed to be my distribution center floor where there's a million stickers. So you tend to go out on a distribution center floor and you come back and you have to make sure you don't have any stickers on the bottom of your shoes. So good intentions, maybe wrong location application for a manufacturer.

We're also seeing manufacturers on the second one down not use the same nomenclator to identify the data elements in the barcode. So the top one is the GTIN, which we've learned to -- I said protect the -- actually, in this example, protect the guilty. The UID, which we believe stands for unique identifier, but really it's the serial number. And it's really not that big of a deal except that by the time it gets to a pharmacy or gets to a hospital or gets to a retailer, the more differences we're seeing manufacturers use, the more trouble it's going to be for them to understand what data elements am I looking at. And then the lot number and expiring date.

The other thing we're seeing, which is on the bottom, is we're seeing some placing them too close to the linear barcode. And to date we know many of the hospitals clearly use the linear

barcode for bedside scanning. And we also have retailers that use that as a means to make sure they're filling the accurate medication to the accurate prescription for the patient. And the closer those two get, the harder it comes to actually read both of them in an accurate form. And these are all things that we've learned over the last 12 to 18 months. Like I said, more about barcodes than you ever wanted to know.

Is there any questions?

(No response.)

MS. ZENK: Like I said, we tried to show it -- it's a little more impactful, a picture is worth a thousand words.

I'm going to take a little bit of time now to go through what HDA as an organization, or all of the primary wholesales, have been engaged in, along with our manufacturer trading partners over the last, I'm going to say about 16 months, what we've been working on. So we've really been focused on that November 2019 requirement where it says when -- the law says when a pharmacy has a saleable return that comes into a wholesaling entity, that wholesaler must validate the serial number's accuracy and we must also know which

transactional information, statement and history is tied to that return.

Well, we started out by, you know, talking with the manufacturers, and the manufacturers are like, oh, well, that's between you and the pharmacies, that's a wholesaler pharmacy concern. And we started to say to them, well, but is it, because we have to have a way to know that that serial number is real and how are we going to do that. And they started out again by saying, again, this is really -- like we want to help you, we really appreciate it, but this is your requirement. Well, then we started to pull some numbers.

So we do at times as a service to the pharmacies take back returns that are sealed and that they've ordered and can provide an invoice number to us that we can take back into our inventory and we resell throughout the US.

It is 2 percent of units, which doesn't sound like a whole lot until you start to look at the unit numbers. So 2 percent of units is almost 59 million units throughout the US. Then it became real, because if you look on the bottom right-hand side of volume, so for a large

distributor like AmerisourceBergen, that's roughly about 19 million units a year.

And like we said, we have succinct processes and procedures today. It must come back, it must be in date, it must have an invoice number associated to it and it must come back in a sealed form. So there are certain requirements today that we already follow procedurally, but now adding on to now I have to know the TI, TH, TS and I must also know the serial number, this becomes a large problem.

Again, many of the manufacturers said, well, you can just send me an email, send me an email with that information in it. And then we said, well, for a large manufacturer, that's 2 million emails a year. So we kind of started to joke -- or they said, call me. So then we started to say, well, do you want us to play the hotline bling songs behind the scenes?

So we really wanted to make sure that they understood and we understood this is an industry opportunity to solve this. It is in the wholesaler requirement section of the federal statute, but we can't do this alone. And if we can't can validate that that product is saleable,

it becomes non-saleable in the marketplace and it would go to a reverse processor for destruction. The dilemma that that becomes is the product is actually viable product and safe product, it could be redistributed in the marketplace.

So then that became real also for me in the financial perspective, that that 2 percent would come out of the supply chain and that a manufacturer would need to produce 2 percent of product sooner. So for those manufacturers, it really replicated into a 4 percent supply chain inventory opportunity.

So what did we look at ways to solve this? So the ways that we look at to solve this are if a manufacturer could provide identifiers, so provide the serial numbers to the entity that they sold it to. So in the event -- and I always preface this by saying I pick on Pfizer, publically I pick on Pfizer. Pfizer sends AmerisourceBergen 100,000 serial numbers and 100,000 units. I accept those units. I sell ten bottles of Lipitor -- let's pick on Lipitor again -- out to Heather's dispenser. Heather inadvertently -- I meant to order one, I didn't mean to order ten. I initiate a return back to AmerisourceBergen for the nine

units that I inadvertently ordered.

We would then at the wholesale level have the ability to look at our internal database to say, yes, those nine serial numbers are real because I received them from Pfizer. One way to solve this problem. But the manufacturer still has to have the ability to provide the information to the wholesaler.

The second way we thought we might be able to solve this is in the event a manufacturer could not provide serial numbers to a wholesaler, that wholesaler could scan each unit that they sold out and then build up that repository inside their database to say now I know that's a serial number the manufacturer had on a bottle so I know that's a valid number when it comes back.

The third way, we talked about do we have a central repository? Would the manufacturers provide all of the serial number information into one location? And then would we have distributors that would access that information once a return came into their wholesaling location, go to that location and validate that number? It could be done.

Some of the concerns were around, if you

will -- we're all in an age where hacking comes up quite frequently, security of data. There was a bit of a concern that there would be one location where all of the serial numbers for the US market would be and many of the manufacturers -- and I don't fault them at all -- had a bit of concern about what that security would be, or if we made it so secure, would it be too difficult for the industry to actually access and use?

Last but not least, we came up with an idea, we're calling it a verification query service. And I'm sure we will acronym it at some point to make our lives even more complicated. We said, what happens if each manufacturer, you couldn't provide the data, they held their own data, like they do today, a return comes in from a dispenser to a wholesaler, that wholesaler, because there's logic, remember, in that product identifier or the NDC? So if I get two bottles back, I scan those two bottles into the verification service and it knows this one is Eli Lilly and this one is Pfizer. And then it has an address that it goes out to and says, Pfizer, can you please validate this serial number is real and, Lilly, can you please validate this serial number is real. And

it would all come back to the distribution and allow that distributor to make a disposition of, I'll call it thumbs up, thumbs down or a red light, green light.

TELEPHONE PARTICIPANT: Drug wholesale. It's a drug wholesale advisory, not the drug advisory wholesale.

MS. GREENE: Please mute your phone.

MS. ZENK: Go ahead, Steve.

CHAIRMAN MAYS: Anyone on the phone, if you could mute your phone, please. Thanks.

