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

COUNCIL MEETING

February 15, 2018
9:30 a.m. - 10:34 a.m.

Homewood Suites
2987 Apalachee Parkway
Tallahassee, Florida 32301

Reported by:
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ORIGINAL

FOR THE RECORD REPORTING TALLAHASSEE, FLORIDA 850.222.5491
COUNCIL MEMBERS

STEVE MAYS, CHAIRMAN
MICHAEL MONE
SCOTT BROCK
DREW WINTERS
ELIZABETH ALSOBROOK
DINAH GREENE
PATRICK BARNES
JENNIFER GOLDMAN
ARLENE ELLIOTT
JEFFREY TULLER

(Appearing Telephonically)
DEAN ELLIS
JEBNU PHILLIPS
PROCEDINGS

MR. MAYS: Good morning everyone, this is Steve Mays I would like to call this meeting of the Drug Wholesale Distributor Advisory Council to order. We do have a court reporter in the room present, I want to remind everyone to identify yourself before you speak so that the court reporter will know who's speaking for the record. And please speak up, it's kind of a large room and we want to make sure that the court reporter can hear everything that's been said.

For anyone on the phone, please mute your line when you're not speaking, but please do not put us on hold so we don't have to listen to your hold music. Ms. Greene, I think we're ready for our roll call.

MS. GREENE: Steve Mays?

MR. MAYS: Present.

MS. GREENE: Jeenu Phillips?

MR. PHILLIPS: Present.

MS. GREENE: Michael Mone? Scott Brock?

MR. BROCK: Here.

MS. GREENE: Arlene Elliott? Dean Ellis?

MR. ELLIS: Here.

MS. GREENE: Jeffrey Tuller?

MR. TULLER: Here.
MS. GREENE: Patrick Barnes? Peter Hart?
And Dr. Goldman?

DR. GOLDMAN: Here.

MR. MAYS: All right, I want to start the
meeting off as we normally do by reading the goals of
the council as stated in Chapter 499.01211 of the
Florida Statutes.

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

Okay. We have no -- as you probably noted,
we have no items on the Chair's report today. I did
want to bring up one thing, we do have a vacancy on
the council and Brian Files has resigned his
membership to the council, and I thought -- I'm not
sure how we've done it in the past, but I thought it
would be good because it's -- I know for members it's a hardship to travel a couple of times a year and participate in these meetings, and I thought it might be good when someone leaves, like Brian, that the council would send a nice letter of thanks or appreciation for your service on the council. Anyone want to make a motion that we do that?

MR. BROCK: So moved.

MR. BARNES: Second.

MR. MAYS: Okay. All in favor say aye. Aye.

(Chorus of ayes.)

MR. MAYS: All opposed? Okay. All right, so the only thing else on the first tab, you'll find a meeting transcript from our December 7th meeting for informational purposes. So if you get a chance, if you haven't gone through that, you might want to go through that and see if there's anything you might have questions about. And with that being said, I'll turn it over to Mr. Winters for the Division Director's report under Tab 2.

MR. WINTERS: Thank you, Chair. I would like to back up just one second --

MR. MAYS: Sure.

MR. WINTERS: -- for your Chair's report to make one other note for the council members and those
on the phone. Because of the vacancy, we have gone ahead -- after Mr. Files did notify of us his change and that he would no longer be on the council, we went ahead and notified the interested parties list regarding the vacancy and requested that anybody that was interested in filling that position that they would go ahead and submit the application to us so that we can provide that to the secretary for review and determination.

Again, for anybody on the phone or any of the members that are aware of members or individuals in the industry that are an employee -- again they do have to be an employee of a retail pharmacy -- but if they are interested in serving, to please let them know of the vacancy. The more members we have, you know, obviously we want to get somebody that's interested in wanting to serve, but we want to make sure that we have everybody given the opportunity to do so. Just so with that in mind, that we go ahead and just get that out there as much as possible, I believe Dinah, we have one applicant --

MS. GREENE: We have one application so far.

MR. WINTERS: -- right now, we generally will give it at least 30 days. Dinah, what date did we actually note that -- send that out?
MS. GREENE: About the 2nd or 3rd of February.

MR. WINTERS: So we'll --

MR. MAYS: We got until right after the first of March.

MR. WINTERS: -- right after the first of March, take a look at what we've got, and then coordinate with the secretary about possible appointments. And so again, just to let people know that they have that time in order to do that so -- thank you Mr. Chair, for the turnover, and again, starting with the director's report, again, Drew Winters on behalf of the Division.

The first item up for us to review at this point time is the rules report. Again, just to give an overall summary of the primary status of our rules, our primary efforts currently have been to adopt our forms in rule. We are required by law when we promulgate forms that we adopt them via rule. You've got the report as prepared by our office, a big thank you to Dinah who's always, again, tracking these items for us.

Going down the list, there's a few that we're still working on as far as developing and getting a finalized initial draft for both the -- again, the
application for device manufacture permit and the
application for limited prescription drug veterinary
wholesaler. So we are going -- the limited
prescription veterinary wholesale distributor, we
actually do have almost a final draft at this
particular moment in time. I believe it has gone
through both Rebecca's shop and Chief Alsobrook's shop
for that, and I'll be reviewing that so we do expect
that do be done here very, very shortly.

We have next on the list is the application
for restricted drug, drug distributor, the blood
establishment permits; we have filed that with JAPC as
a notice of proposed rule. We did receive comments
back from Ms. Holladay from the Joint Administrative
Procedures Committee, and we have submitted a response
and we're waiting for her to have an opportunity to
review that. We expect that our -- we've also been
able to speak directly with Ms. Holladay and go over
our response. She seemed very receptive to it, so we
don't anticipate a problem, but we'll still allow her
to continue to review that. And so we expect to
continue that process and to have that done shortly.

The applications for restricted drug
distributor for the charitable organization,
destruction permit, government programs permit, and
the health care entity permit, those drafts have been
completed at this point in time, we reviewed and moved
through the initial process. If the council members
would like, once now that we've got a finalized draft
as we get it through, we'll provide that to the
council members at the next meeting so you can
actually see the draft of those applications.

