

## **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.

1 Parties Present:

2 ALLISON DUDLEY, J.D., EXECUTIVE DIRECTOR

3 DAVID FLYNN, ESQUIRE, ASSISTANT ATTORNEY GENERAL

4 LYNETTE NORR, ESQUIRE, ASSISTANT ATTORNEY GENERAL

5 GAVIN MESHAD, CONSUMER MEMBER

6 NABIL EL SANADI, M.D.; CHAIRMAN

7 MICHELLE WEIZER

8 JEFFREY MESAROS, PHAR. M.D.

9 HAROLD DALTON D.O., FLORIDA SOCIETY FOR

10 INTERVENTIONAL PAIN PHYSICIANS

11 ANNA HAYDEN D.O.

12 MICHAEL JACKSON, BPARM

13 MARK RUBENSTEIN M.D.

14 JEENU PHILIP, BPARM

15 TASHA POLSTER, WALGREENS

16 GARY CACCIATORE, CARDINAL HEALTH

17 DEBRA GLASS, BPARM

18 AMBER GREENE

19 EMILY ROACH

20 TOM DAVIS

21 SUSAN LANGSTON, DRUG ENFORCEMENT AGENCY

22 JEFFREY WALSH

23 BOB PARRADO, BPHARM, R. PH.

24 DEBORAH BROWN, FLORIDA SOCIETY FOR HEALTH SYSTEM

25 PHARMACISTS

1 Parties Present: (Continued)

2 DR. JOSEPH CAMILLIERI

3 JANET COLBERT, PRESIDENT; STOPP NOW

4 MAUREEN KIELIAN, STOPP MEMBER

5 HANG NGUYEN, PHAR M.D.

6 RITA FALLATEUF, PHAR M.D.

7 NANCY HIGH M.D.

8 TOM CARMALL

9 DAVID MACKAREY

10 SCOTT CORDRAY

11 LUCY G.

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1 THEREUPON:

2 (Proceeding commences.)

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

5 I want to thank everybody for coming here  
6 today.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 MS. GLASS: Debra Glass, pharmacists member.

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

1 Distributor Advisory Counsel, DBPR.

2 MS. POLSTER: Tasha Polster, Walgreens  
3 Company.

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

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

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

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

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

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

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



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

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

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

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

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

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

10 And I was, specifically, interested -- And, I  
11 put on the agenda for them, Florida Statute  
12 499.0121(15)(b) which is, kind of, the section of  
13 the Florida Statute that applies to wholesalers.  
14 And that part states, in part -- I'm not going to  
15 read the whole thing. But, it says a wholesale  
16 distributor must take reasonable ventures to  
17 identify its customers, understand the normal and  
18 expected transactions conducted by those customers  
19 and identify transactions that are suspicious in  
20 nature.

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

25 A wholesale distributor must assess orders for

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

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

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

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

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

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

4           Some of the members indicated that for a  
5 particular controlled substance orders less than  
6 5,000 dosage units per months could actually be  
7 considered suspicious; so it's going to depend on  
8 the controlled substance involved as well as the  
9 particular customer involved.

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

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

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

1 meeting materials for this meeting.

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

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

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

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

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

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

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

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

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

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

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

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

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

15 MR. MESHAD: One more time.

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

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

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

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

3 MR. EL SANADI: Yes.

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

11 MR. EL SANADI: Right.

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

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



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

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

7 MR. DALTON: -- last day of session.

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

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

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

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

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

1 5,000 for -- Okay?

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

7 MR. MESHAD: Well, I -

8 MR. CACCIATORE: Should I go ahead and answer?

9 MR. MESHAD: Yes, sure.

10 MR. CACCIATORE: We had a discussion on that  
11 and it's not clear in the legislation. But, it's  
12 not all controlled substances. The statute reads  
13 5,000 dosage units of any one controlled substance  
14 in a month.

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

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

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

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

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

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

12 MR. MESHAD: Mr. Jackson, please?

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

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

22 MR. CACCIATORE: Not to my knowledge.

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

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

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

14           Is that accurate?

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

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

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

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

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

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

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

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

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

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

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

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

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

16 MR. CACCIATORE: No matter what the size is.

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

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

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

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

5 MR. MESHAD: Anybody can speak up.

6 MR. EL SANADI: Supplied by the manufacturers.

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

10 MR. EL SANADI: Right.

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

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

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

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

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

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

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

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

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

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



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

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

8           MR. MESHAD: Do you want to answer?

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

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

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

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

1 can be shipped after further investigation.