MS. ZENK: So with that said, I think we did come to some conclusions and we did work as an industry to come up with some opportunities. I won't go through a lot of the project management lessons learned because those are pretty much self-explanatory. But we'll work through what came out as preferred solutions.

So what the industry said is the best two approaches that we think we can take those saleable returns in '19 and continue to move in the supply chain would be if a manufacturer sends data and the wholesaler stores that information and/or uses verification service.

This verification service that we just talked

about as a last option does not exist today in the marketplace. We are working with technology companies and with HDA again on how do we develop that and work and bring that forward as a viable solution for use.

Okay. I'm going to take a breath. Is there any questions I guess about what was done and what conclusions, you know, we came to about how the industry, I think, wants to use and what we want to use for the saleable returns requirements?

(No response.)

MS. ZENK: Okay. So I'm going to spend a little bit on an FDA update on some of the hot topics and then see if there's any additional questions or concerns that people are experiencing at this point.

So the FDA to date has released guidelines or guidance for the industry around product tracing for the four dispensers. They do have a compliance policy that's been published. They have published identification of suspect and illegitimate product. They do have -- I'm going to say half of it they have finalized and now they've submitted a second half that's in draft, their own suspects and illegitimate.

They have also gone through and released guidance on 3PL and wholesaler database and how to report up to the federal database. So all of us today in the wholesale or 3PL space are publishing state licenses and state locations into that federal database at this point in time. And they've also released guidance on first responders.

So any ambulatory agency or first responders, at times they actually procure product from their local hospital or local clinic, and that is something that the FDA felt was relevant to keep intact and so they have published guidance on that on how that transaction between maybe a local clinic or a local hospital is exempt from DSCSA requirements in order to provide pharmaceuticals to first responders.

They have not yet released guidance on 3PL licensure and wholesaler licensure, which was actually statutorily required to be released on 11/27 of '15, so we're a little late from them. Albeit, every time we actually pester them, pester where they feel like we're stalking them, they tell us it's in process, it's in process. So we know that there's a lot of agencies that have to

get eyes on that before it's released in guidance form. And then it will go through the public review period and more than likely a couple of drafts before final. But we are eagerly anticipating that.

They have not yet released guidance on grandfathering. And what that means for those in the room is on 11/27 of '17, the statute says the manufacturer shall place this 2D barcode on product. Well, many of the manufacturers, I'll put it my words, are they saying in commerce, anything going into commerce on that date must be serialized or anything that's produced on the production line after that date?

Given I'm from the midwest and I grew up in South Dakota, I think of it as the born-on date, which I realize is a Budweiser reference. But I think of it as is it the born-on date or is it what's in commerce?

That guidance was also supposed to be released over a year ago. And so at this point, a lot of the industry groups that have been working together and the manufacturers have said we need it to be the born-on date or I can't comply with the requirement. So the industry has gone forward

in lack of guidance and used as a general common understanding that it's the born-on date for those requirements that are in place today.

They also need to release something on waivers, exceptions and exemptions. And what that means is say I made a small business and it's an undue burden for me to comply with this requirement, what does a waiver look like, how do I apply for it, how can I prove it's inadvertently burdensome on my business? So they have to release how that would work.

They also needed to release to the industry any exception or exemption around packaging. So think of it as if the package is too small to physically get that 2D barcode on, how does a manufacturer apply for exemption for that product or is there products that -- they do list out a classification of drugs. So like blood product is exempt, radio products are exempt, so they do have categories, but they don't have specifics around them. So the industry was anticipating that they would release something a bit more structured on what those exemptions looked like.

In today's world, how the industry is functioning with exemptions are if a manufacturer

tells me in my 300 pharmaceutical products that I sell to you, ten of them are exempt. We are honoring that decision by the manufacturers so we would not be expecting TI, TH, TS information to come in and we would not be providing TI, TH, TS information for those exempt products based on the manufacturer's decision.

So I'm going to breathe because there might be some questions around, I guess, what the FDA has or has not published or how the industry is functioning, I guess, today in light of these guidances or lack thereof.

MR. PHLLIPS: So the licensure you're talking about here is state licensure?

MS. ZENK: They will issue a federal licensure. And then the states have the ability to replicate that same federal licensure at a state level. And they can inspect against that. They can, if you will, receive revenue for that. But they cannot go -- it's a floor and a ceiling.

So in the sense once the FDA would publish that and the states would adopt that, we are under then for the US market one wholesaler licensure that's standardized. But every state can adopt that and inspect against. That's the big one,

particularly for all of us in the room that we've been -- I said, can I get it, can I get it, can I get it?

Other questions?

(No response.)

MS. ZENK: Okay. We'll go through a few what I call hot topics or industry, I guess, buzz, or maybe it's more industry pain. But what are some of the things that have challenged I think the industry and then what we have done as a wholesaling industry as part of the retail community, as part of the repackaging community, as far as the pharmaceutical community, how have we worked through some of these and what have we done?

A lot of times what happens is if there is a trading partner concern that gets escalated, we tend to first take it to HDA, but we also then take it to another organization called PDSA, so the Prescription Drug Security Alliance. And that group has manufacturers, pharmacies, hospitals, and wholesalers, so it's more of a cross-industry organization that we all belong to.

There is a member -- you do pay to belong to that, but it also has greatly helped in the

implementation and operationalizing of the federal statute.

Drop shipments are an industry hot topic. So the federal statute is focused on the change of ownership. They do not track in the federal statute, the way it's written, the possession or the location of the drug. It cares about upon change of ownership, we pass the data -- we pass the TI, TH, TS to each other, so we pass that upon ownership.

The dilemma becomes with drop shipments are -- the way they work, particularly for the retail and hospital community, is they may order a product that is drop shipped directly from a manufacturer from their wholesaler. The wholesaler produces an order to that manufacturer on behalf of the hospital. That manufacturer fulfills the order and ships the order directly to the hospital or the pharmacy and then the wholesaler invoices that.

So I just said the law really only the cares about who owns the product. The one exception in the statute, and there is specific language that carves out drop ships. So in that example, it says, the shipping entity is accountable to

provide the TI, TH, TS to the dispenser that it's shipping to it. And the reason for it is if you think logically is that at some point the -- well, the TI information that has the lot number on it. The wholesaler never physically sees the product. I couldn't attest to the lot number or the serial number later on down the road. I can't attest to what serial number is on that package, where the entity that ships it at the manufacturer level can. So that's why this is the one time in this statute we break the rule around following the change of ownership with the transactional information, statement of history.

