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DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL
AUGUST 18, 2016

Reported by:
CLARA C. ROTRUCK
Court Reporter

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TELEPHONIC PROCEEDINGS

CHAIRMAN CACCIATORE: Good morning everyone.
This is Gary Cacciatore. I would like to call this meeting of the Drug Wholesale Distributor Advisory Council to order.

I would like to start with a roll call. Do we have a court reporter on the line?

THE COURT REPORTER: Yes, I am on the line.

CHAIRMAN CACCIATORE: Thank you very much. I just want to remind everyone we do have a court reporter. Rather than taking Minutes for the meeting we will just have a transcript prepared by the court reporter. So please identify yourself before you speak so the court reporter will know who is speaking on the call.

And those that are on the line, if you can put yourselves on mute that will help unless you would like to speak and obviously come off of that.

So let's start with a roll call. Ms. Greene.

MS. GREENE: Mike Ayotte.

MR. AYOTTE: Here.

MS. GREENE: Steve Mays.

MR. MAYS: Here.

MS. GREENE: Scott Brock.

MR. BROCK: Here.

1 MS. GREENE: Arlene Elliott.

2 MS. ELLIOTT: Here.

3 MS. GREENE: Dean Ellis.

4 MR. ELLIS: Here.

5 MS. GREENE: Bill Mahoney.

6 MR. MAHONEY: Here.

7 MS. GREENE: Patrick Barnes.

8 MR. BARNES: Patrick Barnes here, yes.

9 MS. GREENE: Jeenu Phillips.

10 MR. PHILLIPS: Here.

11 MS. GREENE: Peter Hart.

12 MR. HART: Here.

13 MS. GREENE: Gary Cacciatore.

14 CHAIRMAN CACCIATORE: Here. Thank you
15 everyone for your participation.

16 So a couple of things just to start out. Tab
17 one we have got the Chair's report. You will
18 notice there is not a lot of stuff on the agenda
19 this time.

20 So first of all let me thank everyone for
21 showing up at a meeting where we don't have a lot
22 to discuss. So I really appreciate that. This is
23 my last meeting as you guys know. So I am sure
24 that is why everybody showed up.

25 But I just wanted to say a few words about

1 that. There is not a lot of stuff on the agenda
2 and I think that reflects upon two things. It
3 reflects upon where we are as a council and where
4 the Division is and the Department is. We have
5 come a long, long way. This council was put
6 together, I think it was 12 years ago or so, yes,
7 10 years, 11 years ago.

8 And at the time when the council was put
9 together there were a lot of issues, there was a
10 lot of problems. There was not a lot of
11 cooperation I think between industry and the
12 Department, and the agenda was full. So this
13 council was put together to address a lot of those
14 issues.

15 And more importantly to protect the public
16 health and there were problems with that at that
17 time as well. And as Florida started to address
18 that very aggressively it formed fruit and we have
19 a very well run council now, a very well run
20 Division and Department.

21 And so as I have been on here for eight years
22 what I have seen is there has been less and less
23 things, items on the agenda. And part of the
24 reason for that I have to say is the Division and
25 the Department, all the work that they have done to

1 work with the industry. Their open door policy to
2 allow, to meet with people to address issues. All
3 of that I think has contributed to the success of
4 the council. So I want to thank the Department,
5 Mr. Dixon and Ms. Greene and everyone at the
6 Division for all the work that they have done.

7 I always like to start the meetings by reading
8 what the goals of the committee is and what the
9 council is. So let me start by doing that. This
10 is in Chapter 499.0121(1).

11 The council shall review, this part being
12 Chapter 499, and the rules adopted to administer
13 this part annually. Provide input to the
14 Department regarding all proposed rules to
15 administer this part, to make recommendations to
16 the Department to improve the protection of the
17 prescription drugs and public health. Make
18 recommendations to improve coordination with other
19 states' regulatory agencies and the federal
20 government concerning wholesale distribution of
21 drugs, and make recommendations to minimize the
22 impact of regulation of the wholesale distribution
23 industry while ensuring protection of public
24 health.

25 And that really speaks to what we have been

1 doing over the past eight years that I have been
2 here.

3 I do want to introduce three new council
4 members who have been appointed. Leaving the
5 council are myself and Mr. Mike Ayotte, our Vice
6 Chair, and also Mr. Bill Mahoney. And I want to
7 thank Mike and Bill for their service on the
8 council for all these years.

9 The appointments were just made like a week
10 ago. So there wasn't time to allow the new members
11 to officially be here, be on the council for this
12 meeting, but they are in attendance today, or at
13 least two I think are here. We may have the third
14 come.

15 So it will be one from the pharmacy,
16 representing the pharmacy at CVS, Mr. Bryan Files,
17 and then for prescription drug wholesaler, Michael
18 Mone, from Cardinal Health and Jeffery Toler from
19 Wellgistics.

