

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

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DATE: Thursday, May 18, 2017
TIME: 9:30 a.m. - 9:51 a.m.

REPORTED BY: JULIE CULVER, Notary
Public in and for the
State of Florida at Large

For the Record Reporting
1500 Mahan Drive - Suite 140
Tallahassee, Florida 32308

ORIGINAL

TELEPHONIC PROCEEDINGS

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

And we do have a court reporter on the line. I want to remind everyone to identify yourself before you speak so the court reporter will know who is speaking for the record.

For anyone on the line, please mute your line when not speaking. And whatever you do, please don't put us on hold, that would be helpful.

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

MS. GREENE: Okay.

MS. GREENE: Jeenué Phillips.

MR. PHILLIPS: Present.

MS. GREENE: Brian Flies.

MR. FLIES: Present.

MS. GREENE: Michael Mone.

MR. MONE: Present.

MS. GREENE: Scott Brock.

MR. BROCK: I'm here.

MS. GREENE: Arlene Elliott.

MS. ELLIOTT: Present.

1 MS. GREENE: Dean Ellis.

2 (No response.)

3 MS. GREENE: Jeffrey Tuller.

4 MR. TULLER: Present.

5 MS. GREENE: Patrick Barnes.

6 (No response.)

7 MS. GREENE: Peter Hart.

8 (No response.)

9 MS. GREENE: Jennifer Goldman.

10 MS. GOLDMAN: Present.

11 All right. You have a quorum, Mr. Chair.

12 CHAIRMAN MAYS: Okay. All right. There are
13 a couple of things I would like to start with
14 before we get to the agenda.

15 I know that Reggie Dixon introduced the new
16 Division Director, Drew Winters, to us at the last
17 Council meeting. But I would like to welcome Drew
18 back for his first full Council meeting as the
19 Division Director.

20 And I've enjoyed starting to get to know
21 Drew. And I'll look forward to working together
22 with Drew and the DBPR staff in the coming year,
23 and I'm sure the rest of the Council members will
24 also.

25 Drew would you like to say a few words before

1 we get started?

2 MR. WINTERS: Thank you, Mr. Chairman. And,
3 yes, I would like to take just a moment to say
4 thank you to all of the Council members; you have
5 been very welcoming to me. I look forward to
6 working with each one of you in the future and all
7 of the opportunities that it incurs.

8 I'd also like to take a quick moment to thank
9 my staff here in the office, Dinah, and Renee, and
10 Rebecca, and Ms. Beth, who is across from me, they
11 have all been incredibly great and welcoming.

12 And I can tell you this that coming on as a
13 new director, we find the staff is well versed,
14 and as great as they are, it makes your transition
15 much easier. Like I said, with that I'll turn it
16 back over to you, Mr. Chairman, but look forward
17 to working with everybody.

18 MR. MAYS: Thank you. Finally, as has been
19 practiced in past meetings, I want to start the
20 meeting off by reading the goals of the Council as
21 stated in Chapter 499. "The Council shall review
22 this part and the rules adopted to administer this
23 part annually, provide input to the Department
24 regarding all proposed rules to administer this
25 part, make recommendations to the Department to

1 improve the protection of prescription drugs and
 2 public health, make recommendations to improve
 3 coordination with other states' regulatory
 4 agencies and the federal government concerning the
 5 wholesale distribution of drugs and make
 6 recommendations to minimize the impact of
 7 regulations on the wholesale distribution industry
 8 while ensuring protection of the public health."

9 Okay. So first -- I guess, secondly, we
 10 don't have a lot of agenda items today. So this
 11 maybe a very efficient call, not so much short,
 12 but maybe an efficient call. So we have no items
 13 on the Chair's report.

14 So I want to take this opportunity to urge
 15 council members to think about providing any
 16 agenda topics for future meetings so we can make
 17 sure that we're fulfilling our role and our
 18 mission.

19 So with that we'll move on. Under Tab 1,
 20 just for reference purposes, you will find the
 21 transcript of our February 16 in-person meeting.
 22 So I'll turn it over to Mr. Winters for the
 23 Division Director's report Under Tab 2.

24 MR. WINTERS: Thank you, Mr. Chairman.
 25 Members, if you'll look at Tab 2. We will start

1 with our rules support for you. Again, we've
2 provided the rules support which gives you an
3 outline.

4 Primarily, right now, our division rule
5 making is focused specifically on adopting our
6 form into rules. And during that timeframe we
7 have been looking at streamlining those
8 applications for the purposes of ensuring that;
9 one, we're trying to effectuate a reduction in any
10 deficiency to help members or applications as they
11 apply and try to get that timeframe down to help
12 us be efficient in our process.

13 Just to look down the report, we have
14 highlighted in blue -- I wanted to draw your
15 attention to those two items. At the last
16 meeting, we had filed those rules and forms for
17 adoption at the Department of State.

18 I am happy to state that Ms. Donna has got
19 those rules we have filed them with the Department
20 of State and they have been adopted, at this point
21 in time, and are effected. That is for Rule
22 61N-2.011 and 61N2.015 that is our application for
23 the non-resident prescription drug manufacture
24 permit and the application for the prescription
25 drug repackaging permit.