Does that make sense? I know it was a little bit confusing.

(Affirmative response.)

MS. ZENK: Okay. So that one causes some consternation. And if you're particularly a hospital entity or you're a retailer, you need to now identify -- and realistically, they're probably receiving drop ships from anywhere between 50 to 70 manufacturers at this point in time, so you need to identify those items, understand how that information is coming into you today and how to store and retrieve it in order to

comply with the statute.

The other thing that's causing the industry a bit of consternation is 340B transactions. So this is also a transaction where the ownership and the physical movement do not stay tied together. So in the event of a 340B, the contract pharmacy orders the product but the covered entity is the accountable financial entity for that product.

So in the wholesaling community, I am required to provide the TI, TH, TS to whom I change ownership with, which is not the contract pharmacy, it's the covered entity, but I physically ship the product to the contract pharmacy so they can administer patient care to that patient.

That took us a little bit to work through on what does that data look like. We had some conversations with a lot of the contract pharmacies and the covered entities to work together on what does that look like when we tried to solve this.

The other industry hot topic that comes up quite frequently is the borrowing and loaning of products, particularly between hospital entities or clinics or some type of emergency care types of

locations that provide care. There is a provision in the statute that allows for a patient's specific need to be an exempt transaction, and so we do try to encourage that for use for our hospital entities when they call to say am I supposed to provide the TI, TH, TS to the second hospital that I'm giving a vial of medication because they have a patient that needs it today?

There's a lot of internal -- we told them SOP's they need to look at and go back. But that in and of itself -- because in theory what they're doing is they're saying -- hospital number two is calling hospital number one to say, do you have this medication, because I had a patient in need that needs this right now and can I have it or borrow it or loan it?

What we tend to see, though, is then that second hospital would reorder it from their wholesaler and give it back to hospital number one. That had been typically the operating procedure and rhythm. Well, in today's world, that second hospital that just did that and gave it back to the first hospital really isn't addressing a patient's specific need at that point, so they would then need to provide the TI,

TH, TS back.

So I think a lot of hospitals and clinics are really looking at what is their SOP on this, what is their policy and procedure so they don't end up with the Saturday night at 11:00 p.m. -- because that's when it always happens, it doesn't happen Tuesday at noon, it's always Saturday night at 11:00 p.m. at night -- so they know how to tell their staff to address that.

Is there questions around those? I know those are pretty specific, but yet the devil's in the details and the 90 percent of what we can all do logically is this 10 percent that tends to be the anchor to anchor everybody down.

MR. DIXON: I did have one question.

MS. ZENK: Yeah.

MR. DIXON: Have you all encountered or has there been any real thought given to doing away with the nomenclator of borrowing and loaning, because I know that has been an issue before in the sense that borrowing and loaning implies that you are returning exactly what you received?

MS. ZENK: Yes.

MR. DIXON: I can loan you my car and you can return my car.

MS. ZENK: Yeah.

MR. DIXON: But if I give you a medication and you use it for a patient, you are not giving me that same item back, you are giving me another one, a supposedly identical product to replace what you had given me.

And I know that for folks within the industry, that can sometimes be difficult, not the concept, but the use of those terms, because from a regulator perspective, it makes it difficult sometimes to have that conversation with the regulated industry. And I was just wondering if there's been any thought or any talks about trying to limit the use of those terms, because as new people come into the industry, it may be difficult to kind of keep that regulatory relationship.

MS. ZENK: We have -- from AmerisourceBergen's perspective when we've had hospitals ask us about exactly what you just said, we've tried to say if it's a patient-specific need and pharmacy number one has it and pharmacy number two needs it, you should give that and cite in your records it's a patient-specific need, thank you very much, transaction done. Versus, if you will, that second pharmacy reordering it.

And coming back to your point, we've tried to get that to be more of the practice. I think it's pretty ingrained in the hospital marketplace. We see it much more significantly come up with questions with hospitals.

MS. GREENE: That's where most of them come from.

MS. ZENK: Yeah, that's where most of them come from.

And I do know that on a public call, the FDA in so many words said, borrowing and loaning are not terms that we want to talk about. And they continue to get specific questions from the hospital community, from ASHP, and they finally just said, borrowing and loaning is not in the statute, it is not anything we want to address, how you choose to handle that, you either need to look at patient-specific exemption or you need to remove that. They pretty much said, you are either selling it or you're consuming it.

And I do believe it was, I think, the Tennessee Pharmacists Association that brought it up, and they were -- it wasn't a shining moment for them, I don't think, on the call.

MS. ALSOBROOK: They're the ones that brought

it up in the conversation with us, too.

MS: ZENK: Was it?

MS. ALSOBROOK: Yes.

MS. ZENK: So at least they're consistent.

MS. ALSOBROOK: They're consistent.

CHAIRMAN MAYS: So, Heather, what typically happens, does the borrowing hospital typically purchase that product at a later point and give it back?

MS. ZENK: Yeah, and then give it back.

CHAIRMAN MAYS: Replace it?

MS. ALSOBROOK: Return it.

CHAIRMAN MAYS: But it's not really --

MS. ALSOBROOK: But it's not borrowed.

CHAIRMAN MAYS: Right. Exactly.

MS. ZENK: Yeah. So we tried to -- we've tried to help them out if we can. It is quite ingrained.

But at the same point, you have also in their defense, the Board of Pharmacy in Tennessee or the Tennessee Pharmacy Association, the FDA said, our law isn't meant to not have you provide patient care. Please don't say that I'm telling you that someone should expire because you don't know what to do about giving one of your partner's care.

And the other strange question is you can move product intracompany and not have to -- because there's no change of ownership then. So if you're moving it from location number one to location number two, and that's all under, I'll say like St. Mary's Hospital umbrella, you do not have to provide the TI, TH, TS to each entity. But if you move it from pharmacy number one to pharmacy number two and pharmacy number two gets asked to produce transactional information, statement and history, the pharmacy still has to have a way to produce that record.

So they're trying to say you don't have to pass data to each other under common ownership, but you are not alleviated from your requirement of producing the record ever. And I think that's some of the things to think through as hospitals, you know, harmonize inventory or some retailers harmonizing inventory between patients, too.

MS. ALSOBROOK: It appears that they keep wanting to go back to using it as inventory control and not understanding the exemption that's out there.

MS. ZENK: Correct.