20 So Michael, do you want to introduce yourself
21 and give everyone a little bit of background?

22 MR. MONE: Good morning. My name is Mike
23 Mone, I am a pharmacist and an attorney. I have
24 been with Cardinal Health about 10 years, but I
25 actually started my career at then called BPR, then

1 it became DBPR, then it became BPR. I was a
 2 prosecutor for many regulatory boards back then.
 3 Left and went to the USP and spent a couple of
 4 years setting standards at the USP. Came back to
 5 the Attorney General's Office and worked for Bob
 6 Butterworth as general counsel for a number of
 7 regulatory boards. Left there, went to Kentucky as
 8 the Executive Director of the State Board of
 9 Pharmacy for 10 years.

10 Left there, went and taught at the Pharmacy
 11 School at the University of Minnesota and then went
 12 to Cardinal Health about 11 years ago, first at
 13 Medicine Shoppe and then at Cardinal Health proper.

14 And thank you very much, I look forward to
 15 working with you all and to come back to
 16 Tallahassee and see a whole bunch of friends that I
 17 don't get to see very often.

18 CHAIRMAN CACCIATORE: Thanks, Michael.
 19 Mr. Toler.

20 MR. TOLER: Yes. My compliments to Michael,
 21 that sounds like an impressive resumé. I started
 22 in the business when I got out of college. I went
 23 to grad school, I was recruited by a company called
 24 McKesson, and then I got recruited by a company
 25 called Cardinal. Worked for Cardinal for a decade

1 or better and then I went to run an Amerisource
2 company for a couple of years, and always in drug
3 distribution mainly.

4 Then I started off working for startup medical
5 services, both in manufacturing distribution,
6 logistics and I have doing that for about the last
7 eight years.

8 CHAIRMAN CACCIATORE: Welcome.

9 MR. TOLER: Thank you.

10 CHAIRMAN CACCIATORE: And if Mr. Files joins
11 us, Mr. Files was appointed as the retail pharmacy
12 representative replacing Mr. Ayotte and is employed
13 by CVS.

14 Next on the agenda is election of officers.

15 MR. DIXON: Mr. Chair, if we could take a
16 minute. We have got our Deputy Secretary here, Tim
17 Vaccaro. He is the Deputy Secretary responsible
18 for our Division.

19 We had a couple of presentations we want to
20 do, and I figured since we have him here, it would
21 be a good opportunity for us to do some
22 presentations for your guys who have been serving
23 our Division and who are departing since these are
24 your last meetings.

25 I first want to present Mr. Ayotte with a very

1 nicely wood grain, carved plaque which basically
2 says, "Presented to Mike Ayotte, Vice Chair, in
3 appreciation for your valuable leadership and
4 service to the Florida Drug Wholesale Distributor
5 Advisory Council." And it has got the dates on
6 there from April 28th of 2008 to August 18th, 2016.

7 MR. AYOTTE: I look the same, don't I?

8 MR. DIXON: We don't have a picture.

9 MR. AYOTTE: Thank you. I will just take a
10 point of personal privilege. This means an awful
11 lot to me. I have been part of Florida for a long
12 time and to me was here when the original, I guess
13 when the drug issue occurred.

14 So to see where we are at today truly it is a
15 credit to you and to everybody around this table,
16 because we have changed a good part of the world
17 and it really makes you feel proud. So thank you.

18 MR. DIXON: And last, but not least, to our
19 esteemed Chair. This is presented to Gary
20 Cacciatore, the Chair of the Drug Wholesale
21 Advisory Board in appreciation for your valuable
22 leadership and service to the Florida Drug
23 Wholesale Distributor Advisory Council.

24 This date is also April 2008, to August 2016.

25 CHAIRMAN CACCIATORE: I knew it had been a

1 long time, but I didn't remember exactly how long.

2 MS. GREENE: We have Mr. Mahoney's and I will
3 send it to him.

4 MR. DIXON: Bill Mahoney is actually on the
5 phone. So he missed the meeting. When you miss
6 the meeting this is what happens.

7 MR. MAHONEY: Sorry about that, guys.

8 MR. DIXON: It is just a short drive. Thank
9 you so much for your service though.

10 MR. MAHONEY: Thank you for letting me be a
11 member of this, it has been a great organization
12 and such a great experience.

13 CHAIRMAN CACCIATORE: Yes, and let me echo
14 that as well. I mean, although I no longer live in
15 Florida, as many of you know I am originally from
16 Florida and have spent a lot of time here. And
17 although I do regulatory work throughout the
18 country for Cardinal Health, anytime there is an
19 opportunity to do things in Florida to serve
20 Florida I always jump at that because it is a
21 chance to come home actually. I appreciate that.

