TELEPHONIC COUNCIL MEETING - PUBLIC MEETING

DATE TAKEN: Thursday, September 12, 2019
TIME: 9:37 a.m. to 10:34 a.m.
PLACE: Florida Department of Business and Professional Regulation
2601 Blair Stone Road, Building B
Tallahassee, FL

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ORIGINAL

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COUNCIL MEMBERS IN ATTENDANCE:

Steve Mays, Chair Prescription Drug Wholesalers
Joseph Lavino, CVS Health, Retail Pharmacy
Michael Mone, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Dean Ellis, Secondary Prescription Drug Wholesalers
Jeffrey Tuller, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Peter Hart, Medical Gas
Jennifer Goldman, MD, Physician.
Walter Copeland, Division Director
Halsey Beshears, Secretary
Tim Page, Deputy Secretary
Renee Alsobrook, Compliance Manager
Stephanie Prine, Government Operations Consultant
Rebecca Bumett, Regulatory Supervisor

Also Present:

Shannon Hartsfield, Holland & Knight, LLP

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<table>
<thead>
<tr>
<th>AGENDA ITEM</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call to Order: Steve Mays, Chair</td>
<td></td>
</tr>
<tr>
<td>&quot;TAB 1&quot; Chair's Report - Steve Mays, Chair</td>
<td></td>
</tr>
<tr>
<td>A. June 13, 2019 Meeting Transcript (information only) - pg. 1</td>
<td></td>
</tr>
<tr>
<td>B. 499.01211, F.S. - Drug Wholesale Distributor Advisory Council - pg. 9</td>
<td></td>
</tr>
<tr>
<td>&quot;TAB 2&quot; Division Director’s Report - Walter Copeland</td>
<td></td>
</tr>
<tr>
<td>A. Legislative Update</td>
<td></td>
</tr>
<tr>
<td>A. HB-19 (Laws of Florida 2019-99 provided) - pg. 10</td>
<td></td>
</tr>
<tr>
<td>B. Safe Importation Action Plan - pg. 37</td>
<td></td>
</tr>
<tr>
<td>C. Shop Smarter for Dental Supplies - pg. 41</td>
<td></td>
</tr>
<tr>
<td>D. Disciplinary Information</td>
<td></td>
</tr>
<tr>
<td>A. Compliance and Enforcement Unit Report - pg. 78</td>
<td></td>
</tr>
<tr>
<td>&quot;TAB 3&quot; Other Business</td>
<td></td>
</tr>
</tbody>
</table>
PROCEEDINGS

(Whereupon, the meeting was called to order at approximately 9:37 a.m. by Chairman Steve Mays.)

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. And I notice we have got a court reporter in the room. I would like to remind everyone to identify yourself before you speak, so the court reporter will know who is speaking for the record. And for those of you on the phone, please mute your line when you are not speaking, and, also, please do not put us on hold, as you can see that it will definitely interrupt the call if somebody puts their line on hold.

Ms. Prine, I think we are ready for a roll call.

MR. PRINE: Okay. Steve Mays?

MR. MAYS: Present.

MR. PRINE: Jeenu Philip?

(No response.)

MR. PRINE: Joseph Lavino?

DR. LAVINO: Present.

MR. PRINE: Michael Mone?

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MR. PRINE: Scott Brock?
(No response.)
MR. PRINE: Arlene Elliott?
(No response.)
MR. PRINE: Dean Ellis?
MR. ELLIS: Present.
MR. PRINE: Jeffrey Tuller?
(No response.)
MR. PRINE: Patrick Barnes?
MR. BARNES: Here.
MR. PRINE: Peter Hart?
MR. HART: Here.
MR. PRINE: Jennifer Goldman?
MR. MAYS: I heard her and Jeff announce on the line. They must not -- can you guys hear us?
MR. PRINE: Can you guys hear us in Tallahassee?
(No response.)
(Off the record for technical adjustments.)
MR. MAYS: We are having technical difficulties here with the phone. We did a roll call, and I know I think I heard Jeff and Dr. Goldman.
You guys are on, right?

MR. TULLER: Yes.

DR. GOLDMAN: Yes, yes, we are here.

MR. MAYS: So anybody else missing that might have been on the phone?

MR. BROCK: Mr. Chairman, Scott Brock is on.

MR. MAYS: Okay. Scott Brock is on. Michael Mone, are you on?

MR. MONE: Mr. Chairman, I am here.

MR. MAYS: Okay. All right.

MS. ALSOBROOK: So that leaves Jeenu Philip and Arline Elliott. Are either of those on, Mr. Chair?

MR. MAYS: Jeenu Philip or Arline Elliott, are you on?

(No response.)

MS. ALSOBROOK: You have a forum.

MR. MAYS: Are we ready to move forward?

MS. ALSOBROOK: Yes, sir, you have a forum.