MS. ALSOBROOK: Okay.

MS. ZENK: And it does explicitly say in the statute even for shortage of products or inventory control, this is not a practice that can be used --

MS. ALSOBROOK: There you go.

MS. ZENK: -- for exemption. It's explicit.

MR. PHILLIPS: I guess at one point will hospital retailers need to have technology required to be able to read these barcodes?

MS. ZENK: The 2D barcodes?

MR. PHILLIPS: Yeah.

MS. ZENK: That requirement -- so the manufacturers place the serialized on the product in 2017. If you look at the timeline, the industry is not required to actually start to use those barcodes outside of returns until 2023, so 2023. So the intent of it was to provide enough time for the industry to understand technology, change processes, change systems, and then allow there to not be any impact to patient access to medications. So there's this six-year window where the manufacturers will continue to push serialized product into the marketplace, but the requirement to be able to actually scan and capture that data will be 2023.

MR. PHILLIPS: What about the returns?

MS. ZENK: Returns is '19, at the end of '19.

MR. PHILLIPS: So really that's -- because everybody does returns.

MS. ZENK: Yeah. But at that point, the retailers are not required to, or the pharmacies are not required to scan anything. It would be the wholesalers who would have to scan it.

MR. PHILLIPS: Makes sense. Got you.

MS. ZENK: And it's just that 2 percent.

MR. PHILLIPS: Right.

MS. ZENK: And I think we have had some people honestly say with the returns, well, maybe I just won't take saleable returns anymore, which I'm not sure from a business perspective that's a good decision, but it is an option. Sorry about all the editorializing.

I think upcoming activities that we're both looking at as an industry and with the FDA, we are looking at what we're calling exceptions pilots. So I think of it as I either have physical product and I don't have data that matches it or I have extra data and no product.

So think about a serialized world, Pfizer sends me 100,000 serial numbers. Did I get the

correct 100,000 units to match those 100,000 serial numbers? And if I didn't, what's our process to resolve that?

So if I got two -- so say I got 100,000 units but I only -- I got physical 100,000 bottles, but I only got 99,000 serial numbers, what do we do? And it's going to happen even if we're at even 1 or 2 percent error, that's a significant amount of units. This is a whole level of data and reconciliation that the industry hasn't contemplated at this point, so how do we start to resolve that?

So we're really starting to work -- actually, we inside ABC we're in actually week two of our exception pilot to say I'm getting data but it's not matching, what types of electronic records can we send? Because calling someone or tracking someone down is probably not an option. And if we have to quarantine the product that I don't have the serial numbers for, we're going to be in a world of hurt because we're going to run out of physical space in unfortunately probably a short amount of time.

We're also working with GTIN database. Remember the new term for the product identifiers?

So the NDC will still exist, but how do we get all of that new information without having to go to every single manufacturer and every manufacturer having to give that data? So what we're attempting to try to do is have one central repository where a manufacturer can load all of their product information and it's standardized, and then the whole industry extracts from that. So they only have to update one time and the whole industry can use that record.

Upcoming activities. There's a lot of serialization pilots in play for different reasons. And the FDA has kept saying they're going to sponsor a serialization pilot. They haven't come forward on what the details around that are, but we are anticipating that to happen, we're hoping within the next 24 months.

And then we also talked about the verification query service, which, you know, I kind of said is that central database where all of the serial numbers come to and it routes it. I think of it is if I search pants on the Internet, it goes out and says, hey, you want to go to the Gap, do you want to go to Banana Republic, where do you want to go, that type of methodology.

(Inaudible.)

MS. ZENK: We're at questions anyway. So that's really all that I had. And I do apologize, I know some of that was very far into the details, in the weeds, but I think -- to be fair, I think that's where we're at as an industry. And we're getting into the what this is going to look like. These are barcodes that we haven't been using. It's a level of serialization and level of data we haven't used before, so we are starting to get into the significant weeds around all of this.

MS. ALSOBROOK: The exceptions pilot, you know, reporting of loss, you know, drugs in transit or loss of samples or complimentary drugs, the exceptions pilots, that will address things like the lost in transit and things like that?

MS. ZENK: It will at some point. Really right now what we're trying to say is I might have the product and I might have the data but they don't match.

MS. ALSOBROOK: But they don't match, okay.

MS. ZENK: So I think the other thing to think through is this is a paradigm shift, too, for the industry because we can move product without data today by law legally in all the

states and in commerce. In the future, though, we're going to have the data that's with the product or we can't move either one.

MS. ALSOBROOK: The reason I ask the question is once those products are found, they're going to have a serial number on it, they're going to meet the requirements of the law and they're going to get back in the chain.

MS. ZENK: Uh-huh.

MS. ALSOBROOK: And who knows where they have been stored, who's had them, et cetera.

MS. ZENK: Right.

MS. ALSOBROOK: Okay. And the other question I had is the contract manufacturers, virtual manufacturers, have you all decided who is going to be responsible for those products that are manufactured by those entities? Will it be the actual manufacturer who hired them?

MS. ZENK: So right now, each manufacturer is making that decision independently. And what we are seeing is typically it's the manufacturer that has put it into commerce and so they are holding their trading partners to get that product to finished good accountable for that.

We do see some that provide -- the contract

pharmacy provides data on behalf of the actual label manufacturer, but most of the time, it's the label manufacturer that's taking accountability for it and providing the data is what we're seeing. There's been some clunky conversations in that space, too.

MS. ALSOBROOK: I imagine that would increase the cost.

MS. ZENK: Cost of service, yeah.

MR. WILLENBROCK: This is John Willenbrock with the Compressed Gas Association. I've got one question.

MS. ZENK: Hi, John.

CHAIRMAN MAYS: Go right ahead, John.

MR. WILLENBROCK: On your FDA update slide, it indicated that we're still waiting for FDA's guidance on exemptions from product tracing requirements. And the act itself -- with regard to medical gases, the act itself has exempted medical gases from the requirements of drug supply chain security.

MS. ZENK: Correct.

MR. WILLENBROCK: I just wanted to make sure that --

MS. ZENK: No, you are correct.

MR. WILLENBROCK: -- it wasn't an expectation that we were waiting for guidance yet on that activity.

MS. ZENK: No, you are correct, they do list a high level category. Like I said, they also list blood products and they list products used for human fluid replacement, so they do have high level categories.