22 So next on the agenda we are going to do
23 election of officers. So we need to elect a Chair
24 and a Vice Chair. Only the current members of the
25 council should be eligible in voting at this time

1 since this is our last meeting. But you can't
2 nominate me since I am going off since I know you
3 guys like to do that.

4 So I am going to open the floor for
5 nominations. Should we do Chair or Vice Chair
6 first? Let's do the Chair first and get that out
7 of the way. So I am going to open the floor to
8 nominations.

9 MS. ELLIOTT: This is Dean Ellis. I would
10 like to nominate Steve Mays as our Chairman.

11 CHAIRMAN CACCIATORE: Steve, you are on the
12 phone I believe. Do you accept that nomination
13 with enthusiasm?

14 MR. MAYS: This is Steve. Sorry, I had myself
15 on moot. Yes, that is fine, I will accept that.

16 CHAIRMAN CACCIATORE: Thank you, Mr. Mays.

17 MR. MAYS: Unless there is someone else, I am
18 very definitely humbled by that.

19 CHAIRMAN CACCIATORE: Do I hear any further
20 nominations for Chair? You can nominate yourself
21 by the way.

22 MR. MAYS: This is Steve Mays. I would like
23 to nominate Dean Ellis.

24 CHAIRMAN CACCIATORE: Mr. Ellis.

25 MS. ELLIOTT: I think Steve would be a really

1 good candidate for it. I really do, Steve.

2 CHAIRMAN CACCIATORE: All right. I am not
3 going to force anyone to do that. So that sounds
4 like you are going to decline that nomination, Mr.
5 Ellis.

6 All right, hearing no further nominations, I
7 will entertain a motion to close nominations.

8 MR. HART: Motion.

9 MR. PHILLIPS: Second.

10 CHAIRMAN CACCIATORE: Motion by Peter Hart,
11 second by Mr. Phillips. No discussion. All in
12 favor signify by saying aye.

13 (Chorus of ayes.)

14 CHAIRMAN CACCIATORE: Any opposed? All right,
15 motion carries. Nomination to close and now we get
16 to vote. All in favor of Mr. Steve Mays being
17 elected Chair, say aye.

18 (Chorus of ayes.)

19 CHAIRMAN CACCIATORE: Any opposed?
20 Congratulations, Mr. Mays.

21 MR. MAYS: I didn't have time to oppose.

22 CHAIRMAN CACCIATORE: Sorry, that was the
23 Chair's fault for not following the proper
24 procedure that time by the way.

25 MR. MAYS: I need to make sure I show up next

1 time.

2 CHAIRMAN CACCIATORE: Yes. Listen, I know you
3 are on vacation, so I appreciate you even calling
4 in. So thank you.

5 We will open up the floor for nominations for
6 Vice Chair. Really the Vice Chair just fills in
7 when the Chair is not there. Mr. Mays indicated he
8 would be at every meeting.

9 MR. MAYS: Yes, as long as my wife does a
10 better job of scheduling vacation.

11 MR. BROCK: I nominate Jeenu Phillips.

12 CHAIRMAN CACCIATORE: Nomination by Mr. Brock
13 of Jeenu Phillips.

14 MR. PHILLIPS: I will accept.

15 CHAIRMAN CACCIATORE: Jeenu says I will accept
16 that nomination. Any further nominations?

17 MR. BROCK: May it be closed.

18 CHAIRMAN CACCIATORE: All right, nomination by
19 Mr. Brock to close the nominations.

20 MR. HART: Second.

21 CHAIRMAN CACCIATORE: Second by Mr. Hart. Any
22 discussion? All in favor of Mr. Phillips as Vice
23 Chair signify by saying aye.

24 (Chorus of ayes.)

25 CHAIRMAN CACCIATORE: Any opposed like sign.

1 Congratulations, Mr. Phillips.

2 MR. PHILLIPS: Thank you very much.

3 CHAIRMAN CACCIATORE: I believe the council is
4 in very good hands going forward and I appreciate
5 everyone stepping up to the plate to take on those
6 leadership roles.

7 I am trying to think if I have anything else
8 under the Chair's report. I do not believe so.

9 So I will now turn it over to Mr. Dixon to
10 give us the Division Director's report.

11 MR. DIXON: Thank you. What you see on the
12 agenda, we basically wanted to just go through our
13 rulemaking to give you guys an idea of where we are
14 at today.

15 We have gone through a lot. You will see that
16 we did a lot working on out applications.
17 Hopefully your permitting folks, if you do have an
18 opportunity to talk to your permitting folks as
19 they go through these, we would ask you if you have
20 any questions or concerns about some of the new
21 applications as we put them out there that you
22 shoot us an e-mail or give us a call or something.

23 One of the things that we have tried to do is,
24 we tried to put in what was statutorily required
25 and only what was statutorily required that would

1 help make those decisions.