MR. PRINE: Okay. Under Tab 1, you will find a transcript of the June 13th meeting for informational purposes only.

Next, also, you will see a section of the

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Florida Statutes that describes the make up and the role of the Drug Wholesale Distributor Advisory Council.

Normally I like to start the meeting off by reading the goals of the council under that paragraph, but since they are in there, feel free to read them on your own. I think it is always good to review that, just to kind of understand why we are here.

So I will, unless there are any questions or any comments, I will go ahead and turn it over to Mr. Copeland for the Division Director's Report, under Tab 2.

MR. COPELAND: Good morning, everyone. I appreciate y'all coming up, and I appreciate all of you on the phone. I feel a little bit under the weather, so if I start sniffing and snorting, I will try to be quick.

You will see the first item we have on the agenda is the House Bill 19. And we had — we had kind of delved into that a little bit in the last meeting. We want to give you an update from our end. And as all of you know, that's the Florida's International Prescription Drug Importation Program, that I think the bill
was passed into law June 11th or 10th.

And real quick, under the bill, there are
two programs that are to be put into play. The
first one is the Canadian program, which is
under the Agency for Health Care
Administration's oversight. And then the other
one is the International Prescription Drug
Importation Program, and that is the one that
Division of Drugs, Devices and Cosmetics is
responsible for overseeing, implementing.

So real quick, in reference to the
Canadian program within the bill, we can tell
you, as many of you probably know, Agency for
Health Care Administration has submitted their
concept paper to HHS, and that, I think, was a
couple of weeks ago.

Again, that's, Canadian side, is their
responsibility. We worked in conjunction with
them on some of the common areas, but they have
presented it to HHS for review, approval, or
whatever the next step is.

On our end, on the International
Prescription Drug Program, we are still working
through our proposal plan that we are to submit
with the Department of Health. Department of
Health is working in conjunction with us on the proposal that we are to submit to HHS, or we are to use to negotiate a pilot program for the importation of prescription drugs.

And so we are making progress. I'm trying to -- I kind of looked through last meeting's minutes and some of the areas that we addressed. We don't have a time frame yet. The bill does not direct us to specifically have a date of when that presentation or when that delivery is going to be made. But we are moving as fast as we can on preparing the document, and with the Department of Health assisting and working as co-preparers with us.

You know, we have gotten feedback obviously from those that are on the pro side, those that are on the anti side. And, again, here at DDC, we are following the directive that the bill mandates, and we simply understand those sides, but essentially we just don't have a dog in the fight. We are working to prepare it as the legislative, the law reads.

So there were some questions last time, I know, looking through the minutes, referencing
the drugs that qualify for importation. And those are in the bill. And there are disqualifying drugs. Our international program that we have here in DDC is not limited to Canada only. It's any foreign jurisdiction that has a relationship as in agreement with FDA is open to participate in the program should it be approved.

And so we are — again, that's where the international program within this bill is different than any other state that is moving on similar bills. Every other state that have passed bills that are moving on developing those programs are all limited to Canadian participants as importers.

That's kind of a broadbrush overview. There is a lot of — we have got a copy of the bill here that is passed into law. And, you know, again, our mandate is to demonstrate a program that saves money to the consumers in Florida while demonstrating and making certain that safety is the priority.

And if you look through the requirements in the bill related to the track and trace and other areas, it's a lot of requirements of the
participants.

And so, again, that was a high level overview, and if there is anything we can try to answer, I will defer to Chief Alsobrook. She has led the project, and I appreciate everything with DOH working in conjunction. So it's really -- it's really taken a lot of time away from the everyday operational side within our department, but we also appreciate the opportunity in our moving forward. So I hope that didn't confuse you, but that's just kind of a broadbrush overview.

MR. MAYS: This is Steve Mays, I have a couple of questions. Have you gotten any -- probably you haven't, but have you gotten any feedback from HHS as of yet?

MR. COPELAND: We have not, Steve. We have not. And we are working -- we are working with the Executive Office of the Governor and senior leadership here. We know what other state relationships or contact with HHS has been, but right now, we have not had any direct contact with them.

And, Chief Alsobrook, is that your understanding, also?
MS. ALSOBROOK: Nothing has been, Chairman Mays. We have received no information about the ACHA presentation or the Florida Bill. Now, there was, and it's also included in your agenda material on page 37, FDA did -- HHS, under FDA's moniker, did put out the Safe Importation Action Plan. So not to mislead anybody, they have spoken somewhat on this topic in a very generic manner, and the Director will be speaking to that subsequently. So that would be a generic public comment, not specifically to DBPR, but generic to the public, some statement by FDA.

MR. PRINE: Can I interrupt for just a second? We have lost connection.

MS. ALSOBROOK: Again?

MR. PRINE: Again, yeah.
(Off the record for technical adjustments.)

