

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

4
5 COUNCIL MEETING

6 (Via Telephone Conference)

7 TRANSCRIPT OF PROCEEDINGS

8 DATE: August 16, 2018

9 TIME: 9:30 a.m. - 10:12 a.m.

10 Stenographically reported by:
11 Deborah Alff, RPR

12
13 COUNCIL MEMBERS ATTENDING:

14 Steve Mays, Chair, Prescription Drug Wholesalers
15 Jeenu Phillips, Vice Chair, Board of Pharmacy
16 Joseph Lavino, CVS Health, Retail Pharmacy
17 Michael Mone, Primary Prescription Drug Wholesalers
18 Scott Brock, Pharmaceutical Manufacturers
19 Dean Ellis, Secondary Prescription Drug Wholesalers
20 Jeffrey Tuller, Primary Prescription Drug Wholesalers
21 Patrick Barnes, Hospital Pharmacist
22 Peter Hart, Medical Gas
23 Jennifer Goldman, Physician

24 DBPR STAFF ATTENDING:

25 Drew Winters, Division Director
Dinah Greene, Government Operations Consultant

ALSO PRESENT:

D. Ty Jackson, GrayRobinson, P.A.
Shannon B. Hartsfield, Holland & Knight, LLP

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1 P R O C E E D I N G S

2 (Whereupon, the meeting was called to
3 order at approximately 9:33 a.m.)

4 CHAIRMAN MAYS: Good morning, everybody.
5 My name is Steve Mays. I would like to call this
6 meeting of the Drug Wholesale Distributor Advisory
7 Council to order.

8 I just want to remind everyone that we do have
9 a court reporter on the line, and that you need to
10 identify yourself each time before you speak so the
11 court reporter will know who is speaking for the
12 record. If you don't, I may interrupt you to
13 remind you to identify yourself, or she may.

14 For anyone who's on the phone -- which
15 everyone is on the phone today -- to please mute
16 your line when you're not speaking and that will
17 cut down a lot on some of the background noise that
18 we hear often. And also, please, do not put us on
19 hold so we don't have to listen to anyone's paid
20 commercial announcement or music.

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

23 MS. GREENE: Yes, sir.

24 Jeenu Philip?

25 DR. PHILIP: Present.

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1 MS. GREENE: Joseph Lavino?
2 MR. LAVINO: Present.
3 MS. GREENE: Michael Mone?
4 MR. MONE: Present.
5 MS. GREENE: Scott Brock?
6 MR. BROCK: I'm here.
7 MS. GREENE: Arlene Elliott?
8 (No response.)
9 MS. GREENE: Dean Ellis?
10 MR. ELLIS: Here.
11 MS. GREENE: Jeffrey Tuller? Jeffrey Tuller?
12 (No response.)
13 MS. GREENE: Patrick Barnes?
14 MR. BARNES: Here.
15 MS. GREENE: Peter Hart?
16 MR. HART: Present.
17 MS. GREENE: Jennifer Goldman?
18 DR. GOLDMAN: Present.
19 MS. GREENE: You have a quorum, Mr. Chair.
20 CHAIRMAN MAYS: Okay. Thank you, Dinah.

21 I want to start the meeting off as usual by
22 reading the goals of council as stated in
23 Chapter 499, Florida Statutes, 499.01211, Drug
24 Wholesale Distributor Advisory Council.

25 "The council shall review this part and the

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1 rules adopted to administer this part
2 annually, provide input to the department
3 regarding all proposed rules to administer
4 this part, make recommendations to the
5 department to improve the protection of
6 prescription drugs and public health, make
7 recommendations to improve coordination with
8 other states' regulatory agencies and the
9 federal government concerning the wholesale
10 distribution of drugs, and make
11 recommendations to minimize the impact of
12 regulation of the wholesale distribution
13 industry while ensuring protection of the
14 public health."

