IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,

Plaintiff,

vs.

(1) PURDUE PHARMA L.P.;
(2) PURDUE PHARMA, INC.;
(3) THE PURDUE FREDERICK COMPANY,
(4) TEVA PHARMACEUTICALS USA, INC.;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC,
(8) ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS;
(9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS LLC; and
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,

Defendants.

STATE OF OKLAHOMA }
CLEVELAND COUNTY } S.S.
FILED

MAR 15 2019

In the office of the
Court Clerk MARILYN WILLIAMS

For Judge Balkman's Consideration

Case No. CJ-2017-816
Honorable Thad Balkman

William C. Hetherington
Special Discovery Master

Doc 1

Part B

MOTION OF DEFENDANTS WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., AND TEVA PHARMACEUTICALS USA, INC. FOR PARTIAL SUMMARY JUDGMENT AND BRIEF IN SUPPORT

MOTION

Pursuant to 12 O.S. § 2056 and Rule 13 of the Rules for the District Courts of Oklahoma, Defendants Watson Laboratories, Inc. ("Watson Labs"), Actavis LLC ("Actavis LL"), and Actavis Pharma, Inc. ("Actavis Pharma") (collectively the "Actavis Defendants"), and Teva

#6
95

EXHIBIT 1-F

IN THE DISTRICT COURT OF CLEVELAND COUNTY

STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, vs. (1) PURDUE PHARMA L.P.; (2) PURDUE PHARMA, INC.; (3) THE PURDUE FREDERICK COMPANY; (4) TEVA PHARMACEUTICALS USA, INC; (5) CEPHALON, INC.; (6) JOHNSON & JOHNSON; (7) JANSSEN PHARMACEUTICALS, INC.; (8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS; (9) JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; (11) WATSON LABORATORIES, INC.; (12) ACTAVIS LLC; AND (13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., Defendants.	Case No. CJ-2017-816

PORTIONS OF TRANSCRIPT MAY BE COVERED UNDER PROTECTIVE ORDER

TRANSCRIPT OF PROCEEDINGS
HAD ON OCTOBER 3, 2018
AT THE CLEVELAND COUNTY COURTHOUSE
BEFORE THE HONORABLE THAD BALKMAN
DISTRICT JUDGE
AND WILLIAM C. HETHERINGTON, JR.,
RETIRED ACTIVE JUDGE AND SPECIAL DISCOVERY MASTER

REPORTED BY: ANGELA THAGARD, CSR, RPR

Think of the importance for my defense of getting access to know who the doctors were, who the patients were, and getting access to be able to do the discovery about this.

The State's case, the State's theory is that the physicians were somehow misled about what the risks and consequences of the drugs were. Under the TIRF REMS program, I can specifically show they were not misled.

Both the physician and the patient had the FDA approved materials about these specific drugs. It directly refutes the plaintiff's case. I'm entitled to discovery to get access to that information.

Here's what else is going on. Paragraph 67 of the petition, the plaintiff alleges that the defendants somehow convinced the doctors that opioids were effective for noncancer pain, and that's part of the State's case.

Well, under the TIRF REMS program, I think I'm going to be able to show of these 245 prescriptions, not one of them was for anything except cancer. I think I'm going to be able to show that, but I've got to get discovery on that claims data and be able to show that.

And there's no reason to play cat and mouse about it. They had the 245 claims in front of them when they made Exhibit 3. We don't need to argue, we don't need to hypothesize, we don't need to guess about which 245 claims it is. They know. They just need to give us the data.

Now, I anticipate -- I anticipate the State will want to advance a couple of arguments. I think they're going to want to talk about generic drugs. Now, keep in mind I represent more than one defendant here. Actavis Pharma, Inc., for example makes generic opioid.

The generics, they're a different deal. They're not branded. They don't do advertising. That's a different argument for a different day. The argument I'm making today is about Cephalon. Those drugs are branded. It's different from the generics.

I also anticipate the State will argue that, Well, Robert's clients are all in the same corporate family, so you just -- just wrap it all up into one, and just call it one big ball of wax. But the law -- the law of the state of Oklahoma has always recognized the existence of corporations.

The law of Oklahoma has always been that you cannot just assume that we're going to automatically pierce the corporate veil and ignore the existence of different corporations. And the State agrees with me on that.

That's the reason they named Cephalon separately as a defendant, because it's a separate corporation. That's the reason why they made separate allegations in paragraphs 37 about Cephalon. And I'm entitled to the information allowing me to defend Cephalon.

In conclusion, your Honor, I hope the Court will not lose

sight of the overall posture of this case. The State is the plaintiff. The State is seeking to penalize our clients, not only to impose liability, but to impose penalties. They're asking for penalties under the Fraud Control Act. They're asking for penalties under the Medicaid Program Integrity Act.