2 So we are looking to get our deficiency rates
3 down, applications so that the lower the deficiency
4 rate the quicker you get someone in the business so
5 you don't have people waiting around having
6 products sit around. So most of our rulemaking
7 deals with our applications.

8 We will start with 51N-1.001. That is the one
9 on this report that doesn't necessarily deal with
10 our applications. That is the rule that deals with
11 our definitions. We recently had a rule workshop
12 in Orlando. The basics, the two items that were
13 addressed at that rule workshop was to get industry
14 input both on the exception to wholesale
15 distribution which allows retail pharmacies to
16 distribute up to a certain amount.

17 The language that we provided set that amount
18 at five percent based on the fact that was kind of
19 the industry standard of what the FDA was going by
20 as well.

21 The second issue on there was there was an
22 exemption put in the statutes recently to allow for
23 the distribution or movement of drugs between end
24 stage renal pharmacies that are in end stage renal
25 dialysis clinics that are in common owned

1 pharmacies.

2 And so what we wanted to do was to put some
3 guidelines in place as to when those distributions
4 actually were distributions which necessitated you
5 having a license as opposed to the distribution for
6 an emergency medical need, of immediate medical
7 need for a patient.

8 So we did it centrally in Orlando and we got
9 some feedback, we got some testimony. We have a
10 transcript of it also. And based on having done
11 that, we went ahead and proceeded with development
12 of the language. So the language should be
13 published and hopefully going into effect pretty
14 soon.

15 With respect to the rest of the report, and
16 one of the things, I don't know if you all noticed
17 this, we actually tried to create a part two of
18 61N-2.001, and as we go through the applications,
19 all of the applications will now be in 61-2. So
20 what we are trying to do is eliminate a lot of the
21 excess language and verbiage that deals with all of
22 the different things and basically saying you have
23 to submit a complete application and the fee, and
24 then the application itself ask for all
25 information.

1 So hopefully for your permitting folks, now
2 you look at the application and see this is what I
3 have to give and you don't have to kind of search
4 through the different rules saying, okay, if you
5 are here you need this, you need that, you need
6 this. So the plan is hopefully by this time next
7 year to have all of the applications done. We have
8 done about a third of them, and we created a couple
9 of new permits.

10 So when you look at this report, everything
11 that is in blue, those applications are now
12 effective. We highlighted which is kind of a light
13 brown highlight, those are the rules that are open
14 for development and those are the applications
15 basically that we are working on.

16 Does anyone have a question about anything on
17 the rules report?

18 I wanted to give you just kind of an
19 legislative update. I am pretty sure by now
20 everybody knows that Senate Bill 1604 went into
21 effect. We are still working, we have pretty much
22 implemented most of it. We have done training.

23 Some of the high notes that I think you guys
24 would have noticed is the fact that the language is
25 in there about the bond requirement, that if you

1 are a wholesale distributor and you distribute less
2 than \$10 million a year, the bond requirement is no
3 longer \$100,000, but it is \$25,000. We have
4 created the forms, the bond forms, and we have made
5 them available. So if you want to go on our web
6 page those bond forms are available.

7 As far as the language that deals with the
8 implementation of the DQSA, that language is in
9 place. We have had at least one meeting with the
10 folks from the ACMA on some questions that have
11 come up. So we are kind of reviewing some of their
12 input to make sure our interpretation of our
13 statute is consistent with what the federal
14 authorities want.

15 One of the issues quite frankly is that
16 sometimes the FDA is a little slow to move. So we
17 do have a little bit of -- we have got a couple of
18 challenges that we want to make sure that we don't
19 get in front of them on some issues. But other
20 than that everything has been going along smoothly.

21 Hopefully the wholesale application will be
22 out there soon and that is the next big issue is to
23 implement the renewal, so that instead of having
24 you all, at least as wholesalers, renewing every
25 year, we are going to try to get to a point where

1 wholesale permits are at least two years and then
2 it will be staggered so that you won't have to have
3 someone constantly in the stage of submitting a
4 renewal application.

5 One of the things hopefully that your
6 permitting folks would notice is that we are going
7 to allow them if you have already submitted a
8 personal information statement and it hasn't
9 changed, just to submit an affidavit that your
10 personal information statement hasn't changed along
11 with the prior information statement.

12 So we hope that some of those changes will
13 expedite the permitting process, and hopefully what
14 you will see is that your folks will have a
15 positive response to it. If not, that is
16 definitely something we need to know about. We
17 really haven't gotten any negative input right now,
18 but if we do that is have something we can address
19 pretty quickly. I mean, most of our units here, we
20 have got a pretty small unit. So it doesn't take a
21 lot for us to kind of respond to stuff.

22 CHAIRMAN CACCIATORE: Mr. Dixon, this is Gary
23 Cacciatore. From my company's perspective the
24 changes in the licensing and permitting process
25 have been very well received.