15 So having said that, we do have a few items
16 on the Chair's Report today. The first order of
17 business is to officially welcome Joseph Lavino
18 as our new council member representing retail
19 pharmacy. Joseph is currently employed by CVS
20 Health as legal counsel for pharmacy regulatory
21 affairs. He's also a Pharm.D. and a J.D.

22 So, Joseph, would you like to tell us a little
23 bit more about yourself, or do you have any words
24 for the council?

25 MR. LAVINO: Sure, Steve. Thanks for the

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1 introduction. And hello, everybody. Thanks for
2 having me. I really look forward to contributing
3 to this council. As Steve had mentioned, I am
4 in-house counsel for CVS --

5 (Telephone interference.)

6 MR. LAVINO: I'm a licensed pharmacist in both
7 Florida and in Massachusetts. I currently reside
8 in Massachusetts. In my day-to-day capacity as
9 legal counsel for CVS, I advise the corporation on
10 various aspects of pharmacy practice, including
11 implementation of the TFCSA across the enterprise,
12 which was a major contributing factor to my
13 interest in serving on this council.

14 So, again, thanks for having me. I look
15 forward to working with all of you.

16 CHAIRMAN MAYS: Joe, we certainly welcome you
17 to the council. Anyone else, anyone have any
18 questions for Joe before we move on?

19 MR. MONE: This is just Michael. Hi, Joe.

20 CHAIRMAN MAYS: The next thing on the agenda
21 is the CDR exam review. So I think we had the
22 group come in and speak to us at the last council
23 meeting about asking for our assistance in
24 reviewing the exam to see if there's any
25 improvements that could be made to it. And I know

1 Michael Mone had volunteered to lead that task.
2 And I had accompanied him to Tallahassee, I think
3 it was about a month or so ago, maybe it was last
4 month, and went through the review.

5 And, Michael, I'd like for you, if you would,
6 to provide everybody a little bit of an overview of
7 what took place.

8 MR. MONE: This is Michael Mone.

9 Council members and to all staff and guests,
10 Steve and I sat down with the testing folks and
11 looked through a representative sample of
12 examination questions, and also looked at some
13 examination questions that whose performance in the
14 past had been difficult for candidates to determine
15 whether or not the exam development process in the
16 item bank was an accurate reflection of what is
17 necessary to be known by candidates taking the
18 examination, as well as whether the examination was
19 designed appropriately for the level of the
20 candidates.

21 And what we came away with after going through
22 several hours of exam items review, as well as
23 looking at the blueprint that the candidates would
24 study from, and the statutes in the areas that were
25 necessary, we came away with the conclusion that

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1 the exam is properly developed; it is properly
2 sourced; it is accurately representative of what a
3 candidate should know. And, in fact, this could be
4 other opportunities to write new items for the
5 examination to bring us to having a more robust
6 item bank so that items would not necessarily be
7 over-used.

8 We looked at the statistics. We looked at
9 everything you could possibly look at, and came
10 away with the conclusion that the examination is
11 an appropriate examination. There's things with
12 every examination that could be done. The most
13 important thing would be to get new items into the
14 item bank.

15 MR. WINTERS: Mr. Chair, this is Drew Winters,
16 Division Director. I just want to take a moment
17 and kind of speak a little bit to that because I
18 wanted to, one, thank Michael and yourself for
19 taking that opportunity to review and having that
20 outside information brought to us so we could do
21 that. And I think that the review that we did was
22 an outstanding one and, again, is something that we
23 welcome the input the council through Mr. Mone to
24 take the time and do that.

25 I also wanted to mention that I think that

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1 after having the review and the information
2 provided, that again it was -- it was something
3 that did show, and I wanted to take a moment to
4 just thank our staff. I know that Chief Dixon and
5 our enforcement chief, Renee Alsobrook, and some of
6 our team spent a lot of time trying to work on that
7 exam, so I wanted to recognize them for their
8 efforts to do that, and to also, with the input on
9 some of our questions, that we can take that back
10 and, again, make sure that the test is commensurate
11 with what we'd expect out of our CDR. So it was a
12 good review and a good opportunity to get that
13 input, and I wanted to thank you for that.