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

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

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

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

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

1 MR. MESHAD: Any other questions?

2 MR. RUBENSTEIN: Mr. Chair, if I could?

3 Limiting comments to distribution alone, let's go  
4 back seven or eight -- maybe 2008, prior to this  
5 process we have crisis with abuse. What were the  
6 limits then for distribution and does that directly  
7 correlate with why we appear to have a supply side  
8 issue at this point?

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

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

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

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

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

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

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

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

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

6 That was a new one.

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

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

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

19 If I --

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

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

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

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

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

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

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

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

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

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

11 MS. MESHAD: Yes.

12 MR. RUBENSTEIN: With all due respect to your  
13 question, were you referring to supply to the  
14 wholesalers or supply to the pharmacies? I'm not  
15 --

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

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

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

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

1 -- I would be screaming at that point.

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

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

8 MR. MESHAD: Absolutely.

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

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

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



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

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

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

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

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

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

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

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

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

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

14           MR. MESHAD: Dr. Weizer.

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

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

23           MS. WEIZER: No; across the board.

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

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

2 MR. MESHAD: Got you. All right. Thank you.

3 I appreciate it.

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

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

9 MS. LANGSTON: Hello.

10 MR. MESHAD: Welcome.

11 MS. LANGSTON: Thank you.

12 MR. MESHAD: We appreciate your being here.

13 MS. LANGSTON: Right here.

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

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

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

1 to --

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

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

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

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

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

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

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

1 needlessly suffering and see no relief in sight.

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

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

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

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

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

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

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

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

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

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

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

25          In 2011, the State of Florida adopted

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

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

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

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

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

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

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

10 Allow me to give you some statistics.

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

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

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

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

25 I can assure you that the pharmacies the DEA's



1 Miami Field Division have taken action against for  
2 ignoring red flags of abuse and diversion, for  
3 undoubtedly contributing on a major scale to the  
4 abuse and diversion of controlled substances.

5 These were not situations where a few questions or  
6 prescriptions fell through the crack or a  
7 pharmacist just had a bad day. These cases  
8 involved unquestionable patterns of behavior that  
9 had to be stopped for the public's health and  
10 safety.

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

19 Under federal law a pharmacist has the  
20 responsibility to fill only prescriptions issued  
21 for a legitimate medical purpose and in the course  
22 of professional practice.

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

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

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

12           What is a red flag?

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

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

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

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

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

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

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

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

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

4           How in the world does this possibly happen?

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

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

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

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

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

1 without.

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

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

10 My family has personally been affected.

11 This has to stop and it has to stop now.

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

19 I want to make myself perfectly clear.

20 Pharmacists do not need to fear the DEA when they  
21 use their professional judgement, experience,  
22 education, training and common sense to fill  
23 legitimate prescriptions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 Thank you.

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

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



1 certainly appreciate your comments.

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

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

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

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

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

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

25 MR. EL SANADI: Ms. Langston, an excellent

1 presentation. Thank you so much.

2 MS. LANGSTON: Thank you.

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

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

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

12 A quick question for you.

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

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

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

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

3 MS. LANGSTON: Yes.

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

6 MS. LANGSTON: Yes.

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

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

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

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

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

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

11 MR. EL SANADI: Yes. Just to keep -- And  
12 then, how much -- That would be up to the board to  
13 --

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

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

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

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

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

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

20           MR. MESHAD: Not at all.

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

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

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

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

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

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

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

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

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

21 Make sense? Right? Absolutely. No problem.

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 the distributor.

