AGENDA

Florida Board of Pharmacy
Controlled Substances Standards Subcommittee

September 21, 2015 at 10 a.m.

Florida Department of Health
4052 Bald Cypress Way
Room 301
Tallahassee, Florida

Subcommittee Members
Jeffrey Mesaros, PharmD, J.D.
Jeenu Philip, BPharm
Michael Jackson, BPharm, Florida Pharmacy Association
Harold Dalton, D.O., Fla. Society for Interventional Pain Physicians
Jesse Lipnick, MD, representing Mark Rubenstein, MD, Florida Medical Association

Board Counsel
David Flynn, Assistant Attorney General

Board Staff
Allison Dudley, Executive Director
Emily Roach, Program Operations Administrator
Amber Greene, Regulatory Specialist III

Participants in this public meeting should be aware that these proceeding are being recorded.

1. Introductions / Roll call

2. Rule 64B16-27.831, F.A.C.

3. Public Comment related to Rule 64B16-27.831, F.A.C.

4. Old Business/New Business

64B16-27.831 Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain.

(1) An order purporting to be a prescription that is not issued for a legitimate medical purpose is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law.

(2) The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

(a) Frequent loss of controlled substance medications,

(b) Only controlled substance medications are prescribed for a patient,

(c) One person presents controlled substance prescriptions with different patient names,

(d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time,

(e) Patient always pays cash and always insists on brand name product.

(3) If any of the criteria in (2) is met, the pharmacist shall:

(a) Require that the person to whom the medication is dispensed provide picture identification and the pharmacist should photocopy such picture identification for the pharmacist's records. If a photocopier is not available, the pharmacist should document on the back of the prescription complete descriptive information from the picture identification. If the person to whom medication is dispensed has no picture identification, the pharmacist should confirm the person's identity and document on the back of the prescription complete information on which the confirmation is based.

(b) Verify the prescription with the prescriber. A pharmacist who believes a prescription for a controlled substance medication to be valid, but who has not been able to verify it with the prescriber, may determine not to supply the full quantity and may dispense a partial supply, not to exceed a 72 hour supply. After verification by the prescriber, the pharmacist may dispense the balance of the prescription within a 72 hour time period following the initial partial filling, unless otherwise prohibited by law.

(4) Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 465.017(2), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substance medications being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substance medications being dispensed to a specific patient.

(5) Any pharmacist who has reason to believe that a prescriber of controlled substances is involved in the diversion of controlled substances shall report such prescriber to the Department of Health.

(6) Any pharmacist that dispenses a controlled substance subject to the requirements of this rule when dispensed by mail shall be exempt from the requirements to obtain suitable identification.

Specific Authority 465.005, 465.0155 FS. Law Implemented 456.072(1)(i), 465.0155, 465.016(1)(i), (o), 465.017(2) FS. History–New 8-29-02, Amended 2-24-03, 11-18-07.

BOARD OF PHARMACY

MEETING

Double Tree by Hilton

100 Fairway Drive

Deerfield Beach, Florida 33441

August 10th, 2015

1:54 p.m. - 4:46 p.m.

Parties Present:

ALLISON DUDLEY, J.D., EXECUTIVE DIRECTOR

DAVID FLYNN, ESQUIRE, ASSISTANT ATTORNEY GENERAL

LYNETTE NORR, ESQUIRE, ASSISTANT ATTORNEY GENERAL

GAVIN MESHAD, CONSUMER MEMBER

NABIL EL SANADI, M.D.; CHAIRMAN

MICHELLE WEIZER

JEFFREY MESAROS, PHAR. M.D.

HAROLD DALTON D.O., FLORIDA SOCIETY FOR INTERVENTIONAL PAIN PHYSICIANS

ANNA HAYDEN D.O.

MICHAEL JACKSON, BPARM

MARK RUBENSTEIN M.D.

JEENU PHILIP, BPARM

TASHA POLSTER, WALGREENS

GARY CACCIATORE, CARDINAL HEALTH

DEBRA GLASS, BPARM

AMBER GREENE

EMILY ROACH

TOM DAVIS

SUSAN LANGSTON, DRUG ENFORCEMENT AGENCY

JEFFREY WALSH

BOB PARRADO, BPHARM, R. PH.

DEBORAH BROWN, FLORIDA SOCIETY FOR HEALTH SYSTEM PHARMACISTS

Parties Present: (Continued)

DR. JOSEPH CAMILLIERI

JANET COLBERT, PRESIDENT; STOPP NOW

MAUREEN KIELIAN, STOPP MEMBER

HANG NGUYEN, PHAR M.D.

RITA FALLATEUF, PHAR M.D.

NANCY HIGH M.D.

TOM CARMALL

DAVID MACKAREY

SCOTT CORDRAY

LUCY G.

THEREUPON:

(Proceeding commences.)

MR. MESHAD: All right. I'll call the meeting to order.

I want to thank everybody for coming here today.

This is our second meeting of the revamped Control Substance Inner Committee Meeting.

The last meeting, I guess, was in Orlando. We spent most of the time listening to public comments. We tried to get our hands around the issues.

So, this go-round we do not have time for that.

At the end if there is some time left over we will revisit having a few comments. But, I think we spent over an hour listening and it was good information. We took a lot of notes. So, I think we got the gist of what's going on and some of the issues out there.

I want to start off by going around and -- We've got some new committee members that have joined the committee. So, I'm going to start on my left and just everybody here introduce yourself, please.

MR. DALTON: Harold Dalton, President of the Florida Society of International Pain Physicians.

MR. SANADI: Nabil El Sanadi, President and CEO of Broward Health -- Emergency Physicians and a member of the --

MR. MESAROS: Jeff Mesaros, Pharmacist; member of the Board of Pharmacy.

MS. NORR: Lynette Norr, Assistant Attorney General, Board Counsel.

MS. WEIZER: Michelle Weizer, Pharmacist Member, Board of Pharmacy.

MR. FLYNN: Good afternoon. David Flynn, Assistant Attorney General and also counsel to the Board of Pharmacy.

MR. MESHAD: I'm Gavin Meshad. I'm a consumer member for the Board of Pharmacy and Committee Chair.

MS. DUDLEY: Allison Dudley, Executive Director, Board of Pharmacy.

MS. GREENE: I'm Amber Greene, -- Board Specialist with the board staff in Tallahassee.

MS. GLASS: Debra Glass, pharmacists member.

MR. CACCIATORE: I'm Gary Cacciatore. I'm Vice President of Regulatory Affairs for Cardinal Health. I'm also Chair of the Florida Drug

Distributor Advisory Counsel, DBPR.

MS. POLSTER: Tasha Polster, Walgreens Company.

MR. PHILIP: Jeenu Philip, Pharmacist Member, Jacksonville, Florida.

MR. RUBENSTEIN: Mark Rubenstein. I'm a Physical Medicine and Rehab Specialist and the Chair of the Florida Medical Association.

MR. JACKSON: Good afternoon. I'm Michael Jackson, Executive Vice President and Chief Executive Officer of the Florida Pharmacy Association.

MR. MESHAD: Okay. Great. Thank you. The next item on the agenda is -- from last meeting and one of them was for -- It was update of his work group. So, I'll tell it over to you.

MR. CACCIATORE: Thank you, Mr. Chair. So, one of the items from the last meeting I was asked to address the issue of -- and access.

So, the Florida Drug Wholesaler Distributor's Advisory Council met just last Thursday. So, I -- being prepared. We just met last week in Tallahassee.

So, for those of you that are not familiar with wholesale, we are not regulate by the Board of

Pharmacy in Florida. We're regulated by the Department of Business and Professional Regulation. Specifically, the Division of Drug, Devices and Cosmetics.

We don't have a traditional board as the Board of Pharmacy does. But, the Division does have and the statutes do provide for an advisory council made up of industry representatives that provides advice and recommendations to the Department and to the Division, to the DDC, on ways we can lessen the burden on industry and also still protect the public health.

The council is made up of representatives from three primary wholesalers, one secondary wholesaler, one pharmaceutical manufacturer, one representative from the Agency for Health Care Administration, one hospital pharmacist, one physician member, one Board of Pharmacy member and also one person from the medical gas industry, who had no interest in --

So, I believe on Thursday I provided a summary of this committee's meeting from the June ninth meeting and advised the council that this committee had requested that we address the issue of access to controlled substances. And, specifically, some

of the concerns that were expressed by some of the pharmacists about not getting adequate supplies to controlled substances to meet their patient's needs.

I asked the council if there were any specific concerns with either statutory or regulatory language that possibly could be changed, noting that this committee had opened a -- to possibly look at some possible changes.

And I was, specifically, interested -- And, I put on the agenda for them, Florida Statute 499.0121(15)(b) which is, kind of, the section of the Florida Statute that applies to wholesalers. And that part states, in part -- I'm not going to read the whole thing. But, it says a wholesale distributor must take reasonable ventures to identify its customers, understand the normal and expected transactions conducted by those customers and identify transactions that are suspicious in nature.

A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions.

A wholesale distributor must assess orders for

greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable.

In making such assessments the wholesale distributor may consider the entity's clinical business needs, location and population served in addition to other factors established in the distributor's policies and procedures.

I was particularly interested in the language in their regarding the 5,000 dosage units per month because one of my concerns was perhaps wholesale distributors, in the industry, are taking that to be a limit, in that it can't sell more than that. And, I know my company does not do that; but, I just have a concern that the rest of the industry does that.

So, there was a discussion about that and I have to say that the discussion, ultimately, turned out that none of the wholesalers or members of the committee or the council felt like this was really an impediment to supply.

There was a concern that language in there is not consistent with the federal DEA regulations. But, no one felt like they were -- apply to strictly 5,000 dosage units per month.

So, I think it's a good things because individual business needs vary. So, that -- that came out of the committee.

Some of the members indicated that for a particular controlled substance orders less than 5,000 dosage units per months could actually be considered suspicious; so it's going to depend on the controlled substance involved as well as the particular customer involved.

The other thing that the council members said was because of the DEA requirement that wholesale distributors have a system to identify suspicious orders that wholesale distributors, in general, monitor all orders of controlled substances. We don't wait until it gets to this 5,000 dosage limit. So, they didn't really pass the supply -- conclusion of the committee members.

I think there was general agreement between the council members that additional guidance from DEA would be the most helpful thing to assist wholesalers, in particular, to meet their obligations under the Controlled Substances Act plus ensuring adequate supply to customers.

This was one of the three recommendations that's in the recent GAO report that's part of the

meeting materials for this meeting.

I think there was some concern with the council members about DEA's response to that recommendation and the lack of clarity about whether or not DEA intends to implement that recommendation of the GAO.

The council felt that DEA enforcement actions have impacted their practices and I think this is also reflected if you read the GAO report. I think it's like 84 percent of the wholesale distributors surveyed in that report said that placing stricter thresholds or limits on the purchase of controlled substances by their customers was influenced to a great degree or a moderate extent by the enforcement actions.

Now, clearly, there is different viewpoints on this because the report also says DEA stated that they don't believe that enforcement actions have had any bearing on the access issues. So, that's probably something that needs to be --

The council agreed with some of the comments that I made at this committee meeting last time regarding communications being the key -- communications between cust -- wholesale customers and the wholesaler as being one of the most

beneficial things that could help customers ensure that they have adequate supplies to meet their needs. The better understanding the wholesale distributor has of a customer's business, the better they will be able to meet that -- those customers needs.

There was also some discussion at the meeting regarding the Florida controlled substance reporting requirements and whether that data, which is reported to the Department of Business and Professional Regulation could somehow be used to provide some generalized feedback or information to the wholesalers such as, you know, what is the average purchase of controlled substances for a pharmacy.

There was some general discussion about that among the council members; but, no motions or recommendations really came out of that discussion.

I think, finally, there was general agreement among the council members that the ensuring patient access and effective drug enforcement -- that's currently pending in Congress would be a positive step to addressing some of these issues. As that -- That legislation clarifies some of the existing authorizations the DEA has under the Controlled

Substances Act and it requires enforcement escalations -- to an opportunity for corrective actions to address its concerns that the DEA has.

We think that this legislation would create a more collaborative working relationship between the DEA and distributors, which I think is ultimately what's needed to help address this issue.

That's all I have. You're welcome to ask me any questions.

MR. MESHAD: Could you repeat that? I'm not familiar with that legislation you just referenced. Could you --

MR. CACCIATORE: The Ensuring Patient Access and Effective Drug Enforcement Act.

MR. MESHAD: One more time.

MR. CACCIATORE: The Ensuring Patient Access and Effective Drug Enforcement Act.

I think it was also mentioned in some of the comments we received from -- I believe -- at the last committee --

MR. EL SANADI: I wanted to -- speaker -- How often are the less than 5,000 -- and how often are there more than 5,000? I know you don't have the exact number; but, I'm looking for approximate ranges.

MR. CACCIATORE: Yeah. It's really difficult to -- Meaning, the orders?

MR. EL SANADI: Yes.

MR. CACCIATORE: Yeah. It's going to vary widely depending on who your customer is and if you have a small pharmacy versus a large hospital or -- So, very often one order can be that large. This -- The statute calls for review of more than 5,000 dosage units per month. So, you'd have to -- accumulate those orders.

MR. EL SANADI: Right.

MR. CACCIATORE: There is some guidance that might be necessary with that legislation because it's not clear if that's by a particular controlled substance or all of the controlled substances in that particular -- or by DEA base code. Is it by NDC number? But, the members didn't feel like it's really an issue because nobody stops at 5,000. Everyone monitors every order as we're required to by DEA federal regulations to identify suspicious orders.

MR. EL SANADI: The reason I asked the question is because it seems that 5,000 is not an arbitrary number. It was probably based on something. It's just how is it arrived at? And

then, can you retrospectively do the calculations so maybe the number should be 3,000 or 7,000? So, I'm just putting it on the table.

MR. MESHAD: I appreciate your optimism -- randomly selected. But, I guarantee it probably was.

MR. DALTON: -- last day of session.

MR. CACCIATORE: And Mr. Chair, that was my concern at the time. I brought up -- was there was a lot of talk at the last committee meeting about arbitrary or -- thresholds and I made the point that, you know, at least in my company they're not arbitrary. There's a lot of science that goes behind it.

But, to me, the 5,000 seemed rather arbitrary and I was concerned that people are taking that as gospel and I can't sell more than 5,000. But, that did not appear to be the case at least from the members of the council.

MR. DALTON: Mr. Chairman, I just want to get some clarification on that 5,000 number.

Is it 5,000 a month for all controlled substances?

Is it 5,000 a month for Oxycodone and then another 5,000 for Hydrocodone and then another

5,000 for -- Okay?

And the other question comes to is that 5,000 -- that 5,000 triggers, hey, I need to look into this more. It's not a hard cut off. I can't get any more. It triggers more investigation. Am I correct in that?