14 And again, just to put out there that we again
15 will continue, as we do, to monitor the test, that
16 we continue to ensure that that test is overseen by
17 our Bureau of Education testing as they monitor
18 those statistics and will continue to do so. So,
19 thank you.

20 CHAIRMAN MAYS: Thank you, Drew.

21 This is Steve Mays. I want to just add that
22 I was just overly impressed with the staff, the
23 testing team and the testing staff and the
24 development staff. I was just really going through
25 the review of the different questions and the

1 exam. I was really blown away with how well it's
2 put together. And I can tell there's been a lot of
3 thought put into it, so I applaud the department
4 for putting together a good exam.

5 Is there any questions, any questions from
6 council members?

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

8 CHAIRMAN MAYS: Go ahead, Mr. Barnes.

9 MR. BARNES: Just -- I'm trying to think back.
10 One of the reasons why, correct me if I'm wrong,
11 why we looked at this is because potentially we
12 felt that the exam was too difficult, is that --
13 does my memory serve me correctly?

14 CHAIRMAN MAYS: This is Steve. I think,
15 part of one of the reasons we looked at it is,
16 I think they actually asked for our assistance.
17 And also, I think the fail rate was pretty high
18 and that was one of the reasons that we wanted to
19 look at it. And Drew and Michael, correct me if
20 I'm mistaken, but I think that was probably the
21 driving force behind it.

22 MR. MONE: Mr. Chairman, this is Michael Mone.
23 If that was Drew that was going to talk, I'll let
24 him talk first.

25 MR. WINTERS: This is Director Winters. Yes,

1 the information that we had is that we did want
2 to provide an update on the CDR exam because we
3 did, we do look to the council to provide some
4 industry input that is available.

5 We did bring our Bureau of Education's
6 director, and our exam development director with
7 him. And I think that, as the Chairman said, that
8 is exactly what we anticipated; one, just an
9 opportunity to get some input and, two, when we
10 reviewed the exam there was concerns.

11 And obviously there's a little bit lower
12 passage rate on this particular exam, so we were
13 concerned to make sure that there was not an issue
14 that the exam was testing on material that was not
15 representative of what a CDR would need to be able
16 to know about.

17 And I think that was just an effort by the
18 council members and coordination with the
19 department to review that, and I think we had a
20 good review and found, so far, that the exam does
21 exactly what we expected.

22 And with that, we'll continue to monitor it
23 and see what we can do about providing additional
24 information out there, maybe making a more robust
25 test prep pack, but also just to get the word out

1 to our candidates that are going to be sitting for
2 it, they do need to prep for that exam. Ind I
3 think that was basically what I took out of the
4 exam review.

5 And I'll turn it over to Council Member Mone
6 to provide any additional comments.

7 MR. MONE: This is Michael Mone. I would
8 agree a hundred percent with what Drew just said,
9 except that I would point out one other aspect.

10 When we looked at it -- and I think there was
11 a concern that we had expressed as a council, over
12 a long period of time, about the pass rate. And
13 the conclusion that I drew was that the pass rate
14 is not a function of the examination itself, but a
15 function of the candidate's preparation for the
16 exam.

17 It is a -- a prudent examinee who studies for
18 that examination should pass that on the first
19 time. There is no reason, based upon the items
20 that are in there, the test design or the
21 instructions of what is to be covered, that they
22 should not be able -- if they study, that they
23 should not be able to pass that exam.

24 And Drew made a very good point that you --
25 that everybody will look at getting better exam

1 prep materials to them, so that they are more
2 focused on what is necessary to do their jobs. And
3 it's not designed to help them pass the exam. It's
4 designed to help them understand the information
5 that they need to study to be able to pass the exam.