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

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

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

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

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

20 I appreciate your time. I really do. Again,  
21 --

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

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

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

10 MS. LANGSTON: Okay.

11 MS. WEIZER: And, I --

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

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

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

3 MS. WEIZER: Correct.

4 MS. LANGSTON: That makes perfect common  
5 sense.

6 MS. WEIZER: Yes.

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

9 MS. WEIZER: Right. Correct.

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

12 MS. WEIZER: Correct.

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

15 MS. WEIZER: Exactly.

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

18 MS. WEIZER: Exactly.

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

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

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

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

2           MS. LANGSTON: Absolutely.

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

8           MS. LANGSTON: Yes.

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

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

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

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

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

9 MS. LANGSTON: Yes.

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

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

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

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

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



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

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

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

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

11 MS. LANGSTON: Thanks for having us.

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

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

18 MR. PARRADO: This is going to take a while.  
19 Good afternoon, board members.

20 MS. WEIZER: Can you use your microphone?

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

23 MS. WEIZER: It's not on.

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

25 MR. MESHAD: There you go. Thank you.

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

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

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

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

22 That problem is growing.

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

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

4 In your materials, in that GAO report, of the  
5 70,000 pharmacies that are out there and the 1.5  
6 million practitioners that are out there working,  
7 that are licensed registrants, seventy percent of  
8 those registrants are no aware that there is a DEA  
9 manual that helps with their practice. That's  
10 almost sad; seventy percent.

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

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

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

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

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

1 policies.

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

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

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

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

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

6 But, those are merely the tip of the iceberg.

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

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

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

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

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

1 in that field.

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

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

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

22 We need to re-look at that statute.

23 Is 5,000 the right number?

24 There again, we've talked about that already.

25 But, is it really the right number? I don't know.

1 That needs to be looked at.

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

5 All it says is that when you get an order over  
6 5,000 that the wholesaler should stop and evaluate  
7 and look at the business needs of that pharmacy and  
8 then go on.

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

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

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

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

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

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

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

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

24 They license the pharmacy, not the pharmacist.  
25 That's another misconception that's out there.



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

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

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

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

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

25           My son took it to the pharmacy where he works.

1 His partner refused to fill the prescription.

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

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

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

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

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

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

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

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

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

23 MR. MESHAD: Thank you.

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

1 and I know you like to a side a little bit. But,  
2 --

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

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

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

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

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

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

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

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

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

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

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

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

12 MR. MESHAD: Mr. Mesaros?

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

1 practice.

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

6 But, I can tell you one thing as much as we --  
7 What is the appropriate form of identification  
8 that needs to be taken -- and the federal  
9 government -- Do you know what that is? I didn't  
10 until I -- closer look at this. So, --  
11 identification -- We can't prepare the --  
12 requirement and then, of course, we -- know someone  
13 --

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

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

21 MR. EL SANADI: Thank you.

22 MS. HAYDEN: -- Allison.

23 MS. DUDLEY: Okay; thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 This is committing fraud or misrepresentation



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

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

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

14 A review of alcohol and substance must be  
15 performed.

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

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

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

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

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

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

13          MR. DALTON: Dr. Dalton.

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

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

20          MR. DALTON: Check the transcript. Check the  
21          transcript.

22          MR. MESHAD: That's a broad --

23          MR. DALTON: 134 to 144.

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

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

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

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

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

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

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

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

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

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

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

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

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

25           MR. DALTON: But, we encourage --

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

2 MR. MESHAD: -- opposite.

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

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

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

8 MR. PARRADO: Yeah.

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

18 MR. PARRADO: Yes; because, we --

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

21 MR. PARRADO: Yes.

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

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

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

4 MR. MESHAD: Right.

5 MR. DALTON: Thank you.

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

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

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

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

24 Mr. Jackson?

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

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

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

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

1 like to hear from you.

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

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

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

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

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

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



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

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

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

14          MS. DUDLEY: Absolutely.

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

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

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

1 out a --

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

5 Is someone here?

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

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

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

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

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

25 At the ASHAP House of Delegates meeting, the

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

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

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

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

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

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

16 Thank you. Are there any questions?

17 MR. MESHAD: Thank you. Any questions?

18 Thank you for your time. We appreciate it.

19 All right. The next item is the Rule  
20 64B16-27.831 which is what we talked about.

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

25 And, it's my recommendation -- put a

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

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

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

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

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

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

2 MR. MESHAD: Yes.

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

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

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

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

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

17 MS. DUDLEY: Of course, yes.

18 MR. MESHAD: So, I want --

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

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

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

25 MS. DUDLEY: Right.

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

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

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

16          MR. MESAROS: Okay.

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

18          MR. MESAROS: Great.

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

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

1 to your board.