MR. MESHAD: Well, I -

MR. CACCIATORE: Should I go ahead and answer?

MR. MESHAD: Yes, sure.

MR. CACCIATORE: We had a discussion on that and it's not clear in the legislation. But, it's not all controlled substances. The statute reads 5,000 dosage units of any one controlled substance in a month.

But, what is any one controlled substance? That may be open to interpretation because is it all Oxycodone products including just Oxycodone and Percocet and Percodan or --

There was some testimony at the council meeting that the legislative history said that it is by NDC number which would be individual -- An NDC number would be specific to a particular product.

But again, I don't think that's really the issue because none of the wholesalers that spoke at

the council meeting wait until they get to 5,000 before they do this assessment; because, it requires to assess every order. And, that review is done below 5,000 and above 5,000.

MR. MESHAD: So, the committee didn't feel like that -- While it's a little nebulous on what the meaning of it is, it hadn't really prevented them from distributing or -- They haven't read it that way.

MR. CACCIATORE: That's what the council's overall opinion was.

MR. MESHAD: Mr. Jackson, please?

MR. JACKSON: Thank you, Mr. Chair. If I can pass on another question here? There are some local municipalities that have written ordinances actually used as 5,000 dosage unit as a ceiling, so to speak.

And through the Chair, to Mr. Cacciatore, has this affected wholesaling in those particular areas where local jurisdictions have written ordinances that put caps like that in place?

MR. CACCIATORE: Not to my knowledge.

MR. MESHAD: That would be my guess. I'm mean these local ordinances -- I don't even know how aggressively they're being followed.

But, I do have a question. So, we heard a lot of testimony last time and -- from different -- I mean patients, pharmacists -- And so, there was a presumption that there is a distribution limitation going on; that pharmacies are having a hard time getting controlled substances.

Now, I recall that you weren't as sold on that theory and it sounded like from your committee -- at least from the committee, while there could be more clarity from the DEA and more education that from your perspective there's not enough widespread rationing or limiting of control substances that are being distributed to the pharmacists.

Is that accurate?

MR. CACCIATORE: I think -- I think most distributors -- and you'll see this in the GAO report -- do have limitations or thresholds and that is part of their comprehensive suspicious order monitoring program. It's a required -- by the DEA.

Now, it's true the DEA regulation doesn't specifically say you have to a limit or -- But, I can tell you that all of the enforcement actions against distributors have mainly been about excessive quantities.

And in response to that, I remember when the very first action happened, back in 2007 if I've got my time line right -- One of the first major actions against a wholesaler, back in 2007, at the first DEA conference, there was a presentation about what the DEA expected and, basically, required -- their threshold or -- purchases and -- something that was excessive.

So, most wholesalers have some type of system. So, I wouldn't say there are no limits put in place. That is part of the system.

MR. MESHAD: But, did you say that the system -- You're not waiting to hit any threshold. You're actually monitoring it from, kind of, square one. So, --

MR. CACCIATORE: Oh, sure. I mean, if the first orders that come in from a new customer -- Of course there are other things in place such a Know Your Customer program before we even set up an account. But, if a customer comes in, immediately, and -- nothing but controlled substances those would immediately be considered suspicious.

But, setting the thresholds is, at least, expected --

I think what DEA has said and I think it's

true is that wholesalers can't rely simply on the threshold system to meet their obligations.

And, I don't think we do that. I think that's just a part of what we do. It's just a piece of the puzzle of the system that we have in place.

MR. EL SANADI: If I heard you correctly, you were saying that all distributors track all controlled substances no matter what the quantity is?

MR. CACCIATORE: Well, the obligation under the DEA regulation is to design a system to detect suspicious orders. So, you have to have your monitoring system of every controlled substance order that comes in to determine --

MR. EL SANADI: No matter what the size is?

MR. CACCIATORE: No matter what the size is.

MR. EL SANADI: Whether it's 5 pills all the way to 5,000 pills?

MR. CACCIATORE: Right. Now, if it's a normal type of order it's probably not going to be flagged in the system. But, you're looking for orders that are unusual size, unusual frequency, things like that which would target the regulation.

MR. EL SANADI: Then my next question -- And I apologize for not being -- The issue of

manufacturers willfully shrinking the supply -- raise the price, has that been addressed or is that a reason at all or was that a factor in this equation?

MR. MESHAD: Anybody can speak up.

MR. EL SANADI: Supplied by the manufacturers.

MR. CACCIATORE: I can't speak to that specific question. But, what I can -- the manufacturers are subject to the same regulations.

MR. EL SANADI: Right.

MR. CACCIATORE: They have to monitor our purchases as the wholesaler from them. And just like we monitor our pharmacies and our hospital customers we're being monitored by manufacture customers under their suspicious order monitoring system as well. So, if we purchase quantities that are unusual to them they can also cut -- as well. So, that may have an impact.

As far as the issue of prices I can't really speak to that.

MR. EL SANADI: But, -- address the solution of actually physically manufacturing the medications that are -- Are they artificially shrinking the supply to increase the demand and possibly increase the price?

MR. MESHAD: I know -- has a question.

MR. CACCIATORE: I can't really speak to that because they do have to meet DEA quotas for production of -- substances.

MR. EL SANADI: I'll -- Mr. Chair.

MR. FLYNN: I want to thank you all -- I also went back through the transcript and that wasn't brought up. But, I -- certain the understanding that -- point out, there's a limitation on the manufacturing and production that you set out from the beginning which -- involvement with the federal government in and of itself. In understanding drug -- you have to also understand that patient's needs for controlled substances is an -- demand.

MR. EL SANADI: That's exactly my point; because, the manufacturer -- There's bigger populations that need the -- for more drugs and if the supply is -- the manufacturers are actually artificially -- Not necessarily artificially capped. That may be -- as far as --

MR. DALTON: I'd like to clarify just the threshold and limit -- that we've been discussing.

As I understand it the thresholds that we've been discussing today are thresholds for investigation of suspicious activities.

It appeared if the testimony that was received from the public and from -- at the last meeting is that there were limits placed on the amount of -- per pharmacy.

Are the members of the distributor's organizations placing limiting on how much they give an individual pharmacy?

MR. MESHAD: Do you want to answer?

MR. CACCIATORE: That's where the call for better guidance from DEA I think comes in. Because, the regulation is nebulous. It just says you should have a system to identify suspicious orders.

Now what DEA has made clear is if an order is identified as suspicious you cannot ship it. So that becomes key. So, --

And here's where I think there was some variability amongst wholesalers is if your threshold -- if anything over a threshold for a distributor is considered suspicious they can't ship it. So, it becomes a de facto limit as you say.

If the threshold is a call to do further investigation before that order is released then the order is not identified as suspicious and it

can be shipped after further investigation.

And, I think that's where the clarification -- some of the clarification with guidance would even be -- because I'm just -- The specifics of every wholesaler program I don't know. But, from comments that I've heard in the industry conferences there seems to be a lot of variability in that.

Some wholesalers consider anything over a threshold to be suspicious. So it is cut and reported. Others do further investigation before making that decision. There's not a hundred percent agreement on how that's supposed to work.

MR. MESHAD: Is there any data out there that shows how often that -- that threshold is hit or where they don't show -- further investigate --

MR. CACCIATORE: I can speak for my company. We do look at that data. But, I've looked at it and compared Florida to other states to see if, maybe, it's -- probable specific to Florida or we're cutting more orders and -- And, actually we're not. It's -- actually compared to other states.

So, we do look at that internally at my company, at least.

MR. MESHAD: Any other questions?

MR. RUBENSTEIN: Mr. Chair, if I could? Limiting comments to distribution alone, let's go back seven or eight -- maybe 2008, prior to this process we have crisis with abuse. What were the limits then for distribution and does that directly correlate with why we appear to have a supply side issue at this point?

MR. CACCIOTORE: I can tell you this; the regulation has not changed. What happened was starting in -- starting in 2007 -- addressed the Internet pharmacy problem as opposed to issues with legitimate pharmacies, trying to treat -- but, more illegitimate Internet pharmacies.

The DEA started what they called the distributor initiative and they met with distributors to try to address the problems with the Internet. And then, they started some enforcement actions.

What was out there prior to this and how wholesale has complied with that suspicious order regulation, there was actually a document that directed, in collaboration with DEA and the industry, that set up a formula and if you followed that formula, suspicious orders were identified and

reported, basically, at the end of the month; but, orders continued to be shipped.

So, there was a change in interpretation, in my belief, that the formula is no longer adequate and you'll see that in terms of the subsequent documents that DEA put out; that you can no longer rely on any other specific formula or anything else that DEA endorsed.

I think that's part of the reason -- I don't want to speak for DEA; but, they seem hesitant to offer more guidance because they don't want to go back to what they had previous to this because it would simply report on suspicious orders and then the orders continued to be shipped and you report it at the end of the month.

So, that's completely changed -- since 2007. I don't think that's what the industry wants and DEA, in my estimation, seems concerned about trying to wrestle or approve of -- specific formula. And, I think that's what the industry wants. The industry wants better guidance on some of the -- if you hit a threshold, is that suspicious or can you do further investigation.

There's questions that have arose about if you terminate sales to a customer because you believe

they are diverting controlled substances -- statements have been made that you must then go back to report all of their previous orders as suspicious because now that you've terminated them all of them are now suspicious.

That was a new one.

So, different interpretations of this one regulation have changed over time.

MS. MESHAD: Maybe you can help me here. There's a presumption that there is a supply issue and I don't know that I'm convinced there is. I mean, I'm sure -- I think that the issue is not a one area issue. It's a multiple problem issue. We touched on both supply -- the pharmacies and their confusion or fear of making a mistake. So, --

And you just said you've gone and done a report within your company and actually your supply is on the higher end --

If I --

MR. CACCIOTORE: Not the supply; but, the amount of times that we've cut an order --

MS. MESHAD: Cut an order -- So, it's -- Yeah. I guess the question would be how could we get out hands on any data to find out if, in fact, that's the case across the whole wholesale spectrum and

when there are holds on distributing? What's the follow up on it? And, if it's suspicious and you've got to investigate it, it's either your right and it was fraudulent or your wrong and it was just a misunderstanding of -- Red flags are only as good as the people that create them and then, you know, they're not meant to be an end all.

So, it would be interesting to see if we, in fact, -- We assume that we have this -- supply issue and I'd like to know whether we can either substantiate or defeat that so that --

MR. CACCIOTORE: I think you're right and I think part of the problem is oftentimes -- I know there are times where there is a supply issue and I'll be able to get -- supply, I believe.

But, as we heard at the last meeting, the response of many pharmacists, when they're not comfortable filling a prescription, is we don't have it. It's not in stock. And, that's not always the case.

So, -- evidence is we don't have it. They can find evidence -- I'm not saying that's -- So, I would say that if it's a supply issue, then the wholesaler, probably, over-stated because of that. And, --

MS. MESHAD: It's the easy way out.

MR. CACCIATORE: A safety factor to do that. So that's one of the issues that, probably, needs to be addressed.

I'm not sure how we determine or not there's an issue or not. I mean, I think GAO report talks about that; the perception -- if you look at the pharmacy responses in that survey. And as Mr. Jackson said -- from some of his members, they do feel that some of these members are --

MS. MESHAD: Yes.

MR. RUBENSTEIN: With all due respect to your question, were you referring to supply to the wholesalers or supply to the pharmacies? I'm not --

MR. MESHAD: Well, I referring to supply to the pharmacies.

MR. RUBENSTEIN: So, you're not convinced that there's not a supply --

MR. MESHAD: No, I'm not. You just brought up the manufacturer supplying the wholesaler. Again, I'm not hearing from the committee that the wholesalers are straining. The problem is we're not getting our supply from the manufacturers.

I would think that if I'm a wholesaler and I'm

-- I would be screaming at that point.

MR. CACCIOTORE: That was not brought up by the council. I mean, I do want to point out that we are being monitored by manufacturers as well.

MR. RUBENSTEIN: And perhaps truth in the denials of the prescriptions would go a long a ways to --

MR. MESHAD: Absolutely.

MR. DALTON: I think -- Mr. Chairman, I've had contact with manufacturers, both generic and brand name, and they admit there is not a manufacturing issue. These are -- manufacturing.

MR. EL SANADI: I think, Mr. Chair, -- is a multi level set of issues. One when you look at the manufacturers, suppliers and then the retailers. And then, the actual consumer which is the patient. So, it would help a lot to get quantifiable metrics of each of those levels to start denying --

I think the most important one is probably providing consumers with, maybe, a hot line where if I'm not getting my prescription filled for whatever it is that they would call in and that way we can complete a study or get a better lead on what the issue is.

MR. MESHAD: Mr. Cacciatore is that something that you could take on and work with -- information that would shed some light on it if there is any sort of thing? Is that a problem or do you know how widespread it is?

For the sake of moving on, I think -- It's clearly from the DEA's -- It's important to moving forward regardless. So, -- But, you know, it would be nice if we could try to pinpoint where the issues are and --

MR. CACCIATORE: I'll be happy to do that.

MR. MESHAD: Okay; thanks. Any other questions on this topic before we move on? Mr. Jackson?

MR. JACKSON: Thank you, Mr. Chair. I appreciate the discussion on this particular issue and our stakeholders actually tell us that they're struggling sometimes in getting the product that they're ordering.

They don't know what thresholds are and they don't know at what point their orders are going to be cut off. And like the wholesalers who are struggling to try to be compliant with DEA standards, our member stakeholders are also struggling to try to find out what it is that

triggers a review, an audit or something that is considered to be a suspicious order.

Could it be the percentage of pain medications they ordered compared to their other product lines that they order?

And, if the pharmacy's business mix changes, how would that have an impact on that?

So, we're looking at situations where wholesalers are looking for clear guidance from regulatory agencies and also pharmacists and pharmacies want similar feedback to know, you know, what it is that they're being looked at so that they can be in compliance.

MR. MESHAD: Dr. Weizer.

MS. WEIZER: I just want to clarify for the record that in an in-patient setting just because we have a -- we're allocated for certain parts -- we're allocated on various forms of -- So, I just want to clarify that we are still dealing with manufacturer shortages, outages and --

MR. MESHAD: But, not just on controlled substances?

MS. WEIZER: No; across the board.

MR. MESHAD: Across the board. Yes. All right.

MS. WEIZER: But, I just wanted to --

MR. MESHAD: Got you. All right. Thank you. I appreciate it.

We'll continue to look forward to further reports from your committee and --

We'll move on with the agenda. The next is Susan Langston from the DEA. Is she here? I see her.

MS. LANGSTON: Hello.

MR. MESHAD: Welcome.

MS. LANGSTON: Thank you.

MR. MESHAD: We appreciate your being here.

MS. LANGSTON: Right here.