We are still working on the initial draft of
the institutional research permits. Again, that one
has also been through most of our shops and we
anticipate finalizing that draft and getting it moved
on shortly; but we'll, again, continue that process.

I did want to note one of the things that we
do do is we get comments back from the Joint
Administrative Procedures Committee or OPARR, that we
try and go back, as we do in the process, and the
forms that are still in process we'll go back and make
sure that any comments we receive during that process
are also applied to the other ones to make sure that
we don't continue to run into those issues.

The institutional research permit, again, is
still finalized in draft, but we do have final drafts
of the reverse distributor; and skipping down to third
party logistics provider permit, so we will have
those. Again, those are the ones that we anticipate
coming very shortly to be able to provide you drafts.

The retail pharmacy drug wholesale
distributor permit, the veterinary prescription drug
retail establishment and the veterinary prescription
drug wholesale distributor permit, again, are under
draft. The veterinary prescription drug establishment
and the veterinary wholesale distributor, again, those
have also both been through Ms. Burnett's shop and
Ms. Alsobrook's shop, and I am looking at those final
drafts now, so we expect to have those shortly and
we'll be moving those on through the process.

We did take a little bit of time recently
because, in review of the information from our program
office, Ms. Burnett keeps a very good track of what we
are seeing and some of the items that we felt were
prudent to go ahead with. We noted that we've added
the applications for changing of mailing address and
change of name, and for the certificate of resale, and
those three were actually added. While they're just
administrative forms, they're going to be forms that
are going to be very helpful to individuals to clear
up those processes for them. And we have submitted
those, JAPC has provided us comments, and we will,
again, have provided draft responses to them, and talk
with Ms. Holladay. We expect that those responses
will be acceptable.

The application for physical location which is a little more involved, again, we do have a final draft and we will be moving forward with that hopefully soon as far as a proposed rule and getting it over to Joint Administrative Procedures Committee.

The final one, the one that we spent the most time on, which is the application for certification of a designated representative, again, we have filed that, we have not received a public comment back on that one at this point in time.

MS. GREENE: No, we have not.

MR. WINTERS: And so we'll -- we're going to give it just a little more time, and then we will file that for adoption shortly. So that is kind of the status that we have on the rules report.

The application for certified designated representative, one of the things we do want to note, that does have the effective date for the 18 months as opposed to the six months, and so once that rule -- and we anticipate the effective date on that will be April 1st, and we've already coordinated with Pierson View and they have that date and are already setting up the implementation so that we'll have a seamless implementation, so that individuals applying for that,
once they've -- if they apply to take the exam or approved on or after April 1st, they would be given the 18 months, so we look at that process.

We will continue, obviously, in this particular case if a rule itself has not gone, we will probably still move forward, as April 1st as are proposed. An analysis of that indicates that at this point it's a benefit to them and it would be beneficial to go ahead and move forward in the -- that the risk of the rule would be outweighed by the benefits, so we will continue that discussion.

That concludes the information on the rules report. I'll stop there and ask if anybody's got any questions or concerns regarding the rule or any other items that you think -- and this is just for our current proposed rules, obviously we've got a few items after this that we'll address regarding possibility of, again, increasing our -- some additional items on that rules report, but for current activity, is there any questions or concerns that you might have?

Seeing no questions or concerns, I will go ahead and move forward. I did want to stop just for a second because we were speaking about the CDR, and give the council members a heads-up. I did anticipate
the ability to provide a more detailed presentation at this meeting for our CDR examination; I know we talked about it previously. Unfortunately, due to an error on my part, the scheduling just did not work out for that. I have, however, talked with our bureau of education and testing and we anticipate, assuming if we do have the next physical meeting, whether they will be able to attend, whether that be in May or in August, we'll be able to have them attend. So again, I anticipate that, and I apologize we were not able to close that loop at this meeting. It would have been a good item to have.

The next item on the director's report is Item B is discussion of a potential rule workshop on virtual manufacturers and prescription drug wholesale distributors. And the reason I brought that -- and I will also, with a nod to Ms. Price, our chief attorney, with any comments that she may have -- is that one of the items that we have looked at in both our enforcement realm with Chief Alsobrook and our legal realm on virtual and broker-only permits is that we don't have a rule that specifically indicates what they do and do not have to comply with.

We provided you the information on the permits under 499.01, and that's Sub (2)(a) and (2)(c)
and (2)(e) are the indications in the statute that basically allow the Department to adopt a rule from which we can exempt these virtual manufacturers from certain establishment, security, and storage requirements. That's because based on their requirements, they're not allowed to actually take physical possession, so there's certain items that if -- currently we may enforce because we don't have a rule adopted that we may be able to develop that they won't have to comply to save them some regulatory costs, and to be able to move forward with that and to identify that.

Today's conversation is mostly to determine if there's any concerns from the council initially as to us going ahead and moving forward with a proposed workshop. The idea currently would be for us to actually move forward, and in order to get the most benefit and anticipated participation, would be to try and hold this meeting in May of this year and to possibly have the council have a physical meeting in May in alternative to a physical meeting in August. So we would have a physical meeting in May in order to coordinate the rule workshop with that council meeting.

The other option is, in coordination with
that, is to have it physically moved from Tallahassee to Orlando to allow for more participation. The Orlando area has more of our wholesale distributors, manufacturers, and permit holders in that area. It's also much closer to the south Florida area, Dr. Goldman, obviously, I think it would be much easier to travel for you. The -- so we would look at that.

Again, we would have to make sure we had a budget for that, we'll look and see if the council approves with us moving forward with that particular rule workshop, we would be able to try and make sure that occurred; one, that we would have a physical meeting in May, and then we would try and move it to Orlando.

Some of the items, of course, that we want to do is to get a consensus from the council members, but also from the industry which is why we wanted to coordinate the two. What would occur is that we would have the rule workshop, we would have it on the same day and then immediately following the rule workshop we would have a council meeting for the council members; that would allow you to attend the workshop, provide any type of input you wanted there, and then also ask individuals in the industry, and then
afterwards we could hold a council meeting, and that
would also allow for a little more participation from
the industry.

So that would be my request from the
Department's standpoint. We do have this as one of
our goals to really try and pinpoint some items that
the industry will know these are the items that you
don't have to comply with, or if you do have a
compliance, that there may be a reduced compliance
regarding those that we could develop by rule, get it
in the administrative code so people will have
something to rely upon.

