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

IN RE: APPROVAL OF MINUTES, CHAIR'S REPORT,
DIVISION DIRECTOR'S REPORT, OTHER BUSINESS

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DBPR
HEARING

DATE: August 6, 2015
TIME: 9:30 a.m. - 11:45 a.m.
LOCATION: Professions Board Room
1940 North Monroe Street
Tallahassee, Florida 32399

Reported by:

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ORIGINAL

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
APPEARANCES:

GARY CACCIATORE, CHAIR
REGGIE DIXON, DIVISION DIRECTOR
RENEE ALSOBROOK, CHIEF OF COMPLIANCE
DINAH GREENE, ADMINISTRATIVE ASSISTANT
STEVE MAYS, PRIMARY PRESCRIPTION DRUG WHOLESALERS
JEENU PHILLIPS, BOARD OF PHARMACY
PETER HART, AIRGAS INC.
WILLIAM MAHONEY, PRIMARY PRESCRIPTION DRUG WHOLESALERS
DEAN ELLIS, SECONDARY PRESCRIPTION DRUG WHOLESALERS

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
MR. CACCIATURE: Good morning everyone. This is Gary Cacciatore, Chair of the Drug Wholesale Distributor Advisory Council, and I'd like to call this meeting to order.

Before we start, a couple of housekeeping items: I'd ask the people on the phone to please put yourself on mute. We're already getting some interference from some of you. So everyone on the phone, please put your phone on mute. And make sure it's on mute and not on hold. We don't want to hear any music from anybody's hold music. So once we open up to the public comments, you can take yourself off mute before you talk. I know we have a couple of council members that are on the phone as well. I'd ask them to do the same.

Thank you.

For the council members, make sure if you want to speak to press the button and speak into the microphone so everyone can hear you. Also, so everyone knows, we do have a court reporter here today -- something that we don't always have -- so I'd ask that everyone to identify yourself before you start speaking so the court reporter knows who's speaking, particularly for those people on
the phone but also for people in the room as well. Okay. With that, I'd like to turn it over to Dinah for the roll call, please.

MS. GREENE: Gary Cacciatore?
MR. CACCIATORE: Here.

MS. GREENE: Mike Ayotte?
MR. AYOTTE: Here.

MS. GREENE: Steve Mays?
MR. MAYS: Here.

MS. GREENE: Scott Brock?
MR. BROCK: Here.

MS. GREENE: Jenn Ugru? Dean Ellis?
MR. ELLIS: Here.

MS. GREENE: Bill Mahoney?
MR. MAHONEY: Here.

MS. GREENE: Patrick Barnes?
MR. BARNES: Present.

MS. GREENE: Dr. Mendez? Jeenu Phillips?
MR. PHILLIPS: Here.

MS. GREENE: And Peter Hart?
MR. HART: Here.

MR. CACCIATORE: So we do have a quorum. Thank you. And I'm going to welcome -- some people have their first in-person meeting.

Jeenu Phillips and Peter Hart, welcome. Nice to
meet you in person, finely.

MR. PHILLIPS: Thank you.

MR. CACCIATORE: As many of you know, we only
meet in person twice a year. So a lot of us have
been on the phone many times. And I think I
missed one meeting, also, as well, so welcome.

We will start out with the Tab 1 in the
agenda, which is "Approval of Minutes," under
May 14, 2015 meeting. Hopefully everyone's had a
chance to review those minutes. Are there any
corrections or edits to the minutes? Hearing
none, I'll entertain a motion to approve the
minutes.

MR. PHILLIPS: So moved.

MR. CACCIATORE: Move, a second? Is there a
second?

MR. ELLIS: I second.

MR. CACCIATORE: It's been moved and seconded
to approve the minutes. All in favor, signify by
saying aye.

MR. MAHONEY: Aye.

MR. MAYS: Aye.

MR. ELLIS: Aye.

MR. AYOTTE: Aye.

MR. CACCIATORE: Any oppose? Minutes are
approved. Thank you. Okay. We're going to turn to Tab 2, which is the "Chair's Report." And I want to spend some time talking -- two things under the "Chairs Report:" We're going to have a presentation from Heather Zenk on the Drug Supply Chain Security Act.

But before we do that, we're going to discuss the Florida Board of Pharmacy Controlled Substances Standards Committee, which I mentioned at the last meeting that I was going to attend that meeting, and Jeenu Phillips was on the committee as well. So we want to give a report from that meeting. And actually, one of the results from that meeting was a request to come back to this council for recommendation. So I'll talk a little bit about that.

So on June 9, 2015, the Florida Board of Pharmacy held a meeting of the -- a subcommittee that they formed, called the Controlled Substances Standards Committee. This committee was put together, as I mentioned last time, in an effort to address issues that have been out in the media and have come out about patients having difficulty getting access to controlled substance prescriptions.
Issues that pharmacists aren't comfortable filling prescriptions and are being denied. And then it spills over a little bit into the wholesale Industry where some of the pharmacies are complaining that they don't have enough supplies to fill the prescriptions for these patients.

So speaking on a very, very big issue. Some of you may have seen the media reports. It's gone to the Governor's Office and to the Attorney General's Office. So to their credit, the Florida Board of Pharmacy said, you know, before we do any legislation to try to address this issue, let's get together and talk about it with all the stakeholders. And they formed this committee to address those issues.

The meeting was packed with people, and they allowed members of the public to come up and provide testimony and then members of the pharmacy profession, the medical profession. I was really the only wholesale representative there, so I gave a statement on the wholesaler perspective. And then the committee's really just trying to find solutions.

The committee's made up of five Board of
Pharmacy members, and then they invited some special committee members or nonvoting members to represent different parts of the Industry. So I was there to represent the wholesale Industry. There's also representatives from the Florida Medical Association, a pain management physician, the Chain Pharmacy Industry, the Florida Pharmacy Association, and Florida Board of Osteopathic Medicine.

So one of the issues that several of the pharmacy commentators had got up and spoke about were difficulty getting enough controlled substances from their wholesalers. And the chair of the committee asked me to come to this council to address that issue and talk about how wholesalers meet their responsibilities under the Controlled Substances Act, at the same time, while still making sure people have that adequate supply.

So what they're looking for from our council today, actually, are any legislative -- possible legislative changes that need to be made, any rule changes that might need to be made that could help address these issues.

So what I put into the agenda was the one
area of Chapter 499 where this is addressed. And if you look at Tab 2, it says -- Section 15 -- that Section 15 of Chapter 499.0121, which talks about "Due Diligence of Purchasers." I put that in there just for discussion purposes to talk -- to talk amongst ourselves about how you guys implement this.

Do you feel like there's language in here that's causing issues for wholesalers? And if there's any recommendations we can make to make sure that the pharmacies have adequate supplies to fill legitimate prescriptions while still meeting our responsibilities under the DEA and the Controlled Substances Act. So Jeenu, do you have any other comments from the meeting you want to add to that?

MR. PHILLIPS: I think you summed it up very well. The primary purpose is to see if we can find solutions. And I think one of the -- you know -- the multiple reasons why patients can't get their medications -- you know -- and one is fear by pharmacists of discipline or possibly lawsuits or, you know, patient harm coming from it. The other side is that pharmacists want to dispense it but they can't because they can't get
And so they struggle with the -- you know -- with their respective wholesalers and actually getting this medication for legitimate patients. And I think we had multiple pharmacists mention that. So I think where we, as a group, can come together and see if we can do anything about it, seeing if we can help the wholesalers be able to delivery these medications to the -- to the respective pharmacies without fear of, you know, any type of government agency coming down on them, whether it be the DEA or the -- or any of the state agencies.

So I think that that's where -- if we can -- I think this section of the -- of the law here is -- I think the only place where we have any -- any opportunity.

MR. CACCIATORE: Thank you, Mr. Phillips. I think, you know, one of the points that was made at the meeting that I tried to make to bring the wholesalers perspective is that we have obligations we have to meet under the Federal Controlled Substances Act and the DEA rules. And there's a lot of -- a lot of the comments that were made by some of the pharmacies were -- they
kept using terms like that the wholesalers are setting arbitrary thresholds and, you know, the fill basis for these thresholds are limits set at the amount of controlled substances you can buy.

So I bought the perspective -- you know -- from my company -- from part of the health perspective -- that we do have thresholds and limits, but they're not arbitrary. You know, there's a lot of science and statistics that go behind that, and we're trying to do what DEA has told us we need to do. So that's one point that I tried to make clear, that they're not arbitrary.

I do have some concerns with statutory language in Florida, because it's not consistent with the federal regulations. I don't know if that's playing a role or not in restricted the supply. You know, as you can see in Section b here, there's language that specifically talks about evaluating the words "for greater than 5,000 dosage units of any one controlled substance in any one month."

That language does not exist under the Federal Regulations Law. I don't know if that's somehow influencing wholesalers to limit quantities of 5,000 per month. So I'd be curious
to find out how people -- how people comply with this, do you feel like this is something that needs to be changes. Because this is a statutory thing. This is not something the Department can do. It would be a legislative change.

But remember our goal is to make -- part of our objectives here at this council is to make recommendation to the Department for new rules. We can also help make legislative recommendations as well. Any discussion on that?

MR. MAHONEY: Hi, this is Bill -- Bill Mahoney. I was at the meeting. I thought you did a good job of discussion what the wholesalers are doing on multiple fronts in order to execute our responsibility. It is not arbitrary. And there are a variety of programs and efforts that we have going on.

One thing I've always thought as a result of 7095, the information that we provide to the DBPR, with regards to our distributions, I think it's intended to be used to analyze what is normal -- where those norms are. Because I think for some drugs, 5,000 is greatly in excess of what the norms are. And yet others are less than the norms in the course of a month for very average
And I think it would be helpful to all of us and to the community to do some sharing publication of that, so we can use that in honing the programs that we have to perform our responsibilities, both for the federal and state requirements.

MR. CACCIATORE: It's a good point. And I think, really to me, the 5,000 is kind of arbitrary. And to me, the statute, itself, is unclear, because it talks about 5,000 unit doses of one controlled substance. Well, is that talking about all Oxycodone products or is it talking about -- is Percocet considered one controlled substance and then Oxycodone -- you know -- Percocet and Percodan, they both have Oxycodone in them.

What is a one controlled substance? Is it just based on the DEA base code or is it based on that particular brand of that particular product? So to me, the statute, itself, is unclear. So I think one of the recommendations would be to get some clarity around what the expectations are here. Any other comments on that?

MR. AYOTTE: Mr. Chairman, this is
Mike Ayotte. I hope you can hear me okay.

MR. CACCIATORE: Go ahead, Mr. Ayotte.

MR. AYOTTE: If I remember correctly, the original legislation was actually a hard stop. And I think the prevail to just do it so that that may be more over the established amount would be assessed by the wholesaler.

I'm not sure 5,000 is an accurate number. I agree, I think maybe looking at the historical issues to try to figure out what's normal. And what is normal today in Florida may be different than what this bill past originally. So there may be some need to look at the numbers. But that process was, I think, a substitute for a hard stop, because that was, I think, in the original bill.