MS. DUDLEY: Ms. Langston, there's a microphone over there. Unfortunately, you're going to have to hold it. You can sit down in that chair or you can pull another chair over.

MR. MESHAD: Ms. Langston, I think you have prepared comments for the board or the committee and then we can get into some questions and answers after that.

I appreciate your being here. I know there was a lot of discussion last week -- the last time about confusion around what the DEA is looking for -- wholesaler and -- I think it's very kind of you

to --

MS. LANGSTON: All right. Thank you. Is that okay? Can everybody -- Okay.

I do have a prepared statement I'm going to read and I'll be glad to answer any questions afterwards.

Committee Chairman Meshad, Committee Chairman Weizer, committee members and members of the public, good afternoon. My name is Susan Langston. I am the Divergent Program Manager for the Drug Enforcement Administration (DEA), Miami Field Division.

I am in charge of all regulatory matters relating to doctors, pharmacies, drug distributors and all other individuals and companies registered, with the DEA in Florida, to handle controlled substances under federal law.

With me today is Jeffrey Walsh, Assistant Special Agent in Charge of the DEA's Orlando District Office.

We are both very honored to appear before you today to discuss the very important topic of patient access to controlled substance.

I would like to start by recognizing the patients and family members here today who are

needlessly suffering and see no relief in sight.

Your voices have been heard by the DEA loud and clear. We have listened to your tragic stories and we truly empathize with you all.

I hope that today's meeting will inform you all of the DEA's roles and responsibilities and to clarify any misinformation or misunderstandings.

We are here today in good faith and with the best of intentions and our goal today is to do our part to make sure all legitimate paying patients receive whatever medications they need to live happy, healthy and productive lives.

Prescription drug abuse has been a devastating public health crisis in the United States for many years.

As you know, Florida has long been known as the pill capital of the world. At one time eleven Floridians a day were dying of prescription drug overdoses. This is still an epidemic that has caused incredible harm to those suffering from the disease of addiction as well as their families and entire communities throughout Florida.

And, I'd like to recognize the members of Stopp Now and they can tell you all about those tragic stories.

The mission of the DEA's Office of Diversion and Control is to prevent the public, which included legitimate paying patients, by preventing, detecting and investigating the diversion of pharmaceutical controlled substances from legitimate channels by ensuring an adequate and uninterrupted supply of pharmaceutical controlled substances available to meet medical needs.

We take this mission very seriously with regard to both preventing drug abuse and diversion and ensuring medications are available to those who desperately need them.

From 2011 to -- Excuse me. From 2010 to 2011, we were at the height of the pharmaceutical drug abuse epidemic in Florida.

Drug abusers from all over Florida as well as the entire country often travelled hundreds or even thousands of miles to go to Florida's notorious pain clinics that had absolutely nothing to do with providing medical care.

At that time, most of the narcotic pain pills prescribed by those criminal physicians were dispensed directly from the pain clinics and the involvement of a retail pharmacy was not necessary.

In 2011, the State of Florida adopted

legislation known as the -- that restricted doctors from selling actual pills from these pain clinics. This new law shifted the dispensing of most narcotic pain killers to actual pharmacies. The shift heightened pharmacist's responsibilities and they were suddenly faced with circumstances many never had to deal with before.

Most pharmacists transitioned just fine. But, some pharmacists failed and got caught up in the criminal law. DEA had to take action to address that problem.

The DEA's Miami Field Division increased inspections at pharmacies as part of our efforts to tackle the criminal problem and to combat pharmaceutical drug abuse and diversion.

Unfortunately, there are still unscrupulous doctors and pharmacists in Florida. But, what we have discovered through our inspection process is that most pharmacists are kind, caring, well trained and highly talkative about their professional relationships with their patients and are a vital part of the patient's health routine.

Our inspections also revealed some very disturbing things at pharmacies like the law enforcement reports of drug dealing and -- a victim

of a intravenous overdose in -- drug seekers lined up at pharmacies to get their prescriptions filled, volume based pharmacists and pressure from owners and pharmacy staff that caused many pharmacists to go get certain professional -- to do --

Although we have increased pharmacy inspections during the past few years less than one percent of the pharmacies in Florida have been formally sanctioned by the DEA.

Allow me to give you some statistics.

As of a few days ago, there are 69,492 retain pharmacies in the United States registered with the DEA to dispense controlled substances. 4,902 of those retail pharmacies are in Florida. Our largest chain pharmacies in Florida are Walgreens with 159 locations and CVS with 744 locations.

Out of almost 5,000 retail pharmacies in Florida, the DEA has initiated formal proceedings to revoke the DEA registrations of 23 pharmacies since 2011.

We are waiting on administrative hearings and/or final decisions in 10 of those cases.

Only three pharmacies, in Florida, have had their DEA registrations revoked since 2011.

I can assure you that the pharmacies the DEA's

Miami Field Division have taken action against for ignoring red flags of abuse and diversion, for undoubtedly contributing on a major scale to the abuse and diversion of controlled substances. These were not situations where a few questions or prescriptions fell through the crack or a pharmacist just had a bad day. These cases involved unquestionable patterns of behavior that had to be stopped for the public's health and safety.

The DEA's pharmacy inspection process is designed to make sure pharmacies are in compliance with federal record keeping, security and other requirements. During these inspections we inform pharmacists of current trends to be on the lookout for and ask for their assistance in both preventing diversion and making sure people with legitimate medical conditions get the medicines they need.

Under federal law a pharmacists has the responsibility to fill only prescriptions issued for a legitimate medical purpose and in the course of professional practice.

This corresponding responsibility regulation is to help prevent the diversion of controlled substances through drug seeking behavior.

Drug seeking behavior is one of two things; a person trying to obtain controlled substances not for a legitimate medical purpose and for the sole reason of feeding a drug addiction or a person trying to obtain controlled substances to divert into the illegal market.

If a pharmacist recognizes a red flag that the prescription may indicate suspicious or drug seeking behavior, that pharmacists must exercise caution and resolve that red flag by their failure to fill the prescription.

What is a red flag?

A red flag of diversion or a red flag of anything is merely a circumstance that something could be out of the ordinary or suspicious. It is a general attention marker.

If a pharmacists encounters a red flag, then asking a question of a patient, calling a doctor's office, combined with using plain old common sense, will have to offer a reasonable explanation to clear that red flag.

We recognize that the vast majority of controlled substance prescriptions are written by highly trained and ethical medical professionals who are treating legitimate medical conditions.

We also recognize that the vast majority of controlled substance prescriptions written by doctors are for legitimate medical purposes and they're issued in the usual course of professional practice.

A great deal of the time a red flag for the pharmacy can easily be explained and once it is resolved there is absolutely no problem filling that prescription.

In watching for suspicious activities we are not asking pharmacists to be medical doctors. We are not asking them to review medical records, MRI reports, x-rays or to diagnose a patient. We simply want pharmacists to be aware that there is an epidemic of pharmaceutical drug abuse in this country and to use their education, experience, professional judgement, ethics and common sense to not knowingly participate in this national health crisis.

I have a deeply troubling story of Aidan Lopez, a four year old cancer survivor, who was recently diagnosed with Stage 3 Kidney Cancer.

Poor Aidan has gone through more pain in this four years of life than most of us will ever have to endure.

He had surgery recently and was prescribed medication for his pain. Incredibly, however, three pharmacies refused to fill his prescription.

How in the world does this possibly happen?

What were the red flags of drug abuse and diversion with Aidan that three pharmacists could not resolve?

What drug seeking behavior could this four year old child possibly exhibit to make any reasonable pharmacist using common sense question the validity of his medical condition.

I'm also deeply troubled when I hear stories of patients who have been going to the same pharmacy for years and all of a sudden that pharmacy elects to stop filling their controlled substances.

Legitimate patients should not have to travel or do the pharmacy crawl to acquire their medications.

The DEA inspects all pharmacies and our actions against pharmacies who fill prescriptions with obvious highly suspicions, blatant and undeniable red flags of abuse, diversion and drug seeking behavior should never in any way cause any person who needs medication legitimately to go

without.

The staff of the DEA's Miami Field Division is horrified to hear the heartbreaking stories of cancer patients, hospice patients, surgery patients and legitimate pain patients being forced to endure needless suffering.

Many of us at the DEA have had family members and friends who have been turned away at pharmacies for no apparent reason whatsoever.

My family has personally been affected.

This has to stop and it has to stop now.

Unfortunately, the DEA cannot force a pharmacist to fill a prescription. But, what I can do is pledge our sincere commitment to this committee, the medical and pharmacy communities and, most of all, to the public and ensure you all that the last thing we want to do is interfere with a valid medical treatment.

I want to make myself perfectly clear. Pharmacists do not need to fear the DEA when they use their professional judgement, experience, education, training and common sense to fill legitimate prescriptions.

DEA works with pharmacists and we are out in the field visiting pharmacies on a regular basis.

We are accessible and we try to answer questions. But, DEA does not give out a checklist or tell a pharmacist that his or her job is black or white because it's not.

Every patient should be treated on an individual basis. Each patient has a different diagnosis and needs that should be addressed by the pharmacist.

The DEA expects that trained pharmacists are able to demonstrate they are filling opioids for a legitimate medical purpose. They can accomplish this by getting to know their customers so that they can make an informed decision.

Pharmacists are the last gatekeepers who provide controlled substances always to the public.

The DEA and the public at large depend on pharmacists to make the final assessment whether a prescription appears to be legitimate or not.

Now, I'd like to clarify misunderstanding about the word -- about the terms quotas and thresholds.

DEA does not impose a quota on the amount of controlled substances a wholesale distributor can sell to a pharmacy. Likewise, DEA does not issue

any sort of threshold in this way either. DEA does not impose a quota or a threshold on the number of prescriptions a pharmacy can fill or the amount of drugs a pharmacy can purchase.

Since the early 1970's, DEA regulations have required non-practitioners such as wholesale distributors to design and operate a system to disclose suspicious orders of controlled substances.

Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

In 2011, the DEA released a document called Know Your Customer. This document contains suggested questions distributors should ask customers prior to shipping controlled substances.

Short of providing arbitrary thresholds to distributors, the DEA cannot provide more specific suspicious order guidelines.

Guidelines as to variables that indicate an order may be suspicious, are very fact intensive and differ from distributor to distributor and from customer to customer.

I would like to emphasize that the DEA has no authority to control otherwise business --

legitimate business decisions of DEA registrants. As a result, the DEA cannot direct how distributors conduct their business, including the amount of controlled substances lawfully distributed or dispensed to customers such as pharmacies.

The DEA has repeatedly and emphatically -- distributors that arbitrary thresholds are inappropriate, negatively impact legitimate patients and are an inadequate substitute for fulfilling their obligations under federal law.

In closing, I want to thank everyone for attending this meeting.

It is very important that the DEA works with pharmacies, doctors, wholesale distributors and all others to prevent diversion and to make sure legitimate patients are able to obtain medications.

I guarantee you all, you have the DEA Miami Field Division's unwavering commitment on both of those fronts.

Thank you.

MR. MESHAD: Thank you, Ms. Langston. I appreciate it. I'm sure there are some questions from the committee. So, -- Mr. Jackson?

MR. JACKSON: Thank you, Mr. Chair and thank you Ms. Langston for being here with us today. We

certainly appreciate your comments.

I do have -- You had mentioned about a number of pharmacies who had their DEA registrations revoked. It was a very small number.

Can you share with the committee how many registrations were surrendered by pharmacies?

MS. LANGSTON: I don't have the exact number in front of me; but, it was over 100.

MR. JACKSON: And also as a state professional association, do you facilitate education programming around the state?

And, I also want to thank you for participating in the ones that you've done in the past and I want to take an opportunity to extend to you an invitation to visit with us again in September when we're back in the Fort Lauderdale area facilitating a panel discussion. You're welcome to appear before that.

MS. LANGSTON: I believe we would like to come. Thank you. And, we are going to put together some of our own educational things for pharmacists. But, I cannot -- I don't have all of the details. But, I know we're still working on it. But, we are putting together a program.

MR. EL SANADI: Ms. Langston, an excellent

presentation. Thank you so much.

MS. LANGSTON: Thank you.

MR. EL SANADI: Is there a way we can get a copy of your transcript?

MS. LANGSTON: I have to -- I'd love to you a copy of my transcript. I simply have to clear that with my office. I've never had to do that before. So, I don't have the answer. But, I would love to give you a copy.

MR. EL SANADI: Understood. All you can do is ask their permission.

A quick question for you.

Do you have a consumer hot line where actually patients can call you regarding them not being able to get their prescriptions filled?

MS. LANGSTON: We don't have an actual consumer hot line for that. But, we have and we've been getting hundreds if not thousands of calls at our various DEA offices that have diversion groups.

But, that would be a good thing and, maybe, I could even see if we could have an e-mail address; not that we don't want to talk to people but sometimes when it's at night and somebody is not there that might be an easy way to get in touch with us, too. So, let me think about that.

MR. EL SANADI: The only reason I'm asking the question is we're trying to --

MS. LANGSTON: Yes.

MR. EL SANADI: And you mentioned that one case of the four year old.

MS. LANGSTON: Yes.

MR. EL SANADI: So, I was just curious as to how you found out and then -- or how big is the -- how many prescriptions -- and then how many are actually being denied for legitimate reasons --

MR. WALSH: Hi. Good afternoon. One of the problems we have is even if that information was to come to our attention -- Again, we're not part of the health care system, nor are we qualified with being in the situation of little Aidan. We couldn't make that pharmacist fill that prescription either way, even if we disagreed with the denial and that's the dichotomy in the system here.

So, while a hot line might prove some statistical -- provide some statistical information for us. It's not -- What we want -- don't want to do is give the impression to the public that we would be the resolution to that instant issue. You know, that's very -- they're in line at the

pharmacy calling on the cell phone, they're not filling this script. So, it's kind of a touchy situation.

MR. EL SANADI: Understood one hundred percent. But, the request is not to have you be part of the health care system. But, as a monitor of the repository and then working with the Board of Pharmacy or any of the other boards.

MR. WALSH: So, just a statistical collection by --

MR. EL SANADI: Yes. Just to keep -- And then, how much -- That would be up to the board to --

MR. MESHAD: I mean, I'm sitting here -- We're going to get further into the agenda. We're going to talk about what we can do as a board to -- and I think that having the DEA participate in some form or fashion in that --

You know, I hear what you're saying. It's hard to right red flags and regulations around common sense. But, there's just a lot of fear and misconception out there and I think the feeling is, well, my judgement or my common sense might not be viewed by the DEA the same as somebody else and because they're the DEA, you know, they're fearful.

And so, I think if you were part of creating a set of protocols -- Again, they're not going to be the end all. You can't create protocols around good practice and common sense. But, you can law the foundation -- go through this protocol and then, you know, you pretty much have shown that you made an attempt.