The plaintiff wants to penalize our clients based on the State's allegations that, Well, the physicians received some representations, those representations were material to the prescribing decision. The physician relied on those representations when they made the decision to prescribe that drug for that patient.

They want to impose penalties on that theory. But when we ask for discovery to find out, are those facts actually true, the State says, No, no, that's secret, that's secret, you don't get to know that.

That posture, that flies in the face of our entire system of justice. We are entitled to the information. We're entitled to defend our client. And we're entitled to the information under the Oklahoma Discovery Code. It's clearly required and clearly required under the due process clauses of the Oklahoma Constitution and the Federal Constitution. Thank you.

THE COURT: Thank you, Mr. McCampbell.

MR. COATS: On behalf of Purdue, we won't make a separate argument. We'll just adopt the arguments made by

EXHIBIT 1-G

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,

Plaintiffs

vs. Case No. CJ-2017-816

(1) PURDUE PHARMA, L.P.;
(2) PURDUE PHARMA, INC.;
(3) THE PURDUE FREDERICK COMPANY;
(4) TEVA PHARMACEUTICALS USA, INC.;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC.;
(8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
(9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS, LLC; and
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,

Defendants.

VIDEOTAPED DEPOSITION OF LYNN WEBSTER, M.D.

TAKEN ON BEHALF OF THE PLAINTIFF

ON FEBRUARY 18, 2019, BEGINNING AT 9:11 A.M.

IN SALT LAKE CITY, UTAH

REPORTED BY: VICKIE LARSEN, CSR/RMR

A. Correct.
Q. Some of the medicines can be short-acting opioids?
MR. DUCK: Objection to form.
THE WITNESS: Some can be short-acting.
Q. BY MR. ERCOLE: There can be long-acting opioids?
MR. DUCK: Objection to form.
THE WITNESS: Yes.
Q. BY MR. ERCOLE: Are there other differences between --
A. Rapid onset, intra- -- intrathecal.
Q. Any others?
A. No.
Q. Yeah, do you want to explain what you mean by "rapid onset opioids"?
A. I think of transmucosal as -- as a rapid onset. So something that's quickly absorbed so that immediate onset, and it's usually transmucosal. So Actiq would be that example, or Fentora.
Q. When you say "transmucosal" -- sorry, just for breaking it down even

farther -- what do you mean by that?

A. Well, you -- it's something you place in your mouth, and you place it on the mucosa, which is the inner lining of your mouth. And that then goes across into the blood stream and is picked up. So that's transmucosal. So the mucous, mucosa, mucosa, so it's transmucosa.

Q. And you mentioned "intrathecal," what do you mean by that?

A. That's giving it into the spinal canal.

Q. Is it fair to say that with respect to opioid manufacturers, different opioid manufacturers may engage in different types of promotional activities based upon the -- the medicine that they manufacture?

MR. DUCK: Objection. Form.

THE WITNESS: Yes.

Q. BY MR. ERCOLE: And some manufacturers -- like some generic manufacturers may not even promote their medicines to doctors at all; is that fair to say?

MR. DUCK: Objection to form.

THE WITNESS: There are -- yes, a lot of generics don't spend any money on marketing or reaching out to doctors.

Q. BY MR. ERCOLE: And is it fair to say that you can't just lump all opioid manufacturers together just like you can't lump all physicians together?

MR. DUCK: Objection to form.

THE WITNESS: Well, I think -- it depends upon what level you're talking about. I mean, I think there is -- each company is different, and so they've got different products so they would be different.

Q. BY MR. ERCOLE: Have you ever heard of the company Actavis Pharma, Inc.?

A. Yes.

Q. Do you recall any communications that you've had with Actavis Pharma, Inc.?

A. No, I don't recall it. It's possible, but I don't recall.

Q. Do you recall, sitting here today, any funding that you would have

received from Actavis Pharma, Inc.?

A. I -- I can't recall ever receiving funding.

Q. Are you aware of any promotional or marketing statements about opioids that were ever made by Actavis Pharma, Inc.?

A. I cannot recall.

Q. Assuming -- sitting here today, you're unaware of any false or misleading statements that would have been made by Actavis Pharma, Inc.?

A. I don't --

MR. DUCK: Objection to form.

THE WITNESS: I don't recall.

Q. BY MR. ERCOLE: Have you ever had any communications with Watson Laboratories, Inc.?

A. I know one of my former employees moved to Watson, and so what do you mean "communication"? I'm not sure I talked to him about anything they were doing, so it kind of depends on what your question is.

Q. Fair enough.

Do you recall receiving any

funding from Watson Laboratories, Inc.?