MR. MAYS: Sorry, guys, we keep having phone problems here, it drops from time to time. I don't know what part of the discussion that you missed, but we were getting an explanation about whether there had been any feedback from HHS, and I don't know if everybody on the phone heard that or not.
DR. MAYLEBAN: No, we didn't.

MR. MAYS: So can you kind of repeat that --

MS. ALSOBROOK: Just summarize?

MR. MAYS: Yeah, summarize that.

MS. ALSOBROOK: Well, what I had said -- this is Renee Alsobrook, what I said to the Chairperson was we, Department of Business and Professional Regulation, have not received anything specifically directed towards the Department from FDA, or Health and Human Services, but that Health and Human Services and FDA had put out a Safe Importation Action Plan generic to the public at large. And that had been the only information that has addressed, generically speaking, the importation issue that we are looking at with the Florida legislation.

And, Mr. Chair, I think you had another question, and Mr. Hart has another question.

MR. MAYS: I had one that is really more detailed. There is a section in there about, the Agency shall contract with the vendor to provide services. Has there been any activity in that area?
MS. ALSOBROOK: That is under the -- this is Renée, again, that is under the Agency for Health Care Administration's plan. And I believe that the Agency for Health Care Administration is drafting an intent to negotiate, which is required under Florida Statutes, for the Agency to hire someone. And they are drafting an intent to negotiate to hire a vendor. That has not been published. It is required to be published, and they have drafted, or are in the process of drafting, that at this time.

MR. MAYS: Okay, thank you.

MR. COPELAND: And, Chair, and obviously on our international program, we don't have the mandate to do that. We are operating ours. But the oversight and the compliance internally and essentially with the Canadian program, as Chief Alsobrook had said, they are required to retain a vendor that will essentially run the program for them.

MR. MAYS: Mr. Hart, you had a question?

MR. HART: I did, just as a clarification for me. Back on the topic of communication with HHS, Florida has not actively proposed
questions that they have not responded to, the
comment really is they haven't given you any
additional feedback from the general document
they published, right?

MS. ALSOBROOK: That is correct. That is
correct, Mr. Hart.

MR. HART: Okay. Thank you.

MR. MAYS: Do we still have the group on
the phone?

MS. ALSOBROOK: I am checking.

MR. PRINE: Do we have any participants on
the line?

(No response.)

(Off the record for technical adjustments.)

MR. MAYS: Okay. So they got disconnected
right after I asked the question about had
there been any activity on selecting a vendor.

MS. ALSOBROOK: So, Mr. Mone, the answer I
had gave was that we were informed by the
Agency for Health Care Administration yesterday
that they were working on drafting the
invitation to negotiate for publication for the
vendor, that draft is not completed, so they
have not published that invitation yet. But
they are able to get that out pretty quickly.
So there hasn't been any publication of the invitation to negotiate for the vendor at this time.

MR. MAYS: And after that, Mr. Hart had a question, it was just asking for clarification.

MR. COPELAND: And just to reiterate, since we got cutoff, the vendor requirements within the bill are only applicable to the Canadian program under the Agency for Health Care Administration. Under the international program within the bill, we are not mandated or required to have a vendor. So just be sure they are separated.

MR. MAYS: Any other questions from anyone in the room?

(No response.)

MR. MAYS: Okay. So we will open it up to anyone on the phone; do you have any questions?

(No response.)

MR. MAYS: Okay. I think we can move on, Mr. Copeland.

MR. COPELAND: Chief Alsobrook had referred to this in her clarification earlier. But FDA and Health and Human Services had issued a Safe Importation Action Plan. I think
it was distributed July 31st. And if you look at the document in your package, it's essentially -- it is a proposed action plan that provides two pathways that the federal government are looking into to essentially allow or work into importation of prescription drugs.

As of yesterday, and our conversations we have had with some other states that have bills passed into law referencing importation, and discussions with others, there has been no movement on this safe action plan at this point. They haven't done any rule making of any sorts or any of the process that the federal government would have to do to move forward with those two pathways.

That being said, it's a variable out there that we know may pop up in this whole importation plan. Right now, we have to run in our program development under what current law and current options are.

The other variable with the Safe Importation Action Plan is that when the rule making starts, or even before the rule making starts, I'm sure there is going to be a lot of
interjection and input from states and others.
So the plan, as it reads right now, could be
adjusted when the rule making -- and, Renee,
tell me if I misstate something -- when it
starts moving forward.

So, again, it shows you that there is some
wheels spinning in the federal government
regarding -- and in Health and Human Services
and FDA regarding importation, but there is
nothing definitive yet in a method to actually
do it.

And, again, if you have any questions on
the safe importation plan, we can try to answer
those for you, but it is in your package.

MR. MAYS: Any questions from anyone in
the room?

DR. LAVINO: I do have one. This is Joe
Lavino.