I think that the intention was we didn't know if the FDA was going to provide around those exemptions maybe a central database where you have to report it. We didn't know if there was going to be some more structure and organization around it. But by federal statute, they do have to release guidance on waivers, exceptions and exemptions. I think the exemptions, though, John, are more for, you know, small businesses or burdens that couldn't be met by businesses.

But good question, or clarification.

MR. PHILLIPS: So I guess I'm speaking from the retail pharmacy, hospital pharmacy. What are the, I guess, technology changes that need to be implemented in the next, say, year? Are there any?

MS. ZENK: We have seen a lot of our,

particularly like the large health systems that have really complicated networks where they might be receiving product at 700 locations in a large campus. It's not uncommon.

Many of them have gone and issued a third party to help them make sure they are obtaining all of the TI, TH, TS in the marketplace. So there are technology companies out there that can integrate into your pharmacy operating systems or integrate into your receiving processes, so we are seeing some do that. But, otherwise, we're just really encouraging the dispenser community, talk to your wholesaler, understand how your wholesaler is providing you the TI, TH, TS. And then if you need any guidance, you know, we're here as a resource, too.

And I know, like I said, my peers in this space are equally as open to it, but we're really trying to say until we understand more about serialization, if I was a retailer, I probably wouldn't invest in any new technology until we work out a lot of the kinks between the manufacturers and wholesalers, not that I want it to be our burden, but I would sit tight.

MR. PHILLIPS: In terms of the drop

shipments, you mentioned that the manufacturers are responsible for switching over to an electronic format.

MS. ZENK: Uh-huh.

MR. PHILLIPS: I guess at what point is it -- because at some point I would assume --

MS. GREENE: Speak up so everybody can hear you.

MR. PHILLIPS: At some point we would need to ensure that the retailers and hospitals also have the technology to receive that electronic information?

MS. ZENK: Yes. Well, the FDA has published also that electronic can be email, because we joke the E stands for electronic. Like, honestly, we joke. But they said they could put it in a PDF record and email that record to a hospital.

What we're seeing most of the manufacturers do is have one of those third parties and they have a hosted website. So in theory, what you would do is they would give you credentials so I could log on as Heather's Pharmacy and I could see all of my drop ship TI, TH, TS records and that manufacturer would provide it to that portal location.

They're saying that that meets the definition of electronic per a previous FDA guidance. So that's what we're seeing most of the manufacturers of the drop ship frequently go down that path to provide that service. We are seeing some, though, that are providing electronic records but the vast majority of them are using the portal concept.

MR. PHILLIPS: Thank you.

MS. ZENK: Good question, though.

Yes, sir.

MR. HART: Hi, Heather, this is Peter Hart.

You talked about in your pilot that you're looking at situations where you may get the material, you may not have the data, and you talked about how in the current state we struggle with situations where the information is being put on but it's not correct.

MS. ZENK: Correct.

MR. HART: So are you encompassing that scenario in your current pilot of what happens?

MS. ZENK: The first pilot we did with all the barcode pictures, that was what we learned. So we've gone back to those manufacturers and applauded them for their effort but cautioned them on the fact that as they go forward, the industry

won't be able to read these barcodes so it's almost like you didn't do anything.

So we're asking those manufacturers to modify and go towards GS1 standards and HDA standards and use those two guidelines and tell them that's where they need to go forward in order to be compliant or in order to have a wholesaler be able to read it.

MR. HART: But even in that, we're still going to have this scenario that you've alluded to here?

MS. ZENK: Yes. And that's where we're really looking at what electronic transactions can we use. So it is going to be I provide here's the serial number I have, I don't have it, I can't read it. You know, what information will we need?

And some of it is it's all new for the industry, we don't have a standardized electronic record. So we're trying to prove one out and then we will share it with the industry and say is this acceptable to everybody because otherwise we're never going to land on one and we're going to end up doing different datasets with each manufacturer or each hospital and it's going to turn into something that's unwielding.

MR. HART: I guess my question is are you looking at any processes of downstream corrections of that information?

MS. ZENK: Not at this point. We know that we can't alter the manufacturer's label. So if they can't apply that right, unfortunately we're kind of dead in the water.

With the data, though, we have talked about if you send me incorrect data, do you want me to request here are the serial numbers I have? Can you give me the right data or did -- some want us to tell them what I received versus what I didn't. So we're really trying to work at it. We don't have it defined yet.

I think most of the manufacturers have said if I have the product without data, tell me what serial numbers you have and then they will do an internal investigation to say, oh, shoot, we accidentally sent those to another trading partner, they're a legitimate product, they were inside our control, I'll just send you the new records, TI, TH, TS. Where others are, oh, shoot, how in the heck did you get that? I don't want you to move it, please return it to me. I'm going to do an internal investigation, it might be

suspect.

So we're trying to work through with that. But that's kind of where we're landing, where we think we're going to just say I have these and I don't have data.

MR. HART: Okay.

MS. ZENK: The other way is a little more complicated.

CHAIRMAN MAYS: Any other questions from Council members?

(No response.)

MS. ZENK: If not, thank you for the time. I know time is precious doing these. Hopefully it was helpful.

CHAIRMAN MAYS: Heather, I do have a question kind of backing up into today's environment. I know a lot of the states, a lot of the other states are implementing the rules and passing statutes in the states. Are there any kind of challenges that have come up, you know, dealing with different state requirements in today's environment?

MS. ZENK: Yeah. So I think what we see is really good intentions but all of the states, knowing that now it's been a couple of years and

it's not brand shiny new anymore, how do we move forward. And they're looking at -- most of the states I think last year tried to figure out what vehicle do I put it on? Do I have to do it legislatively? Can I do it in rules?

I think last year we saw a lot of states what I call getting organized. And this year we are seeing a lot of activities. Don't exactly quote me on this, but I think we're between 11 and 14 states right now that have something in place to fix. And what we see is -- the biggest thing is to mimic the definitions in DSCSA. So if we can get the definitions mimicked, we can typically get the rest of it correct.

Where we are seeing some inaccuracies is around some of the state licensure requirements not being maybe completely cleansed from transactional information records. So we're seeing some states, because it's under their licensing provisions, that they're still feeling that there's some traceability data elements that can stay in that because it's under licensing, where I think the industry feels like, no, that's really a traceability data element and that shouldn't be under that licensing component still.

So we still are seeing I guess some push and pulls.