1 MR. DIXON: Other than that we didn't really
2 have any other updates or anything. But we are
3 open to ask any questions that any of your council
4 members might have.

5 MS. ELLIOTT: This is Dean Ellis. What time
6 frame are you in on the renewal process as it
7 relates to going from a year to two years?

8 MR. DIXON: Right now we are drafting the
9 language on the rule. What complicates it a little
10 bit, and quite frankly, I don't know that we
11 anticipated this part of it, was as you know all
12 your permits expire a year or two years from the
13 end of the month or the date in which it was
14 issued.

15 What that means is as far as the wholesalers
16 you will all expire in a certain month during the
17 year. So if we want to stagger those so that we
18 don't have everybody renewing at the same time, we
19 are contemplating saying, every other month will be
20 a two-year permit, and then every other month after
21 that will be a two-year permits. So only half of
22 your permits will expire every year.

23 So it is a little complicated trying to write
24 that language. We have got -- in one of the other
25 areas of our department they have a rule that kind

1 of sets out the dates and time frames and things.
2 It is in the professions area. It is a very good
3 rule. It tells you when you renew and all these
4 other things. So we are looking at doing something
5 like that.

6 MS. ELLIOTT: Will the body of that
7 application, is that going to change any or is that
8 for some workshops later on?

9 MR. DIXON: The body of the application, the
10 wholesale distributor application will change. It
11 will -- some of the things like the primary versus
12 the secondary wholesale distributor determinations,
13 that is no longer necessary.

14 Some of the information with respect to like
15 the picture. You only need a picture every, I want
16 to say it is 180 days now, not every 30 days.
17 Fingerprints, you are going to be able to submit
18 your fingerprints electronically. So now you don't
19 have to submit a fingerprint card.

20 So a lot of that we think will cut down on the
21 days as far as the application. We need to kind of
22 shore the application up, because some of the
23 things on the application that are asked for are no
24 longer necessary. So that is one of our primary
25 focuses right now is to get the application.

1 MS. ELLIOTT: Thank you.

2 INVESTIGATOR GRIFFIN: As far as time frame I
3 bet we will have a draft of the application next
4 month. It is already open. So I would anticipate
5 filing a rulemaking on the application itself
6 probably in the next couple of weeks.

7 MS. ELLIOTT: Thank you.

8 CHAIRMAN CACCIATORE: This is Gary Cacciatore.
9 Two things that come to mind. You mentioned the
10 DQSA and the tracking, the federal tracking
11 legislation. That is continually evolving waiting
12 for guidance from FDA.

13 I had found it very helpful in the past when
14 we have had updates on that, and I know in the
15 industry we have people who track that. Someone in
16 my group that is their full time job and Mr. Mays'
17 company has someone as well and I think everyone
18 does that. So bringing those people in is
19 something to consider maybe for the next meeting.
20 At least once a year to kind of see where things
21 are, to get an update on what is happening on the
22 federal level.

23 It might be a good idea I think for the next
24 meeting to consider or maybe the next live meeting
25 which would be the one after the next one. But

1 just to get an update on what is going on because
2 that stuff is constantly changing with guidelines
3 from the FDA. It is a 10-year implementation
4 period on that law. We need to make sure we are
5 staying up-to-date with that, make sure everyone is
6 doing everything consistently, which I know the
7 Department is doing that, but for the council I
8 think it will be helpful to consider that.

9 And the other thing I just wanted to ask a
10 question and Mr. Phillips might be able to assist
11 with this being the Board of Pharmacy
12 representative. I was at the Board of Pharmacy
13 meeting, I think it was last week, and they were
14 discussing 503-B pharmacies under the federal law
15 which are the outsourcing facilities. For those of
16 you who don't know, there is two parts to that
17 DQSA.

18 There is the compounding part and then there
19 is a track and trades part. Discounts mainly deals
20 with the track and trades part, but for pharmacies,
21 the compounding part of that federal regulation is
22 a big issue as well.

23 The Board of Pharmacy is licensing those
24 pharmacies that are not doing any patient specific
25 medications in state. There was talk on the

1 sterile compound committee that they were creating
2 a sterile compounding permit for those facilities,
3 correct?

4 MR. PHILLIPS: I am not on that committee.

5 MR. DIXON: I can tell you what we know.

6 CHAIRMAN CACCIATORE: I was curious if they
7 interacted with you guys on that.

8 MR. DIXON: That is something that we watch
9 very closely and we look at really closely because
10 of two things. The 503-C -- I am sorry, the 503-B
11 facilities, they have to be run and supervised by a
12 pharmacist, but they do not have to be pharmacies.

13 CHAIRMAN CACCIATORE: Correct.

14 MR. DIXON: So I know the Board of Pharmacy
15 passed a statute that basically said if you are
16 outside of the state and you are distributing or
17 shipping sterile compounding products into the
18 state you have to have a non-resident sterile
19 compounding permit.