MR. CACCIATORE: Thanks, Mr. Ayotte. That's very helpful.

MR. BARNES: Mr. Chair, this is Patrick.

MR. CACCIATORE: Go ahead, Patrick.

MR. BARNES: One of the things -- and I don't know if this is a legislative adjustment, but we've had times when we met our allocation, and it was stopped. We were no longer aloud to receive, for the rest of that month, that particular...
controlled substance.

And I don't know if there's something in place of how you increase that. And I'm sure it's probably wholesaler specific. But I was sent some pretty good data, but we were still denied. So I don't know if something like that could be addressed as to when -- or the proper way of meeting your allocation increase.

MR. CACCIATURE: Thank you, Mr. Barnes. I appreciate that. That's something else that I think that was discussed at the meeting that I tried to emphasize, too, was that the key to this, really, from the wholesaler's perspective, is better communication between -- between the pharmacies and the customers and your wholesaler.

And I actually talked about that specifically. I said, you know, if a pharmacy -- hospital or pharmacy needs more controlled substances, they need to communicate that information. You know, for instance, if a pharmacy signs a new long-term care contract or servicing a legitimate pain management type of -- or oncology facility or something like that, that information has to go back to your wholesaler so adjustments can be made.
So communication, I think, is the key. So I think one thing we can do is continue to encourage, you know, better communication between the wholesaler and their customers. I mean, I can speak for our company. Those are the types of things that we try to tell our customers, that if you need more than you're being allocated, then you need to let us know why and document that. And I assume other people do the same thing.

MR. MAYS: Mr. Chair, this is Steve Mays. Couple other points to make, and, you know, I don't know if this will actually help solve the problem. But it's part of the problem too is that the requirements placed on distributors by DEA are, you know, fairly vague also. There's no numbers mentioned. This is too much. It's just design a system to this to detect suspicious orders and then we have to determine, ourselves, what is suspicious based on our own parameters.

And also, we don't want forget the manufacturers have a role. Manufacturers are often in contact with us to say, you know, why did you purchase this much more. So they're actually monitoring our purchases from the manufacturers also. So there's a lot of components to this.
But again, I go -- you know -- you know, I agree with your assessment that the communication is key. And, you know, we're being held to a pretty tight standard by DEA to -- as a distributor to conduct our due diligence of our customers. And again, the more information we are provided by the customers, the more that we can make a determination that yes, they have a legitimate need for more than what that statistical quantity that they've been set up for that month.

MR. CACCIATORE: Thanks, Mr. Mays. I agree with that. And I think a report just came out from the Government Accountability Office, GAO, or Report to Congress -- came out in June. If you haven't seen this, it's called "Prescription Drugs, More DEA Information About Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access." So this is a very timely report by the GAO. So I'm sure there's going to be a hot topic of conversation on Monday at the next Controlled Substance Committee meeting.

One of the recommendations from -- from this report that I'd like to read to the council,
because I think it's something, I'm hoping, that
the council can endorse and maybe take back as a
recommendation to the Board of Pharmacy. It says,
"While DEA officials said they generally did not
believe that enforcement actions have negatively
affected access, better communication and guidance
from DEA could help registrants make business
decisions that balance ensuring access for
patients with legitimate needs with controlling
abuse and diversion."

So one of the recommendations of the report
is for better guidance from DEA, which is
something, I think, a lot of people in the
Industry have been asking for for a long time. So
as Mr. Mays said, there's this vague standard that
you have to identify suspicious orders. And a lot
of people have been asking for guidance and now we
have a GAO report that says that's something that
is needed.

It's an interesting report. And if you
haven't looked at it, I encourage you to read it,
because specifically to distributors, they ask for
guidance. They said that there's things like the
DEA pharmacist manual to tell pharmacist guidance
on how they can comply. There's a practitioners
manual. There is not one for distributors. You know, DEA has argued that it can't more specific information because the variables as to what determines a suspicious order vary among distributors. But the report says -- the report says that specifically for distributors, distributors need more specific information and guidance from DEA.

So overall, I think this is something that I think the Industry would support and can endorse and might be a good first step in helping making sure that patients have access and the pharmacies have access to the drugs to fill legitimate prescriptions. So any comments on -- anybody else look at that report yet?

Okay. I'd like to get a couple of recommendations from the council to take back to the committee. A simple resolution stating what the council recommends can assist in this area. So I'm going to open the floor for recommendations for that.

MR. MAHONEY: Mr. Chair, Bill Mahoney. My recommendation would be some kind of publication maybe on a periodic basis of what the aggregate average a pharmacy distribution numbers are for
different base codes, so that we can use that in assessing, for ourselves, added data that will be helpful in determining where these levels, limits, statistical variations come from.

MR. CACCIATORE: And is that something you would expect to come from the Department -- from the controlled substance reporting?

MR. MAHONEY: I'm hoping that it will be an output from our monthly reports to the DBPR. Just feedback that will help us in our responsibilities there.

MR. CACCIATORE: Any discussion on that?

MR. AYOTTE: Mr. Chairman, this is Mike Ayotte. I guess -- I guess when you look at this, you have a lot of different reporting vehicles, and I'm not sure we have a global view of it all.

So you have the E-FORCSE information from the PDMP, you have the information that the Department gets. You know, it may be -- it may be a time to step back and maybe look at the issue in Florida where they are with this whole problem. And if it's still a problem, which, you know, you never know, but maybe there's been some resolutions to where, you know, Section b should be reviewed to
figure it out whether or not it's still applicable or needs clarification. Because I think one of the points you brought up was any one controlled substances, I think is very vague.

But I'd love to see all of the data make it to one place so that we have a -- so there's a few; right? There's a few that the utilization hasn't dropped. But when you read the PDMP data, it shows that the (inaudible) et cetera, has diminished.

So I get if we had a wholistic view of the whole picture of all the reports that are available on the topic. It might help us to go back and say, you know, maybe this is not -- this is not the right sentence. We need to amend Part b to read x. Because I don't ever think you're going to get out of the ability to say that this is not what we should do for orders. And I think you have to know your customers and the DEA piece of this whole pie,

But I think, perhaps, maybe that relief might be a little bit -- maybe it's 7,000, maybe it's 9. I don't know what the right number is. But I think at that point, when this is being done, there was a sense that you clamp it as tight as
you could to solve the problem, and I think we need to maybe go back and (inaudible) swing back a little bit. And maybe that's the way of doing it is taking the data that was just mentioned, look at what's going on with the PDMP data, and really have a bigger picture.

MR. CACCIATORE: Let me ask a question: Do the council members feel like the language in the statute -- even though it is kind of vague and unclear about what they're talking about -- does the 5,000 dosage unit language create problems for anyone? Do we feel like that's actually restricting access? Because if not, maybe it doesn't need to be changed.

MR. MAYS: This is Steve Mays. I don't think the 5,000 number, because we basically review all controlled substance in the orders in our system, so it doesn't matter whether it's 5,000 or 1,000 or 10,000, you know, we're going -- our system, you know, reviews all orders of controlled substances based on their own parameters.

So I'm not sure it really has a lot of value, you know, if you have a sophisticated suspicious order monitoring system. And I guess one other point I want to make is that the substance abuse
has a local and regional nature to it too. So there's different parts of the country -- you know -- being a national distributor, we've see trends of abuse of different drugs in different parts of the country. So it may be Oxycodone in one state, and it may be Promethazine with Codeine in another. So it's really tough just to throw out a number and say that's excessive.

MR. MAHONEY: Mr. Chairman, I agree with what Mr. Mays is saying in terms of the sophistication of our measurement techniques. What I'm hoping for is that we get some feedback at the universal level as opposed to just our slice or segments of customers.

I just think more information out there would speak to where we are, relative to where we've been, and where we're going. What is an emergent trend? Part of the Florida -- or Florida relative to the rest of the country or in the various segments that we deal with?

MR. CACCIATORE: Mr. Mays, go ahead.

MR. MAYS: This is Mr. Mays. And I don't think I'm making this a recommendation, because it's -- I'm not sure about Florida. I guess it's a question. Is the PDMP in Florida a mandatory
program or voluntary? And I know just from what
we've seen in a lot of state where it's a
mandatory program. Substance abuse numbers, you
know, have really decreased. And, you know, I
think that's definitely something to always look
at in every state is the prescription monitoring
program and how robust and how active it is.

MR. CACCIATORE: Mr. Phillips.

MR. PHILLIPS: So the PDMP Reporting is
mandatory. So the pharmacies and physicians have
to report. But in terms of actually having to use
it, that's not mandatory. So, you know, you may
get a prescription and decide you don't want to
review that, but if you dispense a prescription as
a pharmacy, you do have to report that within
seven days.

MR. AYOTTE: Mr. Chairman, this is
Mike Ayotte. If I could just add: They produce
an annual report. And what is going on in
Florida, from the time of the PDMP being put into
play, is pretty dramatic. So I mean it's a huge
drop (inaudible) and numbers. So I would just try
to get a whole look at this issue.

MR. CACCIATORE: The other item, I guess, we
can discuss briefly is in addition to the GAO
report, which recommends further guidance, there is federal legislation, which does similar -- similar things. The Ensuring Patient Access and Drug Enforcement Act requires things like -- it defines things like eminent danger. Because as we all know, DEA has come in on several times and done immediate suspension orders.

And so this pending federal legislation defines what eminent danger -- which they can't do an immediate suspension order unless it's a eminent danger to the public health. So it defines what that is. So that's further guidance that would help. It also has requirements for Show Cause Actions that DEA does.

So that's something else, I think, that's a positive step that allows the Industry to work with DEA, so that we're not in fear of DEA.

That's what causing some of these problems. So that's something I would think that would also be helpful. Anybody have any thoughts on that?

MR. PHILLIPS: This is Jeenu Phillips. So could you -- maybe the wholesaler distributors in the room, could you maybe give me some perspective in regards to decision-making process for, you know, when a pharmacy reaches a -- whatever
threshold is set, is there a warning given to those pharmacies indicating at the certain we're no longer going to be sending you anything until the end of the month or is there -- I guess -- what's that process? What does that look like?

MR. MAYS: This is Steve Mays. You know, in the system that when we were developing -- you know -- enhancing our system back in 2007, I think DEA had a concern with us communicating to pharmacies when they were reaching their threshold because then they felt like that was enabling someone that was truly diverting to make sure they stayed to kind of gain the system and stay under those thresholds.

In many cases -- most cases, pharmacies have secondary and sometimes even third suppliers, so they were concerned that it would enable that pharmacy to go right up to that threshold, if they knew what it was, and then start purchasing from another wholesaler to keep from being reported to DEA. I'm not sure that answers the question.

MR. CACCIATORE: The other thing is -- I think sometimes DEA's response to this is that they don't tell wholesalers to set limits or thresholds. But yet, through their enforcement
actions, their enforcement actions make clear that
they expect -- they expect wholesalers to do that.
So while it's not specifically under regulation,
most of the enforcement actions have been because
of the excess volume.