Director Copeland, thank you.
In guards to the --

DR. MAYLEBAN: We are not able to hear.
MS. ALSOBROOK: We may have to repeat the
question, Dr. Mayleban, because we are using a
small phone.

MR. MAYS: Yeah, go ahead with your

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question --

DR. MAYLEBAN: Okay. I just wanted to make sure that you-all knew we weren't able to hear you.

MS. ALSOBROOK: Okay.

MR. MAYS: Yeah, go ahead with your question, and we will just repeat it for the people on the phone.

DR. LAVINO: Sure thing.

Is the -- are the actions taken in collaboration with Department of Health to present to HHS aligned with the first pathway and the action plan that FDA had put out? I'm just trying to understand.

MR. COPENLAND: Chief Alsobrook, would you -- I'm going to let Chief Alsobrook, who has been more on the technical side of this, Doc, to answer that question.

MR. MAYS: You probably want to repeat his question.

MS. ALSOBROOK: Yeah. Dr. Lavino asked that if the actions -- and make sure I repeat it correctly, that if the actions that we are taking in drafting the proposal are aligned with pathway one with the Safe Importation
Action Plan.

Did y'all hear that on the phone?

Dr. Mayleben, did you hear that?

DR. MAYLEBAN: Yes, ma'am.

MS. ALSOBROOK: Okay. So, yes, sir. To answer your question, simply, yes. The proposal being drafted or the conversations to lead to the draft with Department of Health have been that we meet all of the, A, safety requirements. Because that's the paramount and most important thing that the drugs brought in are safe.

Secondarily, that they comply with the licensure requirements that the Florida license holders are meeting -- or have to meet now, because, otherwise, it would be unfair that people in Florida have to do certain things, and these people would need to comply with those.

And the second thing is that we would have the ability to check on the drugs and the licenses that these folks have to verify that they are doing what the federal requirement -- federal requirements are. So how do we create a technology system so that we can verify that.
So those are the conversations we are having
with Department of Health. So we have two
agencies needing to look at that, and how can
we do that at the same time, and how can we in
a very quick fashion suspend that importation
activity if we find that there is some activity
that brings in unsafe drugs, counterfeit drugs,
or something that is not compliant. So yes,
sir, to answer your question.

DR. LAVINO: Thank you.

MS. ALSOBROOK: Yes, sir.

MR. MAYS: So hopefully everyone on the
phone heard the question and the answer.

Any other questions from anyone in the
room?

(No response.)

MR. MAYS: How about those on the phone,
any other questions?

MR. MONE: No, Mr. Chairman.

COURT REPORTER: Okay, who was that? I'm
sorry.

MR. MAYS: That was Michael Mone.

You said, "no"? Or did you have a
question? I am sorry.

MR. MONE: No, I apologize for the court
reporter.

Yes, it's Michael Mone, and, yes, I said,
no, I have no questions.

(Laughter.)

MR. MAYS: Okay, great. Thank you,
Mr. Mone.

Mr. Copeland, I think we can move forward.

MR. COPELAND: The next item, I am going
to let Chief Alsobrook --

MS. ALSOBROOK: Yes, sir.

MR. COPELAND: If you can go on to that
one, please.

MS. ALSOBROOK: Thank you.

Starting at page 41 of your agenda
material, I included three different examples
of a trend that we are seeing in enforcement.
None of these are meant to be examples of
investigations, but they are trends that we are
seeing an enforcement of, what appear to be,
distributions into Florida, as well as other
states, of prescription drugs from Internet
companies that we cannot find a license for.

It is of concern to me, because the
dispensers who are receiving these prescription
drugs would not be receiving T3 documentation

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transaction information, statements, and
history, and, therefore, would be out of
compliance with the drug security, what do you
call that, DSCSA?

MR. MAYS:  DSCSA, yes.

MS. ALSOBROOK:  I am so used to using the
acronym, I can't even remember the name of it
now. And the drugs we do not know are coming
from approved sources. Now, I understand that
it is a penny saved, because the drugs are
cheaper, that's why they are doing it. But I
don't know that long term a penny saved is the
right way to look at these drugs. Because,
long term, if you injure a patient, or if you
get caught, it's going to cost you more than
the penny saved that you are saving on these
drugs.

So I wanted you to look at it. But the
one is titled on the agenda, Shop Smart for
Dental Supplies. But I am not discriminating,
because I put the Medical 32 in there on page
67, and Net 32 on page 46. So I tried to
provide you examples of them being sold to
medical doctors as well as other companies
doing this.
And what I would like for you to do is think about it, and how we might consider addressing this, getting folks into compliance. I will tell you what I do right now, and I don't know how effective it is, but I will tell you what I do right now, and then what we might be able to do in the future legislatively, or ignore it, or whatever you think is appropriate for me to do.