Chief Alsobrook, I know that you have some --
a lot of dealings with this because your enforcement
staff has to deal with this issue. Did you have any
input or any items that you wanted to put in?

MS. ALSOBROOK: Thank you, Director.

Mr. Court Reporter, just for the record, I hope you
indicated that Mr. Barnes arrived so that we have an
additional member of the council so we need to make
sure we have that on the record, and --

MR. MAYS: Thank you, I was going to mention
that.

MS. ALSOBROOK: -- before we started.

MR. BARNES: Sorry I was late.
MS. ALSOBRook: No, no, no --

MR. MAYS: I've already slapped him on the wrist.

MS. ALSOBRook: There you go. I think one of the most important things to remember is without a rule addressing what the virtual manufacturers do and do not have to have as far as compliance to pass an inspection -- the storage requirement is a good example: They're prohibited from possessing any drugs, and yet they have to meet the storage requirement, which is humidity, temperature control, monitoring, all those kind of things. Well, the absurdity of that, as you can see, is immense. And government doesn't need to be absurd, and regulators don't need to be absurd, and they even looked to the council, and "Why are they doing this?" Well, you know, the council doesn't pass the rules, but -- so when I spoke to the director, he and I both agreed that this is something that is long overdue.

Now, the security equipment, the premises and all of that kind of stuff, we can have long conversations about what needs to be changed and modified in that regard, but the storage is just a no-brainer. I mean, they don't have drugs there, they don't need to have refrigeration and all that stuff,
so we really thought it would be a good idea. But
we're not distributors or manufacturers, so we really
need input from the industry as to how far-reaching the
modification to the rule should be. Because I don't want
to be hoodwinked, but I also don't want to not do enough,
so to speak, Chairman Mays.

So that is why, when I spoke to the director
about it, who is very interested in trying to be
accommodating to both sides of the regulatory scheme,
thought this would be a good way to approach the
virtual manufacturers, as well as the virtual -- as
well as the brokers, for example; they, too, have the
same issue as distributors. They can't possess any
drugs but --

MR. MAYS: I -- this is Steve Mays, I think
it's good -- I think it's a great idea to, you know,
have the workshop and just to give you an example,
I'll -- you know, a state inspected one of our sites
that has a virtual wholesale license, and the state
will remain unnamed, but they were actually
re-inspecting them for storage requirements which, you
know, were kind of like "that really doesn't make
sense and it's a waste of time."

I do think it's important to make a physical
visit to those sites, you know, just to see what's
there, let them know that, you know, they're being
regulated and I think it's a good idea to do that.
But yeah, it makes total sense to look at what type of
requirements that you wouldn't, you know, apply to a
virtual wholesaler.

MS. ALSOBROOK: Yes, sir.

MR. WINTERS: And I think, like I said, the
main focus we had, especially bringing it before the
council, is that we do look to you for some guidance
on what the industry is seeing and whether this is an
issue or any concern regarding the actual process.
And I really do believe this is going to be a good
process, and will, again, provide us an outstanding --

MS. ALSOBROOK: Speak up.

MR. WINTERS: Sorry. I'm being told to speak
up. That this will provide that information. And
again, as Renee had said, one of the issues as a
director that I do want to make sure that we do is
compliance is mostly knowledge, you can't comply until
you have the knowledge, and until we get that out
there, there's always a question of, you know, making
sure we have the knowledge; this will be the method
through which we will do that.

So if the council would simply give me either
a vote that they are okay with one -- two items
specifically: That you're okay with us having a
physical meeting in May that is different than our
normal, it would two physicals in a row, and that you
approve of that; and two, also that in this particular
instance, that if budget does allow and we can get the
approval, that we would move this to an in-person
meeting in May in Orlando, in the Orlando area, to
allow for more participation.

MR. MAYS: So do we have a motion from the
council that we're okay with moving the council
meeting to Orlando in May?

MR. BROCK: So moved.

MR. BARNES: Second, this is Patrick.

MR. MAYS: All in favor say aye.

(Chorus of ayes.)

MR. MAYS: Those opposed? Okay. I would
much rather -- personally I'd much rather -- no
offense to the Tallahassee folks, but I'd rather go to
Orlando in May than Tallahassee in August, so it works
good for me. I don't want to be in Orlando in August,
either, for that matter. I lived there for eight
years, it's a little muggy.

MR. WINTERS: It will be a little warm,

but --

MR. MAYS: Yeah.
MR. WINTERS: -- but I think also the travel
will be better for everybody and --

MR. BROCK: Mr. Chairman, question.

MR. MAYS: Yeah, Mr. Brock?

MR. BROCK: On the workshop, do you envision
that being -- I know that there have been a couple of
manufacturers that had some questions about the
virtual manufacturing permit process and various
issues, would that be the appropriate venue for them
to bring anything forward, or is it going to be -- is
it going to be limited to certain topics?

MR. WINTERS: This will be -- in some
respects it will be limited to a development of the
rule which will specifically go to the sections that
we can exempt virtual manufacturers from under the
establishment, security, and storage requirements
under 499.0121. That very well may fit into many of
their questions, because that is the primary aspect
difference between virtuals and the actual
manufacturers, and the brokers versus the full
distributors.

But you know, obviously, if anybody has any
questions or concerns, they can always contact the
Division, but we would be limited to those topics as
part of the rule workshop. If somebody were to bring
an issue and it's identified as possibly not being on
topic, with the help of counsel and we could -- if it
was identified outside, we could simply take that as
an informational item during that and just we'll take
that -- please -- you know, we'll be happy to talk
with you outside of this rule workshop and see if
there's some other assistance we can provide, but we
would want to confine it solely to kind of that
portion of the workshop so that we don't get too far
awry of what we're doing.

One of the things that you'll notice, we are
being very specific about what we're doing in these so
that we can bite off only what we can chew. We know
there are other items that we can try and fix or focus
on, but if we try and focus too wide a beam, we're not
going to be able to accomplish what we're looking for.
So I really want to take them in those bits that we
know we can address in rule work. But yes, we could
-- most likely I'm guessing most of it is going to be
fitted into what they're looking at in those areas.