And if the DEA is part of that then there would be tons of collaboration there. You know, you can't come in and then, you know, put your badge out there and say you didn't follow standards or practices when you helped create the standards or practices.

So, I think your participation in that would be very valuable and your input.

MR. WALSH: Yes. In -- We're -- You know, this should not be and I don't believe it is an adversarial environment. I mean, we're all on the same team.

MR. MESHAD: Not at all.

MR. WALSH: The -- And we're happy to participate in any method we're permitted. The diversion investigators, which is what -- who Ms. Langston runs for the whole state. I'm the agent in charge of the Central Florida region out

of Orlando. So, some of her people work for me and it's obviously a hot button item. So, Mr. Wright, the SAC, asked me to come and represent him and the state today.

We go out and we see these pharmacists an awful lot. Our people are extremely active; just like the pharmacists are very educated, talented people; very dedicated civil servants whose job is to save lives. That's what we all swore an oath to, just like doctors and pharmacists have. We take it very seriously.

The interpretation of the information we present is, to be quite honest with you, sometimes alarming. How the information is our diversion investigators are presenting is received, it's received in a combative nature and an adversarial nature.

Demographics change. Somebody mentioned -- had mentioned earlier when you were all very eloquently making your statements and questions earlier on that what would trigger DEA -- what number -- what threshold -- what quota is going to trigger DEA to come look at us and I don't think that's the question. The question is -- you can do whatever you need to do to serve your clients, to

protect the health and welfare of the citizens we serve as long as you can articulate why you did it; legitimately why you did it.

And I'll give an example of a town I live in, in Central Florida. There's a chain pharmacy that's been doing business for a long time. I go to it. It's been doing business for a long time. Well, all of a sudden, there's a massive spike in their Schedule 2's; their opioids, their pain medications. So, our folks noticed it and they're like, wow, something must be going on.

Under further review -- And their numbers went up to astronomically. But, lo and behold, right across the street from them they built an emergency room.

So now, their demographics have completely changed because all of these people are coming out of the woodwork with these dramatic injuries and what are they doing? They're walking across the street to fill their prescriptions.

Make sense? Right? Absolutely. No problem.

It wasn't a number that triggered anything. The number brought some attention. They were able to articulate why and everybody is happy and everybody is getting their medication.

So, sometimes, even though we do try to get engaged, we don't -- And, I think Ms. Langston mentioned this. We don't want people to fear us. Belive me. We're all on the same side.

We're actually, believe it or not, everybody in this room along with the DEA folks -- we should be proud that we're in a position where we're negotiating through this collectively because we're on the back end of a success story where several years ago eleven people were dying a day and the loss of human capital, the carnage that this problem caused throughout the state, for any of us that have children or loved ones, was heart-wrenching.

And it's heart-wrenching now when we hear these stories of people that can't get their pain -- It's happened to all of us, all of our families.

My parents are snow birds. They get out of the cold and come down here to Florida. Right?

I get a million people a week visit my area of responsibility in Central Florida. That's a million people a week that are not from here. What are the odds that some of those people are going to need prescription medicine while they're here? Pretty high.

So again, it's the pharmacists that are the final law; the final -- the three P's, the patient, the physician and the pharmacist for getting this stuff out there and we want to work with them. But, they should not fear us.

Again, less than one half -- As this gentleman mentioned before, less than one half of one percent of the pharmacists in this state have been subject to any punitive action. That's a minuscule number. And, those have been pretty egregious.

If told you those stories you, yourselves, would say wow, pretty egregious.

MR. MESHAD: Actually that number strikes me as low. But, considering the number of pharmacies and the problems we've had in the past it --

MR. WASH: Well again, a lot of the -- I think the press -- I think the media does a good job of keeping the public informed in this. They serve a necessary -- a very necessary part in this. I agree with that.

But again, they cover -- they cover the most egregious and we don't have the numbers that the gentleman I was just interacting with on -- he was talking about gaining statistical information through some sort of call-in center. I would

venture to guess the number of people that are being refused is still going to be a small percentage.

Now, the ones that we hear about, they're set. They're heart-wrenching and they're set and we all understand that.

But, it's still going to wind up being a small percentage. Does that make it acceptable and right? No.

But, the ones that you've seen -- the ones that you've read about in the paper, the ones that you've seen that has been absolutely egregious -- And the stories, again -- I have regulatory folks that work for Susan and I collectively and then I have law enforcement folks; gun carriers. They're call tactical diversion squads. They're throughout the whole state. They deal with the criminal element here; not, you know, a law abiding person who is questioning the validity of a script.

The problem still exists. So, it's walking that fine line. But again, we're on the back end of a success story here. We're saving lives. The pill mill epidemic here --

And what we do here, we're trailblazing; everybody in this room. Because, we've pushed this

problem, not on purpose -- We've been successful here. We've pushed this problem north.

The issues we were having years ago are now into other states because they're not getting in cars in Tennessee and Kentucky and Louisiana and coming here anymore. They're going to other states.

And, what we do here is going to be a benchmark for these other states. I really believe that. I believe when they start mirroring the steps that we've taken in the State of Florida, federally and through the state legislatively and Pam Bondi's office, I think you're going to see that they're going to look at what we've done and they're going to come to us for help.

We're going to get through and we're going to fix it; but, what we've done here is we're dealing with the back end of a success story.

MR. MESHAD: I appreciate that. I agree. Yes?

MR. DALTON: Ms. Langston, thank you very much for being here. We appreciate the DEA's efforts in this matter.

We heard earlier today that there seem to be some confusion and a bit of nebulousness regarding

the distributor.

Are there any plans or can the DEA help give greater clarification to the distributors as far as how they should proceed moving forward?

MS. LANGSTON: DEA policies are issued by DEA headquarters. I'm not trying to brush away from that question or anything like that; but, as I'm in the Miami Field Division, we just handle our individual divisions.

We have a whole Office of Diversion and Control at DEA headquarters. They are very aware of what the distributors are asking for.

I'm sorry I can't answer your question. But, what I can do is get in charge -- I mean get in contact with the people at DEA headquarters who handle that and forward them your concerns and, hopefully, come back with an answer.

MR. MESHAD: Thank you. Any other questions for Ms. Langston?

I appreciate your time. I really do. Again, --

MS. WEIZER: I don't really have a question. But, based on the comments that were brought up -- just -- not necessarily from Ms. Langston -- but, comments that were made during her presentation and

listening to the folks around the table, I do think we have to -- talk about at our first meeting. I think what I would like us to do is make sure that in our education -- we talk a lot about some of the comments that Ms. Langston brought up today.

But, there are things about -- I know we're going to talk about our role and fix our role; but, there are some critical things -- I know -- critical thinking skills --

MS. LANGSTON: Okay.

MS. WEIZER: And, I --

MS. LANGSTON: That's actually a great way to put it.

MS. WEIZER: So, I would like us to kind of work on those critical thinking skills and make sure that we present it in our program from training our pharmacists. And, when I looked at that -- this past weekend, some of the bigger facilities, the speciality areas, the cancer centers, the places where patients travel to have special care, those are the people that are having the biggest problems getting their prescriptions filled; because, they travel, you know, 200 miles back home and those are some of the issues that we're having in the --

MS. LANGSTON: Well, that's one thing that's misunderstood.

MS. WEIZER: Correct.

MS. LANGSTON: That makes perfect common sense.

MS. WEIZER: Yes.

MS. LANGSTON: People travel to get their medical care.

MS. WEIZER: Right. Correct.

MS. LANGSTON: People travel to Disney in Jeff's area on vacation --

MS. WEIZER: Correct.

MS. LANGSTON: -- and they need to get prescriptions filled.

MS. WEIZER: Exactly.

MS. LANGSTON: That's entirely different than what we were seeing with the people coming here --

MS. WEIZER: Exactly.

MS. LANGSTON: -- from other states on a grand scale.

MS. WEIZER: I think we just have a complete swinging of a pendulum, that we just need to educate about.

MR. MESHAD: Well, maybe we can have your participation -- because it shouldn't be an

adversarial relationship at all. We're in this --

MS. LANGSTON: Absolutely.

MR. MESHAD: So, I think that there's -- I mean if you put it -- I mean sometimes information is -- or perceived incorrectly depending on the source it is coming from. So, the more we can collaborate together --

MS. LANGSTON: Yes.

MR. MESHAD: -- and communicate what we're here -- Just like this perception of the supply problem. Maybe there is. Maybe there isn't, you know. But, we've got to break through the perception wall and try to work together and -- on education and whatever we can do within our power through rule making and protocols and then the Board of Medicine, too.

I mean, you know, we talk about lot about legitimate scripts. Well, you know, I've heard it once or a thousand times, the pharmacies are like look, you know, I'm not writing these scripts. But yet, all of the burden is put on me to determine whether they're appropriate or not. And there is a responsibility; but, that responsibility start with the physician and carries it into the pharmacy.

So, I'm glad that you're here and you're on

our committee; because, that's been the missing link. We need the wholesalers, the physician, the pain management, the DEA, all to come together and help really put --

It's not about -- It's not about opening up the supply. It's about the appropriateness of it; because, we want to continue to limit the inappropriate use. And, it shouldn't be --

MS. LANGSTON: Yes.

MR. MESHAD: -- an all of nothing type of thing.

MR. EL SANADI: Thank you so much. Thank you for all your comments. I appreciate being here. I'm listening to the dialogue and I'm just going to make a comment to bring you back on what Dr. Weizer said.

It is -- very collaboration and education -- The reason I want to get a transcript is that we post on the Board of Medicine web site. It's very informative. It's very educational. I don't know if you have --

But, you can actually post it and then we can go ahead and --

MS. DUDLEY: Other than Dr. El Sanadi, I was going to -- planning to, actually, order the

transcript of this meeting and we would be including that in the next materials so that we can work with the Board of Medicine and we can be directed on that as well.

MS. HAYDEN: And that goes for the Board of Osteopathy.

MR. MESHAD: Yes. For the sake of -- education --

Okay. Well, we appreciate that. Thank you so much.

MS. LANGSTON: Thanks for having us.

MR. MESHAD: All right. So now the next area of our agenda, we have a copy of individuals in our groups that have some further information -- The first is Mr. Bob Parrado.

So, Mr. Parrado, I'd like to recognize you at this time.

MR. PARRADO: This is going to take a while.

Good afternoon, board members.

MS. WEIZER: Can you use your microphone?

MR. PARRADO: With my big mouth? Good afternoon, board members.

MS. WEIZER: It's not on.

MR. PARRADO: It's not on? Hello.

MR. MESHAD: There you go. Thank you.

MR. PARRADO: Good morning, board members. My name is Bob Parrado. For those of you that don't know me I'm your former Chairman of the Board of Pharmacy and I am President of Parrado Pharmacy Consultant which is a consulting firm that I have that concentrates on patient safety, community pharmacy practice and drug diversion. Hence, my interest in this arena.

I also thank you all for addressing this problem; because, this has been a problem for many years. Not just recently.

A lot of the things you heard today I was going to talk about. So, I may be repeating a few of the issues. But, the reason I may be repeating them is because I have live action circumstances with these situations that have come into play.

If you've seen the materials that you were provided with prior to this meeting there are some misconceptions and misplaced perceptions about the responsibility of pharmacists to verify a prescription before dispensing it.

That problem is growing.

I believe it is a problem related to education. We've talked so much today about education and an understanding of the DEA

regulations and that's where, you know, hopefully, the collaboration between this committee and DEA is going to help clear up some of these situations.

In your materials, in that GAO report, of the 70,000 pharmacies that are out there and the 1.5 million practitioners that are out there working, that are licensed registrants, seventy percent of those registrants are no aware that there is a DEA manual that helps with their practice. That's almost sad; seventy percent.

So, what does that tell you? That information is not getting out there correctly.

You know, there's a lot of DEA books out there -- policy statements in the Federal Register.

Have any of you ever tried to negotiate the Federal Register?

I mean I'm in this arena every day and I have struggled with it. But, if the information that they're putting out is in that kind of a format, that is a barrier to people really understanding where we need to be.

That's something that we need to address; part of that education. It's, probably, maybe, making it easier to understand the policies or where they're being put, where people can access those

policies.

You know, the percentage of people that don't understand the Federal Register is much higher than that seventy percent. So, that leaves a lot of misinformation out there that needs to be addressed.

You heard, you know, earlier about the wholesale distributors. In that GAO report -- and a lot of you have that report -- fifty percent of the wholesalers are -- policies -- medications. Eighty-four percent say they were influenced by DEA enforcement actions. Sixty-two percent of pharmacies -- and it's amazing that the sixty-two percent is consistent between small, independent pharmacies and chain drug stores, report that this decreased distribution limited their ability to supply a needed medication to their patients.

The GAO study recommends greater communication between the DEA and the registrants. And you also -- On page 85 of your materials, the DEA denies any need to increase communication.

That's where I think there's a -- this disconnect becomes a reality. We need to increase that communication to make it easier to access these things that they need to.

I know I had earlier sent in some suggestions in talking with people about this issue. I sent in -- It's on page 93 of your materials. -- some suggestions I made that might help to address some of these issues.

But, those are merely the tip of the iceberg.

These suggestions are -- There's a lot of great suggestions in there. There's a lot of other things that may help. Arizona is going to have some suggestions that may be helpful to you in your deliberations.

What I feel is the first step is the educational presentation prepared in collaboration with DEA to ensure pharmacists understand the corresponding responsibility. That theory of corresponding responsibility is not understood well, I'm afraid, by my colleagues.

Would a mandated continuing education on controlled substances is a matter that would have CE and med errors; would that possibly help?

And, I hate to mandate anything. But, is that something that could be of help on this issue?

Would special pharmacies licensed just to work on controlled substances -- Would that be an issue? And, those people could be better educated

in that field.

But, -- I think we -- red flags a lot. You know, the problem with red flags, red means stop and a lot of people are just stopping. They're making that a hard stop.

If we could, somehow, structure -- refer to this yellow flags where it's cautionary and we are just stopping, taking a look at the matter and going on, that might be a better -- a new way of understanding this problem.

And, all of this fine as long as there is sufficient supply. You know, this -- We're talking a lot about supplies and there is an issue with supply. I hear it every day. My patients yell -- My customers, my clients, tell me this every day about the problems they're having trying to get medication. And, 499.0121, you know, paren 15, is the statute that addresses the due diligence that a wholesaler has to observe in their practice and that's where the 5,000 tablet dosage unit term is and that's what, probably, needs to be addressed.

We need to re-look at that statute.

Is 5,000 the right number?

There again, we've talked about that already. But, is it really the right number? I don't know.

That needs to be looked at.

But, what does that statute say? Does that say you've got stop at 5,000 or you begin this evaluation process?

All it says is that when you get an order over 5,000 that the wholesaler should stop and evaluate and look at the business needs of that pharmacy and then go on.