Currently I conduct an investigation. Obviously it's hard to investigate an Internet company, particularly one that's located outside the state of Florida. But I try to get enough information to establish a reasonable basis in law, in fact that they are distributing prescription drugs into the state of Florida without a permit.

It's very hard to get a doctor to give me the invoices that he actually bought the drugs, because then he's admitting that he bought drugs from an unauthorized source, and that would be a crime. So they don't like to hand me that kind of stuff. The people that report these violations to me don't really want their names to be in the investigative report, they
want to be anonymous. Well, my legal team
says, well, that's really hard to prove a case
because I don't have anybody I can subpoena and
go to DOAH. So imagine that, it would be
difficult to prove these cases.

So what I'm forced to do is send something
that we call a warning letter to them. Well,
you know, it looks like you need a permit, stop
doing this until you get a permit from the
state of Florida. They like say, oh, okay,
fine. And that goes into circular file 13,
also known as the garage can, and they continue
to do what they do.

I also make a referral to FDA, and I refer
them to the postal inspector. Because the
postal inspector does a lot of investigations
for unlicensed activity, also known as Medicare
fraud and insurance fraud, because you can't
buy drugs from people that don't have permits.
So the postal inspector and I are big buddies,
the Inspector General for the postal inspector.

So those are things that I do now in cases
like these. Sometimes it pays off. You
probably have seen some ads, or newspaper press
articles where the postal inspector has
actually got criminal convictions because of referrals that we have made to them. But it takes a long time. You can go five to six years before you see those actions.

So I wanted you to see this, because, for the most part, the Wholesale Advisory Council is the Wholesale Advisory Council, it is something that I do think impacts the safety of the public. I do think it denigrates your compliance activities and the money you spend on compliance to have somebody come in behind you, undercutting your cost, and not providing a product that either is the same as yours, or provides the T3 documentation that you are forced to provide.

So that's why it is on the agenda. I don't expect any solutions today, but I did want to make you aware of a huge trend that we are seeing in the industry at this point in time.

I am open for any questions you have.

MR. MAYS: Yes, Mr. Barnes?

MR. BARNES: Patrick Barnes. I guess it would seem that this isn't just unique to the state of Florida, this problem, and it is
probably happening all over the country.

Have you reached out to any other states,
and maybe they have been successful, and maybe
you don't have to reinvent the wheel? I am
just curious.

MS. ALSOBROOK: To repeat the question Mr.
Barnes asked. He indicated he probably thinks
this isn't just Florida, and asked me if I have
reached out to other states to see what they
have done, and maybe we would not have to
reinvent the wheel.

My response is, that is an excellent
suggestion. Florida does tend to be ahead of
many other states in our regulatory activity,
but I will reach out. That is a good
suggestion, I will reach out to some of the
other states who are more active in their
regulation and see what they have done, because
there are some that have done things. There
are more states who have regulatory actions in
place. And Mr. Barnes, that is a good
suggestion.

MR. MAYS: And this is Steve Mays. I
might add that NABP may be doing some work in
this area, too.
MS. ALSOBROOK: And we have reached out to them.

MR. MAYS: You have? Okay. Any questions?

(Inaudible response.)

MR. MAYS: Yes, could you identify yourself?

MS. HARTSFIELD: Yes, I'm Shannon Hartsfield, with Holland and Knight.

On the top of page 41, it says, keywords manufacturer, and then there is some company names; is that something that is on the website, or is that something --

MS. ALSOBROOK: That was on the website, and it's not good to be on the website.

MS. HARTSFIELD: Right.

MS. ALSOBROOK: But they are comparing -- on the keywords, it lists a couple of companies, and what they are doing is comparing those companies to their prices.

MS. HARTSFIELD: Okay.

MS. ALSOBROOK: And they reflect that their prices are better than those companies' prices. Not good.

MR. MAYS: Are these companies -- this is
Steve Mays, by the way.

Are these Internet vendors, are they marketing to consumers, or practitioners, or both? I may have missed that.

MS. ALSOBROOK: To my knowledge, these are focused on practitioners, but we also have information that others, not these three, but others are direct to consumer.

Dr. Mayleben, do you --

DR. MAYLEBAN: This is Dr. Mayleben --

MS. ALSOBROOK: Yes, ma'am.

I just stuck to my name, but I asked her to be on the call.

MR. MAYS: Okay.

DR. MAYLEBAN: We are also seeing some other platforms. These are just a couple, but there are many platforms out there that basically are connecting pharmacies to pharmacies, pharmacies to wholesalers, physicians or practitioners to wholesalers, typically secondary wholesalers, as well as other pharmacies. So they are the middleman people that are basically connecting it to basically buyers and sellers.

And as Chief Alsobrook stated, many times

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the buyer could be anywhere, but if they are in
Florida, then they are potentially buying from
a pharmacy, a secondary wholesaler, or someone
outside of the state, or even inside the state,
that does not have a permit to do so.