And the other thing is we are seeing this -- because the federal statute is all ownership. We're seeing some states struggle with but I want to know physically where it is, the possession. And that I think now is the industry -- becoming very difficult for the industry to adhere to because we've moved to the federal of I'm adhering to the change of ownership, I'm not necessarily as focused on or have the ability to reproduce records as quickly on where it's physically located.

CHAIRMAN MAYS: Any other questions from Council members?

(No response.)

CHAIRMAN MAYS: Any other questions from interested parties on the line?

(No response.)

CHAIRMAN MAYS: Okay. Thank you, Heather.

Mr. Dixon, are we in good shape for time?

MR. DIXON: Yes, sir.

CHAIRMAN MAYS: We were in a little bit of a crunch.

So we'll turn it over to Mr. Dixon to give us

the Division Director's report under Tab 2.

MR. DIXON: Good morning. What you have in front of you on Tab 2 is the rules report for the Division. As you all may be aware, we've been working on our applications, trying to streamline our applications, so this is an update right now.

We have gone through, and you'll see we actually put kind of a key code at the bottom just to give you an idea of where we're at. The Division has been -- is there, we're working on them. We've got a couple of applications right now that are -- we just received in the last day a correspondence from the Joint Administrative Procedures Committee which is actually basically a very short correspondence that we think we'll be able to readily address and file a response to that.

What we're trying to do with these applications -- and some of them may get a little bit longer, not too much longer, but what we really want to do is make sure that we give people -- that we make the questions obvious. In some sense, when we went through our applications, we realized that some of the applications, it was difficult for people to answer in the sense that

it could be the same and so we've had some conversations with people in the industry when they asked us about the applications. So we hope that the applications will be more user friendly.

One thing to talk about on our applications, we are actually -- our Division and our Agency is trying to move forward more with allowing people to actually apply online, and not necessarily meaning a paper application but applying through our portal.

So as we work through the applications, we're also working with the information that's being requested through the portal because some information for you wholesalers, you realize some information is in statute so it is what it is and there's a lot of information that needs to be supplied.

So the tasks that we have in front of that, if we make that an online process, is to make sure that you can attach the documents, that it's not going to break the matrix, so to speak, that you can process it, you get a notification the application has been received and that kind of thing. So we're moving forward with those.

We've done about half of the applications.

We kind of set a goal this upcoming year to do the other half. And hopefully with that, we'll be able to see our deficiency rates going down, which means that the applications are easier to fill out and they're more understandable.

We don't really have any other rule making that's going forward, but I'm here to answer questions that you might have about anything on our rule report and any upcoming rules that anybody might have a question about.

MR. ELLIS: Reggie, will the application for wholesale drug distributor that's being reviewed by the Department now, will that come out where we'll be able to take a look and see that form?

MR. DIXON: Yes. One of the things about the application now, that application is a significant application and it does have -- we know that there are some automatic deficiencies that we've been trying to work out. We've got a draft of that application complete pretty much. I know our experts in the field are still looking at it.

Part of our process that we try to do internal before we put an application out is it starts off, we come up with -- we look at what's required by statute, we try to organize our

information in a way that seems kind of natural as we come across it. And then once we get the application, we'll send it to our permitting chief, Ms. Burnett, and she'll go through it, get responses from her. Once we get that information together, then we send it to our enforcement folks who are in the field, because part of the application process helps us to not only gather information for the application as far as eligibility but also helps us expedite our inspections.

For instance, if I know what kind of products you're dealing with, then I know what to expect when I go out and do the inspections so now I'm not wasting your time versus if I know you're dealing in controlled substance, I'm know what I'm looking for, I just know that. So if you tell us you don't have a quarantined area, well, we already know you don't have a quarantined area. So we're trying to split the baby a little bit because we know we have limited resources.

So once the application is done and we notice it, we'll provide it to the Council members as well so that anyone who's got a question about why we're asking certain information, then we can get

that input. Changing the application -- and this is a small Division. I mean, there are more people in this room than there is in the Division. I'm being truthful. So being responsive to making a change is not difficult. So that's kind of the plan.

And hopefully -- you know, we think that it's been working pretty well so we don't plan on rocking the boat, we'll just keep sailing hopefully and get everything going with you guys.

CHAIRMAN MAYS: Thank you.

MR. DIXON: Does anybody have any questions about any rule making that the Division is working on?

(No response.)

CHAIRMAN MAYS: Any questions from anyone on the phone?

(No response.)

MR. DIXON: The next thing that we have on here is legislation. Right now this is the only bill that's out there. And basically what this bill does in a nutshell is it removes the requirement for cosmetic manufacturers to register those cosmetic products with the Division, and straightforward that's all it does.

Does anyone have any questions about that?

(No response.)

CHAIRMAN MAYS: It doesn't sound like it.

MR. DIXON: Okay. The next tab was a couple of questions that we had that were raised by Mr. Tuller. We had a conversation a little bit about it so we thought it would be a good idea to bring it in front of the Council and kind of discuss. It's a little bit more about where we're going in the future in trying to make applications and all this other staff more available.

The first question, the first issue deals with electronic submission of the wholesaler application as well as other applications in general. So as the Division, we're looking at it globally. And so part of the process that we have to do when we get applications and stuff electronically is we work with our technology department to come up with a template that closely mirrors the paper application and requires and requests that same information.

So a little bit of the delay has been trying to make sure we get the paper applications together as well as looking at what we want to do globally as a Division and process the

applications because the first one and the second one are kind of tied together.

As you know, the law changed last year to allow us to stagger the licenses. And you think, oh, that's pretty cool because everybody will get a two-year license or whatever, a three-year license or whatever your termination is.

But when you peel back the onion a little bit and you look at where our licensing is set up right now, your license by statute expires at the end of the month in which it was issued. So if you get a license in January, it expires the following January. If you get one in February, it expires next February and so on and so forth. If you got eight licenses that you didn't get all at the same time, so now you got one expiring in January, one in March, one in April, and June and September, okay, and so that's every license that we have.

So part of the thought process for trying to increase the licensing was to alleviate some of the continued licensing every year of wholesale distributors. I mean, because, really, when we talked to the industry, what we found was that there's some folks that are in a constant state of

license application renewal, period.

But the challenge that we have is actually trying to implement it because we have to write a rule to do it. So do we write a rule that says, well, if your permit expires -- if you got your permit in January through March, that's going to be a two-year license, if you got it through whatever, it's going to be a one-year license and you do it for a year and then now you have half of the licenses expiring one year and half expiring next year now you're on a two-year cycle. Or you can do it every other month so that it evens the workload out because worse case what could happen for our permitting staff is you have a whole group of people that all come in now in one month and now we're dealing with that, you know.