MR. BROCK: Thank you.

MS. ALSOBROOK: Mr. Mays, if I might --

MR. MAYS: Go ahead.

MS. ALSOBROOK: -- add onto that, this is

Renee, many of the questions that I get regarding
these applications are directly related to the fact that these are virtuals, and the application currently addresses a manufacturer whether they're virtual or not, and the virtuals are very frustrated by the fact that our application would require them to meet all the requirements; and that, I think, is the frustration that is driving some of the complaints you're hearing. And we're hoping that when we get this rule in place, we'll be able to create a virtual manufacturer-type application which should resolve many of the issues that you're probably hearing complaints about, but we got to get the horses in front of the cart, so to speak.

So that's why I think that this meeting is tremendously-important today, as well as in May, to get the input so we'll know more of what to do. Because if we just start exempting certain requirements, we're liable to put the public health and safety at risk. So we kind of really need some serious input from folks that won't let us make some mistakes. I'm sorry, Mr. Tuller.

MR. TULLER: Yes, and Mr. Director, this is Jeff Tuller, I just have a couple of questions. Who is our target audience for this workshop? Is it the ones that are currently trying to acquire a virtual
manufacturing license, is it those that have a virtual
license, is it all of the above and more?

MR. WINTERS: It's actually all of the above
and somewhat more, because there may be people that
currently are in the full manufacturing realm when --
because as people were originally given licenses, we
didn't have the virtuals, so a lot of virtuals, as we
demean it, have those manufacturer's licenses, and they
may very well be trying to move to a virtual
manufacturer. They're -- even in our program office
as far as applications we see on a regular basis
somebody that comes through and our renewal or
inspection of their facility, they're like, "Well, I'm
a virtual," we have to look at it and say okay, we
need to help you transition because you have a full
manufacturer's license and you can actually take
possession of drugs under your physical license, so we
expect you to meet all those criteria.

So those are some of the main groups that
we're looking for, but this will also, again, I think
will be helpful overall to the industry to have that
kind of more direct bright -- not necessarily full
bright line, but a much more clear line as to where
the virtuals will sit versus the manufacturer; where
the brokers are going to sit versus the full
distributors who are taking possession of drugs.

And so that's the anticipation is that we are
going to try and umbrella that to where anybody that
may possibly be thinking about it or that just is
unaware of what it is, we clarify that rule, that may
help them determine whether they can move to a virtual
if they want to move to a virtual --

MR. TULLER: Right.

MR. WINTERS: -- or not.

MR. TULLER: So my follow-up question is
would it be helpful if you sent notification to the
industry perhaps that this workshop was going to
occur, and perhaps target that -- those segments you
just mentioned somehow? I don't know if we have a
social media account or we're on Twitter, I don't know
but --

MR. WINTERS: We actually -- we can work with
communications on items such as Twitter --

MR. TULLER: Because I think this is cutting
edge stuff.

MR. WINTERS: -- but we -- also, one of the
things that we will do is that we will identify our
interested parties list, but I think it's a great
point that you make that perhaps what we can do is get
the license database --
MS. GREENE: Email list.

MR. WINTERS: -- pull those permit holders currently and get the email list from that; that we can go ahead and shoot a mass email to them.

MR. TULLER: Yes.

MR. WINTERS: "We are going to be developing this rule. It would be great if we could have your input" and have, then, the opportunity, I think -- like I said, one of the reasons we want to move it to the Orlando area is simply Tallahassee is difficult to get to, no matter how you look at it, and so we'll do that, and I do appreciate you mentioning that because that will spur us to put that in our follow-up to go ahead and have our technical director and knowledge team pull those email addresses out.

MR. TULLER: May I also add to that if I may, this is Jeff Tuller again, perhaps when you solicit that market place that you would request probably top two or three concerns that they have, and then you can ferret through all of the information you receive and then pretty much channel down if you wanted to address the key issues by the majority of the constituency to save time and be focused, I think that may be an opportunity for us.

MR. WINTERS: We will take a look and make
sure that we tailor the message out there, and what
information we give them. One of the items that we
will give an opportunity is, if they may not be able
to attend, that they can submit a comment to us as
part of the rule workshop that we can take into
consideration; but that may be helpful if somebody
wants to submit a comment beforehand and then -- even
and still attend -- for us to have pre-consideration.
We'll make sure that we tailor that message so that we
can -- they can gather that and we'll garner such an
item from them.

MR. TULLER: Terrific. One last point:
Every -- the trending of manufacturing here in this
country, obviously we all know it's off-shore and a
lot of these are virtuals and so on and so forth, so I
think we're -- I think this is spot on what we're
trying to do with the council, and far as this trip.

You know, as a board member, I look at this
that every single virtual does have some distributor
on record of some nature, and they must have a
standard operating procedure for the things that may
not be within that four walls. And there may be a
common denominator that we must obtain -- in terms of
temperature requirement or humidity requirement,
ambient storage, whatever it may be, security
protocols, procedures -- as a minimal. Because that
SOP is very important.

Whether that virtual is in a strip mall and
it's whatever it is, I would have to believe that they
would have some kind of SOP for storage and security
of their product which is part and parcel why we have
this committee; correct?

MS. ALSOBROOK: Yes.

MR. TULLER: So just for the record, I'd like
to note that, I think --

MR. WINTERS: I've got it noted, and I'm sure
that will be part of -- you know, one of the reason
why I do look to the council and want you to be able
to -- and move the meetings in conjunction is because,
as council members, like you said, you have the
industry information just as much as you -- our other
interested partners, if not more. And the fact that
you're here means you're extremely valuable to us
so --

MR. TULLER: I drove through the night.

(Multiple speakers, unintelligible.)

MR. MAYS: Yeah, and this is Steve, I think
that there's also -- and again, not being an expert on
the virtual manufacturers, but I know that there could
be situations where you have one that they're using a
CMO to manufacture their product, but then they may
maintain a lab to test that product before it's
distributed, or test something from each lot, and they
maintain a lab and -- again, we're probably getting into
FDA's realm but --

MR. WINTERS: But I think that --

MR. MAYS: -- there's a lot of different
situations out there, I'm sure.