And if you look at the press releases from
most of the enforcement actions, it talks about
they sold so many of this particular controlled
substance to this pharmacy and the average
pharmacy purchases this much. So it's all about
volume; it's all about volume.

So while there's nothing specific that says
that you need to set thresholds, this vague
regulation that says you must design a system to
identify and report suspicious orders, the only
mechanism to do that is to set thresholds. And
that's been the expectation from the very first
enforcement action. The very first enforcement
action that came out, they -- a company presented
at a DEA conference: This is what DEA expects and
this is how we set the thresholds.

So again, that's where you have this vague
regulation. That's the way most wholesalers do it
with some type of threshold. But again, it's not
arbitrary. It has to rely on actual data. And it
can't be an average, because you've got pharmacies that are filling 5,000 prescriptions a day versus pharmacies that are filling 100 prescriptions a day. So it's very difficult for the wholesalers to have a flat number.

DEA's own comments to the GAO report say wholesalers should look at -- rather than giving more guidance -- they said wholesalers should look at enforcement actions that DEA has taken to know what not to do. So when we look at those types of enforcement actions, they are all based on volume. The natural reaction for the Industry's going to be -- you know -- we've (indiscernible) volume.

Because if we don't identify -- you know -- we've got thousands and thousands of customers, but they can take an enforcement action because you sold to one customer who was diverting drugs. And if they take an action against a wholesalers, it affects that distribution center. It's a huge impact, because that wholesaler distribution center services thousands of customers -- maybe multiple states.

So you know, it's a huge risk to a wholesaler for the DEA registration, because they sold to one particular pharmacy who was diverting. Sometimes
there's been enforcement actions where it's been based on sales to two pharmacies or four pharmacies or eight pharmacies. So those types of enforcement actions are going to cause wholesalers to be conservative in their approach.

And as Mr. Mays mentioned, even the manufacturers have a role in this. They are monitoring what we purchase from them. If we increase our sales, they want to know why. So it kind of goes all the way down the line.

MR. PHILLIPS: Is there -- is there an issue with like manpower doing site visits on some of these pharmacies? Would you say that that's part of the problem?

MR. CACCIATORE: Again, there's a lack of guidance on that, but they -- DEA has said they expect wholesalers to know their customer. So what is entailing of knowing your customer is knowing the type of business they have. It may require site visits; it may not. I think that varies from company to company.

I think when we have a question or if someone is exceeding the threshold, needs to increase their threshold, many companies will do site visits to verify that. But that's going to vary.
from company to company.

MR. MAYS: And this is Steve Mays. You know, in the guidance -- what little guidance we've gotten from DEA, as far as what type of due diligence to do, as you said Mr. Chairman, is sometimes -- you know -- they expect us to at least know it's a pharmacy, you know, to go there and visit, make sure that it is really an operating pharmacy.

And a lot of this goes back to the days and -- you know -- the 2005 to 2007 when Internet fulfillment pharmacies were elicited. Fulfillment pharmacies were out there and they were operating out of, you know, storage buildings and houses and things like that. So now it's almost like the suspicious order, because we really don't know -- there's not really a regulation that says here's what your due diligence should consist of -- you know -- of a customer, you just need to do your due diligence.

And so there's a lot of data, and then there's some question about whether, you know, a distributor should be asking for certain data, you know, whether it's dispensing records and things like that because then it's just -- you know --
and you're beholding -- you know, you're not acting like a distributor at that point; you're acting as an agent. You know, you're starting to get information about how patients -- what patients are getting dispensed to.

So that's a tough thing for distributors now is to kind of decide where's that line. How much due diligence is enough. And again, we have -- as a distributor, we don't want to go all the way up to the edge of the cliff where DEA comes in and, you know, serves an immediate suspension. So we don't know where that trip line is and where that number is for a specific customer.

So somewhere you have to draw that line in the sand. And it's very difficult, you know, but we have to base those decisions on, you know, what our knowledge is of that customer and how they fit into those statistical norms, you know, for customers of that size and that nature. And then there's always going to be specific changes, just depending on that pharmacy's business model and what physicians are in the area, whether it's pain management or whether they're close to a hospital. There's so many variables that go into that.

MR. CACCIATORE: Okay. What I'd like to do
is -- I think we got a consensus that everyone wants more guidance. And that seems to be the major factor. And, you know, the GAO report calls for that, and so I think that's something that -- that I'll take back to the Controlled Substance Committee.

And again, I encourage you to read the report if you haven't read it. Again, just to quote from the report, "More regular communication between DEA and the registrants, including clearer guidance, could help mitigate registrants' fears of taking actions that would make them targets of DEA enforcement action and investigations and help registrants make business decisions, set balance insuring the patients have needed medications without controlling abuse and diversion."

I'll take these comments back to the Controlled Substance Committee saying that, you know, most of the wholesalers felt like we're doing our part to comply with the DEA regulations. We do need -- we do want better guidance from DEA. And I think people need to remember from the pharmacy perspective is that if we identify and order as suspicious, we can't ship it. So that's where the restriction comes in. That's something
DEA's made clear to the wholesalers.

Mr. Phillips.

MR. PHILLIPS: Yeah. The problem with that is the patients don't understand that.

MR. CACCIATORE: Right.

MR. PHILLIPS: So unfortunately, they're the ones who are left, you know, without their medications. And the pharmacist who's facing that patient is the one who has to deal with that. So that's where the difficulty is.

And so it doesn't look like there's a -- it doesn't look like there's a clear answer, you know, without -- I guess without clarity or increased clarity from the DEA, you know, allowing -- allowing the wholesalers -- I guess a greater understanding of what they're able to do without -- you know -- without fear of discipline or anything like that.

MR. CACCIATORE: Yeah. And Mr. Phillips, I wanted to mention, also, something that you brought up at the Controlled Substance Committee meeting was a lot of pharmacists answer to the patients, when they're not comfortable with a prescription that may not be legitimate, is that we don't have any or we're out of it. And whether
or not that's true or not, it's sometimes a
question.
And you made a good point at the meeting was
that a pharmacist needs to be honest with them.
Because when that happens, a lot of times, I
think, the patients are left with the impression
that the pharmacies can't get enough of this
stuff. And a lot of times that's just the case.
I was a pharmacist a long time ago. Some of
them are non-confrontational and they just have --
I'm just going to tell them that I don't have it.
And that's not the solution either. And as a
wholesaler now, sometimes that comes back on us.
People think that they really do have it in stock.
So I appreciate those comments that you made. Any
further discussion on that?
MR. MAHONEY: Yeah. Mr. Chairman, there was
one area where -- I was there at the meeting, and
I was surprised at the request for total
transparency because of the pharmacy safety issues
around it. I think that if someone is there
illicitly and they're response is that I am making
a judgment about you, that can be a dangerous
thing for a pharmacist to say. And I think that
whole push, especially on the part of the
practitioners to enforce that, was questionable.

MR. PHILLIPS: I can speak to that a little bit. Like you, I used to practice a long time ago as well. My wife is also a pharmacist, and she's petite. She's like 5 foot tall and maybe 100 pounds soaking wet. So she has to deal with this on a daily basis.

And, you know, there is that fear. But I think it's one of those things where it typically has nothing to do with saying no; it's treating the patient with respect. And if you treat that patient with respect, even if you say no, there's usually almost -- you know -- there's very little chance something will happen.

And most of the time, when there is that confrontation and whatnot, it usually comes down to the patient feeling like they're treated like a drug addict, even if they are -- you know -- or even if they're dependent, it made them feel like that. And a lot of times it's about, okay, focusing on the solution with the patient.

So if it's a -- you know -- if it's a situation where they're not -- the pharmacy's not comfortable dispensing it, being honest with them why, you know, and as much as possible. You know,
and that typically creates that bond with the patient, creates the trust, and they're able to see, okay, maybe this dosing is what I'm more comfortable with. Let me work with your doctor to lower the dosing. This medication is a combination of therapy is what I'm uncomfortable with. I can work with your physician on changing that.

So if they're honest with them about what they're comfortable with, in terms of dispensing it, then, you know, usually that solves that. But a lot of times, they just -- they don't want to deal with that and go through that, so they just tell the patients, I'm out of it.

MR. MAHONEY: Thank you.

MR. CACCIATORE: Any further discussion? Any comments?

MR. AYOTTE: This is Mike Ayotte. I need to check one thing. If I understand you correctly, your recommendation is -- well, we'll have a motion that your guidance is going to be concerning that you're asking for additional guidance from the DEA as the recommended solution?

MR. CACCIATORE: Correct.

MR. AYOTTE: Okay, thank you.
MR. CACCIATORE: Any further discussion?

MR. PHILLIPS: I guess, just for clarity, so when you say "looking for guidance from the DEA" is really clarity or decrease in vagueness?

MR. CACCIATORE: Yes.

MR. PHILLIPS: Okay.

MR. CACCIATORE: And I do encourage other companies and other members of the council to attend the meeting. It is Monday in Deerfield Beach at --

MR. PHILLIPS: 2:00 p.m.

MR. CACCIATORE: -- 2:00 p.m., if you could attend. They do take public comments and the more people we have from the wholesaler Industry there, I think, probably the better, because we are going to be a big part of the discussion, as well as the pharmacy piece of it. So I encourage everyone to attend if they can. Any further discussion on that? Anyone in the audience here?

MR. DICKS: Martin Dicks. Just on this due diligence of purchases, when this past -- and DDC was still over at the Department, Greg Jones had -- held some kind of a conference, and he said the 5,000 unit was per NDC at the time. But whether that's still the Department's position, I
don't know. But that's what -- he held a big
meeting where he went over all the changes that
happened in that bill. And that was one of the
things I recall him saying. But there's probably
a record of that somewhere in the bells of the
Department.

MR. CACCIATORE: Thank you, Mr. Dicks. I
appreciate that. And again, I don't think the
5,000's really creating an issue. I brought it up
because it's in there. I was just concerned that
some people in the Industry may see that as a
strict limit. But that's not must it says. It
just say that you must assess the order and do due
diligence.

And to Mr. May's point, I think most of the
Industry -- because of the DEA regulation that
says that you must have a system to identify
suspicious orders. Most of us assess every order
to see if it's suspicious, because you definitely
can have orders that are suspicious that are below
5,000 in a month if it's something up unusual.

So it doesn't conflict with the federal law.
In fact, I view the federal law as being stricter
because we have to assess every order. I was just
cconcerned that others out there may be
interpreting this as I can't sell more than 5,000. But it doesn't seem to be the case, so it may not be a problem that we need to really address.

Okay. With that, I will turn to the second item in the "Chair's Report." And I'll ask Mr. May's to introduce our speaker.

MR. MAYS: I'd like to introduce Heather Zenk from AmerisourceBergen. She is our Vice President of Secure Supply Chain, and she has pretty much got, you know, hands-on -- every day hands-on work with the DSCSA implementation for our company -- for our entire enterprise. So I'll turn it over to Heather at this point.

MS. ZENK: Thank you. And thank you for the time today during your meeting. A couple level sets here: I do have a doctorate of pharmacy. I graduated from the University of Minnesota. And you have to say it that way or they won't give you your degree. And like Gary and others, it's been quite some time since I've formerly practiced, but I do hold two state active licenses, both in Illinois and Minnesota.