So as easy as it sounds, it's very difficult because not only do you have to implement it in a way that we can still expedite the applications, because we don't want to slow the applications down, but you also have to go through rule making, which requires the rule to be written for it to be understandable and then for it to go through the Joint Administrative Procedures Committee to look at as well.

And then the other side of the Agency and professional side, they have got a rule that sets out a schedule where the renewals occur. So we've kind of looked to that rule to kind of see how it works.

One of the ideas that we're thinking of doing it alphabetically, trying to do -- we've been toying with the idea because we know that some companies may want all their permits to expire at the same time because it's just more efficient. But the statute says it's in the time that you receive it, so that may require another statutory change or it may be a prorated license.

So the technical part of doing something that seems relatively easy is taking us a little bit more time because if we don't do it the right way, it will really be a worse situation because now you've got people trying -- and then we have to fix it.

So we have looked at -- like I said, we looked at the rule that the Division had, that the Professional Division has, and we're trying to figure out a way to stagger it in a way that makes sense. So I think when that first rule comes out, it may be a matter of trying to do a workshop to

see, because I think we all would think that most people in the industry would want, if they could have it, all of their permits to expire at the same time.

One of the things that we tried to do in product registration was make the product registration permits and the products where they expire at the same time as the manufacturer permit. So in addition to the other permitting licenses for the wholesale distributors, we're also looking at that part of it, too. So it's taking a little bit longer just because if you don't do it right, it really can be -- it can really be bad.

MR. TULLER: Hey, Reggie, not to interrupt you. This is Jeff Tuller.

Have you looked at all of the other states and how they do it? You know, I've been intimately involved with this for about three years, and Florida, it seems, the process -- the way the process works, we have to have a 45 -- we have a hard cutoff on 45 days prior or there's a penalty. No other state does that.

And then in terms of when the permit is -- or the license is actually issued, it seems to take

longer than the actual process in comparison to everybody else. Have we looked at how all of these other states do this? Do they have a hard cutoff date? Because if you look at June, for example, I have 16 renewals in June, I've got 14 in April. You know, they do it half year and done kind of a cross-analysis and said, you know, generally speaking what's easier for, you know, taking your resources into consideration, taking into account, you know, what that application involves because that application, it's 11 pages. And then you have a PIS statement for every individual within the corporation that has to be filled out, and it is very comprehensive.

And I'm not faulting us for doing comprehensive work. I think it's terrific. And for all the reasons you mentioned in terms of compliance, in terms of regulation, in terms of enforcement, you have a back story here to do that.

What I was hoping was, number one is we slim this process down where your initial process is all the paperwork and you do the due diligence proper and very forthright and great, that's the way to do it. California does it very similarly.

But after that, you go to a renewal process that's somewhat streamlined, as long as there's no significant changes, change of ownership, change of location, those type of things where you have to drill into a little further to the details. And you guys drill into details so I'm preaching to the choir here from what I see. So that was kind of my impetus of that. So looking at other states and comparing that, I would be happy again as a sidebar here.

MR. DIXON: No, one of the things that we have not done, we have not looked at other states. Truthfully we just didn't have the resources. A perfect example of that is we were recently tasked with the Office of Policy -- OPPAGA, it stands for the Office of Performance and Governmental -- Program Performance and Governmental Accountability -- with some regulations that we were working on, and we ended up having to do a 50-state calendar survey. It took two months. I mean, it really choked out our performance as a Division in that, you know, we've got 30.5 people. And just imagine trying to do, you know, the cross-section study of all 50 states.

But having said that, one of the things that

we have looked at with licensing is a renewal process where -- like, for instance, one of the things we put in the statute for wholesale distributors, it talks about their personal information statement. We're trying to streamline it.

One of the ideas we got from the industry was if nothing changed, why not create an affidavit, submit an affidavit and attach the prior PIS statement. So we're looking at that. We've also looked at the possibility of allowing folks that if nothing has changed, to provide us an affidavit to that effect.

One of the issues that we do have is right now in the statute for at least the wholesalers, it requires to provide all of that information. So that's one of the things that we were looking at.

But as an Agency and as a Division, we have been looking at that to try to make sure -- because if we can streamline that process, then it gives us an opportunity to get permits out, issued fast. So we have looked at that. I know we're looking at the statutory requirements for renewals.

As far as the penalty, I'm not sure why the penalty went into place. I could guess that it's probably to incentivize folks to apply early enough so that you don't have the situation where if you don't -- because if you don't apply on time, then your permit expires. If you get your application in ahead of time before the permit expires, then you can continue to operate.

But I think the way Florida law is written is if your expiration date is on the 31st and that application is not postmarked by the 31st, the application is postmarked on the 1st, you have not timely renewed and we cannot as an Agency tell you that you can continue to operate.

So I think that penalty was put in there -- like I said, I wasn't around, I'm not sure how many people were around -- but I think it was put in there to say, well, most folks want to save the money so they're get the application in in a sufficient time so even if we don't get the application approved prior to the renewal, then we can tell you based on the fact that you got your renewal application in early you can continue to operate.

MR. TULLER: Reggie, again, not to interrupt

you, but I think when you come to that penalty, you can do it in reverse. You can actually -- you pay it by this date, you pay X, you pay it by the end date, you pay Y, versus you're paying, you know, Y plus the fee.

Do you follow what I'm saying?

MR. DIXON: Absolutely. I think that's okay.

MR. TULLER: So these are little things. I don't know what it means to us in comprehensive numbers, and I have no idea what those numbers are, but I would be happy to give you some of those ideas.

MR. DIXON: Yeah, I don't think it's a revenue-generating issue.

MR. TULLER: Then if it's not, then incent to have it early.

MR. DIXON: I think the problem is --

MR. TULLER: And then I think you'll have the response that you're looking to get.

MR. DIXON: I just think the problem might be, from what I can tell just from the last couple of years, we would not want -- we try not to be in a position of having to tell folks you can't operate. And we've come across that a couple of times where people accidentally didn't do it. And

what we've had to tell folks -- and it doesn't happen a lot, but we've had to tell people we can't give you a letter that says you're authorized to continue working.

MR. TULLER: Yeah.

MR. DIXON: Even though what you are providing, the service or the medication that you're providing -- in some cases, there was a shortage of medications. So I do think that that may be the problem for it.