A. No.

Q. Do you recall any promotional or marketing statements about opioids from Watson Laboratories, Inc.?

A. I don't recall any.

Q. Are you aware of any false or misleading statements by or attributable to Watson Laboratory, Inc.?

MR. DUCK: Objection to form.

THE WITNESS: I haven't seen anything from them, I don't believe.

Q. BY MR. ERCOLE: And counsel today for the -- for the State never mentioned Actavis Pharma, Inc.; correct?

MR. DUCK: Objection to form.

THE WITNESS: I don't remember that being mentioned.

Q. BY MR. ERCOLE: Sure. He never showed you any documents involving Actavis Pharma, Inc., did -- did they?

A. No, I don't think so.

MR. DUCK: Objection to form.

Q. BY MR. ERCOLE: With respect to Watson Laboratories, Inc., did counsel for

the State today ever show you any documents concerning Watson Laboratories, Inc.?

A. Not that I'm familiar. No, I don't recall.

Q. Did counsel for the State ever reference Watson Laboratories, Inc.?

A. I don't believe so.

Q. How about Actavis, LLC, have you ever heard of that entity?

A. Well, I know Actavis. I don't know what the other part of it is, and if there's a difference.

Q. Sure. About -- ever received, to the best of your recollection, any funding from Actavis, LLC?

A. Not that I recall.

Q. Are you aware of any -- aware of any promotional or marketing statements about opioids that were ever made by Actavis, LLC?

A. No.

Q. Aware of any false or misleading statements attributable to Actavis, LLC --

A. No.

Q. -- sitting here today?

A. No.

Q. You've -- counsel for the State mentioned -- has used the word -- the name "Teva."

Do you recall that?

A. Yes.

Q. And counsel for the State never differentiated as to what Teva entity it was referring to or not referring to, but have you ever heard of the -- of the company Teva Pharmaceuticals USA?

MR. DUCK: Objection to form.

THE WITNESS: You know, I think of Teva as Teva, and I'm not sure I know the difference with -- if there are different Tevas.

Q. BY MR. ERCOLE: Fair enough.

Are you aware of any false or misleading statements, sitting here today, that Teva USA has made?

MR. DUCK: Objection to form.

THE WITNESS: No.

Q. BY MR. ERCOLE: Are you aware of any marketing at all that Teva USA has

done regarding opioids in Oklahoma?

MR. DUCK: Objection to form.

THE WITNESS: No.

Q. BY MR. ERCOLE: There was some discussion earlier about Cephalon. Do you recall that?

A. Yes.

Q. Cephalon is different than Teva; correct?

A. Well, I don't know what you mean by that. Cephalon is what developed Fentora and Actiq, and it was acquired by Teva, is what my understanding is. So it was a different company, but then it folded into Teva, is what my understanding is.

Q. Would you be surprised to learn that Teva USA and Cephalon are two distinct companies even today?

MR. ROBINSON: Objection.

Form.

THE WITNESS: I guess I would be surprised. I didn't know that.

Q. BY MR. ERCOLE: With respect to Cephalon, at any stage in time are you aware of any false or misleading statements that

EXHIBIT 1-H

IN THE DISTRICT COURT OF CLEVELAND COUNTY

STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.
MIKE HUNTER, ATTORNEY GENERAL
OF OKLAHOMA,
Plaintiff,

vs. Case No. CJ-2017-816

PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC.; ALLERGAN, PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS, LLC and ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,
Defendants.

VIDEOTAPED DEPOSITION OF SCOTT FISHMAN, M.D.

February 26, 2019

9:43 a.m.

4860 Y Street, Suite 3020

Sacramento, California

REPORTED BY:

MARYANN H. VALENOTI

CSR #11266, RPR, CRR

BY MR. ERCOLE:

Q. And is it fair to say there are many different manufacturing --

A. There are many different manufacturers. I think they're all manufacturers. So I'm not sure that there are a variety of them. They're all manufacturers.

Q. That's an excellent clarification. I appreciate that.

But different companies manufacture opioids; correct?

A. Yes.

Q. And those manufacturers manufacture different types of opioids; is that fair to say?

A. Yes.

Q. And opioid medicines are different; is that correct?

MS. BALDWIN: Object to form.

THE WITNESS: Opioid medicines are, yeah, an overarching group of different molecules and different formulations.

BY MR. ERCOLE:

Q. And different opioids may be approved by the FDA at different times?

A. Correct.

Q. And some of those medicines may be generic medicines; is that true?

MS. BALDWIN: Object to the form.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. And some may be branded medicines?

MS. BALDWIN: Object to the form.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. And some may be short acting opioids?

A. Yes.

MS. BALDWIN: Objection, object to the form.