And one more disclaimer: I'm not an attorney. I'm not as smart as Gary is and others in the room -- back here, too, I'm sure -- so some...
of this is what we'll go over. And I know I have
an esteemed colleague, Martha Russell at Cardinal
Health who spoke with you in a previous meeting.
And I know she went through a lot of definitions
and a lot of the jargon -- I'll call it -- in the
statute.

What I'll show you today is a bit of a recap
around that but also, how we're communicating at
AmerisourceBergen, both with all of our trading
partners, in addition to particularly pharmacy
level, what the requirements are. So we've tried
to take that language and make it commonplace. So
by all means, if there's a few words that may not
be the same as the statute, it's not meant to
cause controversy. It's meant to be some type of
a common language that can be understood.

And then as a quick wrap-up, we'll do what
I'm calling "Hot Topics" -- so a little bit like
the View or the Talk -- at the end to provide some
insight as to what's happening out in the market
place and where is there concerns, issues, and how
is that being addressed currently.

So on the first slide -- for those on the
phone if you have slides that you're following --
what we've been doing as an organization is, both
using this time line slide, both on internally, candidly inside my company's four walls but also, externally with creating partners to make them understand that this is not a federal statute that has a -- in my words -- a one and done.

There are various requirements over the course of the next eight to nine to years that will fall into place. Some of that was by design candidly as we drafted the legislation, which also was a, you know, three to five year process. So by no means is the statute perfect either. When you negotiate for that long, clearly there's going to be gabs and differences in definitions and some gaps that the Industry's still working with.

With that said, what we're trying to vectorially show here is there are times where additional requirements will come into play, but it allows the Industry time, particularly, around serialization at the end of 2017 going forward to 2023. And I know that seems like a lifetime away, but as you're looking at budgeting, planning, and particularly in the manufacturing community, how this is going to happen, many of them are already furiously working at trying to meet that end of 2017 date.
With that said, in addition to that, as more of our companies become global in nature, particularly -- maybe not the pharmacies but the manufacturing community. As a note, we also participate in various global standards organizations, as do my peers, both in Cardinal Health and in McKesson.

And with that said, we are trying to use global standards in a since, one version of the way to comply with these complicated requirements, so we don't have a situation where, particularly -- and I'll just pick on Pfizer -- and I -- disclaimer, I tell them I always pick on them. For example, there wouldn't be a problem with a manufacturer not having the ability to have product available in the U.S. market because of a different requirement that might be happening in South Korea or in Brazil.

So the Industry, particularly the manufacturing and wholesaling Industry, continues to migrate towards global standard. So even though this is a U.S. based law, we're using global standards to comply with that. So some of that is going to be clearly an education level that we need the pharmacies up to speed as to, why
is this happening; I've never heard of this
organization; who are they; how does this work.
And so we really are committed to play that
education role with the pharmacies.

So just a little bit of level set here: The
other thing that we're seeing in the market place,
clearly is we love acronyms, right, but we can't
get away from -- is it DQSA, "The Drug Quality
Security Act," which is the title of the law,
which has two titles in it. Title 1 was the
"Compounding or Outsourcing." And then Title 2 is
"DSCSA" or The Drug Supply Chain Security Act.

So even that is causing, at times, a bit of a
concern. People think it's two requirements; is
it different. You know, we kind of joke. I
remember DQSA as Dairy Queen is Super Awesome,
being a Midwest girl. But at least it's a way.
But DSCSA is the actual title that has all the all
the traceability requirements where I show the
timeline. Those are all the requirements that are
in that requirement.

The other thing is you'll see on this
slide -- so in January when it went into effect
were the passing of the transactional information
statement in history, which are three new terms.
And we'll go over the details of what that encompasses next. But we'll go over -- that was new to the Industry. And so that was information that started to be passed between manufacturers, re-packagers, and wholesalers.

So the intent was to -- in January, let's start to pass this information between manufacturers and wholesalers first and then let's layer in that pharmacy in dispensing level in July, which is now is enforcement discretion until November. And we'll get into more details around that too.

With that said, the other requirements that went into a place in January had to do -- in my words, I call it more business process changes or things where a pharmacy would need the ability to capture and maintain a system and a method if they think they have a suspect or illegitimate product that they see as maybe suspect or illegitimate. What does that look like and what does their internal process look like?

And the other thing that fell on the whole pharmaceutical supply chain, including pharmacies, was only conducting business, what was defined as authorized trading partners. And we'll go into
what that definition is in a minute here.

As I alluded to, there are specific
requirements in July that went into place. That
is when the pharmacy and dispensing community was
now under the ability to accept that transactional
information statement in history. You may see it
as TITHTS. You may also see it as the three T's.
Again, two different acronyms, same concept, not a
different requirement, and also maintain that data
for six years.

On June 30th, the FDA did announce
enforcement discretion around the acceptance of
that data until November 1st. With that said,
they did state that the law is still in effect,
but they were not going to go out and, if you
will, audit or check the tests for that at that
point in time. So by no means is the law not in
effect. That isn't something the FDA had the
pursery to do, but they said, "We are not going to
come out and inspect against that."

With that said, there was kind of -- I'll
call it a subset. They said if you are a
dispensing entity that is required to pass
transactional information statement in history for
whatever business you have in the statute, you're
still required to do that. So in a sense, they said -- in my words -- if you're a traditional pharmacy where you're accepting product from a manufacturer and wholesaler, and you're dispensing product to the patients, more than likely, you do not have a data transmission requirement until November -- or data acceptance.

If you are conducting other types of business where a pharmacy may be perceived as selling pharmaceuticals to a clinic, having maybe a joint distributor/pharmacy license: One, they should be following the distributor and wholesaler requirements. But if there was any reason where they would think they need to pass that information forward, that is not part of the enforcement discretion at this time.

Questions about that one? Because there was a little bit of a nuance there. Okay. And just as a refresher, a lot of times there tends to be a lack of understanding in the marketplace what is the transactional information statement in history. So we really just took these, actually, directly out of the statute.

And with that said, the transactional information is typically static information. So
if you picked up a bottle of Lipitor, again --
sorry Pfizer -- you could see the vast majority of
these items on that physical product, the name of
the product, the strength, where we would not have
that on the product, would be anything to do with
the dates. So any date transmission, clearly, is
not on there.

With that said, there are some
(indiscernible) here under lot number and
transaction date. And the reason for that is if
you are a primary or direct purchasing wholesaler,
this statute does allow for an exemption of not
having to pass the lot number and the initial
transaction date from the manufacture to the
distributor onto other trading partners at that
time.

And the policy reason for that exclusion that
congress agreed to was because of the fact that
right now if you look at packages, the lot number
is a stinky little data set to get ahold of.
There isn't a mechanism to scan or capture that
electronically. It would be human-capture data
intervention, which would cause a lot of stress on
the availability of product and the timing that a
pharmacy could typically order product up until 8
or 10 at night, and the ability for a distributor
to turn that order around quickly for the next
morning, the product access became in jeopardy at
that point. And because of that, congress agreed
to the lot number and transaction date would not
be required data elements if you procure product
directly from a manufacturing entity.

The transaction statement is attestation that
is placed on every transaction set that gets
passed between trading partners. And it attest to
those six sub-bullets under there that the entity,
providing this information is authorized, that
you've received it from an authorized entity,
you've also received all the appropriate
information that you're suppose to have received,
and you didn't knowingly ship, (indiscernible)
anything, et cetera.

And then last but not least, the transaction
history is that attestation and the transaction
information, if you will, if there are multiple
steps in the supply chain. So that's as close to
the concept of Pedigree, as a term that most are
familiar with, that exists in the federal statute.
But the actual term "Pedigree" is not defined and
is not included in the federal statute at this
point in time.

Questions about any details on that? Okay.

So I'm going to go into a few more examples around what specifically is going on and happened in January, and then we'll go into a few more specific details about what's happening in July -- or happened in July.

So one of the things, too, is the preemption. So on the day that President Obama signed the law -- you know -- we kind of jokingly say that it was the day before Thanksgiving in 2023. So we don't know if he pardoned the turkeys and signed the law or singed the law and then pardoned the turkeys, but there wasn't an immediate preemption at that point in time regarding any state laws that had -- any documentation that had to do with recordkeeping, Pedigree requirements, traceability requirements.

Clearly, it was not meant to be, you know, overstepping. It was meant to be -- as an Industry, this is a new requirement and we had some very tight timelines of January 1, 2015. So you're looking at about a 13-month turnaround for an Industry to start to do something different and new and passing that transactional information
statement in history. And so the Industry said, we need a break and a breath to be able to adhere to the federal requirement.

So it'd be very difficult as both a pharmaceutical dispensing and also a wholesaling Industry to change requirements that quickly and also be able to continue to adhere to 28 to 35 different state requirements that were currently in place at that time.

Licensing, particularly around wholesale distributor and the Third-Party Logistics Licensing was also, if you will, preempted. And I know there's a lot of conversation around that also and what's happening and what's coming up. We will talk about what the FDA and what the next steps are for licensing, both at a wholesale distributor level and at a 3PL level. But that was also something that was, in a sense -- I don't want to say -- put on mold or having a breath around that date when the law went into effect.

So they said the states could not alter standards that would be established by the federal law. But they may continue to regulate wholesalers and 3PLs, but it would be one common standard at the federal level that would be
adhered to. And I know Martha covered that, but we can go into additional detail in a few more minutes here.

The other thing that happened on July 1st that is causing a little bit of consternation -- I'll call it that -- in the market place is there is a list of products that are contained within the statute that are exempted. So the products that are in scope, it says finish human goods or human labeled products that are pharmaceuticals that are legend pharmaceuticals at the federal level.

So with that said, they list a series of items that are exempted, but they just list them by category. So what's happening is you have a manufacturing community that's looking and saying; for example, compounded drugs. That one's actually pretty easy or medical gases.

The intervenous products that are used for fluid replacement -- I mean, think as a hospital pharmacist, that's a pretty easy one. But when you are a distributor with the data set, when you're looking at an SKU and you have a subset of manufacturers telling you well, these products are exempt and then there's a similar product by
another manufacturer and they're saying, no, it's in scope. It gets a little confusing for, particular, the pharmacy community to try to adhere to.

So what most of us in the wholesaling community have aligned around is that's really a manufacturer's decision. So what we have done, particularly to (indiscernible), is every pharmaceutical that we have in our portfolio of products that we sell, it is in scope until a manufacturers tells me that they have a reason to say it is not. And I know that's what others in the marketplace have also made that decision around.

So for example, an imaging drug. We have asked the manufacturing community, "We think this is an imaging drug; is that correct?" Or we've waited for them to come to us to tell us that. So that is causing a bit of a concern. Because if you're a hospital entity and you're ordering 300 pharmaceutical products, the transactional information statement in history that comes to you may only be for 150 of those products.