1 Moving forward with what we had talked about ⁷
2 and moved from the last meeting if you will look
3 at our 61N-2/012 and 61N2.016 these are the
4 applications for our out of state prescription
5 drug wholesale distributor permits and the
6 application for the prescription drug wholesale
7 distributor permit both of these we did go through
8 the internal development and revise those forms
9 help streamline them taking into account some
10 information that we had received from Mr. Vecca's
11 area and processing and did draft those we did
12 provide those for each one of you Council members
13 and appreciated the opportunity to receive
14 feedback from you and did incorporate several
15 change items and they are based on those again,
16 thank you.

17 We did file those with both OPAR and the
18 Administrative Procedures Committee we had
19 received a letter that is in your package from a
20 joint administrative procedures Committee and did
21 respond to the APC with information and made some
22 changes to the forms to resolve their concerns.

23 I am happy to say that we have received a
24 callback from the APC, which at this point in time
25 has only notified us of any technical changes so

1 it looks like we are moving well on our way to
2 adopting both of those applications at this point
3 in time we're going to be doing and Donna correct
4 me. We've got a notice of change that has been
5 sent both to (indiscernible? And OPAR and we're
6 waiting to hear back from, officially, back from
7 the APC but our initial contact with Ms. Holiday
8 at the APC has been very positive and then we will
9 wait for Ms. Reddick from OPAR.

10 Once that is done we can go ahead and file
11 those notices change. Specific changes that we
12 did make to the application is that we
13 incorporated the personal information statement
14 specifically into the application and that made
15 Ms. Holiday with the APC happy to hear that we did
16 take into account those items and it became part
17 of the application.

18 We'll make and attempt this week to ensure
19 clarity that they are one application so we look
20 forward to moving forward with those rules again,
21 the other point that I wanted to bring up and in
22 this particular item is that these two
23 applications are moving forward with our process
24 to move the Wholesale Distributor Permit to a
25 biannual renewal which, again, we hope to have

1 completed by the end of fiscal year or at least
2 initial implementation around the July 1 timeframe
3 so we expect that this is the first major piece to
4 that.

5 And it looks like we are right on schedule.
6 The other thing that I did want to note for you is
7 that we know that these are probably one of the
8 two most difficult the permit application for
9 revision so we think these will be very helpful as
10 we move forward through the rest of the
11 applications that are noted on your rules report.

12 We will be moving through the other items
13 that at this point in time are highlighted and why
14 we will be looking at those again to determine
15 which ones we want to move forward next.

16 Currently, right now, we have filed a
17 proposed Notice of Rule making for the 61N-2.022
18 for the Healthcare Clinic Permit, the HCE Permit,
19 but we will be working on having a trial and a
20 proposed rule for that wit the Department of
21 State.

22 We will also as we -- again, I know that at
23 the last meeting or Council meeting we had a
24 request and we did want to go ahead and let you
25 know we would continue to fulfill that request,

1 which is as we get these applications revised to
2 give the Council the members an opportunity to
3 review, but we just want to make sure that we get
4 them finalized internally before we give them out
5 to the Council members, but we will continue to do
6 that.

7 Again, we hope to have the rest of these
8 applications approved by the end of the year and
9 it looks like we are at this point in time on
10 track. So if there's any questions or concerns or
11 any items that you'd like in regards to the rules
12 report please I'll take those now and we'll make
13 sure to try and answer them as best we can.

14 MR. MAYS: Any questions from Council
15 members?

16 MR. ELLIS: Mr. Chairman, this is Dean Ellis.
17 I missed the roll call. I just wanted to let you
18 know I'm in attendance.

19 MR. MAYS: Well, thank you for joining us,
20 Dean.

21 MR. Miller: Hey, Mr. Chairman, this is Jeff
22 Miller. I just like to thank Drew for these great
23 efforts, and much appreciated. Thank you.

24 MR. MAYS: Any other questions from council
25 members? Any questions from other interested

1 parties on the line? Okay.

2 MR. WINTERS: All right. Well, Mr. Chair
3 with that what I'll do is if you'll look at our
4 Rules Report, our 2017 Legislation Rules Report in
5 that you will find two proposed bills that were up
6 before the Florida Legislature this year. They
7 are House Bill 211 and Senate Bill 114, dealing
8 specifically with cosmetic product registration
9 and would have an effect on certificates of
10 presale for those items.

11 Again, these two bills were in the
12 legislature. Just kind of roll through the
13 overall impact of it, is that pursuant to 499.015,
14 we currently are registering cosmetic products
15 before anybody can engage in the sale of those
16 products here in the State of Florida. The
17 purpose of this legislation directly was to remove
18 the Department's requirements that you register
19 those cosmetic products before you were able to
20 sell those products. It does not specially remove
21 the Department's ability to regulate cosmetic
22 manufactures.