20 CHAIRMAN CACCIATORE: Correct.

21 MR. DIXON: If you are in the state I know
22 there are a couple of permits in the state. There
23 is a special sterile compounding pharmacy permit
24 that you get in the state, and there is other like
25 an interim sterile compounding permits as well that

1 are offered by the Board of Pharmacy.

2 I think the revolving issue probably in the
3 next couple of years with that particular 503-B
4 facility is going to be the fact that some of the
5 facilities, and it is not just Florida, some of
6 those facilities are not as aware that sterile
7 compounding is not manufacturing. And sterile
8 compounding by itself means that you are making a
9 product that is different from what you start off
10 with.

11 And you have some entities that may be
12 repackaging as opposed to compounding. So I think
13 that is going to be an issue because I know the
14 federal government has put out some guidelines
15 about those outsourcing facilities compounding as
16 opposed to actually -- I mean, repackaging as
17 opposed to actual conducting sterile compounding.
18 So I know the FDA is working on that.

19 I know that from the Board of Pharmacy
20 perspective we had some interactions with them as
21 well from the perspective of trying to delineate
22 where their jurisdiction starts and our
23 jurisdiction stops.

24 CHAIRMAN CACCIATORE: And that was kind of my
25 question. And I have seen this in other states. A

1 lot of those facilities do patient specific as well
2 as non patient specific. If they're doing patient
3 specific based on a prescription, they are licensed
4 pharmacies.

5 MR. DIXON: Right.

6 CHAIRMAN CACCIATORE: But I have seen odd
7 situations in other states where they have said
8 that if they're not doing any patient specific,
9 like you say they don't have to be a pharmacy then,
10 so the State Board of Pharmacy in some states are
11 saying, we not going to license them as a pharmacy.

12 And then you have similar to Florida a
13 different agency that does manufacturing and they
14 say they're not a manufacturer either. So no one
15 is going to license them which is probably not a
16 good idea and that is not happening in Florida.

17 But I just wanted to make sure those lines of
18 who has got the jurisdiction are clarified and then
19 you have got the repackaging issue it gets a little
20 bit complicated.

21 MR. DIXON: Right, that is something that we
22 are definitely drafting.

23 CHAIRMAN CACCIATORE: It occurred to me when I
24 was at the Board of Pharmacy meeting. I wanted to
25 make sure that the Department was involved and was

1 tracking those issues.

2 MR. PHILLIPS: I had another question.

3 CHAIRMAN CACCIATORE: Mr. Phillips, go ahead.

4 MR. PHILLIPS: I guess for those of you who
5 have experience around the country with multiple
6 states, Gary and Michael, maybe you can help. I
7 have a question for one of the pharmacists that
8 works in the state around donation of HIV
9 medications.

10 Do you know if any of the wholesalers ever
11 take back and redistribute those medications? Have
12 you heard of anything like that?

13 CHAIRMAN CACCIATORE: This is Gary Cacciatore.
14 When you say, take back?

15 MR. PHILLIPS: They donate them, you know,
16 those patients, the ones who have donated them back
17 so that they can be reused again. I was told that
18 there are some states that do that.

19 CHAIRMAN CACCIATORE: Mr. Mone, go ahead.

20 MR. MONE: This is Michael Mone. I can give
21 you some places to look. Both Kentucky when I was
22 there we drafted a regulation at the Board of
23 Pharmacy to be able to engage in that activity, and
24 Ohio as well has a regulation that allows the small
25 team distribution. It is never to a wholesaler.

1 It is going directly from the pharmacy to the
2 charitable institution. It is going directly from
3 the pharmacy to the physicians. It may in fact
4 even be going overseas with the drugs. So there
5 are rules that establish the policy and procedures
6 around that as well as the recordkeeping
7 requirements.

8 MR. ELLIS: The pharmacy regulation?

9 MR. MONE: The pharmacy regulation.

10 MS. ELLIOTT: This is Dean Ellis. Reggie,
11 would that fall under the cancer donation program?
12 Wouldn't those drugs --

13 MR. DIXON: No, sir. Our cancer donation
14 program right now is benefit only to cancer drugs
15 and those drugs that treat cancer.

16 MS. ELLIOTT: Okay. Thank you.

17 MR. MONE: It is really a legislative thing.

18 MS. ELLIOTT: You could expand the drugs on
19 the donation list because there is a mechanism for
20 cancer drugs you have to expand it to HIV drugs,
21 that might be the best way to do that.

22 CHAIRMAN CACCIATORE: But to answer your
23 question specifically, I think that Mr. Mone's
24 point, I am not aware of that going through the
25 wholesaler in other states. There is mechanisms

1 and laws in other states that allow it to be
2 donated directly from pharmacy to be donated, take
3 them back into a pharmacy to be donated.