Also, in January, we talked about authorized trading partners and also the suspect in an
illegitimate requirement. So these are more of those business process changes or documentations of new standard operating procedures that the entire supply chain has gone through to adhere to these requirements that went into effect on January 1st.

The definition of authorized trading partner in the federal statute states that a manufacturer would be authorized if they have a valid FDA registration. There is a way and there is a link on the FDA website that you can go to and look up a manufacturer. Clearly, this is more of a jump through a hoop and make sure you have documentation correctly.

And I know there are particular manufacturers that have nuanced products that might be in the marketplace. But for the most part, it's actually that that manufacturer has a valid FDA registration. How are you authorized if you're a wholesaler or a Third-Party Logistics company? It states in the federal statute that you have a valid state or federal license. And it is a dispenser that you have a valid state license.

And dispenser is defined as any entity that can also administer product. So the physician
base gets included as a definition of dispenser, dental offices, any place where pharmaceuticals are being administered to patients can also be identified as a dispenser according to the definition in the federal statute.

Two quick slides: One on "Suspect" and one on "Illegitimate." And like I said this is information that we are talking to our pharmacies about at this point in time. So with "Suspect," the key words that we've been trying to key in on is "You have a reason to believe that something is not right. You have a reason to believe it's potentially counterfeit. You have a reason to believe it's been adulterated. You have reason to believe it potentially was -- you know -- suspect or fraudulent transaction."

This is when I say -- when I was a pharmacist -- the pills were blue yesterday. Why are they red today? Did something change? Does the label look different? That type of due diligence. And the FDA has published an initial guidance on some things to look for if you are a practicing pharmacy or you're a supply chain trading partner.

Then you get into what happens if it's actual
illegitimate. So this is when now you have creditable evidence. So we've moved away from a reason to believe and you're into the credible evidence at this point. And the vast majority of the community, as we've worked through this, clearly you need to work with the manufacturer in this event. We don't envision a wholesale distributor or even potentially a pharmacy would ever declare something as illegitimate without the manufacturer being a part of that conversation or actually chemical analysis.

So with that said, the definition of illegitimate is that there is credible evidence around these topics. And in addition to that, the FDA has issued Industry draft guidance. They keep stating that it will be finalized very soon. I know very soon for us is not maybe very soon by definition in the same quarter, maybe, month, or year.

But with that said, they have issued draft guidance. And one of the documents in the draft guidance is how you would actually report to the FDA that you have an illegitimate product at this point in time. And this is what the form looks like. And right now I think they're seeing -- and
you're seeing the Industry work through how does that work.

So if a pharmacy fills out a form and then a distributor does and then a manufacturer, how are they linking that together to one event? So I think right now the FDA is also going through -- I'll call it a growing pain on how do they manage the entire pharmaceutical supply chain around the issuance of suspect and illegitimate product.

A few quick details here around what happened in July: So this is as we've talked about a little bit already that' pharmacies and dispensers were required to accept this information and enforcement discretion was issued. So this is a big one. So clearly a lot of the pharmacies are saying, "How do I get that information? What does it look like? I'm confused as to who do I get it from. Where does it come from? Is it in a paper form? Is it in an electronic form?"

So those are the types of questions we're seeing at this point where I think it was very judicious of the FDA to listen to the dispensing community and provide them with 120 more days to refine processes and procedures around this topic.

Here's an example of what the transactional data
would look like.

So this is one that we provide to our customer base. It's actually -- this would be if you hit the print button -- I'll put it that way. And that's how most of the Industry's providing information to the dispensing community would be using an online portal system or an online website link where you can go into a system and look at that transactional information statement in history.

And this is if a pharmacy wanted to extract that information from that online system, this is what one of the documents would look like. There is not a standard as to how the document looks. There is a standard, clearly, to the data elements that need to be contained within it. So I know if they are receiving product from a manufacturing entity or from another wholesaler trading partner, clearly it won't physically look the same, but the data elements would all be incorporated within that.

And then a little bit of last but not least, so I do eat, live, and breath this every day, so if there's an acronym or there's a question, I understand. I'm in my own little world along with
Martha and Scott Mooney and a few others from various entities of my peers. What we're seeing now, just so you understand kind of the buzz in the marketplace, is the Industry hot topics come around transactions that are more complex. I'll put it that way.

So in the event a pharmacy is ordering directly from a wholesaler, and they're receiving product directly from a wholesaler and being invoiced directly from a wholesaler, those are pretty easy transactions. As long as -- any time we have transactions, such as drop-ships or anything to do with 340B, where we're seeing a divergence of where a pharmaceutical product is shipped and where it is invoiced are different is where the Industry is struggling with what do I do with this federal requirement.

So the definition of transaction in the statute is based upon change of ownership. So the federal statute is in that change of ownership position. But these issues that keep coming up around drop-ships, 340B, or borrowing and loaning of product between particularly hospital entities. These have been areas where the Industry has been clamoring, and in my words,
almost bugging the FDA for additional guidance or clarity.

In the event of a drop-ship, there is a clause in the statute that states the manufacturer or the drop-shipping entity is accountable to provide that information to the dispensing location it's shipping to. So in the event, I'm Heather's Pharmacy, and I order a drop-ship product from Pfizer, but my wholesaling entity invoices me for that product, the transactional information statement in history would actually be provided by Pfizer directly to the pharmacy.

So you have a pharmacy community that is now looking at, I receive 118 products drop-shipped, and I have to figure out now where does Merck have their information? Where does Pfizer have their information? How do I get it from Hospira? So you've opened up, if you will, a bit of a messy can of worms for a pharmacy that's used to dealing with maybe one or two or three wholesalers and maybe three or four manufacturers into now potentially hundreds of direct manufacturing entities. Yes, sir.

MR. PHILLIPS: So this went into July first but will not be enforced until November?
MS. ZENK: Correct.

MR. PHILLIPS: Okay. Just want to make sure.

MS. ZENK: Correct. And then anything to do with 340B, clearly there's many agencies and many regulations involved in the concept of 340B and servicing an access for patients around at that program.

And so at this point, particularly any entity that is the covered entity in the contract pharmacy, there's a lot of concern around who gets the data, who touches the data, who gets the invoice, how does that all, if you will, work in the marketplace. And so that topic has really also been almost inundating the FDA with a the clamoring of, can you help us provide additional guidance as to what the Industry needs to do, in their eyes, what would be defined as compliance with that requirement.

And then last but not least, a few details around the borrowing and loaning. Clearly it's new to the FDA to have any type of oversight; one, for wholesale distributors and also for pharmacies and hospital community. So in there defense, this is an explosion of new entities that they are dealing with as a complex pharmaceutical supply
chain. And so I'm not sure it was commonly
understood that there's as much, maybe, borrowing
and loaning is common practice between retail
entities and also hospital entities.

So with that said, the FDA has hosted two
public half-hour sessions where they've gotten
online with the community and, in a sense, read
through, as I just did, here are the requirements
in January; here are the requirements in July. If
you're a dispenser, here's what you need to do.
If you're a wholesaler, here's what you need to
do. And both times, the borrowing and loaning of
product between non-commonly owned entities came
up.

And the FDA, at this point in time, has been
very rigid, in my opinion, on how they've
addressed that topic. So they've addressed that
topic to say that if you're hospital No. 1, and
you give a product to hospital No. 2 to administer
to a patient, they do feel there is a clause for
specific patient need in the statute that would
not require there to be any passing of information
but clearly you're servicing that patient's needs.

Where I think they have concerns is when it's
been brought up to them around -- well, they may
need it on Friday or Saturday, so I'm going to
give them five or six bottles, and then that
second hospital reorders those products and gives
it back to the pharmacy that they borrowed it from
on Monday or Tuesday of the next week. And in
that example, the FDA said, "Unfortunately we've
seen a lot of diversion and potentially
infiltration of bad actors with those types of
transactions." So they're saying that you need to
look at and consider if you're actually
functioning as a wholesale distributor in those
types of transactions.

So clearly the -- I think the dispensing
community does not feel that they are, but that
has been a very hot topic around, how do they
service patients, how is their patient access, and
how do they comply with the requirement without,
if you will, stepping on their own toes in this
example. Yes, Mr. Chair.

MR. CACCIATORE: Heather, it's
Gary Cacciatore. Is that issue limited to
hospitals? What about retail pharmacies as well?

MS. ZENK: The hospital community's been the
most vocal on it, but it does happen in the retail
community also. The retail community seems to
bring up more examples of just, maybe, giving 20 tablets. They don't talk about full bottle sizes or full types of products being borrowed and loaned. It seems to be more of a (indiscernible) and more a limited amount of quantity. But they also brought it up but not at the level that hospitals have.

MR. CACCIATORE: And have they also discussed a lot of states have allowed pharmacies to do limited to wholesale transactions without being licensed as a wholesaler. I know Florida has a specific permit for that but a lot of states don't. Has that come up in discussions as well?

MS. ZENK: It has come up in discussions. And there is not a provision to do -- if you are doing one transaction as a wholesaler, the federal requirement would say, "You are a wholesaler."

MR. CACCIATORE: And just to remind the council and others: We've had the borrow and loan issue come up in Florida before and if I recall correctly, it's really not allowed as a borrow or loan. It's viewed as a wholesale transaction in Florida.

MS. ZENK: Uh-huh. And we're also seeing where you have dual licenseships. So there is --
and I'll be honest. We just had our national trade show, where we invited over 3,500 pharmacies -- our pharmacies that we service. Very little knowledge around this requirement or what they're suppose to do.

And even a smaller amount of information is understood if they have dual licenses, so if they do have a pharmacy license and a distributor license. Some of them didn't even know there was a requirement as a distributor that they should already be adhering to at this point in time.

Other questions around hot topics? If not, we'll just kind of hit what's upcoming, both with the Industry activity and also within the FDA coming up here now in the rest of 2015. There are, believe it not, already serialization pilots, so on that timeline slide, clearly serialization for the manufacturers. They're the first ones that have to adhere to that requirement at the end of 2017.

With that said, the Industry already is trying to move to, how are we going to use these numbers. And so just as a refresher, what serialization means is if you have two bottles of Lipitor, there's a unique way to identify bottle
No. 1 from bottle No. 2. So every single package in this supply chain will now have a barcode that can identify package No. 1 from package No. 2 from package No. 3. And so the Industry's already starting to look at what does that impact look like as far as (indiscernible), can we read the barcodes. I mean, just kind of some basics here. How do we get it in and get it through?

The FDA's also currently working on and set to publish both the 3PL Federal License Draft and also the Wholesale Federal Licensure Draft. So what that means is the FDA at the federal level will issue a draft around this is what we think licensure looks like for these two entities. They'll be an open comment period, and then, at some point, they will finalize that. Usually, I believe, the open comment period -- knock on wood -- I think is 18 to 24 months at the federal level.

And then as a state, you can adopt those requirements but you couldn't alter them. So if you wanted to continue to be, you know, a licensing entity for wholesalers, you would need to amend and adopt those licensure standards that the FDA published at the federal level. Yes, sir.
MR. PHILLIPS: So just out of curiosity, you mentioned, I think, barcodes?