What I have seen in my practice and I've seen it often and often and often is that 5,000 tablets becomes a hard stop and when the pharmacy calls to find out what's going on, if they complain too much some of my pharmacies have actually had their accounts closed down just for questioning their quota, their limit, whatever you want to call it. Their accounts have actually been closed by the wholesalers.

I've seen accounts where their controlled substances account is shut down. You can order non-controlled; but, if you can no longer order controls any longer. That's just wrong.

You know, that just needs to be addressed and if that's what needs to be addressed in 499 that's where I think we need to look.

You know, I know later in the agenda we're

looking at 27.831. That rule, I think, as we all know is out-dated. That rule was written in 2002. There are a lot of things in there that need to be re-addressed and, hopefully, that will help with the clarification; because, this is all misconceptions -- misconceptions leading to the reality that people cannot access their meds.

I think at the end of the last meeting Dr. Rubenstein made a great comment. I almost wanted to end with that comment. He said we no longer have a prescription drug abuse problem. We have a prescription drug access problem. And, that's where this situation has gotten us.

Now, why has it gotten there? Because of fear. You know, call it what you want. You know -- I hate to get into my -- truck mode and get politically incorrect here. But, it is what it is. It's fear. Fear of sanctioning.

I hear so many pharmacists tell me I can't fill that prescription because DEA will take my license away. And, I've got to tell them DEA doesn't license you in the first place. DEA didn't give you a license. They can't take your license.

They license the pharmacy, not the pharmacist.

That's another misconception that's out there.

The Board of Pharmacy has purview over their license; not them.

So, in closing, education ensuring everyone involved, including state and federal licensing bodies are on the same page will allow this pendulum to swing back to where valid prescriptions will no longer be automatically denied due to fear and misconceptions about the law or possible sanctioning.

As Mr. Jackson mentioned, the FPA will be having a law conference here in September. I'm going to be presenting at that conference. I have a presentation I did at the FPA convention and I'm going to do it again here on critical thinking, as Ms. Weizer put it to so eloquently. Because, there is no common sense out there that you can teach. You can't -- In sports you can't teach speed and in pharmacy you can't teach common sense, I'm afraid.

I have a great example of that, of the fear.

My son is a pharmacist. My daughter-in-law had a baby and went to have a C-Section. She had a little bit of problems, so she leaves the hospital with a prescription for 20 Percocet 5. How innocuous a prescription that is.

My son took it to the pharmacy where he works.

His partner refused to fill the prescription.

Now, that's just pure lack of common sense.

Fortunately, my son fired him the next day because you can't teach stupid.

But anyway, there's a lot of situations out there. There's -- I've heard a lot of things going around back there and there's a lot of hmmm, I'm not sure about that; hmmm, I'm not sure about that.

You know me. You know I'm not the politically correct person in this room.

But, if you have any questions I'm willing to answer anything you may have for me.

MR. MESHAD: Thank you. Any questions for Mr. Parrado?

MR. PARRADO: Dr. El Sanadi, good seeing you again so soon; sir.

MR. EL SANADI: Thank you. We appreciate your insights.

MR. PARRADO: Sir. And, I'm willing -- I am more than willing to work with DEA on these education processes.

MR. MESHAD: Thank you.

MR. FLYNN: I have a couple of questions. We've been highlighting this in the beginning here

and I know you like to a side a little bit. But, --

In looking at this from the supply side, the Board of Pharmacy is not going to be individually able to handle the supply side. But, if we accept that there's a problem with the supply side and we can continue to work on that. But, if we also accept -- that there's a problem with the proper validation of the prescription and education, education, education -- And, Dr. Rubenstein and I were working on this. As I told you guys --

It looks like one of the things is the process would -- It's like thirty hours. So, it didn't cost you any more money to add and maybe make it part of the school -- There's continuing education I'll talk about --

I've heard a lot sitting here for three years that there's just limited concerned on, well, what is a valid prescription? What is a prescription versus what is a valid prescription probably -- If you've got a prescription that's written -- it's got all of the -- Now, how do we legitimize that prescription?

I think the practitioners have to teach others what that is and the doctors -- So, I'm only going

through this because I -- actually make progress -- that one of those changes in that rule may be some -- education for validating prescriptions --

MR. MESHAD: I for one think it's right -- At the end, we're going to get into how we structure a little meat around this and you're right on. We can continue to talk about the -- side, the wholesale side and I think we should.

But, we -- You know, we're action oriented and I want to do what we have in our power as a Board of Pharmacy and I think we've identified the rule that we can work on and through that create some educational --

I don't know if there's any further discussion on doing that. But, we can kick that off -- a sub-committee. We'll talk about that later.

MR. EL SANADI: I was going to say -- an excellent -- This is not a -- practitioner; physicians, pharmacists and I would work on -- as far as the Board of Medicine to come up with something as far as CEU and -- I can also work with the --

MS. HAYDEN: At the Board of Osteopathic Medicine we have five -- that's required for -- And one of them -- We have two hours of -- in medical

errors. But, we also have one hour of state and federal laws in controlled substances; because, this -- Even though less than one percent of osteopathic physicians have ever had a -- that's been sanctioned related to controlled substances, it is the number one disciplinary issue coming before us that has -- And then, the second is -- lack of --

So, that being said, those are five hours that we can put our licensure renewal -- and we've been doing it for a couple of years now.

MR. MESHAD: Mr. Mesaros?

MR. MESAROS: I think the education -- is important and -- where we need to go with it -- of the DEA. My concern with the requirement of the CEU is the content has to be practical and to be applied. I think pharmacists, doctors, -- and the problem that we're having is the application of it with the interpretations of -- So, the CEU is a just a -- go out and get two credits of controlled substance education. All we're going to have is two credit of controlled substance along with the rest of your twenty-eight requirements. And I think we need to make sure that the content is something that we could apply to our day to day

practice.

MR. FLYNN: Yes. And that's also -- continuing education requirements -- validation of prescriptions would cover -- you know, validating prescriptions --

But, I can tell you one thing as much as we --

What is the appropriate form of identification that needs to be taken -- and the federal government -- Do you know what that is? I didn't until I -- closer look at this. So, -- identification -- We can't prepare the -- requirement and then, of course, we -- know someone --

MR. EL SANADI: -- where the DEA, Board of Pharmacy, Board of Medicine and the Board of Nursing could get a white paper that actually outlines all the elements as far as -- from there create a pamphlet for education identifying the --

MS. HAYDEN: I know my -- I think the -- So, here's a copy. I have one on my jump drive.

MR. EL SANADI: Thank you.

MS. HAYDEN: -- Allison.

MS. DUDLEY: Okay; thank you.

Dr. El Sanadi you can collaborate in any way that the committee sees fit.

I do think -- I take a lot of phone calls as the Executive Director and end up -- There's a lot of confusion out there about the laws. We have federal laws at play. You have 893. You have 465.

And so, I would definitely -- I like Mr. Parrado's idea that -- for all three web sites that could -- I'm thinking that we need to get all of those laws and rules and try to address some of the common questions that I take on a regular basis.

MR. DALTON: -- some of the laws and rules that are stated in the packet.

According to 64B16-27.831, the standards of practice for dispensing of controlled substances for the treatment of pain -- if there is a question as to whether the prescription was issued for legitimate medical purpose the pharmacist must verify the prescription with the prescriber.

A pharmacist who believes the prescription for a controlled substance medication to be valid; but, who has not later verified with the prescriber may determine the supply -- may not supply the full quantity and make dispense a partial supply.

After verification, then, the prescriber -- with the prescriber, the pharmacists may dispense

the balance within a seventy-two hour period after the initial partial has been filled.

And, if the pharmacist believes that this is not a valid prescription, which we just heard the definition of a valid prescription, contact the prescriber.

If they believe it's not a valid prescription the pharmacy must contact the Sheriff or local legal authority within twenty-four hours.

We're not here today -- My members of my society are not here today because we're being inundated with calls my pharmacists to verify valid prescriptions.

We're not hear today hearing from law enforcement that they're being called with all of these concerns that these prescriptions are not valid.

We're here today, quite frankly, because pharmacists are scared and the pharmacists are lying to our patients.

We heard in the last meeting, in testimony -- and you can look at the transcript; page 134 t0 144 of the transcript, pharmacists are lying to their patients about not having the medication in stock.

This is committing fraud or misrepresentation

in the practice of pharmacy and the Board of Pharmacy must deal with this issue.

Let me tell you what physicians have to do before they write a controlled substance.

There must be a complete medical history and physical examination. The medical record must contain, as a minimum, the documentation of the nature and intensity of the pain, current and past treatments for the pain, underlying and co-existing diseases and conditions, the effect of the pain on physical and psychological function, a review of the previous medical records and previous diagnostic studies.

A review of alcohol and substance must be performed.

The medical record shall also document the presence of one or more recognized medical indications for the use of the controlled substance.

Each registrant must adopt a written -- for assessing the patients risk of inherent drug behavior and that may include drug testing.

The registrant must assess the risk of aberrant drug behavior and monitor the risk for aberrant behavior in an on-going plan.

This is what has to be done before a prescription is written. This is all that goes on in the physician/patient relationship.

Then, it goes to the pharmacist who doesn't have a history or physical examination or any of the other history and documenting information we have and that pharmacist is saying no and they're altering the treatment plan. And, the Board of Medicine -- or the Board of Pharmacy needs to address this.

MR. MESHAD: And I appreciate that, Mr. Dalton, with all due respect.

MR. DALTON: Dr. Dalton.

MR. MESHAD: Dr. Dalton. We wouldn't have a problem in the first place if prescriptions were written appropriately and that was --

Let's don't get -- I think that making a statement that pharmacists are lying to their patients is a broad --

MR. DALTON: Check the transcript. Check the transcript.

MR. MESHAD: That's a broad --

MR. DALTON: 134 to 144.

MR. MESHAD: -- characterization. Are there pharmacists out there that aren't truthful, at

times, about writing a script? I would say probably not.

Are there physicians out there that are writing scripts inappropriately? I would say yes.

Okay. So, we're in a situation where we have a huge problem and the corrective action has caused undue consequence. And now, we've got to address those documents.

But, I believe, just like the DEA said, this is a success story and we've got to continue to improve on the success story.

So, the standards of practice that you referenced, that's the area for -- That is the area that -- I mean there are things in there that are appropriate. There are things in there that are inappropriate.

So, there are things in there that -- This was written, I think -- Mr. Parrado, I think you were involved in writing this back in '02 before we had any of these issues come up or, at least, before --

MR. PARRADO: Well, that's why I came back up here; because, I wanted to -- The point I wanted to make -- Two points now -- But, one; when that rule was written back in 2002 Ms. Postin, from the Board, was with me when we did that.

That was originally written as guidelines. The term of that was not standard of practice for the dispensing of a controlled substance. It was written guidelines. And JEPSI came back and told us that we couldn't have a rule that used the term guideline; because, now it's a rule. It's no longer guideline. Which is why we have been asking to get an FAQ type of thing to answer these type of questions.

But, I just wanted them to be aware of when that rule was written.

Originally, this came up because we had -- we were getting so many calls at the Board of Pharmacy office in the early 2000's. Can I fill this prescription? And they'd tell them I don't know, call Bob. And they'd call me and I would say, you know, I can't see it from here.

But, you know, they needed guidance at the time so we tried to give them guidelines and then we had to go the -- we had to change the term.

But, to Dr. Dalton's comment about why pharmacists call so many times; there is a -- the only reason we're calling is because we have a question.

MR. DALTON: But, we encourage --

MR. PARRADO: Yes. And it's usually --

MR. MESHAD: -- opposite.

MR. DALTON: We're not getting the calls.

MR. PARRADO: Yeah. Yeah. A lot of times, you know, we get --

MR. MESHAD: I think that's a point well taken.

MR. PARRADO: Yeah.

MR. MESHAD: We need to encourage -- We're going to here this with a pharmacy as busy as they are -- you know, to stop and call every time. But, I think that we've got to find a middle ground on -- You know, I think what Dr. Dalton is saying is they should be calling more. They should be verifying the protocols that went behind the script; the diagnosis that went behind the script, if, in fact, you know, in their judgement it's --

MR. PARRADO: Yes; because, we --

MR. MESHAD: So, we've got to emphasize that more, I believe, in our rules and in our education.

MR. PARRADO: Yes.

MR. MESHAD: Because, if they're doing that more there's more communication and the physicians that aren't writing appropriate are going to be exposed.

MR. PARRADO: That's what I'm saying.

MR. DALTON: Yes; that's exactly what I was -- exactly where I was going.

MR. MESHAD: Right.

MR. DALTON: Thank you.

MR. MESHAD: So, I think that's critical.

MR. EL SANADI: Mr. Meshad, just -- if I may. There were 98 out of the possible prescribers of Oxycodone in the whole United States out of 770,000 physician in Broward County. So, this is a stark success story and I think it --

MR. MESHAD: Right. I think we're creating a division between the professions with the -- and I think creating a collaborative document that would be very -- Again --

As long as I've been on the board and we've -- the absence of the representation of the medical community and I've been -- with taking the time and the energy to participate in this; because whatever we do, we can only -- can only effectuate what's under our control. We can't go to -- supply side -- We can't -- We need to -- And, it needs to flow. So, you know, I appreciate it.

Mr. Jackson?

MR. JACKSON: Thank you, Mr. Chairman. And I

want to get us back to the discussion on the rule that I think Mr. Flynn brought up. I think there was some interest in looking at educational protocol. Also, I want to share with you that, I believe, the medical -- or the -- board have a requirement for continuing education on controlled substances. Plus, also, there is a requirement for pharmacies to have procedures -- written procedures, protocols, in their pharmacies for handling fraudulent prescriptions. So, there's enough content in there. We as the Florida Pharmacy Association have developed a lot of that content and we -- in that area of developing educational programs and conferences that we do, at least, twice a year.

MR. MESHAD: Thank you. Okay. So, let's move on. I think, you know, again, we're touching on some very poignant topics and -- my recommendation, again, that we create a sub-committee. It's just too difficult to move the ball forward every other month in this kind of forum. So, we should go from the Board to the committee to the sub-committee. But, unfortunately, that's not --

I think -- Lucy, did you want to address the committee. I see you waiving over there. So, we'd

like to hear from you.

LUCY G.: Hello, committee members. Lucy G. here. Director of Medical Quality Assurance.

Thank you all so much for your time and the healthy discussion that we're having here.

From the Department's standpoint, an educational program is exactly what we've talked about. I know Dr. Dalton and I have talked about it. I know Michael Jackson and I have talked about it.

We would like to see an educational program that is cross-professional and would capture, also, osteopathic medicine and pharmacy and medicine; but also, any other prescribers of controlled substances including Dentistry.

We think if the Department offered that -- Michael close your ears -- it would be free.