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

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

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

14 MR. MESHAD: Uh-huh?

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

17 MS. DUDLEY: That's our rule.

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

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

24 MR. MESHAD: That's our --

25 MR. MESAROS: I was referring to their rule,



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

3 MR. MESHAD: I though it was our rule.

4 MR. MESAROS: No.

5 MS. DUDLEY: No.

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

7 --

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

9 --

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

11 MR. MESAROS: I was asking about their rule.

12 MR. MESHAD: Okay.

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

15 MR. MESHAD: Sure.

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

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

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

24 MR. MESHAD: Sure.

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

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

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

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

25 I'm talking about --

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

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

7 We all see that people have been and  
8 potentially will be arrested for misusing  
9 prescription -- database. It's going to those --  
10 and, I've already seen it -- that are probably the  
11 --

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

14 MR. MESHAD: Yes.

15 MS. HAYDEN: There are places --

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

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

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

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

1 the medical records. That's the --

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

3 MR. FLYNN: Well -- Yeah.

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

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

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

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

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

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

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

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

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

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

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

16 UNKNOWN SPEAKER: Okay.

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

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

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

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

6 MR. MESHAD: Okay.

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

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

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

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

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

24 MR. MESHAD: Very good. Please.

25 MR. CAMILLIERI: So, good afternoon to the

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

7 But, just a little background about myself.

8 MS. DUDLEY: Turn the microphone on.

9 MR. MESHAD: Your mike is not on.

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

12 MR. MESHAD: It's still not on.

13 MS. DUDLEY: It's still not on.

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

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

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

25 As a floater for a chain pharmacy, a lot of

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

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

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



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

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

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

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

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

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

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

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

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

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

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

25                   I think that should be directed at primary

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

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

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

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

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

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

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

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

1 me.

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

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

10 MS. DUDLEY: Yeah.

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

20 MR. CAMILLIERI: Uh-huh.

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

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

25 MR. MESHAD: Okay. We can certainly look at

1 that as --

2 MS. DUDLEY: For the separate -- Yes.

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

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

7 MR. MESHAD: Sure.

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

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

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

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

1 rule.

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

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

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

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

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

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

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

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

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

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

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

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

17 We understand -- which is also necessary to --

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

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



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

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

7 This will also address the issue of  
8 questionable supply --

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

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

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

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

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

25 Perhaps even -- as Ms. Langston so eloquently

1 stated earlier -- These are reasonable  
2 suggestions.

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

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

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

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

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

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

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

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

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

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

16 Thank you.

17 MR. MESHAD: Thank you. Mr. Davis?

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

1 work group.

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

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

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

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

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

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

25 Again, to reiterate; a lot of what we touched

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

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

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

14 MR. MESHAD: Yes.

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

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

21 His firm, in particular, -- A very short  
22 synopsis -- But, at his firm, we had problems with  
23 mental health and anti-psychotics in children in  
24 our state. So, what Medicaid did was we had over  
25 1.2 millions recipients on the -- Medicaid. They

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

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

15 Thank you.

16 MR. MESHAD: Thank you. Any other comments?

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

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

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

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

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

12 So with that, --

13 MS. DUDLEY: We have Janet Colbert.

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

16 MR. MESHAD: There you do.

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

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

22 In 1997, 8.3 tons of Oxycodone was produced.  
23 2011, 105 tons. 2012, 113 tons; a 1,747 percent  
24 increase over the amount produced in 1996, the year  
25 Oxycodone first came on the market.

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

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

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

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

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

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

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

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



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

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

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

12          I would also like to --

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

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

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

18          MS. COLBERT: Okay.

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

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

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

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

5 MS. COLBERT: Yes.

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

8 MS. COLBERT: Yes. Thank you.

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

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

15 MR. MESHAD: Are you Maureen?

16 MS. KIELIAN: I am.

17 MR. MESHAD: Okay.

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

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

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

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

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

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

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

21           MR. FLYNN: Ma'am, do me a favor. As a point  
22 of law, you file the complaint. Please know that  
23 if it was not ever -- public, you're not at liberty  
24 to disclose confidential information in the public  
25 --

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

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

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

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

11 Where's Florida in all of this? Okay?

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

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

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

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

25 Someone -- some doctor somewhere has to

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

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

6 MS. KIELIAN: Okay.

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

9 MS. KIELIAN: Yes.

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

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

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

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

25 And, I appreciate your comments. But, please

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

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

10 I am going to have to move on.

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

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

16 MR. MESHAD: I appreciate it.

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

18 MR. MESHAD: All right. One more --

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

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

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

25 The DEA, back on June first of 2010, has

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

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

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

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

20 MS. NGUYEN: Right.

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

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

2 MS. NGUYEN: Correct.

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

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

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

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

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



1 the web site.