MS. ZENK: Uh-huh.

MR. PHILLIPS: So is barcoding going to be continued, you think, in the future or are they going to switch over to RF chips or some type of other technology?

MS. ZENK: Yep. So actually the barcode is a mandated standard in the statute. So it will be a 2D data matrix dimensional barcode. So if anybody has kids that are smarter than we are with technology, it's usually that little -- I call it the heavy dense tic-tac-toe board. It's about 2 by 2 in all the magazines. It will probably be smaller than that in pharmaceuticals, but it will be that (indiscernible) barcode.

In addition to that, the data elements that are contained within it also are mandated in the statute to be human readable. So the four data elements in that barcode would be a product identifier, NDC number, a serial number, which create the uniqueness, and then the lot number and the expiration date.

So those four data elements are mandated by the statute. When a manufacturer places that
barcode on a product, those four data elements must be in that and they must be next to it and human readable. RFID technology is not in the statute and has not been accepted at this point as the Industry standard. Yes, sir?

MR. HART: Hi, this is Peter Hart. I'd like to go back on your comments about draft guidances.

MS. ZENK: Uh-huh.

MR. HART: And I'd like to get your take on what you feel is going to happen with the combination of both the draft guidance, whether you anticipate that to be more formalized or that will be -- that the term "draft" is really saying it's there, and then when you combine with enforcement discretion.

Ms. ZENK: Yeah.

MR. HART: Because we've seen interesting things that in the medical gas word.

MS. ZENK: Yes. And I think we've all have lived through PDMA, where it was draft guidance that was for years and years draft guidance. We have expressed that as a concerned to the FDA that -- they are thinking of it as when they issue draft guidance, they've met their statutory date. So there are -- and the FDA has published their
entire series of work that has to do with the statute. And I believe they have 16 to 18 guidances, regulations, or they have to publish something, the statute says.

They came out and said if it's draft by that date, they feel they've met the statutory mandate. But then they said, clearly, they'll move their usual process of public comment, meeting, et cetera to drive it to final. But at this point, as you've seen, the Industry typically is taking that draft guidance and using it as (indiscernible) formal. I know it's kind of dancing, but yes, that's exactly what we're -- to be safe.

MR. HART: Thanks.

MS. ZENK: Uh-huh. Other questions?

MR. BARNES: Mr. Chair, this is Patrick.

MR. CACCIATORE: Hold on Patrick. I'm going to let Reggie go first.

MR. DIXON: I just had a question: Going back a little bit to the borrowing and loaning, did the FDA give any -- any sense of guidance to the folks who called? Because it appears that -- at least from a perspective -- that the FDA is a little concerned that folks making the borrowing
and loaning part of a systematic way of an alternative supply of --

MS. ZENK: Yes.

MR. DIXON: -- medications and where it would look like -- at least to me, being a nonmedical professional -- that it is more of a risk assessment, risk adjustment as well as kind of a statistical, this is what I usually need; this is how I should order it. Preplanning, forecasting type of an issue.

And I'm wondering if that was some of the basis for what the FDA was trying to get at with regards to borrowing and loaning. Because I can tell you, just from a perspective of a regulator, you're not necessarily borrowing a pill. I'm giving you a pill, and you're replacing that pill with a --

MS. ZENK: Yeah.

MR. DIXON: -- similar, hopefully, identical pill --

MS. ZENK: Yeah.

MR. DIXON: -- but it may not be the same. We know it's not the actual one, because the one that you gave was being consumed. So that's -- I think that's kind of what they struggle with.
Because when you got the lawyers involved -- you know. So I'm just trying to see if that's the kind of sense of guidance that they give you all.

MS. ZENK: That is the direction that they -- they're really trying to, I think, challenge the community to define -- clearly they don't want there to be an adverse patient event, or they don't want a patient to expire because, you know, some hospital's going to say, I can't give you that, because I can't give you the transaction information statement history.

Clearly they don't want there to be patient impact, but they are also challenging the professional community to say, hey, come on guys. You know if you're systematically replacing, and you just have poor-ordering practices, lesson learned, but get it right the next time.

So they're looking for that continual pattern of abuse. And I think there very cautious on when they answer that question in a public forum on being more rigid versus being more flexible due to exactly the question that you just raised, Reggie.

MR. MAYS: Heather, this is Steve Mays. I know one thing, too, that FDA is very much aware that this is kind of a sensitive issue, because
they're very much aware, especially in a lot of states that don't require any sort of wholesale license for a pharmacy that engage in wholesale distribution.

There's this whole grey market that takes advantage of that so-called loophole in a lot of the licensing requirements, and pharmacies are solicited to purchase drugs that are in short supply by these gray marketers. And so I know FDA is very much aware of that, because they have their whole drug shortage program, and they see that there's a lot of leakage into that area.

MS. ZENK: Correct.

MR. CACCIATURE: Mr. Barnes, did you have a question?

MR. BARNES: Thank you, Mr. Chair. Just maybe a comment on Reggie's and then I do have a question. I think, certainly in the hospitals, we have an awful lot of growth shortages. I know, personally, here at our hospital, I am not going to be using the secondary wholesalers. If I can't get it, I'm going to try to go direct to the manufacturer.

But there are times with all these shortages that we do have to -- I'm going to use the term
"buy or sell," rather than borrow or loan, so it's really a one-way transaction. But it is certainly a reality here with all these drug shortages.

And then my question is to Heather on the 340B side of things when you're talking about the -- I think it's more -- it's in the contract pharmacy arena --

MS. ZENK: Uh-huh.

MR. BARNES: -- where you pretty much described it very well. Do you get a sense that the FDA's going to be willing to work with the 340B world on trying to resolve that?

MS. ZENK: I think they are. They have stated in Industry meetings, where they've, if you will, brought people into testify and have a listening session. This topic comes up, and the last one we were at, it was interesting enough, they said, "Can we not talk about 340B, because we've gotten a litany of information around that."

So I think they know they have to, if you will, speak on the topic or provide additional direction.

The impression -- and this is Heather speaking. The impression we have is that the FDA is being very cautious in working with HRSA,
working with, you know, (indiscernible), working with the entities that have software solutions that the entire community is using, also working within all the other regulatory agencies and federal agencies that have a piece of the pie in the 340B arena and making sure they -- they vet that very thoroughly before publishing.

It is, particularly, the contract pharmacy community that is pushing to try to obtain the information locally. Even though that is not the change of ownership transaction, that community seems very concerned that they would have product on their pharmacy shelves that they may not have transactional information statement in history for, and so they are engaged in an effort.

And I know now there are also efforts to go back to the sponsors of the law to see if they could also encourage the FDA, from a community and patient access perspective, to speak and act on that. We do have indication they have enough information to speak. It's just, what will they speak on and when. That's a great question.

MR. BARNES: Thank you.

MS. ZENK: Well, thank you for the time. And if there's other additional questions at any
point, I'd be more than pleased to come back. Like I said, it's a pleasure to sit here today. Hopefully this is one less issue that you have to deal with. Thank you.

MR. CACCIATORE: Thank you. I appreciate you coming down and doing that. It was very informative. We're going to take a five-minute break.

(Brief recess.)

MR. CACCIATORE: Okay. We're going to turn to Tab 3 in the agenda, "Division Director's Report." I'll turn it over to Mr. Dixon.

MR. DIXON: Thank you, sir. Just wanted to go over our rules report. As you all have been following as we've been doing a lot of rule work the last couple of months, so this is just an update.

61N-1.001 deals by definitions. We actually just received a letter from the Joint Administrative Procedures Committee giving us a question about some of the incorporation of the federal statutes and also, as well as dealing with limited quantities. So we're going to probably have to at least respond to that letter and maybe do another workshop on the language with regards
to limited quantities.

Quite frankly, what the Joint Administrative Procedures Committee is looking for is a number of transactions, which is something that the Industry has. They have vastly indicated to us it is something that is not possible to be done. So either there's going to be someone putting forth a legislative change this year, probably, or as a division, we are going to put a number and someone is going to have to challenge us with a number because we cannot just -- we can't spend valuable resources of the Division doing a rule that we know is not going to be able to be done, and it's statutorily required rulemaking.

So every time that we don't do it, and we put it off and put it off and put it off, we get letters and then at some point, the secretary for the Division is going to be called before the Joint Administrative Committee, the secretary for the Department. So we have a obligation to try to do what the legislature has mandated us to do.

So I think the next version of this rule that is published is actually going to have a number of transactions in it, and it's going to have to be some number that the Industry's comfortable with.
So we're probably going to be noticing that, just with regards to incorporating the federal statutes.

Those of you who are maybe not as familiar with Florida Rulemaking, if you reference a federal statute, then part of what you have to do is you have to provide a complete copy of that federal statute and code that you're relying on to the Joint Administrative Procedures Committee.

And so we've got some questions about whether or not we're relying on certain subsections versus the entirety of the federal code.

So we'll be responding to that. That letter got here -- I guess -- maybe two days ago, so I did link it to your materials. And let me ask: Did anyone have any questions about some of the changes to the definitions? I know we put those in there. We tried, for the most part, to put changes to definitions and clarify stuff to make it easier for the Industry to read it. But if you all have questions, we'll answer those questions.

So chapter 61N-1.010 is the -- that was the rulemaking on the "Requirements for Manufacturing Cosmetics." That went into effect July 5, 2015.

1.012 and 1.013, those are all connected to the
limited quantities. Those -- that language we
workshopped and we published that language. And
at least the 1.013, there was a technical error
that we had in 1.012 that we had to correct. So
we'll be publishing that one shortly.

MR. CACCIATORE: Mr. Dixon, was the letter
you got from JAPC related only to the definition
or to the other rules as well?

MR. DIXON: It was only to the definitions.

MR. CACCIATORE: Okay.

MR. DIXON: With regards to 1.015, we are
actually going back through all of our
applications. One of the things that we're trying
to do is we're trying to reduce the deficiency
rate of our applications. So we've asked our
processors to kind of give us a list of the most
common deficiencies that they see in our
applications.

And so with the thought process being
(indiscernible), if there's a deficiency because
we're not asking for it right up front, then we
need to change the application. If it's
deficiency because someone doesn't understand it
because the application is too complicated, then
we need to try to make the -- make it more user
friendly.

So we're going back through those applications with the hope that we can reduce our application deficiency rate. If the rate is reduced then the number of days that it takes to get someone license actually working is reduced, you know, et cetera. So we're looking at that.

So that's 1.015. We've got that rule open. It's been open for some time. For those of you to understand, we do have a different applications. All of our applications are wrapped up in that one rule. In the future we're actually thinking about doing a separate rule for each application type. So what that would do is whenever you open up a rule, you would only open up that one application versus all 30 applications. So you'll see some significant rulemaking continue over the next, hopefully, maybe two years or so.

The "Product Registration," 1.016, we put together some new Product Registration applications that we hope will reduce some of the deficiencies that we've gotten, provide some more clarity to the Industry, and those actually became effective Sunday. So those applications are out there. The (indiscernible) rule is already -- it
became effective on June 3rd.