6 CHAIRMAN MAYS: And this is Steve. I totally
7 agree. I mean, that's kind of what I came away
8 from the review process also, is that it really
9 comes down to preparation. So I think, in my
10 opinion, a lot of folks take this exam probably
11 too lightly and, you know, that they think they
12 can just show up and answer it on their common
13 sense and not prepare to, you know, understand
14 the Florida statutes and rules. So I think
15 that's probably, you know, that seems to be the
16 bottom line is it really is all about
17 preparation.

18 So, you know, obviously there's some things
19 that we thought we might could tweak, very minor
20 things with some of the questions, but other than
21 that, I think it's a very fair exam and it just
22 requires some preparation.

23 Any other questions from council members?

24 MR. TULLER: Yeah. Hey, good morning. It's
25 Jeff Tuller. I apologize for being late.

1 I just wanted to concur with most of the prior
2 comments. Having taken the CDR exam myself, I did
3 exactly what Steve said. I thought that because of
4 my experience that I'd get through it on the first
5 time, but the first sitting I did not pass. So it
6 did do exactly what Mr. Mone said. You have to
7 prepare for this exam. And I've consequently,
8 maybe by a little luck, got through the second then
9 in time.

10 So the questions themselves, I have two things
11 I'd like to bring up here. One is having a system
12 to go back and reevaluate the questions to make
13 sure we are covering the categories that we think
14 is appropriate to -- and is a good process. But
15 the exam preparation piece is where, I think, a lot
16 of people are left in the dark and left in the
17 cold, so we could, I believe, get a lot better at
18 that.

19 And I know, for example, California, before
20 you take their DR exam, they have specific
21 companies that you have to, that you engage with,
22 and they will take you through a multitude of
23 classes in various sections of business. So
24 there's options to look at, but I concur with the
25 test itself, I can, with the example -- thinking I

1 could have gotten through it on the first time and
2 did not, and then realized that the -- you really
3 have to get through it. And it does take some
4 study time, which is what we want, so I think it's
5 important, so I just wanted to be the living
6 example of what you've just spoken about. Thank
7 you.

8 CHAIRMAN MAYS: Thanks, Mr. Tuller.

9 Any other questions from council members or
10 any questions from any other interested parties on
11 the line before we move on?

12 (No response.)

13 CHAIRMAN MAYS: Okay. All right. The next
14 item on the agenda is nominations for chair and
15 vice-chair. So the -- I think we're a little past
16 due on it, but, the chair and vice-chair terms are
17 for one year, as I recall.

18 Now, although I have, you know, reapplied to
19 stay on the council for another term, I want
20 to make sure that we open it up for nominations for
21 a new chair and vice-chair.

22 And what we'll do is we'll take those
23 nominations at our next call, which I believe is
24 in December. So this will give everyone time to
25 be thinking about anyone that they would like to

1 nominate. And if there's any questions or anything
2 like that, feel free to reach out to Dinah. She
3 can give you some advice on that.

4 So, anyway, I just want to make that
5 announcement, so be thinking about that, and then
6 we'll take those nominations and select a different
7 chair and a vice-chair at our next scheduled call.
8 Any questions from any council members on that, or
9 other parties?

10 (No response.)

11 CHAIRMAN MAYS: Okay. Last thing on the
12 Chair's Report is just to call out that the meeting
13 transcript from our last meeting is in there for
14 informational purposes for your review.

15 So at this point, if there's not any other
16 questions from council members or interested
17 parties, I'll turn it over to Mr. Winters for the
18 Division Director's Report under tab two.

19 MR. WINTERS: Thank you, Mr. Chair. I do
20 appreciate it and I'll move right now just to start
21 with our rules report as the first agenda item
22 under my tab.

23 Just kind walking through this, we've got, as
24 many of you are aware, our goal has been to make
25 sure that we have adopted all the applications via

1 rule in the Florida Administrative Code at the
2 request of the joint administrative procedures
3 committee for many years and we are continuing that
4 process.