BY MR. ERCOLE:

Q. Some may be long acting opioids?

MS. BALDWIN: Object to form.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. And may be different delivery systems with respect to those opioid medicines?

MS. BALDWIN: Object to form.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. And with respect to marketing, is it fair to say that opioid manufacturers may engage in

different types of marketing, if any?

MS. BALDWIN: Object to form.

THE WITNESS: I assume so.

BY MR. ERCOLE:

Q. For instance, generic manufacturers may not market their medicines at all?

MS. BALDWIN: Object to form.

BY MR. ERCOLE:

Q. Is that fair to say?

A. Yes.

Q. Dr. Fishman, do you have -- do you recall any communications that you've ever had with anyone from a company known as Actavis Pharma?

A. I don't recall.

Q. Do you recall receiving directly or indirectly any funding from a company called Actavis Pharma?

A. I don't.

Q. Are you aware of any promotional or marketing statements ever made about opioids by such a company?

A. I do not.

Q. How about do you recall any communications that you've ever had with a company by the name of Watson Laboratories?

A. I don't.

Q. Are you aware of any funding that you received directly or indirectly from any company known as Watson Laboratories?

A. I don't. I would not be surprised if the American Pain Foundation received funding from those or the American Academy of Pain Medicine or the American Pain Society, organizations I had a role in. So when you say "indirectly," maybe there is a connection there, but I don't recall working with those companies or receiving anything from them.

Q. Sure. Well, sitting here today, do you recall any of those other entities that you've just -- third-party entities you just described ever receiving any funding from Watson Laboratories?

MS. BALDWIN: Object to form.

THE WITNESS: I don't recall, but I wouldn't be surprised if they did.

BY MR. ERCOLE:

Q. Okay. But sitting here today you don't recall? I just want to make sure.

A. Correct, I do not recall.

MS. BALDWIN: Object to form.

BY MR. ERCOLE:

Q. Are you aware of any promotional or marketing statements made about opioids from Watson Laboratories?

A. No.

Q. Have you ever had any communications with a company known as Actavis, LLC, to the best of your understanding?

A. Not that I recall.

Q. Do you ever -- were you ever aware of any funding that you've received directly or indirectly from a company known as Actavis, LLC?

A. Not that I know of.

Q. Are you aware of any promotional or marketing statements about opioids made by Actavis, LLC?

A. Not that I am aware of.

Q. Are you aware of what medicines, if any, Actavis Pharma, Watson Laboratories or Actavis, LLC manufactures?

A. I am not.

Q. Do you recall any documents that the State showed you today about any of those entities?

MS. BALDWIN: Object to form.

THE WITNESS: I think there was one

document that listed Watson, and, I mean, it could have even been in my book. I think I saw the name "Watson" somewhere.

BY MR. ERCOLE:

Q. Sitting here today, can you recall specifically about --

A. I don't know if that happened today, no.

MS. BALDWIN: Object to form.

BY MR. ERCOLE:

Q. Are you aware of any -- Dr. Fishman, are you aware of any -- you've heard of the company Teva, USA; is that fair to say?

A. Yes.

Q. Are you aware of any false or misleading statements that Teva USA has ever made about opioids?

A. No.

Q. You've heard of the company Cephalon; is that fair?

A. Yes.

Q. Are you aware of any -- strike that.

Do you have any personal knowledge of any false or misleading statements that Cephalon has ever made about opioids?

MS. BALDWIN: Object to form. I should

EXHIBIT 1-I

IN THE DISTRICT COURT OF CLEVELAND COUNTY

STATE OF OKLAHOMA

- - - - - - - - - - - - - - - - - X

STATE OF OKLAHOMA, ex rel.,	:	Case No.:
MIKE HUNTER, ATTORNEY GENERAL	:	CJ-2017-816
OF OKLAHOMA,	:	
Plaintiff,	:	Judge Thad Balkman
vs.	:	
PURDUE PHARMA L.P., et al.,	:	
Defendants.	:	

- - - - - - - - - - - - - - - - - X

CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

3230(c)(5) Videotaped Deposition of the

FEDERATION OF STATE MEDICAL BOARDS,

By and Through the Agency Designee,

LISA ROBIN

Washington, D.C.

Thursday, January 24, 2019

9:02 a.m.

Job No. 253522

Pages: 1 - 365

Reported by: Dana C. Ryan, RPR, CRR

Page
worked very closely with the National Council of State Boards of Nursing and National Association of Boards of Pharmacy.

So -- and then there are -- you know, and what -- whatever topic that you are dealing with, there's many stakeholders. And I think that you've seen a number of these stakeholders, many nonprofits, whether they be, you know, of associations, of physicians, the anesthesiologists or others -- but others that have a -- that are stakeholders in the whole area of pain care.