So, we think that something like that, that we would offer on our web site -- We do know that there are some programs that have been developed -- some corporate programs that have been developed that sound really good and healthy and well best in that very area of teaching pharmacists how to do this. But, it would be educational for physicians, also, to know what pharmacists are looking for.

So, we think that's an awesome idea because it's something we've already discussed at a leadership level at the Department; something for free, offered on the web site and that we would -- And then, I know that, Dr. Dalton, you and I have also talked about that. So, we think it's a great idea. But, just thank you.

MR. MESHAD: All right. Thank you. Mr. Jackson?

Mr. JACKSON: Thank you, Mr. Chair. I also would recommend -- educational programs, that they be case based; because, there's a lot of learning from those types of experiences.

MS. DUDLEY: Absolutely.

MR. MESHAD: Okay. We need to move on in the agenda. On the end; Ms. Glass, please?

MS. GLASS: I'm just going to reiterate what she said. I believe -- whatever program you -- I think it should be the same program -- for everybody that has -- that -- because -- seems to be where the breakdown is. There's a program for pharmacists. There's a program for doctors. And, it somehow is not --

The only way we're going to be successful is -- the same message that -- So, maybe we can put

out a --

MR. MESHAD: All right. Let's move on. I think the next item on the agenda is to hear from the Florida Society of Health Systems Pharmacists.

Is someone here?

MS. BROWN: Good afternoon. I'm Deborah Brown representing the Florida Society of Health System Pharmacists.

I think you Chair Meshad and Board Chair Weizer and the committee for giving us this opportunity to present a statement from the Florida Society of Health System Pharmacists.

The attempt to solve a public health crisis of the abuse of prescription drugs that often led to addiction and numerous deaths has now resulted in another crisis.

The allotment of medications has resulted in patients that legitimately need pain medications and are not able to get them.

This is a national issue that has been reported by Health System patients that are having extreme difficulty and access to pain medications especially Hydrocodone containing products across the United States.

At the ASHAP House of Delegates meeting, the

National Pharmacy Organization meeting in June, the delegates presented this issue as new business asking ASHAP to lead a meeting with all stakeholders to determine why these medications are not accessible to patients with legitimate health care needs and develop plans to resolve inaccessibility.

The ability to obtain these medications is resulting in disruption of pain management to patients transitioning from acute care settings to the ambulatory setting.

In addition, patients who attempt to find legitimately prescribed pain medication by visiting numerous pharmacies have been labeled as drug seekers and are prevented from obtaining these medications at local drug stores.

Health System Pharmacists have begun filling out-patient medication prescriptions for their patients which is jeopardizing the availability of pain therapy for in-patients due to allocations and medication shortages.

This also creates ethical issues for pharmacists in all setting that have to decide which patients will get pain medications and which will not.

FSHAP would like to recommend that the National Board of Pharmacy, DEA, the national organizations, patient representatives and other stakeholders have a forum to work out a resolution that would improve patient access to the medications that they need as well as improving the methods used to monitor and prevent abuse; education and the utilization of -- establish -- performances; a recommendation to change the language in Rule 64B6D27.831, standards of practice for the dispensing of controlled substances for treatment of pain; the DEA corresponding responsibility being clarified and to focus on gross negligence or obvious patterns in regards to patient -- to the pharmacy --

Thank you. Are there any questions?

MR. MESHAD: Thank you. Any questions?

Thank you for your time. We appreciate it.

All right. The next item is the Rule 64B16-27.831 which is what we talked about.

And that, I believe, is the area that we under our control to evaluate, build upon, expand what we talked about; a better protocol and education on how to evaluate legitimate threats.

And, it's my recommendation -- put a

sub-committee together to -- really to work with -- you know, to sit down and spend a day -- maybe two -- maybe after the two meetings -- I don't know. I've never been part of -- to really try to start writing something with input from the various constituents.

What's your recommendation, David? Do it in Tallahassee or do it --

MR. FLYNN: I feel like we can do it in Tallahassee. We've done this with situations before in pharmacy -- what I felt was -- sub-committee where we're only asking a few people -- I've been writing and taking down information from all -- and we can actually put it up on the board. It's going to be a work session of writing. It's not a session where we're taking comments. It's more of a collective group and as we're drafting we might make comments to that right there and -- Yes, that's what we talked about or we have -- getting pen to the paper and -- That's the type of work -- workshop --

MR. MESHAD: Should we decide here who should be on that committee or do we want to --

MS. DUDLEY: I guess if we're talking about the committee occurring before the next committee

which is what I think we're talking about --

MR. MESHAD: Yes.

MS. DUDLEY: -- here, I would like to make the decision today and see if we have volunteers.

I think that it would be logistically better and easier for us to get a quick reading -- the next meeting if we do it in Tallahassee. So, if anybody is interested -- that we are -- It's easier for us to get through --

MR. MESHAD: Okay. So, I see Dr. Mesaros is raising his hand. Dr. Dalton is ready. Mr. Jackson. I think we somebody from the wholesale side. Okay? Oh, Mr. --

Let's do this, we've got a few here.

Should you follow-up with an e-mail to -- I guess the question is we're going to have to --

MS. DUDLEY: Of course, yes.

MR. MESHAD: So, I want --

MR. MESAROS: There's only one member from each board that --

MR. MESHAD: I said that with Mr. Flynn --

MR. MESAROS: I'm not trying to avoid anything. I'm just trying to make sure that we don't --

MS. DUDLEY: Right.

MR. FLYNN: We need to -- because I want to do it, probably, as a workshop deal. If they come -- But, we only have to one board member there so you can call a sub-committee. But, we can just call it a workshop for this rule. I just want some members in the room with a technical background and knowledge to help me write it. That's all.

MR. MESAROS: I was just asking -- I'd like somebody from -- We've got Dr. Dalton here representing the pain management side. I'd like somebody who is a physician, M.D. side, whether it be Mr. Rubenstein or maybe Mr. El Sanadi. We have to -- Do we want to -- Maybe we can talk and --

MR. RUBENSTEIN: We may able to supply someone from --

MR. MESAROS: Okay.

MR. RUBENSTEIN: I'd be happy to do that.

MR. MESAROS: Great.

MR. FLYNN: I don't want anybody to be disappointed in that if you're an M.D. or a D.O. or a Dentistry member, I'll explain to you, maybe a little more, what kind of rule-making authority and power the Board of Pharmacy does have in change.

We work with the pharmacy side and then we can also build off of your ideas for you to take back

to your board.

MR. MESHAD: Yes. And that's why I want them there. Both for their input for us; but also, so they can take it back to their boards and then spearhead something --

Again, I can't do anything with the Board of Medicine or FMA. But, we can certainly lead by example and then pass that on and, hopefully, by having representation here that will happen --

MR. MESAROS: I was just going to ask -- I know that Dr. Dalton read off some of the requirements for the prescriber who writes the prescription.

MR. MESHAD: Uh-huh?

MR. MESAROS: Is that -- Were you citing a specific --

MS. DUDLEY: That's our rule.

MR. MESHAD: That's our rule. That's the rule that -- We're revisiting that rule. And some of it is, probably, very pertinent still. Some of it needs to be --

MR. MESAROS: Yeah. I just wanted to make sure that wasn't -- that was the rule that --

MR. MESHAD: That's our --

MR. MESAROS: I was referring to their rule,

not our rule. I wanted to make sure that everybody is aware, that's their rule.

MR. MESHAD: I though it was our rule.

MR. MESAROS: No.

MS. DUDLEY: No.

MR. DALTON: What the physicians have to do is --

MR. MESHAD: Right. We can read the first one --

MR. DALTON: I did. Yeah, I did. I read --

MR. MESAROS: I was asking about their rule.

MR. MESHAD: Okay.

MR. MESAROS: I think that would be helpful for, you know, -- board to have their rule.

MR. MESHAD: Sure.

MR. MESAROS: That's all I was -- I was asking about -- I want to make sure that's what --

MS. DUDLEY: And we'll -- For the materials in this committee meeting, I'll go ahead and forward their rule and then we can see what their responsibilities are.

MS. HAYDEN: I just want to make a comment if I may?

MR. MESHAD: Sure.

MS. HAYDEN: A very simple comment. You know,

I talk on this subject a lot and I had a big disconnect this year and I'm actually a member of the Federation of -- and one of the things that I talked to another -- a board member from another state -- she says, you know, the PDMP Board says we access prior to writing the prescription is -- and I -- in my medical record -- part of the -- is a third degree felony --

If you copy or give them your medical record and that person copies the medical records and gives it to another provider that's a violation -- that's a third degree felony which I was not aware of this year until I went to that Federation meeting and --

MR. MESHAD: You know -- See, that's what -- That's what very concerning. I have a sanction on -- which they don't make that mandatory. But, all of these reports -- a lot of them have a lot of points that are valid which is exactly what Dr. Dalton is saying. I happen to know from the PDM, those types of -- PDMP -- I'm sorry -- But, this information in here, I'm using the PDMP; because, of an accidental non-knowing -- You know, a knowing violation --

I'm talking about --

MS. HAYDEN: Yeah. I'm just talking about --

MR. MESHAD: In the -- In the United States of America there is only a very few strict liability criminal offenses and they're environmental. They always come with a general intent or specific intent. You know what you're doing.

We all see that people have been and potentially will be arrested for misusing prescription -- database. It's going to those -- and, I've already seen it -- that are probably the --

MS. HAYDEN: I don't know. But, we check off that box --

MR. MESHAD: Yes.

MS. HAYDEN: There are places --

MR. MESHAD: Well, I know in Sarasota we passed a local ordinance that requires printing out the -- So, I've never --

MS. HAYDEN: But, if that medical record clerk may not have -- makes a photocopy of that -- that's potentially a -- the way I read it --

MR. MESHAD: Well, aren't the medical records subject to privacy any way?

MS. HAYDEN: Not unless you have that exemption in writing from the person who requested

the medical records. That's the --

MR. MESHAD: We'll have to look at it.

MR. FLYNN: Well -- Yeah.

MS. HAYDEN: That's what I'm saying.

MR. FLYNN: I don't want to -- I really don't want to --

MS. HAYDEN: I know. But, -- disconnect --

MR. FLYNN: We'll make sure we understand the -- and clarify --

MR. MESHAD: Right. And I think we'll address that as an avenue -- But, certainly that's a common sense method that we may able to -- on this issue. -- professional, independent judgement and concerns. If you pull that out, as a pharmacist, -- Okay. No, clarify it. I have to call Dr. Dalton now. I just can't -- his point, you may have to actually slow down and assess the appropriate -- valid -- prescription which those bullet points are on my paper and we'll talk about it and, hopefully, present the full board with alternatives; so, a couple of different alternatives. And then, we'll go through the -- process and I'll explain to you at the sub-committee --

MS. DUDLEY: And can I just -- I just want to

reiterate the list of people that have volunteered to be on this sub-committee if we're going to move forward and -- between now and the next meeting: Dr. Mesaros, Mr. Philip, Mr. Jackson, Dr. Dalton and Dr. Rubenstein will be getting somebody from the FMA. Okay?

Oh, I'm sorry. And, Mr. Cacciotore.

MR. MESHAD: Okay. We need to move on. Sir, I see your hand. But, I can't take the time right now. At the end, if we have time, I can --

UNKNOWN SPEAKER: It has to do with what you're doing.

MR. MESHAD: Okay. Thank you. We will -- If I take you, I've got to take everybody whose hand comes up.

UNKNOWN SPEAKER: Okay.

MR. MESHAD: We could be here all night. So, I appreciate -- Hopefully, we'll have time at the end. Thank you.

MR. FLYNN: Let me just -- the point that he's making. Under Chapter 286, you do have a right to participate in the public meeting before the board or committee takes a vote on any final action. No vote is being taken at this time. The Chair will be offering public comments at the end of --

MR. MESHAD: All right. So, item number five; education opportunities. We have a couple of items that are here.

MS. DUDLEY: Is Dr. Joseph Camillieri -- Did he make it?

MR. MESHAD: Okay.

MS. DUDLEY: And, Mr. Philip you had met Dr. Camillieri. Could you -- What you thought that he could provide the committee?

MR. PHILIP: I've worked with Dr. Camillieri in the past. He's an -- in Shands. So, we had issues with controlled substance prescriptions being written out of his practice because he works with pain management physicians.

So, I work with him to help with that pharmacist to make better decisions.

In that process, he's taught me a lot of things; educated me on a lot of things. So, I thought he would be a good person because he is actually a pharmacist who works directly with pain management physicians on a regular basis.

So, I thought we could get a different perspective -- to see both sides of --

MR. MESHAD: Very good. Please.

MR. CAMILLIERI: So, good afternoon to the

board members. I guess a lot of my topics were, kind of, covered all ready. I was really focusing on education. But, for the sub-committee or work group, whatever you're going to do, I'd have some points that I think you should address during these education -- whether it's CE or whatever.

But, just a little background about myself.

MS. DUDLEY: Turn the microphone on.

MR. MESHAD: Your mike is not on.

MR. CAMILLIERI: So, a little background about myself.

MR. MESHAD: It's still not on.

MS. DUDLEY: It's still not on.

MR. CAMILLIERI: How about now? So, a little background about myself.

I work at UF Health in Jackonsville which is formerly Shands. Full-time, I work with our pain management population and help primary care doctors service their patients and I'm responsible for about 1,000 patients receiving their monthly pain prescriptions.

Also, I work for one of the chain pharmacies as a part-time pharmacist so I get to see things on both levels; prescribing it and dispensing it.

As a floater for a chain pharmacy, a lot of

times when I got to -- You know, I float around in different stores, on the weekend. And, a lot of times the answer is we don't have it in stock; whether that's because it's restricted from the distributor or the actual pharmacy is just not order it because they don't want to deal with it. And, I think that's a big problem.

Also, another problem that I've seen -- I know we're not here to discuss the problem. But, I know there is a problem and we want to be more solutional and -- But, the other problem is sometimes the technician just says we don't it in stock and doesn't even ask the pharmacist because they're not taking any new pain prescriptions; because, they know they have a limited supply and they don't want to mess that up and take new patients. So, I see that often.

So, I think the biggest push needs to be for education. I provide CE education for pharmacists, currently, through the Florida Pharmacy Association and I think we need to have topics that are not just the laws around it. But also, what's responsible opioid prescribing and what does it look like? How do we identify patients who are, maybe, abusing or misusing their medications?

Because, our pharmacists, frankly, right now, don't know that. And then, overdose prevention.

Even, you know -- Just, if you put water in balloon and you push one end it's going to the other end and we're seeing that now with the Heroin epidemic.

We've stopped a lot of controlled substance prescribing and we're decreasing opioid related deaths; but, our patients are still dying because they're getting Heroin, which is now mixed with Fentanyl and it's a huge problem, you know, currently.