MR. WINTERS: I think they're -- and that's
one of the reasons why we will send out that blast,
because one of the things that we'll note is that
sometimes we have the bigger picture, but we also need
to have people with the smaller picture to be able to
look into, or a different picture. And that's really
what this workshop is going to be about is to gather
everybody's input and get the full picture and try and
develop -- again, it is a rule which means it is a
broader brush --

MR. MAYS: Um-hmm.

MR. WINTERS: -- but it means that we are
going to have to, again, try and get everybody's
input, see if we can get a consensus and try and
develop a rule so that everybody at least will be on
notice as to what we expect. Dr. Goldman?

DR. GOLDMAN: Just a question -- yeah, this
is Jennifer Goldman, can you clarify for physicians and for patients what constitutes a virtual manufacturer and how it would impact, you know, patient safety and prescribing for those of us?

MR. WINTERS: Yeah, and like I said, I know that we provided just the basic information, and a lot of this will also be, again, provided in much more detail during the rule workshop. But again, the virtual manufacturer is an individual that is -- the key is a manufacturer, they meet the qualifications bother under FDA and under Florida law that they meet as a manufacturer, but they may not take physical possession -- or they're not supposed to take physical possession of any drugs. That means that they're coordinating with a contract manufacturer, they're co-licensed by the actual manufacturer in order to be the product marketer. And so we deem them under law to be a manufacturer, but they're not --

DR. GOLDMAN: But they're not, okay, okay.

MR. WINTERS: -- they're not actually one that's holding the drugs, they don't receive the drugs, nor do they receive any of the prescription items that are going into it. So they're not physically taking possession or handling the actual pharmaceuticals, which is why some the requirements
that we have, as noted by Chief Alsobrook and Councilman Tuller and Chairman Mays is that having a requirement that you have all this storage requirement, humidity and temperature controls and things like that, you're not storing anything but computers and paper, you know, you have a hard time meeting those requirements.

And so the health, safety, and welfare issue is that we still need them to maintain compliance with good manufacturing processes through their contract manufacturers, and also that record keeping requirements -- that they know that their labeling is required, we know who is actually manufacturing and distributing the product, whose name the people are going to be seeing out there on the product, those are all items that we still need to make sure that they comply with in their licensing. That's kind of a major overview, Chief Alsobrook, anything that you wanted to add?

MS. ALSOBROOK: I would add that some of these virtual manufacturers, not actual manufacturers, purchase the raw ingredients or active pharmaceutical ingredients for the product and control the laboratories that do the testing of the product. So the individual making -- and by "individuals" we mean
corporations for the most part -- making the product, which are usually overseas and are not inspected on a routine basis by the federal Food and Drug Administration, could be bringing product into the United States that is substandard and is not caught until it has caused some damage.

Frequently, products are recalled; you probably know that as a physician, because of particles in the product or glass in the product or whatever that happens, and it's only when something bad happens that we know of the recall.

So when you set up a corporation that's a virtual manufacturer, it has nothing to lose; it's not like AmerisourceBergen that's got physical land and buildings invested that has something that can be sued and taken from them, these are just businesses that may be in a very-small, 200-square foot facility. What can you sue? What can you take away from them? They have no real name or anything.

So the thought process is that we have to really think through what we're going to exempt them from, because 499.121 that places the responsibilities on these manufacturers and distributors, requires due diligence of suppliers, due diligence of purchasers, all kinds of responsibilities that we want them held
to, but it does allow us to exempt a few things, and a few things they should. As we indicated, the storage; what are they storing?

But if they do have a laboratory there, then there are things that we do need to think about, you know, they need to maintain those at proper temperatures and that kind of stuff, so those are the areas that we need to think about. But it is wrought for possible harm, we just need to be very careful.

It's not the good people that you have to worry about, it's those that --

DR. GOLDMAN: Sure.

MS. ALSOBROOK: -- are in it for the buck.

MR. MAYS: And this is Steve Mays, and somebody can correct me if I'm wrong, I may be mistaken, I think typically those virtual manufacturers that have that label or code and their names on the label, I think FDA holds them responsible for any recalls that have be done. I don't think they go back to the contract manufacturer, I think it's the label owner. I could be mistaken, but I -- so that's --

MR. WINTERS: I believe you're correct but we'll obviously make sure that's --

MR. MAYS: But they do have some skin in the
game, you know, for a bad product.

MR. WINTERS: They have skin in the game, they do, but we also need to make sure that we maintain that balance of level, which is to know that if we've got somebody that they're maintaining the requirements, that they can, if we go back to them and say you need to produce a recall --

MR. MAYS: Um-hmm.

MR. WINTERS: -- as you indicated, they can do that. That's really a health, safety, and welfare record. We need to know where the product is and where it came from; all those items, the SOPs, things like that. So those are all issues that we have to weigh when we start to decided what we can and cannot exempt. Again, we're limited to what's in 0121 for those categories, but we'll take care of all that as part of the rule workshop, and we'll provide a very specific notice to everybody plus outreach, and then also have a rule workshop package that will include a lot of the reference materials that we'll have for everybody to look at, so that -- we'll do that. And -- and --

MR. MAYS: Mr. Barnes?

MR. BARNES: Patrick Barnes. So I'm glad you asked that question, because I was sitting here and
didn't want to be ignorant sounding. So if they have the bulk product, some sort of a chemical, I would think that would need to be stored under proper humidity and temperature and that. So what we're doing here is not going to remove that; correct?

MR. WINTERS: Correct. This is for --
MR. BARNES: Okay.
MR. WINTERS: And we keep saying "virtuals," it applies to the broker-only, too. But they're not taking physical possession of those pharmaceuticals or the --

MR. BARNES: The finished product, but the --
MR. WINTERS: The finished product --
MR. BARNES: But they're --
MR. WINTERS: -- or the API.
MR. BARNES: Oh, they're not -- oh, they're not --
MR. MAYS: Yeah, that -- that contract manufacture typically is handling the API, and doing the actual --
MR. WINTERS: Now, they may -- as Chief Alsobrook indicated that there is a line there you got to remember, though: They may be responsible for ordering that API and having it shipped directly to their contract manufacturers, so we will still need to
know that they're getting it from an authorized
source, or what's going on, that it's meeting the
requirements. And so those are all part of that chain
of information that we need to maintain while also
trying to balance out not having them have to have a
storage locker or a cage for controlled substances,
other items, you know, that just don't apply. But we
do need to make sure that we look at that, other
items, SOPs things like that; what happens if they do
get an inadvertent drug sent to them and they didn't
realize it, what they do with it, things that we'll
expect them to have the ability to handle.