And as she also stated, they are typically
not complying with the transaction information.
And some of them may be purchasing, and part of
the chain may involve a gray market or a health
care entity.

We are seeing this, as Chief Alsobrook
said, it is definitely a trend, and there are a
lot of different platforms cropping up across
the country. And some are more pharmacy to
pharmacy, and some are pharmacy to pharmacy
and/or wholesaler, and some are wholesale
platforms.

MR. MAYS: Thank you. It kind of reminds
me of a few years ago when there was a lot of
activity with Internet pharmacies filling
prescriptions for controlled substances based
on an online survey, and a doctor says -- I
think the online, you know, Internet activities
continued with noncontrolled substances,
because DEA passed the Ryan Haight Act, and it
pretty much put a big stop to the controlled
substances part of it. But that is concerning
the buyers purchasing these drugs, and they
really don't know where they came from, if
there is no transaction history. I think the
safety is the biggest --

(Simultaneous speech.)

MR. MAYS: -- concern.

DR. MAYLEBAN: (Indiscernible) Are using
the drug shortages and high priced dollar
items, also.

MS. ALSOBROOK: This is Renee, one of the
interesting things is yesterday, there was an
arrest in south Florida for Botox purchases.
They had purchased counterfeit Botox because
they can get it very inexpensively. And it was
obvious the box is not in English. Everybody
knows that is not US made, FDA approved Botox.
But it's cheaper so we buy it. And the patient
doesn't know because it's in a syringe when the
patients see it. So there was a pretty big
bust. And, again, our buddies, the postal
inspector and the criminal authorities came in
and took care of it because it got here through
the mail.
But those are the situations that they are going on the Internet, they are seeing these drugs are $20 instead of $120. Well, it's kind of like you buy something that's been stolen, you should know that if a TV cost you $20, and at Costco it's $300, there is some reason for that.

But with non drug inspectors, it's hard to beat on every door to find out that these things are happening, and you need to prioritize what you can.

So think about what we might be able to do with these kind of cases.

MR. MAYS: It's a tough one.

MS. ALSOBRICK: Yeah.

MR. ELLIS: Mr. Chairman, this is Dean Ellis.

MR. MAYS: Mr. Ellis?

MR. ELLIS: My particular company, we service those practitioners. And this has been going on for since there was a fax machine. We didn't bring up the faxes, that these offices are getting faxes all day long. I mean, I am hearing it all day long. Well, I can get this. And then when I research it, I

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find just what this report says. But hopefully you can come up with a solution to stop this, but we sure haven't been able to. We just try to educate our customers. But it's 25 cents less. You know, and it's the old saying, if it's on the Internet, it must be true and good. So I just thought I would add that little comment. We have seen it for a long, long time. It started with the faxes, and now it's moved into the online world, so hopefully we will solve that.

MR. MAYS: Okay. Any other questions from anyone in the room?

(No response.)

MR. MAYS: Or on the phone?

(No response.)

MR. MAYS: Okay. I think we have one more agenda topic.

MS. ALSOBROOK: Yes, sir, Mr. Chair. At the last meeting we had talked about getting some information on the specific types of violations that we found during the inspections of wholesale distributors, and I told you I would go back and look at the cases and bring you that information.
So on page 78 of your agenda materials, I kind of broke those down for you. For the nonmedical gas cases, the most were the unauthorized source purchases. The other, the second most was for no transaction information, history, statement, or transaction information, or transaction histories. And then it is just broken down as to the types of violations that we found when we wrote these cases.

So kind of look for those yourself, and I am here to answer any questions that you might have on those.

I will tell you that we did not begin enforcement activity, and by "enforcement activity", I mean, writing cases on T3 activity, for, I believe it was, 3 years after the law became effective. We educated on it, and then we started writing cases. So it's really somewhat shameful that that number is 9.3 percent. That it took -- we gave education, said this law is in effect, you should be getting these documents to people, and nobody like listened for three years, and so finally we started writing cases. But it's...
working now.

MR. MAYS: Yeah, I found it interesting that 100 percent of the prescription drug wholesale distributors inspected had violations. So I don't know if that's attributed to the rigor of the inspections, or just that everybody is missing something out there.

MS. ALSOBROOK: Well, I think it's both. The inspections are rigorous. And, y'all, it's a tough -- that's what I'm saying. That's why I'm so offended that somebody without a permit can sell on the Internet a drug that is .25 less. Sure they can. Because you know the cost of compliance is substantial. So you take away the cost of compliance, and your drugs would be cheaper that you sell.

I mean, I have been to your facility, and I know what it costs to keep the temperature and the humidity at the appropriate level, and to monitor that. And to train your employees. And to keep your cages locked. And your staff appropriate to have your invoices right. To make sure that the people you are buying your product from are appropriately licensed. And
that costs money.