Q And -- and are there stakeholders from the federal government?

I believe we --

A Yes.

Q -- saw a reference to SAMHSA.

A Yes, we've received funding from SAMHSA.

Q And was SAMHSA involved in the development of Responsible Opioid Prescribing?

I believe it's Exhibit 16.

A The -- I'm trying to remember exactly when -- I believe SAMHSA was on the original -- the first -- the first version. I would have to go back. I'm sorry. It's been a few years.

Page

Q Yeah. If you want to take a look, that was Exhibit 16.

A Yes, the advisory board included Dr. Bizzell from the Center for Substance Abuse Treatment. So the -- SAMHSA was involved early on.

MR. BRODY: All right. Thank you, Ms. Robin. I have no additional questions.

EXAMINATION BY COUNSEL FOR THE DEFENDANTS CEPHALON, INC.; TEVA PHARMACEUTICALS USA; ACTAVIS LLC; ACTAVIS PHARMA, INC.; AND WATSON LABORATORIES, INC.

BY MS. COATES:

Q Thank you very much for your time, Ms. Robin. I just have a couple of questions. Melissa Coats, and I represent Cephalon; Teva Pharmaceuticals USA; Actavis LLC; Actavis Pharma, Inc.; and Watson Laboratories.

To return to Exhibit 4, I believe, and if you just recall your testimony that these represent complete answers to question number 1. We can start with that one, pages 11 through 13.

Did you receive funding from Teva Pharmaceuticals USA for this project?

A (Witness reviews document.) No.

Page

Q And did you receive funding from Actavis LLC for this project?

A (Witness reviews document.) No.

Q And did you solicit funding from Actavis Pharma, Inc. for this funding?

A I don't recall. I don't really recall the name of the company.

Q And -- but according to your answer that you provided to the Senate Advisory Committee in response to this query --

A Uh-huh. (Witness reviews document.) Are you referencing 10 through 13?

Q Yes.

Did you receive funding from --

A Actavis?

Q Actavis.

A No.

Q And did you receive funding from Watson Laboratories, Inc.?

A (Witness reviews document.) No.

Q And again recalling that you just testified that your answer to question 2 is also complete, did any of the five clients I just -- that I represent provide funding for this project as to question 2?

Page

A No.

MS. COATES: Thank you very much. I have no further questions.

EXAMINATION BY COUNSEL FOR THE PURDUE PHARMA LLP

BY MR. EISENBERG:

Q Ms. Robin, good afternoon. I just have a few questions. We -- WE met before. My name is Jared Eisenberg, and I represent Purdue.

You were asked some questions earlier today about the 2004 model policy for the use of controlled substances for the treatment of pain.

Do you recall that?

A Yes.

Q And the 2004 model policy for the use of controlled substances for the treatment of pain was the result of revisions to the 1998 model guidelines; correct?

A Correct.

Q And the work group -- there was a work group that issued these revisions that led to the publication of the 2004 model policy for the use of controlled substances for the treatment of pain; correct?

A Yes, I -- I believe they refer to it as an advisory council. It was a larger group than

Page

our normal work groups.

Q AND are you aware of the fact that one of the expert members who participated in the revisions for this policy included the then Oklahoma Attorney General Drew Edmondson?

A Yes.

(Robin Deposition Exhibit 24 was marked for identification and attached to the transcript.)

BY MR. EISENBERG:

Q I'm handing you what's marked as Exhibit 24 to your deposition. Have you seen this document before?

A Yes.

Q What is this document?

A The guidelines for the chronic use of opioid analgesic.

Q And if you read the first paragraph of these guidelines under the introduction section, it says, In April 2015, the Federation of State Medical Boards Chair, J. Daniel Gifford, appointed the work group on FSMB's model policy for the use of opioid analgesics and the treatment of chronic pain to review the current science for treating chronic pain with opioid analgesics and to revise

Federation of
STATE
MEDICAL
BOARDS
[redacted]
1912-2012

June 8, 2012

The Honorable Max Baucus
United States Senate
511 Hart Senate Office Building
Washington, DC 20510

The Honorable Charles Grassley
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

Dear Senators Baucus and Grassley:

The Federation of State Medical Boards (FSMB) is pleased to respond to your letter of May 8, 2012. The FSMB agrees with the Senate Finance Committee that the abuse and misuse of opioids is a serious national problem. We remain committed to raising awareness of the problem among physicians and the public and working to reduce the risk of addiction, abuse and diversion of opioids, while ensuring that patients who suffer from pain have access to needed treatments. In this regard, we respectfully urge you to review the FSMB's Model Policies and *Responsible Opioid Prescribing* publication, described within this letter.