One of the things that we had to do to the legislature -- sorry. We were directed by executive office to go back through our rules and see if there were rules that could be repealed to reduce regulations. One of the rules we had was 1.020. It was just basically the form's rule. And the language of the rule simply said, "You want the forms, come to the Department." So we thought that -- we didn't need that, so we got rid of that rule.

1.023, we're working on that one to, again, incorporate some of the restricted permits. The next set of rules, I think, would be pretty interesting to the folks on the council as well as anyone on the phone. 1.027, that's a rule that we've noticed and we're going to be doing a workshop on that later this afternoon regarding distribution of emergency use medical oxygen.

We've got some recent language that we put together. Hopefully we have distributed to try to comply with our statutory requirement to write the rules but also, to accommodate some issues that came up before that were brought to our attention that we were previously not aware of. So we hope
that we have some language that, at least going forward, we'll be able to be responsive to the concerns that were brought to us by the Industry. And then the next group: 1.028, 1.029, 1.030, 1.031, and 1.032, these are our attempts as an agency to incorporate the language from the DQSA with regards to the requirements for tracking and tracing, for manufacturers, wholesale distributors, dispensers, re-packagers, et cetera. We have some draft language that we are passing around that we're trying to work so that -- what we do is take that language, incorporate it into our rules so that now, with regards to those products, we actually are right at the federal standard where we're suppose to be at.

So our hope is that, by that way, we can incorporate so that there are changes in the federal statute. We won't have to have statutory changes to incorporate them. We can just incorporate them by rule, which is a little bit -- we can pretty much control our rulemaking as opposed to us trying to control statutory changes. So we hope that we'll have that in there. Like I said, we've got some drafts, and we've included information in there for you guys to look at.
MR. CACCIATORE: Can I ask a question on that, Mr. Dixon?

MR. DIXON: Uh-huh.

MR. CACCIATORE: So is there any concern there, though, about statutory authority to do that? I mean, I'm glad to see you're doing it. I think it's fantastic that you're trying to get ahead of the game and not wait for the legislative changes. And I think we still -- that still needs to be made. But any concern that -- that whether or not you have the authority to do that without the legislative change?

MR. DIXON: We think 499 gives us broad discretion with regards to -- or authority with regards to recordkeeping. And we look at the tracking and tracing as recordkeeping. It tells you as a manufacturer, as a wholesalers, whatever records you have to keep, are the records that you have to pass. And as long as we're -- as long as we're not going beyond what the federal statute requires, I don't think that we'll have a problem from the legislature telling us that we can't do it because it's a federal standard. So we just have to be very careful not to impose anything that's addition to an onerous to whatever it that
the DQSA requires. So we think we do have statutory authority. We'll see.

MR. CACCIATURE: And don't forget if you've reference that federal standard, you've got to give them a copy of the whole thing.

MR. DIXON: Yes. Well, the best thing about it is -- what we've tried to do and especially, once we know this language, what you'll see is what we tried to do is any -- we don't actually -- we do not actually reference the DQSA. We just take the language from it, put the requirements in there, and then anywhere where the DQSA refers to another federal statute, we try to make sure that we have a specific statute listed, and that statute is what we have to provide once we try to incorporate it.

MR. CACCIATURE: And this is limited to the track and trace provisions, not the wholesale licensing? So those standards aren't even out yet from the FDA.

MR. DIXON: Right. Now, the definitions that are being used for the purposes of tracking and tracing, that's what those definitions are as well. So it'll be an interesting read. Because it's kind of like the DQSA is a dense, thick text
that you really want your folks to really have a
good handle on it because if you don't -- you know
-- give you some ideas.

Some of the changes that we, I think, we're
required to make is the -- our rulemaking has to
be specific enough to put folks on notice. So if
there was something along the lines of notifying
the appropriate federal agency. You know, what is
appropriate? So in instances like that, what we
may have done is instead of saying notify the
appropriate federal agency, we may say something
to the effect: Notify the federal agency that has
jurisdiction over this product.

You know, you may have to -- you have to be
specific. Be general enough, but you give enough
direction. And if that doesn't pass, it may be a
matter of saying, notifying the federal drug
administrator. We may have to do that; whereas,
the DQSA says the appropriate state or federal.
You know, it's little things like that that you
folks who are looking at it -- because when we
published the rules -- you know -- you only a
limited amount of time.

So that's one of the things for the folks who
are on the phone and for the people who will be
looking at this, take a really good look at that part of it. We're going to try to highlight -- we won't be able to (indiscernible), but we'll be able to provide it to the Industry where we have changed the language from the DQSA so that it'll give you an opportunity to look at it and actually see it. You don't want to be in the process of having something go through (indiscernible) never saw that. That's going to cost us however much more money to comply with it.

MR. CACCIATORE: Is there an anticipated timeline on that one? I know everyone was looking forward to that one.

MR. DIXON: I would hope that it would be by the end of the month. Hopefully by the end of the month. I know we're on our third review and our legal folks have got to look at it too. Before we send the language up to the secretary, you know, all of our legal folks within the Department have to believe that we've got the draft.

Okay. Let's see. Anybody have any questions about the rulemaking? Seeing no hands, okay.
Next thing I want to do is -- and we try to do this around this time of year -- is give you an idea of legislative proposals that we've received
and things that we're -- that we would like to see
implemented in chapter 499.

At this point, we are not sure whether or not
the Division will have a division, whether the
Agency will have an agency bill, or whether or
not -- the hope is that we'll have a sponsor or
someone will make changes to 499. But these are
the things that the Division -- based on the input
that we received -- thought would be good items to
help the Division but also, good items for the
Industry as well.

So we put these in there with the thought
that if anyone had any questions or concerns about
any of them, that they -- you know -- either give
us -- either bring it up now or even maybe shoot
us an e-mail or something. That way -- because
ultimately, any package that goes before the
legislature -- and guys know this better than most
of us is that ultimately they're going to ask you
all. If there's a sponsor, they'll ask the
sponsor, "Where does the agency sit at on this
bill?" And they also ask the agency, "Are there
any folks who oppose this bill? Will it
negatively affect anybody, you know.

And so what we think is by putting this out
there, giving you all, giving the Industry, an
idea of the things that we would like to see, it
kind of starts the dialog early, and also, it will
give you an idea of where we, as the Division, as
an Agency, trying to regulate in an open -- you
know -- in an open way.

So I can go through them if you'd like or if
you have any questions about specific ones -- I
mean -- that's your preference, Mr. Chair.

However you would like us to do. Like I said,
it's not that big of a deal. How would you like
us to go on now?

MR. CACCIATORE: I think if you can go
through them briefly, I think they may help.

MR. DIXON: Okay. This first one -- one of
the things -- with the first one, basically says
that the Division would like to be able to have
the ability to work with the FDA in a way that we
haven't in the past. In a sense that, if the FDA
is doing some criminal investigation of entities,
right now they don't share that information with
us as readily as we would like them to, simply
because of our statutes and our rules are open in
our public records laws that they're a little
hesitant to do so.
We're aware that there are other agencies that have statutory authority to maintain confidentiality information that they receive from the federal authorities until such time the that the federal authorities think this information isn't confidential anymore. And so we're looking for a change to 499 that would give us similar authority.

The second one deals with the renewal of wholesale distributor permits. Actually the next two deal with it. The first one -- ever since this Division has been here, we've had folks who would come to us and say, "Look. It's kind of onerous in how we renew -- we have to submit this personal information statement, fingerprints, pictures, and those kinds of things."

So one of the ideas that we had was to either to figure out a way to relax what information has to be provided. So for instance, one of the ideas that we had was if it's a personal information statement that maybe you could submit an affidavit that basically says, "My personal information statement from the prior year remains the same." Do that for a certain number of years or, you know, maybe three. So for three years, two
renewals, or whatever. You don't have to submit one unless there's a change. Then you can do an affidavit or something of that nature.

We're still working on the (indiscernible). But we don't think that -- you know -- it's kind of difficult to ask you to have a current picture within the last 30 days. If you have multiple licenses with multiple dates, you know, interesting enough, through the course of a year, people, hairstyles, hair colors, beards, and things change. So ultimately you may have six to eight different pictures of the same person.

So something like that we're looking at relaxing maybe the personal information statements. And they're trying to assist people with the renewal process. So we did do an inquiry of some of you all, just to kind of see how much time it takes for you to do the renewal. Some of you all have been renewing. You have a permit. You may have to go back and forth on a renewal. You may be in the state of renewal every year.

So that's why the second one we were thinking about moving the wholesaler renewal permit to two years. So now you'll save that time every other year, and it will give you time to breathe and get
the paperwork together. So if you got a two-year renewal cycle and it's relaxed a little bit on the personal information statement requirements and some of the financial requirements, where it would help you all to do is kind of take a breath have the applications corrected, and then hopefully reduce the number of deficiencies.

So a lot of the things that we're trying to do is be business-friendly but also to reduce, you know, the workload in our area. Because, quite frankly, if only -- if only half of the folks renew, then we could better work with the Industry making sure that folks get in there applications thoroughly and completed. So those are two that we would like to see.

MR. CACCIATORE: I think most of the Industry would be in favor of that. I don't want to speak for everybody. I know my licensing people got really excited when they saw that.

MR. DIXON: The next change deals with -- dealing with the bond requirement. As you all are aware, the DQSA has changed the bond requirements for wholesale distributors. So we would like to see changes to Chapter 499. Essentially adopt the federal requirement for the bond. What that would
do is lower the bond to 25,000, just to entities who make less than $10,000,000.

And so the one hitch in the giddy-up, quite frankly on that one is how do you do it? The federal folks have not come forward yet on any guidance that specifically talks about the bond, itself. So if you've got multiple locations, you may have one bond, but right now Florida -- but it does not say that bond has to be payable to whomever. And so in Florida, our requirement is that you have $100,000 bond payable to the Department and to remain in place for a year or however. So we have some ideas on how to change that.

And then we're thinking about language that says that of the different folks on your bond, that one of those be Florida. You know, so we've got to try to see how that works. But that's one of the things that we think we have to change. And so we know if the Department had a bill, that is something that we would have to include. So we think we have to include that as well as other things to comply with the DQSA.

So those next two things are what we're thinking about, as far as when it comes to
complying with the recent provisions of DQSA, we think that those are must, not -- you know -- that's not something we think is discretionary.

With regards to the next one -- the next one deals with product registration -- I'm sorry -- applications. A lot of our applications do not expire. We have several hundred applications that we believe that have been pending or maybe folks have abandoned the application. And the way our system works is it keeps giving you prompts to process an application.

And so, either, you may have people who are not even in business anymore, and so what we were thinking is if your application has been expired or if your application has not -- you haven't had any activity on your application in 24 months, then we can just go ahead and close out the application and then it will expire, and that will clear out a backlog. And quite frankly, if you file an application, you've got deficiency letter, and you haven't done anything in 24 months, you probably (indiscernible). So we think that's just -- you know. That's just kind of a cleanup. Yes, sir?

MR. PHILLIPS: This is Jeenu Phillips. So
there's no ability for the Department to deny an
application in those scenarios?