4 MR. DIXON: And if there is a specific issue
5 that you have or a scenario, we can talk about it
6 afterwards and we might be able to find someone to
7 assist you.

8 MR. MONE: I think it is that specific. It is
9 actually much wider spread where we have
10 pharmacists that handle a large number of HIV
11 population. And so there is a large number of
12 medications that go unused. This is something I
13 think could be helpful to a lot of people and
14 decrease the amount of waste that is happening.

15 CHAIRMAN CACCIATORE: Mr. Dixon, anything
16 else? We did have in our packet I thought we had
17 something from the self inspection report.

18 MR. DIXON: Yes, I am sorry. One of the
19 things that we are trying to do as an agency, our
20 division recently instituted our risk based
21 inspection program. What we are trying to do is
22 maximize our resources. Given the fact as you all
23 are aware, we only have a few inspections around
24 the state.

25 And so one of the things that we did was when

1 we put folks on the schedule and came up with our
2 program, we realized that it would be a while
3 before we got around to doing inspections of health
4 care clinic establishments.

5 And so what we decided to do instead of
6 necessarily having our inspectors go out and try to
7 some type of a surge or whatever you want to call
8 it, doing inspections of health care clinics, we
9 put together what is called a self inspection
10 survey.

11 And the purpose of the self inspection survey
12 is twofold. One, to conduct inspections of these
13 facilities, but also two, to kind of give them a
14 sense of a self-reflection of what they're doing
15 and what the laws are changing and how that might
16 affect them.

17 We have gotten some questions from folks who
18 were not as aware of the changes to the DQSA. They
19 didn't understand the difference between a product
20 versus a prescription drug because the definition
21 changed. So that was an opportunity for us to
22 provide education to folks without actually having
23 to go on-site and see them.

24 Our hope is to do that over the next couple of
25 years with all the health care clinic

1 establishments, and also to use that model to
2 assist with inspections of out of date facilities,
3 so that sometimes I know especially with wholesale
4 distributors there is a provision that requires you
5 to be inspected before or soon thereafter you
6 getting your permit.

7 So we think that the self inspection may be a
8 tool that some folks may be able to use and say,
9 look, we have been inspected with the Department of
10 Business Professional Regulation. If for whatever
11 reason during the course of the self inspection
12 there is an issue that comes up, then that is
13 someone that we can go back out and determine on
14 the risk base schedule to go out and do an in
15 person inspection.

16 What we hope to do is facilitate more
17 inspections of those folks that fall in our
18 jurisdiction without actually being in a facility
19 and disrupting business and that kind of thing. It
20 also helps us better with our resources. So the
21 folks that are in the lower categories of risks
22 that we don't necessarily go out to that often, now
23 we have been able to look at them, and we will get
24 the surveys back and have some analysis of what
25 they are doing and then decide who we actually do

1 need to inspect. If you have got someone who is
2 purchasing drugs and don't even know it is a drug
3 for instance. If I have a person who tells me
4 medicine gas, medicine oxygen is a drug, those may
5 be folks that we go back out and inspect. It has
6 been real useful. We sent out about 500, but is
7 was actually 300 and something e-mails that
8 represented 500 facilities. So we have gotten
9 pretty good response rate so far, but they still
10 have about a month and a half to respond.

11 CHAIRMAN CACCIATORE: This is Gary. I think
12 it is an excellent example of the Department really
13 doing a good job of using their limited resources
14 in a smart way. And just to remind everyone that
15 the health care clinic establishments were set up
16 because you have to sell to someone who is
17 authorized to possess prescription drugs, and you
18 have got clinics with multiple doctors sometimes
19 and you can only sell to an individual doctor for
20 use for their patients.

21 So sometimes you have one facility and each
22 individual physician. So this allows a clinic or a
23 health care establishment to get a license for the
24 facility and can be used by any of the physicians
25 at that facility. And it is lower risks I think

1 because there is less drugs there normally and they
2 are under the supervision of a health care
3 practitioner or physician or under the practitioner
4 or someone there to store the drugs and watch the
5 drugs.

6 So excellent example I think of using limited
7 resources. So we will see how that goes.

8 MR. DIXON: We have gotten a pretty good
9 response.

10 CHAIRMAN CACCIATORE: I was surprised to see
11 how many health care clinic establishments there
12 were. I didn't realized there was so many.

13 MR. DIXON: There are about 4,300 health care
14 establishment facilities.

15 CHAIRMAN CACCIATORE: If I was a practitioner
16 at one of those clinics I would rather have the
17 clinic that has the responsibility for the products
18 than my personal license. It makes a lot of sense
19 if you are a practitioner in one of those
20 facilities I believe.