5 One is a big thanks to Dinah for all of her
6 efforts going through that. Many of you don't
7 realize the background to that, but she does a lot
8 of work to make sure those rules and applications
9 as we create them are moved through the rule
10 process.

11 The first item on our rules report is the
12 application for a device manufacturer purpose, or
13 permit, excuse me. That one has been noticed for
14 development, but we have not finalized the action
15 on that.

16 The next two items, I'm going to just mention
17 briefly because I want to spend a little more time
18 which will be on my second agenda item under my
19 tab, what is rule 61N-1.001, which is, we have
20 noticed for development for the solely
21 administrative services definitions, and did hold
22 the -- an initial rule hearing on that, a rule
23 workshop to provide an opportunity for people to
24 put comments in on that.

25 And then also the next rule underneath that,

1 which is 61N-1.0155, which is a new rule, but that
2 will be to adopt the establishment, security, and
3 storage exemptions for virtual manufacturers, both
4 in-state and out-of-state and the broker-only. And
5 that we'll talk about under my second tab for
6 today, but, just moving forward, we are going to
7 move through that.

8 Currently, we are in the process of the next
9 applications, which is 61N-2.007, which is the
10 application for limited prescription drug
11 veterinary wholesale distributor; 61N-2.021, which
12 is the application which is the restricted
13 health care prescription drug distributor
14 government programs permit; the 61N-2.022, which
15 again is the restricted health care entity permit;
16 and 2.023 of 61, which is the institutional
17 research permit; the 61N-2.025, the retail pharmacy
18 drug wholesale distributor permit; 61N-2.027, the
19 application for a veterinary prescription drug
20 retail establishment; and 61N-2.028, which is the
21 application for the veterinary prescription drug
22 wholesale distributor permit.

23 Those applications have all been finalized and
24 we are noticing them for proposed rulemaking.
25 We're routing those sort of internally and we'll

1 expect to notice those here shortly, once they've
2 gone through internal processes.

3 As has been our standard protocol, once we do
4 notice that for rulemaking, we will bring that to
5 the next council meeting to provide copies of those
6 applications for people to review and to provide
7 any input they have regarding those, but we will
8 notice those for proposed rulemaking shortly. I
9 believe that they have finished through most of our
10 internal processes and we'll move those through
11 shortly. So with that, that's our base rule
12 reports.

13 As you'll see, the finalized rules on the
14 other side that are listed in green, those are ones
15 that we've already completed rule development for.
16 And again, we will continue that process for the
17 current ones that are going to be adopted. Again,
18 those are aimed specifically at adopting our forms
19 via rule so that they are officially adopted and
20 have the effect of law, and so we have that out
21 there.

22 With that general report, if there's any
23 questions generally about our rules report, you can
24 let me know now. But otherwise, I think that most
25 of our general questions are going to come

1 regarding the second and third rules that I
2 mentioned, which are our solely administrative
3 services, and our establishment, security and
4 storage exemptions, which I'll address now if
5 there's not any initial questions.

6 Okay. Hearing no initial questions, I'll go
7 forward with that, if you'll again move to the
8 second item on our agenda. This is a draft rule of
9 61N-1.0155, which is going to be our establishment,
10 security and storage exemptions for virtual
11 manufacturers and broker-only distributors.

12 I wanted to bring this to the council. I know
13 that this is a little bit different than our normal
14 process, because normally I would go ahead and
15 notice this for rulemaking, but I felt that based
16 on how we've proceeded with this, and the related
17 rule which is under 61N-1.001 for the definition of
18 solely administrative services, I felt that this
19 would be a good opportunity for me to present this
20 to the council members, just for any comments or
21 other items that we would like to take care of
22 beforehand, and also just an opportunity for those
23 in the interested parties and the public to have an
24 opportunity to see that rule.