You know, and if you don't care about that stuff, and you buy it from Tom, Dick, or Harry, and then you just sell it through the mail, and ship it through the mail, and you don't really care, and do due diligence on who you are selling it to, or who you are buying it from, your product can cost less.

MR. MAYS: Yeah, I guess just to add to that. I know how much my company has spent just putting a system together to be able to provide that transaction history and statement and information to our customers, and be able to track that through our enterprise, and to see there is, you know, firms out there that aren't even attempting to comply with that DSCSA requirement, yeah, it gives you pause --

MS. ALSOBROOK: Yeah.

MR. MAYS: -- to think that we put all of the effort and time. And I appreciate you recognizing that, that the legitimate wholesalers are putting a lot of effort into compliance.

MS. ALSOBROOK: What I think is amazing is do you think one of these Internet companies,
if there is an illegitimate product identified, do you think they are going to be able to locate it? No.

MR. MAYS: Not at all.

MR. COPELAND: What's unfortunate, you have the demand -- it's just like illegal drugs, you have the buyer, and the seller, and there is an error on both sides.

MR. MAYS: To add onto that, or if they determine that it's an illegitimate drug, are they going to report it to FDA, as they are required to?

MS. ALSOBROOK: No, no, that's not going to happen. So the entire system breaks down, and you just have to hope that it doesn't become an Avastin issue where the drug is compromised and people lose their sight or die, and not an NEC situation where lots of people get sick and die. I mean, you just have to hope that doesn't happen, or other things.

COURT REPORTER: Avastin, did you say?

MS. ALSOBROOK: Avastin, yes, ma'am.

MR. MAYS: Avastin, yeah.

This is Steve Mays. I want to just make a final comment, and then we will take questions.
I do greatly appreciate you providing this information. I think it's helpful for distributors to see what types of -- I know for me personally it's helpful to see what types of violations are out there, and it helps us to go back and, you know, redouble our efforts to make sure that we are fully compliant in these areas as a distributor. So, again, I want to thank you, Ms. Alsbrook. I'm sure this was not an easy task to pull off, so I appreciate you pulling this information together for the council.

MS. ALSBROOK: Yes, sir.

MR. MAYS: Any there any questions from anybody in the room on this report?

MR. ELLIS: This is Dean Ellis again.

MR. MAYS: Mr. Ellis?

MR. ELLIS: I would like to second what Chairman Mays said about the Department. This information is valuable. I'm disappointed that 100 percent of distributors have violations, so hopefully, as an industry, we can improve that.

MR. MAYS: Any other questions from anyone in the room?

DR. LAVINO: Mr. Chair, this is Joe
Lavino.

MR. MAYS: Dr. Lavino?

DR. LAVINO: I have a question. Thank you for the information, first and foremost.

In regards to the 9.3 percent that failed to provide any of the DSCSA specific data, in your view, was it that there were specific elements that were missing, or they just didn't do it at all in those cases, or is it a combination of both?

MS. ALSOBROOK: Dr. Lavino, they did not know about the law.

MR. MAYS: For the folks on the phone, the question was regarding the failure to provide the transaction history, information, and statement, was it that they completely were not doing it, or was it just that parts of it were missing. I think and —

MS. ALSOBROOK: The answer was they didn't know about the law.

MR. MAYS: Yeah. That sounds like -- it is a little surprising, but there's wholesale distributors out there that don't know what the requirements are. But 9.3 percent, that's a pretty high number.
MS. ALSOBROOK: Yeah, I mean, there is about 300 plus of you guys, then that would be about 35 of you that just don't know about the law. So actually that's not too bad.

MR. MAYS: Out of a total of how many?

MR. ELLIS: If you say so.

MS. ALSOBROOK: I think there is about 360 prescription wholesale distributors in Florida.

MR. MAYS: Any other questions from anyone in the room?

(No response.)

MR. MAYS: How about on the phone?

(No response.)

MR. MAYS: Okay. Any other business?

MR. ELLIS: This is Dean Ellis again. At our last in-person meeting we had discussed in the state of Florida -- I know this is not going to fit in with all of the things that are going on right now, but maybe continued food for thought, I really think that we need a device permit, because I think there are med-surg dealers who are selling prescription drugs that are a very small amount, but yet we have to have a prescription drug license, and in some cases we don't -- these distributors...
don't want to sell prescriptions drugs, but when you deal with device manufacturers, they still want a license. You know, it doesn't matter, you know, that you are not selling prescription drugs, they want a license. And a distributor in the state of Florida right now that is distributing devices has to have a prescription drug license.

So, you know, there is a possibility that the number of licensed prescription drug distributors could drop if we could get some sort of a device permit. And I'm not trying to push for more regulations, but it just seems that we need some sort of a device permit.