So, we need to provide education and focus on that with, maybe, some take home -- information in our CE program.

And then, part of the education as a profession and a I think what the Board can really put out for pharmacists is some guidance for professional refusals, which is what I call it.

You know, there are pharmacists out there that are not truthful with patients because they don't know how to give bad news. They don't know what to say to a patient. So, it's easy to say I don't have it in stock. But, if we have real education that says, you know, this is how you tell a patient

why -- you know, the reason why you aren't going to fill the prescription and you should have black and white answers.

I think there is a lot of fear going on and I think education is really the key.

I would like to see the Board mandate pharmacist CE. I think it should be just like medical errors; one or two hours every renewal period. And, I would encourage the Boards of Osteopathy and Medicine, both, to have some mandated CEs for physicians; because, there is not just the laws around controlled substance but what I called responsible opioid prescribing.

As a pharmacists I see, you know, on occasion where a physician will double the dose of Methadone, for instance, along with giving, you know, overdose of Xanax -- 6 mgs a day of Xanax. And when I talk to them about it they're, like, oh, I just really didn't think about it that way.

So, I think there's a lack of education in prescribing and dispensing and I think together we can, you know, formulate a CE program that could cover both aspects so that everybody is on the same page and know what's responsible.

I think that should be directed at primary

care physicians. I don't think we should get involved in pain specialist physicians. They're board certified anesthesiologist; you know, intervention physicians. They have their own skill for practice and a lot of times as pharmacists -- for me, when I see a board certified pain specialist, if it's a high dose I'm more comfortable with it because they're supposed to have extra training. But, primary doctors, there is a big problem that's out there.

And then, also the increased supply. I think there is a big problem with supply. You know, whether we're going to omit it or not.

I know local pharmacies that are independent, that cannot get enough Percocet. That seems to be the biggest problem right now; Oxycodone containing products. And they tell you, you know, there is a limit. I hit my limit. I'm cut off. It's done.

They have patients who come in and want to fill their prescription, they can't get it filled.

And the reason why I think it's limited to independents, at least from where I'm at, is because patients who go to chain pharmacies and are rejected for whatever reason -- then they make their way to an independent pharmacy -- the

independent pharmacies usually aren't as busy, have more time for their patients and they can really look into the patient and for them not to be able to fill it because they can't get the supply is a big problem. Those are the people that should fill those prescriptions.

So, I think that maybe the Board could consider a special pharmacy permit for pharmacies that is a controlled substance permit that allows these speciality pharmacies to do a certain amount of education type credits and then provide, maybe, some pain management/medication therapy management programs to these patients to, kind of, work with their doctor; have their designated pharmacy and the patient and then allow them to go over whatever that quota is or allow them to provide, you know, the list of patients and their actual prescriptions to the distributor, so then the distributor is, okay, you know, I understand why you're getting more than the normal pharmacies that are around here and, you know, above, maybe, a fifteen percent quota or whatever they're using because I'm sure there is something off the books.

So, really, that's all my comments. I'd be happy to take any questions if you do have any of

me.

If you like me to help on any of the sub-committees or anything I'd be willing to do that also.

MR. MESHAD: Thank you. You know there's a lot of good stuff that came out of there. What I encourage anybody that has suggested ideas is to specifically write them out and -- Send those up with a copy to you guys --

MS. DUDLEY: Yeah.

MR. MESHAD: -- so that this work group can take all of these great ideas and -- I can't have fifty people in a work group or a hundred people. So, what I can do is take some great ideas and pass them down that to work group to really, kind of, tear into it and take the best of the best out of it. So, there's some great stuff that I've heard. I'll certainly send the follow-ups so that we can use that in our work groups. Thank you.

MR. CAMILLIERI: Uh-huh.

MR. MESHAD: The next item is examples of other states.

MS. DUDLEY: I think we can just -- That was -- We can move on.

MR. MESHAD: Okay. We can certainly look at

that as --

MS. DUDLEY: For the separate -- Yes.

MR. MESHAD: Okay. So, you know what? Yes, Dr. Rubenstein?

MR. RUBENSTEIN: -- last time, assimilating some things that could be set.

MR. MESHAD: Sure.

MR. RUBENSTEIN: I want to talk about different ways of -- it's not that simple. I can speak for Dr. Dalton and myself. Both of us happen to be board certified pain practitioners and -- So, it's not so simple an issue as --

-- in this committee -- public and professional -- access -- We've heard references to the drug abuse -- and -- legitimate pain patients who withstand humiliation, embarrassment, tragedy, devastation, disruption of life, -- and examples of -- lack of medications are affecting people's ability to function in society.

-- in medications has left the patient suffering as well as pharmacy frustration. Testimony from pharmacists showed evidence of this as well.

At the last meeting it was clear that there was an inappropriate application of the red flag

rule.

Societies across the country including the American Medical Association have been publicly concerned with the overdose crisis and now the rising --

States are developing their own best practice guidelines as evidenced by the November 2014 Arizona State Guidelines that you just mentioned.

Today, -- solutions for the prescription drug abuse problem with -- taking a role.

We have an opportunity, in this State, to take that role and this Board has an opportunity -- to be a leader and --

What is clear is that -- is required. The balance needs to be between this and --

Since the dispensation of -- been reduced we have seen a noticeable increase in non-prescribed medication abuse; specifically, -- With that abuse has also been a public outcry --

Physicians need to be responsible for proper prescribing habits. This means we need to have best practices and offer what is an optimal care -- function, reduce risks and improve quality of life.

Physicians need to be responsible for policing our own and that includes the Board of Medicine and

the Department of Health. And, I appreciate Dr. --

We also need to look at sure each and every patient and determine if the medications prescribed are really medically necessary or are they more effective regiments with less risk available.

Pharmacists, like the doctor, require some responsibility. They are actually part of a team. But, we've had too many complaints of improper denials of medication where they didn't -- corporate guidelines and corresponding responsibility factors as an excuse not to fill rather than attempt to properly vet the prescription.

Also, as is -- a scientific explanation of the basis to reduce to supply and hence increase public demand is not improper. And, I would --

We understand -- which is also necessary to --

So, where are the solutions? It is -- this meeting? Or, actually, is it -- rather best practices --

The American Academy of Pain Management proposes suggestions for -- standard of practice for dispensing controlled substances. They also -- the pharmacist should not be -- based on their own prescription and it is suggested that the

pharmacists be -- of why the prescriptions aren't being filled.

-- also is suggested that -- and refusing prescriptions to be subjected to mandatory reporting. I would agree that -- so proper identification of --

This will also address the issue of questionable supply --

Here again, I also suggest that retail pharmacies should have -- process for the use of the -- requests for increased supplies. If these protocols -- submitted to the appropriate agency for approval and -- implemented for approval.

The American Medical Association has taken on an active role in the public domain related to prescription drug abuse.

The AMA -- access to -- services as the central component of their plan to curb prescription drug abuse.

The AMA is -- and the national chains to make their internal -- policies public and subject to regulatory review.

To my knowledge and to the AMA's knowledge, this has not been occurring.

Perhaps even -- as Ms. Langston so eloquently

stated earlier -- These are reasonable suggestions.

Fundamental to any -- solution are the principles of education, collaboration and best practices and that seems to be the -- today.

We need to educate our respective disciplines relating to this -- and proper -- We need to work together for optimization of -- and need to -- modify the solutions -- based on the results of --

Pharmacists and physicians should be encouraged to have a open dialogue in the best interest of the patients rather than unilateral decisions about prescription necessity.

As one physician jokingly said at the last meeting, take your pharmacist to lunch.

Both the relationships and the ability to converse in a HIPPA protected fashion should benefit the patient, provider and society.

Currently, it appears that the most significant issues -- addressed -- were they to perceive supply issues and dispensation of same.

All stakeholders in this situation need to make the proper -- This includes reducing the stigma of pain while properly providing access to comprehensive evidence based pain care.

Patients in pain deserve the same care and compassion as any other patient.

I can speak for the Florida Medical Association, the Florida Society of Physical Medicine and Rehabilitation, the Florida Academy of Pain Medicine, the Florida Society of Interventional Pain Physicians and the American Medical Association when I say that organized medicine is -- help ensure that the public is optimally served by best practices in the field of pain medicine.

Today you have heard from the Board of Allopathic Medicine, the Board of Osteopathic Medicine and the DEA -- to assist in the education of information processing.

Thank you.

MR. MESHAD: Thank you. Mr. Davis?

MR. DAVIS: I think it may be helpful to add a point of clarity with respect to the doctor's -- Through the National Association of Boards of Pharmacy there's actually been a stakeholder's group that's been meeting for about a year and a half and recently published a -- in and around red flags and that -- many of the major chains and the medical society, the AMA. I was also part of that

work group.

So, I do think as it pertains to understanding, you know, what the requirement are out there that the --

I think that there is a fair amount of visibility on both sides. And the consensus -- actually created it with the hope that by educating both sides of the profession, both the prescribers and the dispensers, each would gain a better understanding for the challenges that the other was facing and considerations that they had within the scope of their medical --

So, that document is available. It may be something that I can leave for everyone to look at when they're considering the CE or training programs.

MR. MESHAD: Okay. So, we have that.

MR. RUBENSTEIN: I believe that was supplied at the last meeting. We have that available. We were referring to the -- referring to the internal checklist. It's not so much the stakeholders list, which was made available.

MR. PARRADO: Okay. Thank you. I comments. Hopefully, we're going to get to the heart of this.

Again, to reiterate; a lot of what we touched

on is out of the purview of the Board of Pharmacy. Still, I think we have a responsibility to continue to carry this on and do what we can in our power and a continued challenge to other associations, the other boards and the other -- to work with us to implement their own --

So, I wish I could -- something comprehensive to -- for the Board of Medicine all the way pharmacy and the wholesale and manufacturer side of -- We don't have that power. But, a lot of this stuff is, you know, --

At some point, a lot of what we're talking about may require legislative changes.

MR. MESHAD: Yes.

MS. HAYDEN: Okay. -- to read something else to -- insurance companies and the benefits managers.

I met Mr. Philips in the parking lot. Mr. Philips and I served on another committee for the organization of -- for Medicaid.

His firm, in particular, -- A very short synopsis -- But, at his firm, we had problems with mental health and anti-psychotics in children in our state. So, what Medicaid did was we had over 1.2 millions recipients on the -- Medicaid. They

hooked up with -- through the University of Florida, best practices that we just heard about. But then, they identified what the best practices are and it benefits them -- It's software adjusted the point of sale to implement those best practices -- point of sale.

So, I think missing at this table is perhaps the insurance companies that -- We have about three or four in our state and, you know, when this consensus of best practices comes forth perhaps -- implemented and have another way of protection to provide for -- overall concern is the safety of our patients in Florida with a legitimate practice of pain medication.

Thank you.

MR. MESHAD: Thank you. Any other comments?

Okay. What I think I'll do at this time -- we do have a few cards that are filled out. I know that the gentleman out there raised his hand. I will entertain public comment. I'm only going to ask a couple of things.

We've got three items to complete. One is to keep it keep it to three minutes, no more.

And two is, -- I can't regulate what you're going to do. We heard for over an hour last week

-- We're very aware of some of the most tragic stories of not getting access to pain medications and the suffering and what goes on with that. That's why it's a serious concern and we're taking it serious. So, you know I think we've got a good flavor for it.

If you would like to come up and add to those stories, feel free. But, I'd like to really not -- I'd really like to turn this into some action now. What we need to do to move the ball forward with appropriate prescribing.

So with that, --

MS. DUDLEY: We have Janet Colbert.

MS. COLBERT: Thank you very -- Can you hear me? No?

MR. MESHAD: There you do.

MS. COLBERT: Thank you very much for listening to me and I also appreciate what you're doing here with the workshop as well.

It's been addressed many times about the supply. So, I'd just like to give some facts.

In 1997, 8.3 tons of Oxycodone was produced. 2011, 105 tons. 2012, 113 tons; a 1,747 percent increase over the amount produced in 1996, the year Oxycodone first came on the market.

So, I don't think that we do have a supply problem. There are plenty of pills out there on the street.

The DEA is here today or was here today. I want to question your 5,000 -- should be 60,000 a year. When they did go into -- and give them fines and similar -- In 2009, they went from 388,000 in a year to 2,000 alone in over -- is that they were doling out.

-- went from 95,000 in 2009 to 2,165,000. So, this is the abuse that we're talking about here.

The DEA approves the amount of Oxycodone produced every year. I would actually like to have that number severely run down. There's too many pills out there on the street.

I'm very sorry that -- left the -- because we also need to discuss the inaction of --

The Board of Medicine is not revoking licensure of all of -- I'm not talking about the doctors here.

I have two -- here. There's many, many more.

I know that I have very limited time. Cynthia Caudett (phonetic). I know you're familiar with her name. -- No. Public complaint? Yes. She had a settlement -- two different State Surgeon

Generals that -- The last one was when she was convicted of running her own pill mill. She still has her license. It's still up on -- and it's still clear.

Another one I have is -- his mother was addicted and his friend was addicted by -- A complaint was signed by Dr. -- excuse me, Surgeon General John -- in September 2012. It still has not been heard yet.

And the other one, I'll describe as ridiculous.

I would also like to --

MR. MESHAD: I hate to interrupt you. But, we hit the three minutes.

MS. COLBERT: Okay. Could I make one more comment?

MR. MESHAD: I have to be strict on that.

MS. COLBERT: Okay.

MR. MESHAD: I really do. I had to do it last time. It was horrible. But, I appreciate your comments and your point is taken.

MS. COLBERT: All right. I'd like to just give this to you because I want the support for -- We need legislation here. We need lots of -- I'm sorry.

MR. MESHAD: Mr. Mesaros, has a question.

MR. MESAROS: I just want to test my eyesight and the Stopp Now is Stop the Organized Pill Pushers Now? Is that what --

MS. COLBERT: Yes.

MR. MESAROS: Okay. I just wanted to make sure.

MS. COLBERT: Yes. Thank you.

MR. MESHAD: All right. Now, I know you've got other representatives here. Are we going to hear the same thing from them or -- I mean I don't mean to minimize it. I just --

MS. COLBERT: No. No. Do you have something different you want to say?

MR. MESHAD: Are you Maureen?

MS. KIELIAN: I am.

MR. MESHAD: Okay.

MS. KIELIAN: Thank you. My document is more of a -- I can tell you that. So, I will briefly go through it and recommend that the workshop include -- and professional -- about statute 462 for that third degree felony issue.

In any event. I fully support -- We all fully support every legitimate chronic pain patient have access to their medications.

The problem is the word legitimate. We all know it.

We've got, in Broward County, 189 closed pill mills pain clinics. 101 of those physicians are still practicing medicine.

So, how do we determine legitimate? Did they, all of a sudden, change their prescribing behaviors?