25 Again, what we went through is, based on the

1 language in the statutes, it says specifically that
2 for virtual manufacturers and for the broker-only,
3 as well, that we can waive certain storage,
4 security, and establishment requirements. The way
5 that I've read that in the statute, I believe
6 that it does limit us to the first three elements
7 and so we focused on those specifically.

8 I have had a question when we initially
9 addressed that, which is, an application of the
10 4 through 15 of the remaining sections of 499.0121,
11 that how would those read out? I think, if you'll
12 note, I put some language in here that makes clear.

13 I hope that, in the event that those are not
14 applicable to the business model, i.e., you don't
15 have anything that would be effectuated by those,
16 4 through 15, but again, the division recognizes
17 that in some of those instances, because you are a
18 virtual, they would not be applicable. But going
19 through there, again, we looked at that as part of
20 our development. I think that we've got a pretty
21 good rule here and would like to provide any
22 opportunity for anyone to make a comment.

23 Again, with the establishment requirements, we
24 basically would waive all those requirements for
25 virtual and out-of-state virtuals and broker-only

1 permit holders. The only thing that they would be
2 required to maintain in those sections is to be of
3 suitable size in construction to facilitate proper
4 operation, and that they have to be maintained in
5 orderly condition. And they have to maintain the
6 written policies and procedures regarding the
7 receipt of prescription drugs, and to ensure that
8 those policies and procedures are adequately
9 addressed in the event that an inadvertent delivery
10 or attempted delivery were to occur at that
11 establishment. That would be the only requirement
12 to be maintained, and otherwise the establishment
13 would not be required to maintain those
14 requirements in subsection one.

15 We did make sure to put clarifying language
16 that, again, that relieving of the establishment
17 requirements did not otherwise take out the
18 necessity to maintain compliance with the other
19 provisions of 499, and applicable fair law
20 regarding authorized trading partners and the other
21 specific requirements, and especially the due
22 diligence requirements.

23 On the security requirements, again, we did
24 waive those, except that they need to make sure
25 that the outside control for the facility was well

1 established, and that they ensure that their
2 recordkeeping computer systems were appropriately
3 protected to ensure the integrity of any records
4 and electronic records being transmitted from the
5 facility. And again, as far as the storage
6 requirements go, we did waive those in their
7 entirety based on the information.

8 So with that, that is the presentation of the
9 draft rule. If there are any comments or questions
10 that people would like to provide initially, I did
11 want to make sure that everybody did understand
12 that this is, again, just an additional opportunity
13 for comment. Once we do propose it again,
14 everybody will have the same ability and authority
15 through the rulemaking process they would have.
16 This was just an additional courtesy and step that
17 we decided to put in, to make sure we did have a
18 good rule.

19 So with that, I will turn it over to any of
20 the council members and the chairman to receive
21 comments on the draft and go from there.

22 CHAIRMAN MAYS: Any comments or questions from
23 council members?

24 (No response.)

25 CHAIRMAN MAYS: How about from interested

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1 parties on the line?

2 (No response.)

3 CHAIRMAN MAYS: Okay. Mr. Winters, it doesn't
4 seem like there's any comments at this point.

5 MR. WINTERS: Well, I generally take this as a
6 positive, that overall the rule does what we want
7 it to do, and we'll move forward.

8 Again, we will notice it through the normal
9 rulemaking process, which will again give additional
10 time to comment, as well, but, hopefully, that
11 means we've got a good rule here.

12 CHAIRMAN: Great. Mr. Winters, do you have
13 any other business you want to --

14 MR. WINTERS: The only other item I wanted to
15 mention is that I did mention 61N-1.001, the soley
16 administrative services definition. We continue
17 to strive to find a good definition regarding
18 that. We've got a working draft, but, again, I
19 don't think it's in a position now that we're ready
20 to bring it out and to notice it. We're being very
21 cautious and diligent in that rule to make sure
22 that what we attempt to do is going to be good for
23 both the regulatory portion under the division, but
24 also that it's cognizant in recognizing the
25 circumstances of the industry, and that we -- we

1 don't roll out a rule that's going to cause more
2 problems than it would good to resolve those issues.