The FSMB is actively addressing the important issues surrounding opioids on multiple levels. These efforts include collaborations with a variety of federal agencies and leading health care organizations. The American Medical Association (AMA), for example, has adopted formal policy specifying that "... states should examine their pain policies and seek to improve them, based on the Federation of State Medical Boards Model Policy..."[1]

Gil Kerlikowske, Director of the Office of National Drug Control Policy (ONDCP), said during a recent speech at the 2012 FSMB Annual Conference: "There is a real gap in the amount of education and training that is provided around pain management, addiction, treatment, tolerance and dependence. We know that's an important issue. I could not be more pleased, frankly, and I could not be more proud of the work that you all have done in this area... I was just given the latest edition of the Clinician's Guide for Responsible Opioid Prescribing by Dr. Fishman... The second edition of this is just a wonderful, wonderful step in the right direction of putting something that is so well written in the hands of very busy professionals that need that information."[2]

Background

The problem of prescription drug abuse and related deaths has grown at an alarming pace in the United States. According to the Centers for Disease Control and Prevention (CDC), deaths from prescription painkillers more than tripled between 1999 and 2008, and nearly half a million emergency department visits in 2009 were due to people misusing or abusing prescription painkillers.[3]

At the same time, the nation faces a serious and related problem: Millions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids.[4] Studies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life.

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Physicians must constantly weigh these dual realities as they consider treatment options for their patients in pain. Similarly, the nation's state boards of medicine must also weigh the risks and advantages of opioid prescribing as they establish the rules and regulations under which medicine is practiced in their jurisdictions – balancing the pressing need for patient safety with the equally important need to ensure that patients have access to treatment.

This dual responsibility – ensuring public safety and access to appropriate medical treatment – is the fundamental mission and purpose of the nation's system of state medical boards. Each of the 50 states, the District of Columbia and the U.S. territories has a medical practice act that delegates to a state medical board the authority to protect the public from the unprofessional, improper, incompetent, unlawful, or fraudulent practice of medicine. With this authority, boards typically establish parameters for the safe practice of medicine, including the prescribing of medicines such as opioid analgesics.

About the Federation of State Medical Boards

Established in 1912, the Federation of State Medical Boards is the national non-profit organization that represents the 70 medical and osteopathic boards of the United States and its territories. The FSMB promotes excellence in medical practice, licensure, and regulation as the national resource and voice on behalf of the boards as they protect the public and ensure access to medical treatment. To assist its efforts, the FSMB launched the Federation of State Medical Boards Research and Education Foundation (FSMB Foundation) in 1980. The FSMB Foundation is a supporting non-profit organization to the FSMB that expands knowledge and awareness of issues of importance to state medical boards, the public and the medical profession.

The FSMB enhances the role of state medical boards in a dynamic health care environment by leading, anticipating and responding to trends in medical regulation; serving as an informational and educational resource for the boards; and assisting the boards in developing and using consistent standards, language, definitions, and tools to regulate the practice of medicine.

The FSMB helps state medical boards adapt and respond as medicine evolves and various new issues emerge that impact the public. In the constantly changing environment of medical practice, the FSMB plays a key role as a thought leader and shaper of policy. In recent years, its work has helped the medical community respond to emerging issues such as outpatient surgery, use of the Internet in medical practice, maintenance of licensure, re-entry to practice, and physician impairment. In addition, the FSMB has been the recipient of multiple license-portability grants, authorized under the Public Health Service Act, and coordinated with the U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA), to develop and expand multi-state cooperation between licensing boards and to create and implement state policies that will also help facilitate telemedicine, and improve access to care.

FSMB Activities Related to Treatment of Pain and the Misuse, Abuse and Diversion of Opioids

Until the mid 1990s, physicians and state medical boards struggled with a lack of consistent policies related to the treatment of pain, which contributed to the dual public health issues of the under-treatment of pain and the improper use of controlled substances in addressing pain. Increased public demand for improvement in the medical management of pain and advances in medical knowledge regarding the use of controlled substances (including opioids), combined with a lack of physician awareness of the laws and regulations governing the prescribing of these substances, led the FSMB to launch a series of initiatives. The FSMB's goal was to provide a policy framework that would bring consistency to differing regulatory processes and to encourage states to clarify their guidelines and laws addressing pain management and appropriate and responsible prescribing.

Since its first major initiative related to pain and opioid prescribing in 1997, the FSMB and its state medical board partners have sought to balance efforts to ensure patient access to appropriate pain care with efforts to reduce the

potential for prescription drug misuse, abuse and diversion. These multi-pronged efforts have included policy-making, educational outreach, and collaboration with key federal and state agencies, physician organizations, foundations, academia, and many other stakeholder groups.