So those will all be part of the rule
workshop in doing that, and then I think --
Dr. Goldman, I think your question, though, has
pointed out that perhaps as part of the rule workshop
would be a good lay-out from us to maybe get with our
legal team to provide a good presentation on the
actual virtual manufacturer from our side, to give
everybody an understanding of generally where we see
that virtual manufacturer's at, and then we'll roll
into what we think we can and cannot exempt them from.
So I think it's an excellent comment, and it's going
to help us when we start the rule workshop process,
and -- which is really the purpose why we're out here
to day is to kind of make sure we launch the ship in
an upright and even fashion. We don't want to have it
upside down before we get going, so --

MR. MAYS: Any other questions from council
members? Okay, so I know we've got other folks on the
line, so I just wanted to open it up for any questions
from any other interested parties on the line before
web move on? Okay. Mr. Winters, anything else?

MR. WINTERS: No. I think what we'll do is
move on because the next item is very similar to this,
but it's one that's going to a little more -- I think
this one's going to be a little more -- not
contentious or difficult, but just it's going to have
a little more exacting nature to it.

We are currently wanting to also, at the same
time, have another rule workshop on a different item
which is administrative services. When the DSCSA was
adopted, there was a exemption from the definition of
wholesale distribution for an entity providing solely
administrative services. The provision under the FDA
Statute is actually in 21 USC 353(4) and it is --
excuse me, (c)(4) -- the issue is is that one of the
items that we're seeing right now in cases in other
individual areas is that people are not necessarily
misinterpreting, but we don't an exact definition of
administrative services, what it constitutes; where the line is from where you cross over from just providing solely administrative services to you're providing actual distributions under the wholesale distribution.

Again, I want to be careful with this one right now because we are not to really get too far into conversation regarding this, so -- because I think this is going to be a rule workshop that's going to be very interesting and coordinated with the industry, because this will have some substantial effect for them regarding who and where licensure would be needed.

Again, the idea would be is to get all the individuals in the industry to go ahead and send a blast email out to them to know where that line for administrative services is. I can't -- won't go into any detail, but it's something that our Office of the General Counsel has dealt with this, our Enforcement division has dealt with this when we find individuals that have indicated, "Well, I'm only providing administrative services." When we review it, we don't believe that they have -- are providing only administrative services; that they're actually maybe going beyond that, and that they don't fit into that
exemption. If you don't fit into that exemption, you need licensure, they don't have it, then of course we've got an enforcement method.

And so we want to look at really trying to provide an administrative definition at this rule workshop trying to get a consensus inside the industry that we can go ahead and develop for Florida the definition of administrative services; and that is, again, what we're looking at.

If you're wanting to know inside obviously from a reference in 499 -- under 499.003(48) under the exemptions from wholesale distribution is the administrative services -- it says solely for administrative services. We would want to hold a rule workshop to discuss that and see if we can't develop an administrate definition to be developed into the administrative code.

That is, again, going to be something that will be beneficial to the industry and to us that we can at least put into rule the line that we have by definition in trying to develop that so everybody's aware whether they do or do not meet the definition.

Some of the items regarding this one that make it a little more difficult and a little different than our virtual is the fact that this is developed
and was implemented based on the exact language being
in to the DSCSA. So we have a counterpart here in
Florida, we could only develop the definition based on
what Florida has; it would not be applicable to any
other state, it would only be applicable here.

Currently there has not been a definition
defined by the FDA, and it does not look like we're
going to have -- they're still developing it
through the -- and through guidance documents, we see
that they are working on it, but again, we feel like
it's time that we may go ahead and try and get this
clarified for Florida and for our permit holders to
try and get that definition put in place.

It will be, again, held at the same time, and
we would, again, provide a blast email outreach to the
industry so that we can get as much input as possible,
and that we would provide a package ahead of time for
people to see the items that we would be looking at
and go forward at that particular moment in time at
that May hearing, and that would be what we would do.

This one, like I said, is probably going to
be a little more lengthy than the virtual, I think,
but -- they could both be a substantial discussion but
we want make sure that we're, one, want to go there,
if you advise it, we think it would be beneficial to
get your input if we want to try and develop that --
that definition. If there's anybody who has any
comments, concerns -- Chief, did you have anything
that you wanted to add?

MS. ALSOBROOK: You know what I would add --
Mr. Court Reporter, Renee Alsobrook -- during our
investigations, we run upon individuals and we receive
complaints that individuals are conducting wholesale
distribution of prescription drugs without permits.
And within our rules, Dr. Goldman, there are
exemptions from wholesale distributions that are based
upon what the drug -- what the federal government
passed as the Drug Security Chain Act. And Florida
passed exactly that verbiage into our statutes in
2016, thinking that eventually -- and eventually they
will -- the Food and Drug Administration will develop
some definitions and rules, et cetera.

So we didn't define certain terms because we
thought they would be forthcoming -- and they will. I
will be retired, but they will -- so one of those
terms that we've run into in our investigation is the
claim that we're only doing administrative services.

And I'll give you an example: We walk into a
facility and we find six people on the telephones and
they're calling all around selling products to
hospitals, to doctor's offices, and they're buying
them, and they're bargaining for the prices and
they're telling the doctor we can get you this cheaper
and they're actually calling their warehouse and
shipping it there too, and they tell me "we're only
doing administrative services." Well, I don't agree
with that, I don't think that's right, but I don't
have a definition so I don't know.

So I've gone to the director a couple times,
and of course those people go to the director and say
"I'm not doing wholesale distribution, see, it's
administrative services." But I think that that's
anti-competitive to the people that pay the price to
regulate -- be falling within the regulation and get
the permits and have the CDRs and post the bonds and
all that stuff. And I think that we need a level
playing field one way or another, and this a big hole
that people keep falling into and diving into and
claiming that it's just administrative services. So
we don't know what it is.