23 So in that respect, we will still be
24 continuing the cosmetic manufacture permitting and
25 regulation and inspection in addition as part of

1 our cosmetic regulation we will still have
2 oversight to look at those products just to make
3 sure that there aren't any major concerns with
4 products that are being produced and marketed here
5 in Florida, excuse me manufactured here in
6 Florida.

7 The two bills were specifically, also, aimed
8 at the Department's ability to issue certificates
9 of resale. So once we no longer register the
10 cosmetic products we will also not be able to
11 register, or excuse me issue a of resale to and
12 these upon request the bills does go into effect
13 July 1 and so between now and July 1 if we do need
14 that certificate of resale on our products that
15 are already registered, we will still go ahead and
16 issue those up through the July 1 effective date
17 of this bill.

18 Now, I did want to note, specifically, though
19 there was a distinction between the two bills.
20 And it was regarding a -- at the very end of the
21 bill, if you will look in the last section before
22 the effective date, the information regarding the
23 funding portion to this, in Senate Bill 114
24 because the product registration will no longer be
25 generating any fees for the Division.

1 Senate Bill 114, had in it a general revenue
2 provision. This would have allowed the Division
3 to pull general revenues from the general revenue
4 trust fund to, again, continue funding the efforts
5 of the Division. That was originally in both 211
6 and 114. The after review of the bill and the
7 information submitted the House provided a updated
8 version amended their version to instead of
9 providing general revenues that they've elected
10 instead that in this particular case that they
11 would allow the Division to review the
12 manufacturing permits for cosmetic manufactures
13 and if the cost were not sufficient to cover the
14 regulatory activities on that one particular
15 permit that they would be able to -- the Division
16 would be able to move forward with making rule
17 making to raise that permit and they did remove
18 the \$400 limit on that.

19 Both the Senate version and the House version
20 passed for chambers based on what you see in front
21 of you. When it came to conference on this the
22 Senate side elected to go ahead take up the House
23 side. So the House version of HD-211 is the
24 version that passed. At this point in time, the
25 version has been enrolled that simply means that

1 those Houses have passed the legislation.

2 It is currently in the enrolled status. It
3 is in the process -- and it will be signed off by
4 the Speaker of the House and the Senate Chair and
5 that will then be forwarded to the Governor for
6 review and determination of whether to sign the
7 bill into law.

8 Again, we are simply awaiting that process
9 and will await the Governor's determination on
10 this particular bill and we will continue to do
11 that. However, in the meantime, the Department is
12 in the process of ensuring that we are ready to
13 implement this bill in the event that the Governor
14 does sign it.

15 At this point in time, that is within the
16 Governor's purview and we will await his decision
17 on that. In regards to the items inside of the
18 bill for implementation, specifically the Division
19 has a general, good plan in order to again
20 implement this bill and we will be looking at the
21 impact regarding any reduction in fees as we move
22 along to determine if and what steps we need to
23 take in order to adequately adjust for any
24 reduction in fees that we would receive from the
25 cosmetic product registration, again, that will

1 require us to do some fiscal accounting and review¹⁵
2 to better determine what our actions are going to
3 be in regards to that.

4 However, the most important part to this is
5 that beginning July 1 cosmetic manufactures will
6 not need to register their products. Again, we
7 have been in the process and in light of the
8 progress of this bill of going ahead and making
9 initial steps to be prepared for the
10 implementation. So with that that is the Bill
11 that is before us.

12 And, again. I'll take any questions that you
13 have regarding that. But I think the most
14 significant portion to that is that we are, again,
15 looking at this bill and preparing in the event
16 that the Governor is going to sign the bill, or if
17 the Governor signs the bill.

18 MR. MAYS: Any questions from council
19 members?

20 (NO RESPONSE.)

21 MR. MAYS: Okay any questions from any other
22 interested party's on the line.

23 (NO RESPONSE.)

24 MR. MAYS: Okay. All right. Is there any
25 other business?

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(NO RESPONSE.)

MR. MAYS: Hearing none, do we have a motion to adjourn.

(CHORUS OF SECONDS.)

MR. MAYS: I think I heard a second. All in favor say aye.

(CHORUS OF AYES.)

MR. MAYS: Opposed?

(NO RESPONSE.)

MR. MAYS: Okay. The meeting is adjourned. Thank you very much everyone.

(WHEREUPON, THE TELEPHONIC PROCEEDINGS WERE CONCLUDED AT 9:51 A.M.)

CERTIFICATE OF REPORTER

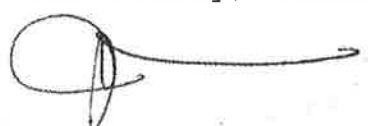
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STATE OF FLORIDA)
COUNTY OF LEON)

I, JULIE CULVER, Notary Public for the State of Florida at Large, do hereby certify that I was authorized to and did stenographically report the foregoing telephonic proceedings; and that the foregoing transcript is a true and complete record of the telephonic proceedings within the limits and quality of the telephonic proceedings.

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

DATED this 18th day of May, 2017 at Tallahassee, Leon County, Florida.



JULIE CULVER, Court Reporter