Also, we have the campaigning by Attorney General Pam Bondi -- 23 percent decrease in mortality rate due to accidental physician prescribed drug poisoning. If we're at eleven a day, you do the math. Is that acceptable for our state? Is that where you want to be?

I know how to file a citizen complaint. I did it; two physicians. Vincent Collangelo is in federal prison, the owner. Those two physicians, per the Department of Health and the DEA -- the Department of Health found no issues and you should be happy the clinic is closed.

MR. FLYNN: Ma'am, do me a favor. As a point of law, you file the complaint. Please know that if it was not ever -- public, you're not at liberty to disclose confidential information in the public --

MS. KIELIAN: So the letter back to me is not public, then?

MR. FLYNN: If -- Under 456, when you're talking about the law -- if probable cause is not found on a complaint is does not become public record and it remains confidential. Okay?

MS. KIELIAN: I don't quite understand it. But, okay.

Then we have the clinic busted on Federal Highway by the Kentucky DEA.

Where's Florida in all of this? Okay?

Those physicians still have their licenses except one. He died.

Florida is number one in the United States for Dilaudid. Our rehab admissions are Dilaudid patients.

So, it's a prescribing privilege. There's still a privilege to write controlled substances in our state. That's unacceptable.

We are in a CDC declared modern day epidemic that start with over prescribing of opioids. Our physicians, unfortunately, were educated by a Dr. Lynn Wexter who claimed that opioids were not addictive. We obviously know that's not true.

Someone -- some doctor somewhere has to

prescribe that first opioid and it could be that first opioid that leads to addiction. That's what we're not realizing here.

MR. MESHAD: You've hit your three minutes. I appreciate it.

MS. KIELIAN: Okay.

MR. MESHAD: So, let me just -- for point of clarity. We're the Board of Pharmacy. Okay?

MS. KIELIAN: Yes.

MR. MESHAD: And this problem goes beyond our purview. So, -- And trust me; no one has been more vocal on this Board than I around the issue you're talking about.

I've been personally affected by it. So, I take it seriously.

So, we're going to do everything we can to continue this, to do what we can as the Board of Pharmacy to make sure that appropriate prescribing is occurring, that patients with legitimate concerns get their medicine and those that are illegitimate get washed out of the system.

And, as far as, physicians out there, we all, as consumers, have to be vigilant and we've got to report it and we've got to --

And, I appreciate your comments. But, please

understand, some of which -- a lot of which you're addressing is really beyond our ability.

And so, we'll continue writing -- We've got the medical community represented here. We've got the distributors represented here. And, you know, I take it upon myself, as a board member, to do what I can as a board member and as a consumer to do what I can outside this Board to further this cause. So, I appreciate it.

I am going to have to move on.

MS. KIELIAN: Can I just say one thing for the work group purposes?

We have to move away from criminalizing this. There -- The addicts, the mis-users and abusers are this much of a much bigger population. So, that --

MR. MESHAD: I appreciate it.

MS. KIELIAN: -- needs to be taken into --

MR. MESHAD: All right. One more --

MS. DUDLEY: The next person is Ms. Nguyen.

MS. NGUYEN: Good afternoon. Thank you very much for allowing us to be a part of this.

We believe that we are here and we are going to be able to ask what the board members can do to help us.

The DEA, back on June first of 2010, has

expanded its rule to allow for e-prescribing of controlled substances.

In this matter, what it mean is that the physician is able to enter into using electronic health records -- It doesn't matter -- certain ethic -- whatever it is. And, automatically, electronically route the controlled substance directly to the retail pharmacy.

What we're seeing is, even though the DEA has allowed the rules and regulations, the Board of Pharmacy, the Florida Board of Pharmacy, does not really have very clear cut wording to say the pharmacists is able to accept such prescriptions.

MR. FLYNN: We've addressed that since the day I came on board for this. I'm the one who said that controlled substances, electronically, are written under 894.04 and it's been put in all -- As far as the federal electronic software and prescriptions -- Is that what you're talking about?

MS. NGUYEN: Right.

MR. FLYNN: And that helps keep it within the controlled distribution system which helps diversion. And, if you look on the Internet you'll look at all of the states where the software vendors have changed Florida to be inclusive of

C-2. So, it's 2, 3, 4, et cetera --

MS. NGUYEN: Correct.

MR. FLYNN: -- are all there. All in the inspectors are very aware of it. It's been that way -- I came on about November of 2012 and I've re-addressed it three or four times. And, I know that I check it and make sure that it's on line, it's known and that we're going to be able utilize electronic prescribing as a way to control and prevent unnecessary diversion.

So, if there's any confusion amongst -- The Board office knows. I've sent -- Calls should be very easy to field to the Board office. Okay?

MS. NGUYEN: Thank you very much. Any other comments on --

MS. FALLATEUF: Yes. We just wanted to read something about -- We just entered into that process at all of our hospitals and -- in the State of Florida and we're just -- a rejection from the pharmacy side when it comes to controlled substances and -- So, that's why we wanted to bring this to your attention.

MS. DUDLEY: And, I think there is confusion out there. So, I think this is something that we will address when we work on those FAQs to go up on

the web site.

MS. FALLATEUF: Thank you.

MS. POLSTER: One of the issue that we have seen is that if the vendor software is not certified it will come through as a reject. So, that is a big piece of it.

MR. FALLATEUF: That is correct. But, our vendor has been certified by the DEA and we know that --

MS. NGUYEN: We don't have to give you the name right now; but, we can certainly let you know right afterward. It's definitely certified.

MR. MESHAD: Thank you.

MR. NGUYEN: Thank you.

MR. MESHAD: All right.

UNKNOWN SPEAKER: --

MR. MESHAD: Sir, please. If you'll --

MR. CARMALL: My name is Tom Carmall.

MR. MESHAD: Hold on one second. Did you --

MS. DUDLEY: I think the court reporter had a question.

THE COURT REPORTER: I was just trying to get their names.

MS. DUDLEY: Okay. All right. That's what I was just trying to clarify.

MR. MESHAD: Okay.

MR. CARMALL: Okay. My name is Tom Carmall. I'm a registered pharmacist in the State of Florida and I'm a past President of the Florida Pharmacy Association.

I thank you very much for allowing me to speak.

I'll try to wrap it up and make it very positive.

I'm speaking, maybe, for all the pharmacists who are not here and are working right now. Maybe, I'll try to -- Because, we're not here being represented.

First, I want to apologize for all of us that think that we're not doing our job. We try to do a very, very respectful job and try to take care of our patients.

I know I've done a very good job in my forty years as a pharmacist. Ninety-nine percent of the time you call doctors back it's probably because the prescriptions aren't written right.

I know the DEA just left -- very strict guidelines. Now, with the DEA, a prescription has to be written, for the physicians that are here, alphanumerically. If a prescription is not written

alphanumerically I have to call you back. Unfortunately, I hate to do it being a pharmacist forty years. I don't why. But, that's their rules.

Okay. If you write the word forty, you have to write the number 40. If it's not written that way I have to call you back. That's their rules. That's what I have to do.

That's ninety-percent of the problem. Okay?

Don't ask me why; but, that's what we have to do.

The other time -- patient comes in too soon. We have a thing called e-force. Okay? I have to put through the computer patient's one day early. Guess what? They can't fill it. Okay?

Welcome to America 101. That's what has to go through. That's what ninety-nine percent of the problem is and that's what we have to do. Okay?

The 72-hour rule -- The doctor you were talking about -- I'm have a partial fill -- Don't ask me where this rule came from. I inherited it. I think it came from Moses. Okay? 72 hours -- Why can't it be five days? Why is it 72 hours? I mean think about it. I live in Pinellas County. See Pasco County with the rain they got. They didn't

get shipments for four days. They didn't fill any controlled substances. That's the one rule we have to fix folks. 72 hours. No way in God's creation -- fill prescriptions. Please get that rule fixed. I know its federal.

How about stocking ahead of time? Our -- I know our pharmacy here is -- Guess what? I anticipate it. I stock it ahead of time. I can't anticipate Percocet anymore. Gee, let me put a couple of more in stock for anticipating on my patients. You can't do that anymore. He stops me.

Do you remember, you used to put three or four bottles -- I had my own store. Let me get a couple of extra bottles so when patients come in. And, guess what? Mary Jones is coming in tomorrow. Guess what? Mrs. Smith comes in. Did I give Mrs. Smith her prescription -- my prescription? I don't have enough for Mrs. Jones to take -- Guess what? Mrs. Jones, I don't have your pills.

And yeah, we do have to train the pharmacists.

You know what they're saying. I don't have the pills instead of saying I don't have enough. That's the problem.

You're talking about sixty pills. I only have thirty-five. So you know what they're saying? I

don't have it. Yeah, they're right. But, their context is wrong. I don't have enough. And that's where the problem comes in.

And last, but not least, is safety. Doctor, you write the prescription; but, I have the pills.

I had three guns to my head in my career. The guy behind me had two. Okay?

Did you ever have a gun to your head? It scares you.

You know what? That little Dilaudid is worth more than the money in my register.

And, everybody saw the thing that happened in Baltimore? They weren't robbing the 7-11, folks. They were robbing the CVS.

MR. MESHAD: I have to --

MR. CARMALL: Thank you. You get my drift?

MR. MESHAD: Thank you for your time.

MR. CARMALL: That's one thing about -- The last thing. Pharmacists also end up at the DEA. And, guess what? Nobody goes to theaters anymore without a gun in their hand. See what happens? Remember that, too. That's another thing they're scared about.

MR. MESHAD: Yes, sir. Thank you.

And again, if you have any constructive

recommendations to be taken up by the Board, please submit them to the Board.

Thank you.

So, we've got a few more people, I think, that want to speak.

Please announce yourself for the court reporter can get your name?

MR. MACKAREY: Sure. David Mackarey. Thank you committee members for allowing me the opportunity to speak today.

My name is David Mackarey, a Florida registered pharmacist for the past twenty-six years and current Board Chairman of the Palm Beach County Pharmacy Association and previous President for the past six years.

I represent over 500 members from all areas of pharmacy; retail, independent, hospital specialty, compound and consulting and others.

After much discussion with many of my constituents we concur that we need to be pro-active, unified and dedicated to find a resolution regarding this very important and very serious issue.

We have recently shown that this task can be successfully accomplished when e-force was created

along with pharmacists, physicians, law enforcement and DEA to work together regarding controlled substances, already proving to be extremely useful, effective and beneficial to all authorized user.

As a concern for the pharmacy profession along with the health and well being of the citizens of Florida I bring forth some idea, suggestions and recommendations that my constituents over the controlled substance committee can consider and, hopefully, aid in their challenge to create resolutions regarding controlled substances.

Number one, with the creation and success of the e-force program and its cost already established, be it resolved that physicians be legally mandated to use e-force before prescribing any controlled medications.

Number two, be it resolved that physicians must write the diagnosis of all C-2 opioid Rxs.

Number three, to help prevent diversion, be it resolved that chronic long-term C-2 opioid prescriptions have a maximum quantity limit. For example, 180 pills would be one every four hours, thirty day supply.

Number four, to also help prevent diversion, be it resolved that chronic pain patients must be

re-evaluated every six months and by a different physician to ensure patient safety and proper treatment.

Number five, similar to the I Pledge Program, be it resolved that for chronic pain patients that a physician agreement contract is signed and a card is issued, good for six months, to present to the pharmacist along with their C-2 prescription.

Number six, to establish safety for both pharmacists and patients as well as eliminating any prejudice or bias towards anyone, be it resolved that the committee establish a uniform proper procedure and protocol regarding verification of C-2 prescriptions.

Similar to the signs legally required by the Board of Pharmacy, be it resolved that a sign be posted stating that all controlled prescriptions will be required a photo ID and verified by the pharmacist and the right of the pharmacist to accept or deny any prescript --

MR. MESHAD: I'm sorry.

MR. MACKAREY: Okay.

MR. MESHAD: All good stuff. Again, I recommend that you send it into the Board.

MR. MACKAREY: Yes.

MR. MESHAD: I think they're good. I tried to keep up with you. They're very quick comments. I think as much as we can take on --

MR. MACKAREY: Of course.

MR. MESHAD: Some of it we can't deal with. But, we can pass on that information.

MR. MACKAREY: I completely understand and I thank you.

MR. MESHAD: I saw one other gentleman raise his hand. We'll take him and then we -- We're kind of reaching of our time limit here. So, if you would state your name please.

MR. CORDRAY: Thank you very much. Good afternoon, everybody. My name is Scott Cordray. I'm a pain management patient. But, not to redundant -- But, my group has been working on a proposal of law which I think was mentioned up here. This is probably not going to be solved legislation or something like that -- clear cut guideline and what we've been working on is using a Florida Medicaid preferred drug list -- standard drug notations and we've taken the controlled substances off of that and then added ICD-9 and ICD-10 codes.

The standard notations actually gives standard

notations for each drug. You can have six of this a day or two of this and four of this. So, it's already started there. It's already in black and white and I think the simplest way to do this might be to take that as a template and, you know, have your -- the corresponding medicine and what they will be used for; what will be a primary indication for the use of that medicine.

And then, on top of that, a -- for any type of a deviation off of that, the Department of Health would administer some type of a REMS program or REMS protocol or something like that; an evaluation of mitigation strategies.

There is already one for -- I think the -- administers one. It's the Total Friends Access Program. It's for -- So, you know, something like that could be expanded and administered by the Department of Health.

And then the third of that would be that there's got to be some type of a protection for the State's licensed practitioner; something with some teeth that -- We envision something where the Attorney General is going to come where there's action where there's no probable cause and the State is going to defend its people; because, I

think that -- something like this could take care of everything in one fell swoop.

But, anyway; for the -- I think had a rebuttal for the folks; the Stopp folks, you know -- I'm sure you guys have --

MR. MESHAD: Right on time. All right. I appreciate everybody's comments. And again, I encourage you to send any constructive points and items that the sub-committee can digest if they determine there is some need for rule changes, guidelines and educational programs.

With that, we have future meetings that will be set up and then we'll have this committee before the next Board Meeting, next time.

I want to thank everybody for being here.

(Thereupon, the proceeding was concluded.)

CERTIFICATE OF COURT REPORTER

THE STATE OF FLORIDA:

:ss.

COUNTY OF PALM BEACH:

I, NICK BRUENS, a Court Reporter in and for the State of Florida at Large, do hereby certify that I was authorized to and did report the proceedings in the above-styled cause before the Board of Pharmacy, at the time and place set forth; that the foregoing pages, numbered from 1 through 138, inclusive, constitute a true and complete record of my notes.

I further certify that I am not an attorney or counsel of any of the parties, not related to any of the parties, nor financially interested in the action.

Dated this 7th day of September, 2015

Nick Bruens

Court Reporter

NBR/IMG