MR. DIXON: What we can do -- we could go
through and deny applications, but a lot of the
problem that you have there is you have incomplete
applications. You know, it's kind of squishy
sometimes whether or not it's an incomplete
application versus an application that you
provided us all information that you believe is
actually responsive.

For instance, I know the Department of
Health, their applications expire after a year.
So if you submit an application and you don't get
an application approved, denied, or any action on
the application, they have one year and that
application expires and you have to file a new
application. And so we didn't want to do that.

What we're trying to say is from the last
time that we told you have a deficiency, if you
have not responded to that application, then that
application in 24 months will expire. So we don't
have to take -- and what you don't have is you
don't have an application denial on your history
either.

So what you'll have is an expired
applications versus the Department affirmatively issuing you a denial. And you may not know about it, and so you apply for a license somewhere else, and you say no, I haven't had an application denial and in those licensing application checks, it pops up that Florida denies your application. Your first answers going to be, well, I didn't know about it. And Florida's going to be like, well, we denied it and we sent it to you. So we think it prevents that as well.

MR. HART: Mr. Dixon, so -- just so I get this. So it's really not a hard expiration in two calendar years? It's two years of inactivity?

MR. DIXON: Yes. There's going to be two years from -- there's going to be two years from -- and we have something similar to this on our professional side. It's two years from the last deficiency letter that you haven't responded to.

MR. HART: Okay, good. Thanks.

MR. DIXON: One of the things that we want to do is we want to be able -- right now, the folks that have to submit fingerprint cards have to actually get a card, have your fingerprints rolled, send that card into our office because
that's what the statute requires.

What you all do not -- well, I'm not sure if you're aware of this. We get that card and we go
to a scanner, we scan that card in, and send it to
FDLE. Well, there are a lot of vendors out there
now who will actually scan your fingerprints and
send them directly to FDLE. So we're trying to
get a statutory change to allow us to accept
fingerprints that way.

The next one is we would like to have the
authority to actually have our inspectors issue
citations. One of the things that we're trying to
do is we move a little bit more away from taking
enforcement action. There's a lot of instances
where we may see violations that are -- they're
technical violations, but they're not
health-safety violations, not violations that we
believe -- they're violations that we think can be
taken care of without the need of going through an
entire formal process.

And so if our inspectors are authorized to
issue citations and we put together a rule that
says citations for certain violations are this,
and then building a system that says if you
receive a citation and you disagree with the
citation, then you can go through the formal process.

What we think that will do is it will allow entities to receive the citation, to make that -- to make that assessment as to whether or not the citation can stand or whether or not they should actually go through the process of having it investigated and all this other stuff.

That's something that on the other side of our agency you see happening where, for instance -- this is not a good example, but it's the first one that comes to my mind. Sometimes in contractors or electrical contractors, you got to have your permit number on the side of your truck, and if you don't have that on, then you might get a citation for that. Or if you disagree with it, you may say, I did have it on the side of my truck and maybe it wasn't my truck or whatever, then you can go through the formal process of getting it dismissed or maybe there are other violations that are found.

But we're trying to figure out creative ways to alleviate the cases that come through our legal folks so that they can focus on different cases and try to reduce the amount of formal, you know,
enforcement actions that we take. So this is an idea that we've been thinking about for a while, and that we would like to see. Because we would have to go into rulemaking to kind of establish what violations were fallen into that; what the fines would be.

So it's not like if the statute changed today -- I mean, if the statute changed, it would be six months away, because we've got to go through rulemaking, have a hearing, and try to establish what our obligations are. Yes, sir.

MR. CACCIATORE: Just a couple of comments on that. I'm not necessarily opposed to the idea, but just a couple of things I'd be concerned about: One is I'd be concerned about current process where it is a minor issue and the inspectors allow the licensee to get into compliance, where it doesn't even rise to a level of citation and fine of losing that ability. I think that works well right now. But I understand -- I kind of understand the need for this.

And my other concern would be that there's some -- there has to be some type of process, as you said, to contest a citation because different
inspectors have different viewpoints sometimes about is it a violation or not. So there has to be some type of mechanism to, at least, take the citation away completely if you can show no, we really were in compliance and this is how we were. So that would be a concern.

And then one more thing is just to consider -- even though is -- I assume this to be nondisciplinary then?

MR. DIXON: Yes.

MR. CACCIATORE: That does become an issue sometimes because of the fact that there's a fine involved, because other states that have this authority, where it's nondisciplinary and you get a citation and a fine, unfortunately other states don't recognize it as nondisciplinary. Even though you can prove to them it's nondisciplinary, other states don't care. They say, you pay a fine.

So when you are applying for licenses in other states, they expect you to reveal that information even though their application says, "Have you been disciplined?" If you say no and they find out you've been fined by another state, and you say well, that's -- that's not
disciplinary action, they say, we don't care. You pay the fine. To us that's disciplinary action.

So it does have implications beyond just Florida. It's something to think about. So I'm not saying I'm opposed to it, but there would have to be some protections there and it's going to have to be done very carefully, I think, through the rulemaking process if this does happen.

MR. DIXON: Were there any other questions about that one? Okay. The next one deals with (indiscernible) donation program. Every since this program came over, one of the things we really wanted to do was to open up this program and maybe enhance the program to allow more sources of drugs to actually come into the program and also to allow more drugs.

So some of the things that we're thinking about is maybe relaxing the expert -- I think right now there's a requirement. It's a 30-day -- drugs can't expire within 30 days. We're thinking about moving that -- no, I'm sorry. It's 90. So we're thinking about moving it down to 30 days. Hopefully that will open up some more drugs that will be available.

We are also thinking about the idea of
including different entities that can participate, you know, like Modified 2B, pharmacies. We're even considering -- you know -- we'd like to see what Industry and what other folks would think about allowing medications that may have come out of an institution into a patient's home and they have not been opened; they've been stored. We've got some wavers and some other type of little things in there.

Part of the issue truly is that we have any number of phone calls that we receive from people who have had loved ones pass and they have thousands of dollars of unopened properly-stored medications that either get wasted or go into the grey market anyway. And so we're hoping for an opportunity to be able to allow people to share those drugs in a somewhat open way and not having to, you know, sneak around and do things that are illicit just because you want to be able to provide some assistance to someone else. And so we're thinking about making some changes to the statutes that regard that Cancer Drug Donation Program to maybe facilitate that.

The last one we had is just -- it's kind of a technical change. As you are aware, the Board of
Pharmacy created the sterile compounding permits last year, in Chapter 465, which required anyone that was doing sterile compounding to have the sterile compounding permit. What that has done, however, under our statute, the only type of pharmacy that we can issue a permit to is a nuclear pharmacy. Well, nuclear pharmacies have to have a sterile compounding permit issued by the Department of Health.

And so now we have a statutory destruction issue where, you know, technically, we're probably not suppose to allow a nuclear pharmacy permittee that actually had -- that also has the new sterile compounding permit to receive one of our distribution permits -- distributor permits. So we wanted to make a change to 499 to account for that. Because truthfully, even though it says it's a permit, it appears that the sterile compounding permit is more of a modifier than an actual -- I mean, I don't know that you can have a sterile compounding permit without having a pharmacy permit or outsourcing permit.

So we just need to make changes to Chapter 499 to make sure that we can still issue that permit. So that's what that change is about.
Other than that, we didn't have anything else.
Like I said, we don't know if we're going to have
agency bill. We are working with our folks in
legislative office to give them ideas and give
them drafts and stuff that we would like to see.
But whether or not we actually have an agency bill
and whether or not there are different sponsors
who may have a particular interest in anything, we
don't know that just yet.

MR. CACCIATORE: Thank you, Mr. Dixon. I
just want to congratulate everyone. This is
really, really helpful, and you guys have put a
lot of work into it. I don't think there's a lot of
critical issues here.

So to the extent we can assist somehow in
trying to get an agency bill or get the Division
to get the bill sponsored, I think the Industry
would be willing to do that, because there's a lot
of things here that are helpful to the Industry.
And particularly, you know, with the DQSA stuff,
Florida, being the state that was probably
preempted the most, it's going to look bad if we
don't get that change pretty soon for the state.
So that was critical.

But again, the stuff around the licensing
changing every two years, I think it would be very, very helpful. So I think the Industry would very much support this, and I think we should do everything we can do to get all of this into one cleanup bill, probably. I'd like to say it's easy to get it done in one bill but maybe not.

But to the extent that there's sponsors for different portions of this, that'll be helpful as well. Anyone have any other comments on that?

MR. MAHONEY: I agree. Mr. Dixon, is there any anticipated change to the CDR requirement to DQSA or anything you talk about?

MR. DIXON: We don't know. We don't have any -- we didn't have any suggested changes on that. Part -- I think part of the reason is we just don't know what the standards are going to be from the FDA when it comes down to the wholesaler licensing requirement. And so in an absence of direction, we're just kind of standing here right now.

If for some reason they make -- because I don't know if you guys -- our CDR permits -- once you pass the exam, your permit doesn't expire, you don't have to take any more continuing education, your permit doesn't renew. So it's a one-time
permit. I mean, you have to be there. You have to be at the facility, and you have to be an active employee engaged in the day-to-day business.

And we think those requirements make sense. But I'm not sure -- and we don't have anything to tell us whether or not those requirements are in direct conflict with the DQSA and until the FDA gives us any guidance. So right now we're just standing down.

MR. MAHONEY: Thanks.

MR. DIXON: Were there any questions from anyone or anyone on the phone about any of the legislative suggestions?

MR. CACCIATURE: Okay, thank you very much. We're going to turn to Tab 4, "Other Business."
The only thing we have there is to talk about the meeting dates for 2016. And Dinah provided some suggested dates for the council: February 25th will be the in-person meeting; May 19th by conference call; August 18th, either by conference call or in person. We can discuss that. Or December 1st.

Does anyone have any particular conflicts with those dates at this time? If not, those will
be the proposed dates. Any preference on the
August meeting for an in-person meeting or
conference call? We could go both ways on that.
So it's only twice a year. I think we can manage
to come in person twice a year. So I suggest we
just keep it in person if we can. Is that good?
We'll make that an in person call then.

Okay. Any other new business that anyone in
the audience would like to bring before the
council? If not, I will entertain a motion to
adjourn.

MR. MAHONEY: I move that we adjourn.

MR. PHILLIPS: I second it.

MR. CACCIATORE: It's been moved and
seconded. All in favor, signify by saying aye.

MR. MAHONEY: Aye.

MR. PHILLIPS: Aye.

MR. MAYS: Aye.

MR. ELLIS: Aye.

MR. CACCIATORE: Any oppose? Meeting's
adjourned. Thank you very much.

(Thereupon, the proceedings were concluded at
11:45 a.m.)
CERTIFICATE OF REPORTER

I, JESSICA RENCHEN, Registered Professional Court Reporter, certify that I was authorized to and did stenographically report the foregoing proceedings and that the transcript is a true and complete record of my stenographic notes.

DATED this 6th day of August, 2015.

JESSICA RENCHEN, Court Reporter