3 Again, a thank you to many of the
4 representatives out in the industry that have
5 provided those comments. They have been very
6 helpful and continue to provide some assistance to
7 us, as we try to develop an appropriate language.
8 And I hope to have that closer when we get to the
9 December meeting, hopefully have something to
10 provide to the council, but, again, we are going to
11 strive to continue that. And I think we've gotten
12 some good resolutions to policy items and concerns,
13 and we're just trying to figure out how to formulate
14 that into the best rule possible. Again, I will
15 continue to strive for that.

16 If anybody has any questions or comments,
17 of course, I'm always here to try and take those,
18 and we'll try to address them as we go forward
19 through the rulemaking process.

20 CHAIRMAN MAYS: Thank you, Mr. Winters.

21 MR. WINTERS: And that concludes my report
22 otherwise.

23 CHAIRMAN MAYS: Okay. Great. One question
24 of Dinah. What is the date of our -- do we have a
25 date set for the December meeting call?

1 MS. GREENE: Yes.

2 CHAIRMAN MAYS: It's going to be a call, right?

3 MS. GREENE: Yes, it will be a conference call
4 on December 6.

5 CHAIRMAN MAYS: December 6. Okay. This is
6 just as a reminder to everyone, that will be our
7 next meeting and it will also be a call.

8 So is there any other business from the
9 council?

10 (No response.)

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

13 MR. WINTERS: We've got a tab three.

14 CHAIRMAN MAYS: Uh-oh, did I miss something
15 here?

16 MR. WINTERS: We've got a tab three for
17 Dr. Philip to provide information on NABP update.

18 CHAIRMAN MAYS: I'm so sorry, Dr. Philip.
19 I totally missed that. I apologize.

20 DR. PHILIP: No worries. Thank you. Thank
21 you, Chair Mays. So, and I guess, Mr. Mone, I know
22 Mr. Mone is on the call.

23 Michael, if you have anything to add, you may
24 be familiar with this if you've been involved with
25 it at all, but this is, this is really just a brief

1 recap of a call that I had with Josh Bolin, who's
2 the Associate Executive Director at NABP, regarding
3 two pieces. One is the definition of "suspicious
4 orders," and the second is the central reporting
5 system where NABP acts as a repository. And this
6 was mentioned at the NABP annual meeting, and so I
7 subsequently followed up with Mr. Bolin at NABP to
8 get a little more information with regard to what
9 the status is on this.

10 So my understanding is that NABP has met with
11 certain regulators and industry folks to really
12 understand where they are when it comes down to the
13 definition of suspicious orders. So they wanted to
14 facilitate some discussion on some meaningful
15 information, including looking at the different
16 data elements that will be useful for regulators.
17 So I think that discussion is going to continue.
18 It's just a matter of looking to get some consensus.

19 Ideally, they want to be able to, you know,
20 provide a definition that can eventually be rolled
21 into the NABP model act. Also that they're looking
22 at, in terms of the reporting system, they're
23 looking to, you know, reduce or eliminate multiple
24 reporting, and so, so the concept here is that NABP
25 can act as that repository and hopefully eliminate

1 some of the unneeded multiple reporting. So you're
2 looking at having all the information reported
3 from, you know, the information reported to a
4 singular place versus multiple places.

5 So my understanding is, in Jersey, California
6 and Ohio, specifically, you're looking at more
7 useful regulations. And there seems to be some
8 consensus that a central reporting system makes
9 sense.

10 There is a task force schedule to meet on
11 August 29 and 30 this year. It's going to be
12 attended by NABP, a DEA regulatory industry, really
13 for the purpose of looking for some consensus on,
14 you know, on the definition of suspicious orders.