MR. MAYS: Are you talking about a device only permit where --

MR. ELLIS: Yeah. And devices can be exam gloves, suture, needles, or syringe, all of these type of things. They don't necessarily -- are not locked tracked, but we still -- the manufacturers still want a license and, Drew, our last director, had spoken to several manufacturers on it, and it didn't matter, they still wanted that.

And I just thought it's something that
maybe later on, when we have some time, that's something that you can look at. I don't know all of the details of it, but I just think a device permit would be something that maybe we should look at.

MR. COPELAND: Chief, we can move forward in looking at that with our legal team. And I understand, it is more compliance, but then it takes away some --

MR. ELLIS: Right. Exactly.

MR. COPELAND: Again safety is the number 1 goal, but we do want to be business friendly in common sense. So that's a good point. And as we look at potential areas of legislation and rules, we will work with the team and keep you updated.

MR. ELLIS: I just thought it was something we should maybe think about later on.

MS. ALSOBROOK: This is Renee, I think currently the statute does have a device permit. It's in (o), 499.01 (2)(o). We have authority for device manufacturer's permit, but a permit is not required if it's an FDA registered device. So the decision then would be the interpretation of the permit not being
required. So could it be issued if someone wanted it to be issued? That's the key. It's how it's been interpreted in the past versus how you interpret it now. So if I wanted it, even though I'm not required to have it, could I get it?

MR. ELLIS: Yes, that's the question. That's a good question.

MS. ALSOBROOK: That's the question. So that's what the director should discuss with the legal team.

MR. COPELAND: In education.

MR. ELLIS: Is that in 499?

MR. MAYS: Yeah, it's in 499.

MR. ELLIS: Oh, I didn't see that. I will look.

MS. ALSOBROOK: Look in 499.01 -- 01 -- 499.01 (2) (o), as in Octopus.

MR. ELLIS: One more time.

MS. ALSOBROOK: 499.01, paren (2), (o), as in octopus.

MS. ELLIOTT: Okay. Thank you.

MS. ALSOBROOK: You know I'm slick. That's what you do with 30 years of legal practice.
MR. ELLIS: I just looked at the permits
the state issues, and I didn't see anything
like that.

MS. ALSOBROOK: It says that, except that
a permit is not required if AB are there.

MR. ELLIS: So there might be something
already there that —

MS. ALSOBROOK: There may be. But, again,
as the director said, that kind of policy
decision was made not to require those permits.
And that's what it says, it is not required.
But then do you offer them if somebody wants
it? Then that's a decision that you, and the
council, and the director, and the secretary
need to make.

MS. ELLIOTT: Well, and that's what has
happened, the manufacturers, and it's not just
one, it's several, they are under certain
guidelines in their state about selling their
products.

MS. ALSOBROOK: Yes.

MS. ELLIOTT: I just think that some of
the prescription drug wholesalers now are
putting a lot into this, and if they had
another license, there could be an
opportunity -- it would be a win, win for everyone. It would be less people that you are regulating on the drug side, and still have some sort of inspection type of thing on the --

MS. ALSOBROOK: On the device side.

MS. ELLIOTT: On the device side. Which basically would be everything that you have, except more track and trace and that sort of thing. You know, you want the records and the like and all of that. So, anyway, thank you for reviewing that.

MS. ALSOBROOK: For the audience and for people on the phone, currently if a device has a prescription drug in it, we license them as a prescription drug manufacturer, so it may be a device, but we don't treat it as a device, we treat it as a prescription drug --

MS. ELLIOTT: Correct.

MS. ALSOBROOK: -- because it has a prescription drug in it. And we still would, by the way, Mr. Ellis. It would have to have a prescription drug manufacturer. But there are so many devices that are Rx only, they aren't regulated in Florida because of this provision that says they are not required to have a
license.

MS. ELLIOTT: Thank you, that's -- for
clarification.

MS. ALSOBROOK: Well, look at everything.

MS. ELLIOTT: I will look at that. Thank
you.

MS. ALSOBROOK: And y'all and the director
talk, and we will do whatever you want us to
do, I mean, on the reinforcement side.

MR. COPELAND: That's not a true
statement.

MR. MAYS: It's on the record.

MR. ELLIS: I'm glad you said that.

MR. MAYS: Any other questions or business
for the council?

(No response.)

MR. MAYS: Okay, hearing none, do we have
a motion to adjourn?

MR. BARNES: So moved. This is Patrick
Barnes.

MR. MAYS: And do we have a second?

MR. ELLIS: Second, this is Dean Ellis.

MR. MAYS: All in favor say "aye".

(Chorus of ayes.)

MR. MAYS: Any opposed?
(No response.)

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

(Thereupon, the proceedings adjourned at 10:35 p.m.)
REPORTER'S CERTIFICATE

STATE OF FLORIDA
COUNTY OF LEON

I, REBECCA HUGHEN, Certified 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 3rd day of November, 2019.

[Signature]
REBECCA HUGHEN, CCR

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