2 MS. FALLATEUF: Thank you.

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

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

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

13 MR. MESHAD: Thank you.

14 MR. NGUYEN: Thank you.

15 MR. MESHAD: All right.

16 UNKNOWN SPEAKER: --

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

18 MR. CARMALL: My name is Tom Carmall.

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

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

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

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

1 MR. MESHAD: Okay.

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

6 I thank you very much for allowing me to  
7 speak.

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

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

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

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

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

1           alphanumerically I have to call you back.

2           Unfortunately, I hate to do it being a pharmacist  
3           forty years. I don't why. But, that's their  
4           rules.

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

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

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

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

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

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

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

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

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

20 And yeah, we do have to train the pharmacists.

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

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

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

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

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

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

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

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

15 MR. MESHAD: I have to --

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

17 MR. MESHAD: Thank you for your time.

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

24 MR. MESHAD: Yes, sir. Thank you.

25 And again, if you have any constructive

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

3 Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 MR. MESHAD: I'm sorry.

22 MR. MACKAREY: Okay.

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

25 MR. MACKAREY: Yes.



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

4           MR. MACKAREY: Of course.

5           MR. MESHAD: Some of it we can't deal with.  
6 But, we can pass on that information.

7           MR. MACKAREY: I completely understand and I  
8 thank you.

9           MR. MESHAD: I saw one other gentleman raise  
10 his hand. We'll take him and then we -- We're kind  
11 of reaching of our time limit here. So, if you  
12 would state your name please.

13           MR. CORDRAY: Thank you very much. Good  
14 afternoon, everybody. My name is Scott Cordray.  
15 I'm a pain management patient. But, not to  
16 redundant -- But, my group has been working on a  
17 proposal of law which I think was mentioned up  
18 here. This is probably not going to be solved  
19 legislation or something like that -- clear cut  
20 guideline and what we've been working on is using a  
21 Florida Medicaid preferred drug list -- standard  
22 drug notations and we've taken the controlled  
23 substances off of that and then added ICD-9 and  
24 ICD-10 codes.

25           The standard notations actually gives standard

1 notations for each drug. You can have six of this  
2 a day or two of this and four of this. So, it's  
3 already started there. It's already in black and  
4 white and I think the simplest way to do this might  
5 be to take that as a template and, you know, have  
6 your -- the corresponding medicine and what they  
7 will be used for; what will be a primary indication  
8 for the use of that medicine.

9 And then, on top of that, a -- for any type of  
10 a deviation off of that, the Department of Health  
11 would administer some type of a REMS program or  
12 REMS protocol or something like that; an evaluation  
13 of mitigation strategies.

14 There is already one for -- I think the --  
15 administers one. It's the Total Friends Access  
16 Program. It's for -- So, you know, something like  
17 that could be expanded and administered by the  
18 Department of Health.

19 And then the third of that would be that  
20 there's got to be some type of a protection for the  
21 State's licensed practitioner; something with some  
22 teeth that -- We envision something where the  
23 Attorney General is going to come where there's  
24 action where there's no probable cause and the  
25 State is going to defend its people; because, I

1 think that -- something like this could take care  
2 of everything in one fell swoop.

3 But, anyway; for the -- I think had a rebuttal  
4 for the folks; the Stopp folks, you know -- I'm  
5 sure you guys have --

6 MR. MESHAD: Right on time. All right. I  
7 appreciate everybody's comments. And again, I  
8 encourage you to send any constructive points and  
9 items that the sub-committee can digest if they  
10 determine there is some need for rule changes,  
11 guidelines and educational programs.

12 With that, we have future meetings that will  
13 be set up and then we'll have this committee before  
14 the next Board Meeting, next time.

15 I want to thank everybody for being here.

16 (Thereupon, the proceeding was concluded.)

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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

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