We do know that it says including processing
of orders and payments. Well, that's okay. You know,
you've already decided what drugs you're going to buy,
you've already decided the price, and I've done it all
and I send it to somebody to do the paperwork, I've
got that; that's probably administrative services.
But what does the industry think that is? You know, do you think that that's all there is to it; that that's administrative services? So we don't know. I mean, I'm a regulator, I don't know.

But that's when I went to the director and I said can't we figure out from the industry what this is? So we had a long discussion. But this is a federal term. Yeah, it is, but do we wait ten years?

So what we know is when the feds do define the term, Florida's term will probably have to go away, because we'll have to defer because it's preempted. But in the meantime, are we entitled to implement Florida law for the safety of the public? And I think that we probably are. But that's part of the, I think, the conversation that will come out at the rules workshop.

Is it a good thing for us to do, can you give us some definitions, do you think that we should just let all this happen all around us and have this definition be an exemption for all regulations. But anyway, that's what I'm finding in the field.

MR. MAYS: I think -- this is Steve -- I think it would be important to kind of take a look at it, because I'm sure in the industry, I think there's
probably some confusion about where you cross that
line from being just a call center which, you know --
I know, you know, AmerisourceBergen has call centers
around the country, and they're just basically taking
calls from customers, and basically that's where
customer care is, so it's a more-centralized process
in some of the larger companies. So you know, that --
I think there's probably some confusion about where
that line gets crossed to where you're a call center,
or you're actually providing those administrative
services.

MS. ALSOBROOK: Um-hmm.

MR. WINTERS: And that's exactly the point.
And this is truly when I call it -- this is purely get
the knowledge to everybody and so that we can all
hopefully come together all in agreement that this is
where we all think that that line is after a
discussion; because without that, again, it's on a
case-by-case basis, it leads to situations where,
again, we may be getting good people, good companies
that are trying -- think they're doing something okay,
we don't think they're doing something okay, or we
have a case that we believe cross that threshold. If
we had it out there inside of the industry for
everybody to be able to have the full definition or
something to better define that -- because let's be
hones, "administrative services" is kind of an
amorphous term, all right? We don't know -- you could
take that from any which direction you want to. If we
can -- we want to try and bring that in for a landing.

And again, as we've said, this is because we
don't have one now. If we get one we -- as 499 says,
we always have to do the best we can and always stay
in compliance with federal law, so if this were to
later be reassessed and we get a FDA determination
administrative services is more or less restrictive
than what we have defined it as, we will either remove
our rule completely or we'll tweak it so that it
conforms with what FDA is, so that everybody has that
information.

But that would be down the road; until then,
we want to try and be a leader for our industry here
in Florida and give them the tools that they need to
work, and for our regulatory scheme to be able to
work, we need those tools as well.

MR. TULLER: So this is Jeff Tuller, what I'm
hearing you tell me is -- I see this as most
businesses today obviously out-source lots of
different functions. I think that's probably a
reasonable situation everywhere within our industry.
So you have a legal -- kind of a contractual legal line to these companies that you can pretty much ferret out with your due diligence -- I think Florida does a pretty good job of that -- and also you have a physical side of this. So you really have really -- if I'm thinking this through properly, there's a physical side.

All right, if I have a telemarketing group and a warehouse that's distributing product, that is an administrative services, correct, that's you know, we're -- like you walked into that situation in your example, that's somehow a stretch of administrative services unless those people have different uniforms or in a cube that -- I don't know --

MS. ALSOBROOK: There you go, I mean --

MR. TULLER: So I think, you know, when you look at your due diligence on this, you really have two things to consider: One is what is the legal tie to that particular administrative service; and two, where is the physical presence of that administrative service?

So you know, in my old days at the big boys, we were -- we may have been in one city, but we were in a lot of other little cities. And some of those little city were different contractual arrangements.
So if I am licensed in that particular place, am I
burdened by my license in this state even -- so
there's a lot of gray --

MR. WINTERS: Well, there's a lot of that --
MR. TULLER: -- I don't know --
MR. WINTERS: -- I think you're point -- and
I think that the conversation today is really to look
at -- there's so many different permutations --

MR. TULLER: Oh, gosh --
MR. WINTERS: -- what are out there --
MR. TULLER: Yes.
MR. WINTERS: -- depending even from small
size to big size, how you out-source. Even if you're
not out-sourcing, you may be splitting up the
functions inside of your realm --

MR. TULLER: Um-hmm.
MR. WINTERS: -- and you may have different,
as we talked about, call centers in multiple cities;
that you're a large corporation that, you know, you
have to centralize certain functions to one location.
Is that location providing administrative services or
not? That's all part of the conversation that we're
going to have and look at that, because there's so
many ways as -- there's a thousand shades of gray here
that you could apply if -- and so you're really
looking at a situation where, because the rule
workshop is intended for us to get each person's idea,
their shade of gray where they think it's at, and get
on more of a consensus and get that determination
where it's at, so it's going to -- it's going to be --

MR. MAYS: Just for the record, Michael Mone
has joined the meeting. Better late that never.
Right here.

MR. WINTERS: We'll put you --

MR. MAYS: Right there on the -- right there
on the corner.

MR. MONE: Oh, okay. All right, sorry.

MS. ALSOBROOK: One of the things,
Mr. Tuller, I think is important: As regulators
trying to be fair, when a law is passed, businesses
are businesses, you know, and I think --

MR. TULLER: Yes.

MS. ALSOBROOK: -- hopefully we got input and
got the involvement of businesses when the statutes
were written -- and that's kind of pie in the sky
because that doesn't happen, but anyway, so maybe we
can hope that happened -- but businesses evolve and
they change and they -- more quickly than regulations
do.

And if we don't try to get this input from
the business entities, then our regulatory scheme is not going to address the changes in business. And we're going to be running around wasting the few resources we have, the nine inspectors I have, chasing what I think is unlicensed activity when it's not. And the public will be harmed from that, because running around chasing -- I'll use AmerisourceBergen's -- customer care centers thinking that they're unlicensed activities, is not the way to protect the public.