15 My understanding is that there are regulators
16 from Indiana, Michigan, Ohio, Illinois and
17 Tennessee that are going to be in attendance. The
18 goal here is to try and provide better tools for
19 all the regulators. They will have a report that's
20 going to be created after the meeting, and so, I
21 can look to report back on the next call after this
22 task force meets to see what the outcome of the
23 meeting will be.

24 I don't have much more to add, but I can, I'll
25 take any questions. And Mr. Mone, I don't know if

1 you have anything else to add on top of this, what
2 I just said, or if you can correct me if I said
3 anything incorrectly.

4 MR. MONE: Mr. Chairman, this is Michael Mone.
5 Everything that Jeenu said is correct, as always.
6 And that the only point that I will make is that
7 it's an effort to drive efficiencies in the
8 reporting system by providing that single
9 repository, with a single set of definitions, to
10 create the uniformity that is necessary, so that
11 regulatory agencies can timely act on that
12 information. And that's the real genesis of this.

13 CHAIRMAN MAYS: Okay. And this is Steve.
14 I actually can add a little bit of color to
15 this. I was invited to attend this meeting at
16 the end of August. They've invited, I know,
17 representatives, I believe, from McKesson,
18 Cardinal, AmerisourceBergan and HD Smith. I'm
19 not sure who else.

20 I have accepted and plan to attend. They're
21 calling it the meeting of the suspicious orders
22 workgroup. It's taking place August 29 and 30.
23 So they -- and again, the way Jeenu has spelled
24 it out is the way it was kind of described to me
25 as far as what that meeting will be.

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1 And I would like to also confirm that there
2 are a lot of states looking at the various
3 different suspicious order reporting requirements,
4 and it kind of reminds me of the old pedigree days
5 where we started running into, you know, 50 states
6 with 50 different requirements. And we're starting
7 to see that now with suspicious order reporting.

8 I know California has one now that they
9 wanted all these suspicious order reports and now
10 they're asking, you know, the companies that are
11 reporting the orders to also give them the reasons
12 why for each one. So it's getting a little more
13 complicated, the deeper we get into it. So, I
14 think, the more that we can standardize that whole
15 process is going to be for the betterment of the
16 industry and the regulators.

17 Any questions from the council for Mr. Philip?

18 (No response.)

19 CHAIRMAN MAYS: And again, I apologize, Jeenu,
20 for skipping tab three and jumping right to the end.

21 DR. PHILIP: Of course.

22 CHAIRMAN MAYS: All right. Are there any
23 questions from any other interested parties about
24 the NABP update?

25 (No response.)

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1 CHAIRMAN MAYS: Okay. Is there any other
2 business?

3 (No response.)

4 CHAIRMAN MAYS: So we'll try this again.
5 Okay. Hearing none, do we have a motion to adjourn?

6 MR. BARNES: Motion to adjourn. This is
7 Patrick Barnes.

8 DR. PHILIP: And I will second it. This is
9 Jeenu Philip.

10 CHAIRMAN MAYS: Okay. Thanks for the second.
11 All in favor, say "aye."

12 (Chorus of "Ayes.")

13 CHAIRMAN MAYS: Any opposed?

14 (No response.)

15 CHAIRMAN MAYS: Okay. The meeting is
16 adjourned. Thank you. And we'll talk to everyone
17 in December.

18 (Whereupon, the meeting was adjourned at
19 approximately 10:12 a.m.)

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CERTIFICATE OF REPORTER

COUNTY OF LEON)
STATE OF FLORIDA)

I, DEBORAH ALFF, do hereby certify that
I was authorized to and did report the foregoing
council meeting, and that the transcript, pages
1 through 32, contains a true and complete record
of my stenographic notes and recordings thereof.

Dated this 30th day of August, 2018, at
Tallahassee, Leon County, Florida.

DEBORAH ALFF, COURT REPORTER