Changing the legislation on that can be difficult in a sense that it took us I guess two, two and a half years to get at least as close to being as DQSA compliant as we could with the bill last year. As an Agency, what we try to do is we solicit input from the industry as to possible bills, but at some point it is a policy call on whether or not the Agency actually will put forth a bill that changes the provisions of Chapter 499.

But what we will do if someone in the industry puts forth a bill, if they work through their lobbying efforts to get a bill, what we do -- they always -- normally folks will meet with us ahead of time and then we'll talk about the language. And then if they write a bill and they

get a sponsor or whatever, then we will give them our input on how to make the bill better or possible ramifications to the industry or we've contacted people and we've spoken to people about the bill.

I can tell you this year our Agency does not have a bill that changes anything in 499. I know that there is a cosmetic regulation bill -- registration bill. I'm not sure of the process as to whether or not that's open to someone to tag on changes to the licensing applications for wholesaler distributors. It may be something that someone may want to look into.

MR. TULLER: Sure.

MR. DIXON: You know, we can provide input and resource into background information that you all like on that, that wouldn't be a problem at all.

MR. TULLER: Correct me if I'm wrong, but your PIS statement that every wholesaler has to fill out this year does have a signature and a check box that says if there's no changes you move to, you know -- and I think there's two sections where you check off and move on. I did them last night so I was kind of looking over all of this

before I came to see you, so I think you do have that in place, an affidavit. You do have a signature affidavit. You do have to supply the proper documentation, pictures and so on and forth.

MR. DIXON: Right.

MR. TULLER: Nobody else requires those things.

MR. DIXON: We tried to update the PIS statement to make it easier for folks.

MR. TULLER: Right. If I don't get a deficiency letter, Reggie, I'll be glad. I think you've moved in that direction and I thank you for moving in that direction.

MR. DIXON: One of the things about us being a smaller Division, truthfully, is we have to be more efficient, we have to try to work on the applications, we have to try to do things. Because if it's a deficiency for you, that means we've got somebody in the office that's got to be responsible for tracking it, for following up with you, for reviewing additional information that you send in, so that's time on our staff where they could be doing something else, too.

MR. TULLER: Well, Reggie, at the point where

your license is in limbo, that's when the due diligence process starts because everybody's asking you for that copy of your Florida license. And we're distributors in Florida so, you know, I get the calls and we don't have it and they go to the website. We don't want to go to the website, we need the verification. So that creates the $25 check that goes to the board that we have to get a verification to send to people while we're all in limbo and all in process even though I've submitted in 45 days. I'm just trying -- whatever we can do to shorten that process, streamline, make more efficient would be very helpful I think to us all in the wholesale world.

MR. ELLIS: There is a chapter in -- or a statement in 499 that addresses, that you can send to the manufacturers or whomever.

MR. TULLER: I do. I have.

MR. ELLIS: Okay.

MR. TULLER: The problem is some of them want the gold seal, you know, they want the gold seal. And then they get the gold seal. And it seems like when the application comes in, the check goes in one direction, I guess, and the processing happens in another. So a lot of times I have to

go back and research a check to send over to you to again release the gold seal.

MR. DIXON: Yeah. And part of our process is that when an application comes in, the check and the application gets separated on the profile so that the revenue is received and the application. We have a team within the Agency that will scan all the applications in, profile it, meaning putting certain demographic information with the application so that our licensing team can process the application without always having to have all the paper all over the place. And sometimes there's a lag between the time that the check is received and the time the Division actually gets that profile information, yes. We try to cut the time down.

MR. TULLER: Yeah. Just a point of interest here that I wanted to bring up, so I appreciate your comments on that, Reg.

MR. DIXON: I tried to put those two together. But were there any other questions about what the Division is trying to do with respect to our applications, online applications?

(No response.)

MR. DIXON: Like I said, again, as the paper

applications get done, what you'll see is hopefully the PIS statements, we will make it a lot easier for you all to fill out those. And as you come across those, I suggest that you see things about them and you submit them to us, we'll look at them and we'll try to -- and that's kind of how we try to improve the application.

And sometimes it takes a little while longer to do the rule making, it takes usually about 90 days. So it may be a little bit longer sometimes when the applications are more complicated or you're trying to make sure that you're putting certain things in the right way so that, you know, you're not answering the same question four or five different ways, that kind of thing.

But any questions that you all have regarding the applications or any rule making? If you don't have any, you can always send them to us. You can send them to Ms. Greene and she will make sure they get to the appropriate folks.

MR. ELLIS: Reggie, is the licensure term, is that a legislative change or is that a rule that --

MR. DIXON: It is a legislative change that gave the Department rule-making authority. So

before that legislative change if you were a wholesaler, you could only get a one-year permit.

MR. ELLIS: Okay. So the term that the permit can be is a rule change now?

MR. DIXON: Right.

MR. ELLIS: You can do that under a rule change?

MR. DIXON: Right.

MR. ELLIS: Okay. Great. Thank you.

MR. TULLER: 3PL's are two years, correct?

MR. DIXON: 3PL's are a two-year permit, yes.

Are there any other questions about Tab 3?

(No response.)

CHAIRMAN MAYS: Any questions from anybody on the phone?

(No response.)

CHAIRMAN MAYS: Finally the last thing under Tab 4, just for informational purposes, you'll see the meeting transcript from our December 1st meeting.

Is there any other business for the Council?

(No response.)

CHAIRMAN MAYS: Anything from anyone on the phone?

(No response.)

CHAIRMAN MAYS: Hearing none, do we have a motion to adjourn?

MR. TULLER: So moved.

MR. ELLIS: Second.

CHAIRMAN MAYS: All in favor, say aye.

(Chorus of ayes.)

CHAIRMAN MAYS: Opposed.

(No response.)

CHAIRMAN MAYS: The meeting is adjourned. Thank you.

(Whereupon, proceedings were concluded at 11:00 a.m.)

CERTIFICATE OF REPORTER

STATE OF FLORIDA)
COUNTY OF LEON)

I, MICHELLE SUBIA, Registered Professional Reporter, certify that the foregoing proceedings were taken before me at the time and place therein designated; that my shorthand notes were thereafter translated under my supervision; and the foregoing pages, numbered 3 through 80, are a true and correct record of the aforesaid proceedings.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 2nd day of March, 2017.

MICHELLE SUBIA, CCR, RPR
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