The way to protect the public is finding unlicensed manufacturers of prescription drugs that are actually making the drugs, substandard distributors who are actually not maintaining adequate temperatures and monitoring those properly; that's where I need to put my resources. So the clarity that I have in the law is what allows me to do a better job, and this does not allow me to do a better job. I may not like that you can split up your functions, I may like that AmerisourceBergen or Cardinal has to be responsible for every single aspect of a distributor's job, but I don't know that legally that has to be the case. As you indicated, I think you can subcontract out a bunch of functions and still be perfectly legal.
MR. MAYS: I mean, the traditional wholesale
distributor model from years ago, and probably some
still today, is all those functions were in one
building. You know, you had accounting, you had
accounts receivable, you had accounts payable, you had
customer service, telephone sales, and the operation.
And now those -- those functions are centralized,
especially for the larger companies, they're in
different places, so I guess my question for you,
Renee, is do you really feel that comfortable that FDA
is going to adequately define that?

MS. ALSOBROOK: I always live in hope.

MR. MAYS: You think they'll define that in
the wholesale licensing --

MS. ALSOBROOK: I think they have to.

MR. MAYS: Yeah.

MS. ALSOBROOK: We've talked to them enough
to convince them that it is -- it's an absolute
necessity because we've addressed it in Florida, and
if you don't address that component, they're going to
have the same issue that we're having. How are you
going to properly identify who needs to be licensed if
you don't identify your exemptions, because that just
creates this massive hole.

MR. TULLER: Renee, your point -- this is
Jeff Tuller again -- your point is well-taken. It's really -- we have all of this stuff going on, as Steve said, that old box that had every department in it including the trucks that drove the drugs to your drugstore, is no longer. So as we change, and we try to interpret the law, let's come back to what that's supposed to be, and that's the safety of the patient.

MS. ALSOBRook: That's --

MR. TULLER: And if we drive towards the safety of the patient in every single communication, and not get bogged down with all that other stuff that, in my opinion, can be onerous to a business and to a -- of course, to a facility, I think we're way ahead of the game.

MS. ALSOBRook: Yes, sir.

MR. WINTERS: That's the hope. We'll get in --

MR. TULLER: We always hope, we always hope.

MR. WINTERS: And again, this is -- in talking about this, this is a hope that we will be able to get a good product out of the workshop. We always find the best product comes out of coordination, that's what this is going to be.

Again, we'll -- as the things change, we'll ebb and flow with that, but to try and get something
on paper and really take the effort -- we wanted to 
make this year a year that we started trying to find a 
couple of the items that we really wanted to tackle, 
and this was one of the --

    MR. TULLER: Might as well take on the big 
ones.

    MR. WINTERS: Well, if you're going to do it, 
go for it.

    MR. MAYS: I think to Mr. Tuller's point, you 
know, it's just that -- you know, and I've had 
conversations with you -- it's like, you know, the bad 
guys are the unscrupulous players in the supply chain 
will find those weaknesses and those holes in the 
rules and in the law, so I think any time that we can 
try to plug those, you know, where it doesn't disrupt 
the whole supply chain, I think it makes a lot of 
sense to try to find those weaknesses --

    MR. TULLER: Agreed.

    MR. MAYS: -- plug them.

    MR. WINTERS: So the only thing I would ask 
is just a vote of council that you're comfortable with 
us going forward with a workshop and coordinating it 
with the council.

    MR. MAYS: Do I hear a motion?

    MR. TULLER: (Indicating.)
MR. BROCK: Second.

MR. MAYS: All in favor say aye.

(Chorus of ayes.)

MR. MAYS: Those opposed? Okay.

MR. WINTERS: I think Mr. Tuller was the motion maker on that one.

MR. TULLER: Yes, I made a motion to --

MR. MAYS: All right. All right.

MR. TULLER: -- approve that one, for the record.

MR. WINTERS: And council members, that is all I have at this point in time for you.

MR. MAYS: Okay. Any other questions from council members on the subject? All right, Mr. Mone?

MR. MONE: The question I have is at what point would you guys like me either to come in to help with the examination?

MR. WINTERS: And I apologize, Councilman Mone, I addressed that in one of my prior comments. We hoped that I was going to be able to get a coordination or presentation here today, unfortunately due to a scheduling error, it didn't occur. We're going to try to move that to the -- also to the May council meeting.

MR. MONE: Okay.
MR. WINTERS: But I've also talked with them, we've got implementation April 1st for the 18 months, but I've also talked with them as far as a time frame to start working -- we're coming up to that time frame where we're going to start coordinating and overhaul -- again, the -- we generally do it on about a three-year cycle, and I think we're coming up on that, so what I will do is set a meeting for you and myself and -- to discuss that with Andrew Janicek, our Bureau of Education and Testing --

MR. MONE: Okay.

MR. WINTERS: -- just to get you some ground work --

MR. MONE: And it seems lately that I've been coming to Tallahassee a bit more, so if there's a -- if you want to do it live, that's also a possibility.

MR. WINTERS: And for sure what I will do is make sure that it's the most-convenient method for you because I don't want to inconvenience you. The fact that you're willing to help and the council's taking that effort to provide you that authority I think is going to be a great asset to us, so we'll make sure that --

MR. MONE: Okay. Perfect. Thank you.

MR. WINTERS: Dinah, if you could --
MS. GREENE: I got it.

MR. WINTERS: -- make sure my keeper keeps me keeping on.

MS. ALSOBK: She got you.

MR. MAYS: All right? All right, any questions from any other interested parties on the line before we move towards closing out? Okay. Any other business? All right, hearing none, do we have a motion to adjourn?

MR. TULLER: Motion to adjourn.

MR. MAYS: Second?

MR. PHILLIPS: Second. Second, this is Jeenu.

MR. MAYS: All in favor say aye.

(Chorus of ayes.)

MR. MAYS: Opposed? The meeting is adjourned, thank you.

(Whereupon, the proceedings were concluded at 10:34 a.m.)
CERTIFICATE OF REPORTER

I, JEFFREY R. BABCOCK, do hereby certify that I was authorized to and did report the foregoing proceedings, and that the transcript, pages 1 through 55, is a true and correct record of my stenographic notes.

Dated this 4th day of March, 2018 at Tallahassee, Leon County, Florida.

[Signature]

JEFFREY BABCOCK, FPR

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