21 MR. DIXON: I think the best thing about it
22 is, and I think a lot of folks don't understand as
23 a health care, if you have got three or four
24 doctors in a health care clinic and they are
25 purchasing under their own license, when you leave

1 you take your drugs with you or you have to dispose
2 of them. Because of this, now the doctor can leave
3 and the drugs still belong to the clinic. So you
4 don't have the kind of fight over what drugs belong
5 to whom and we have seen that.

6 CHAIRMAN CACCIATORE: Yes, and I can tell you
7 as a wholesale distributor we do have both. I
8 mean, we still have a lot of places that we are
9 selling to individual physicians at the address and
10 you kind of wonder what the reason is for that. We
11 open accounts both ways according to our licensing
12 folks. Anythings else, Mr. Dixon?

13 MR. DIXON: I think the only other thing that
14 we may have that may be of interest to folks is we
15 did create -- well, two things, I take that back, I
16 am sorry. We created a non-resident repackaging
17 permit. I think it may not affect many, but there
18 are some wholesale distributors, there are out of
19 state wholesale distributors who only have the out
20 of state wholesale distributor permit because we
21 didn't offer a repackaging permit.

22 So now if you are outside of the state of
23 Florida and you have that wholesale distributor
24 permit because all you did was repackaging, now you
25 can actually get a repackaging permit. You don't

1 have to have the \$100,000 bond. You don't have to
2 have the CDR. So we hope that is going to help
3 some of those folks who specialize in repackaging
4 to actually have a permit that fits their activity.

5 And you also have the virtual permits now. We
6 are working on the applications for the virtual
7 permits. And the virtual permits are there for
8 those entities that previously had to get the
9 prescription drug manufacturer permit and you
10 really don't fit in there in the sense that you
11 don't physically take the product.

12 You are more of an administrative office
13 because you probably contract with somebody else to
14 make your product and label it for you anyway. And
15 so that virtual permit now allows you to get a
16 permit that fits you. You don't have to comply
17 with some of the physical requirements because you
18 are not engaged in the possession of those
19 prescription drugs. Someone else is making your
20 product for you.

21 So we hope that those types of permits come
22 about really from responses that we get from the
23 industry about different things or things that we
24 see during the course of our licensing folks. So
25 we think that those permits will help a lot of

1 folks out.

2 CHAIRMAN CACCIATORE: Thank you. Any
3 questions for Mr. Dixon? Okay.

4 Turning to tab three. Other than setting our
5 meeting dates for 2017, is there any other business
6 that any of the other council members, questions
7 that the council members that would like to raise?
8 Any of our new council members?

9 If not, before we do the meeting dates, let me
10 open up to comments or questions from the audience
11 or the public. Anyone here in the room? Anyone on
12 the phone would like to bring up an issue or ask
13 any questions?

14 Okay. Hearing none, let's move on to setting
15 of dates for 2017. The proposed dates in your
16 packet on tab three. As you recall we do,
17 traditionally you have to have at least one meeting
18 per year in person. We decided over the last
19 couple of years we are going to do two in person
20 meetings, I believe in August and February.

21 If we want to stick with that schedule if
22 there is okay with everyone. Ms. Greene is
23 proposing some proposed dates of February 16th,
24 May 18th, August 17th, and December the 7th.

25 Any council members have any particular -- I

1 know my calendar is full in December of next year.

2 MS. GREENE: Just as a note, session is a
3 regular session this coming year in Florida. It is
4 not early.

5 CHAIRMAN CACCIATORE: It is not early.

6 MR. HART: This is Pete Hart. A motion for
7 these dates.

8 CHAIRMAN CACCIATORE: There is a motion from
9 Mr. Hart, a second from Mr. Brock. Any discussion?
10 All in favor of setting those meeting dates signify
11 by saying aye.

12 (Chorus of ayes.)

13 CHAIRMAN CACCIATORE: Any opposed like sign.
14 Any opposed like sign? The motion carries.

15 All right, if there is no further business I
16 will entertain a motion to adjourn.

17 MR. AYOTTE: So moved.

18 CHAIRMAN CACCIATORE: Moved by Mr. Ayotte.

19 MR. PHILLIPS: Second.

20 CHAIRMAN CACCIATORE: Seconded by
21 Mr. Phillips. All in favor signify by saying aye.

22 (Chorus of ayes.)

23 CHAIRMAN CACCIATORE: Thank you very much.

24 (Whereupon, the proceedings were concluded.)

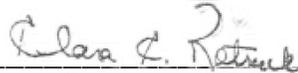
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CERTIFICATE OF REPORTER

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I, CLARA C. ROTRUCK, do hereby certify that I was authorized to and did report the foregoing proceedings, and that the transcript, pages 02 through 37, is a true and correct record of my stenographic notes.

Dated this 11th day of October, 2016, at Tallahassee, Leon County, Florida.



CLARA C. ROTRUCK

Court Reporter

Commission No.: FF 174037

Expiration date: November 13, 2018