Throughout its work on these issues, the FSMB has sought to raise awareness with physicians and the public of the risks that opioids pose – in addition to their benefits for patients in need – while striving to bolster safeguards for their appropriate use. The FSMB's policies and educational materials do not advocate for opioid therapy by physicians; rather, they offer a framework to ensure that physicians who choose to prescribe opioids do so responsibly and safely, and remain in compliance with legal regulations regarding their use.

The FSMB has worked vigorously with the physician community to raise awareness of these issues and has worked closely with state and federal policy-making and law enforcement agencies to develop strategies aimed at addressing the misuse, abuse and diversion of all controlled substances.

Model Guidelines for the Use of Controlled Substances for the Treatment of Pain

The FSMB's efforts began in 1997 with the development of its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain.* Developed with a grant from the Robert Wood Johnson Foundation, the guidelines were created to address the dual issues of under-treated pain and improper prescribing of controlled substances, providing physicians with best practices to ensure safe and responsible prescribing and public access to appropriate and effective pain relief.

The guidelines represent an extensive effort at achieving consensus on these important topics. They were formulated with input from a diverse group of major stakeholders, ranging from pain and addiction specialists and medical societies to federal law enforcement agencies, many of whom participated in an invitational symposium hosted in March 1998, where they were able to provide formal testimony.

Before the model guidelines were finalized and formally adopted as Federation policy at the FSMB House of Delegates meeting in May 1998, a copy of the draft guidelines were distributed to more than 300 individuals, representing state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, state and federal regulatory agencies, and representatives from pharmacy and nursing regulatory boards for additional review and comment. The result was a set of guidelines that represented consensus from key national stakeholders.

The *Model Guidelines* stressed that all physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances. They stipulated that all prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state and federal law. The *Model Guidelines* set forth state medical boards' expectations for physicians to incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances, including thorough examinations; the use of written treatment plans and maintenance of accurate records; the critical importance of discussing both risks and benefits of controlled substances with patients; and the need for periodic review of treatment goals.[5]

Since their adoption, the *Model Guidelines* have been extensively distributed to state medical boards, medical professional organizations, other health care regulatory boards, and patient advocacy groups, as well as state and federal regulatory, law enforcement and other agencies, including the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) and U.S. Drug Enforcement Administration (DEA). They have been endorsed or supported by a variety of organizations, including the American Medical Association (AMA) and the National Association of State Controlled Substances Agencies (NASCSA).

In 2004, the *Model Guidelines* were revised and updated at the direction of the FSMB's 70 state member boards, with language intended to ensure they were consistent with emerging medical insights regarding pain management and the use of controlled substances. They were also renamed the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* to better reflect the practical use of the document.[6]

The FSMB subsequently hosted a series of regional educational workshops titled "Promoting Balance and Consistency in the Regulatory Oversight of Pain Care," for members and staff of state medical and pharmacy boards. The objectives of the workshops were to create a regulatory environment that supports accessible and appropriate pain care; to define controlled substances abuse and diversion and the appropriate regulatory responses to these issues; to distinguish between criminality and negligence and acceptable medical practices; and to define key terms and concepts related to pain and addiction. The workshops were accredited by the University of Texas Southwestern Health Science Center.

In March 2012, the FSMB, in collaboration with SAMHSA's Center for Substance Abuse Treatment (CSAT), brought together experts in pain management, addiction medicine, law enforcement, pharmacology, psychiatry, public health, medical regulation and other disciplines to once again review and update the *Model Policy*. The review process will be completed this year, with the goal of an updated and revised policy in 2013.

National Clearinghouse on Internet Prescribing

The FSMB has been a leader in addressing the problem of illegal prescribing through "rogue" Internet pharmacy sites, which operate without appropriate licensing and allow anonymous physicians to prescribe medications based only upon online questionnaires completed by patients never seen by the physician. In 2000, the FSMB launched an initiative creating a clearinghouse for the collection and dissemination of information to state and federal regulatory authorities on the operation of rogue Internet pharmacy sites – leveraging its formal relationship with all state medical boards in the United States and its well established lines of communication with state and federal agencies and the national pharmacist community.

This program gathered valuable information about illegal online activities for state and federal regulatory authorities, identifying more than 1,000 questionable Web sites as a part of its activities. The program received an Award of Excellence from the American Society of Association Executives for its results benefiting the American public. It supplied or assisted with information about 122 illegal prescribing cases on the federal level and 178 cases on the state level. The Clearinghouse was cited in multiple pieces of federal legislation, including: *H.R. 1298/S. 525, Pharmaceutical Market Access and Drug Safety Act of 2009* (March 4, 2009); *S. 3415, Fair Pricing For Prescription Drugs Act* (May 25, 2010); and *S. 319, Pharmaceutical Market Access and Drug Safety Act of 2011* (February 10, 2011). Among their provisions, these federal legislative initiatives called for the Department of Health and Human Services to partner with the FSMB Clearinghouse. Additionally, the FSMB supported a number of federal legislative proposals to address the problem of rogue internet pharmacies by writing endorsement letters and providing testimony at hearings.

Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office

In 2002, the FSMB House of Delegates adopted the *Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office*. These guidelines were intended to directly address the issue of opioid addiction, one of the key components of the FSMB's work related to opioid prescribing.

Developed with substantial funding from SAMHSA, the guidelines encourage state medical boards to adopt consistent standards, promote public health by helping direct opioid-addicted patients to appropriate treatment, and educate physicians and others on new modalities in the treatment of addiction. Following their adoption in 2002, the

- FSMB and SAMHSA hosted a series of regional educational programs to help build awareness and visibility of the need for new policies to address opioid addiction treatment.

Responsible Opioid Prescribing: A Physician's Guide

Among the FSMB's educational initiatives has been the development and distribution of a guidebook intended to help physicians recognize the risks of opioids and follow responsible and safe prescribing standards. The first edition of Responsible Opioid Prescribing: A Physician's Guide was released in 2007, and later accredited by the University of Wisconsin School Of Medicine and Public Health and designated for 7.25 AMA PRA Category 1 Credits™. Written by one of the nation's leading experts in pain medicine, Scott M. Fishman, MD, the book offers practical steps for reducing the risk of addiction, abuse and diversion of opioids, and for achieving improved patient outcomes. The book was developed with the assistance of an advisory board, which included a diverse range of physicians, academicians and health-policy experts who reviewed its content.

From its release in 2007 through January 2012, the book has been distributed in each of the 50 states and the District of Columbia. The book has been widely acknowledged and supported in the medical community as an important educational resource for physicians, and has been used extensively by state regulators and others to address the need for safer, more responsible and better-informed opioid prescribing.

The North Carolina Medical Board, for example, has sent a copy of the book to any physician who demonstrated deficits in knowledge of prescribing issues. It has also provided the book at educational seminars given to local physicians, emergency department personnel and county social service workers. The State of Michigan Bureau of Health Professions has made the book available annually, and has distributed more than 40,000 copies to physicians, physician assistants and other prescribers.

In Maine, every practicing physician in the state received a copy. Similarly, in Washington, more than 14,000 copies were distributed to the state's licensed physicians and physician assistants. Virginia distributed 20,000 copies of the book to all of its licensees. In Iowa, physicians seeking renewal of a medical license must complete two hours of accredited training on chronic pain management; the Iowa Board of Medicine provides free copies of the book to help physicians fulfill this requirement. In 2011, the FSMB sent 1,500 copies to the Iowa Board of Medicine, which offered the book free of charge to physicians. Montana received 1,800 copies of the book in 2008 for distribution to all licensed physicians in the state. More than 9,000 copies of the book were sent to Florida for distribution to licensed physicians, and more than 5,000 copies were distributed in West Virginia.

In a letter describing the Virginia Board of Medicine's use of the book to raise awareness of opioid prescribing issues, its executive director stated: "I write on behalf of the Virginia Board of Medicine in support of the Federation's efforts to educate the nation's physicians on the safe prescribing of opioids.. From a regulatory board standpoint, education of physicians and other prescribers is first and foremost. Knowing the drugs one is writing, their hazards, and the red flags for abuse, addiction and diversion are critical. The more a prescriber knows, the safer his/her patients will be, and so will the public."[7]

In 2010, Maine Attorney General Janet Mills described the book as "... recommended reading for all primary care doctors and pain specialists." Attorney General Mills also noted: "As a non-physician reading that book, what I found most cogent was the emphasis on measuring progress through documented improvements in life *functions*, if and when prescription opioids are required for treatment of a serious and chronic condition. Documentation of concrete progress in specific areas such as work, sleep and social interaction will improve the patient's life, minimize the risk of addiction and keep your practice within the professional standard of care."[8]

As cited above, Gil Kerlikowske, Director of the ONDCP, has also praised the second edition of the book and the FSMB's efforts to promote responsible opioid prescribing.[9]

In April 2012, recognizing the continuing growth of the nation's prescription drug abuse epidemic, an updated version of the book, now titled Responsible Opioid Prescribing: A Clinician's Guide, was published, with new statistics and data on opioid addiction that were not available in 2007. The new edition, funded in part by SAMHSA, is accredited by the University of Nebraska Medical Center and again offers *7.25 AMA PRA Category 1 Credits™* . Copies of the first edition are no longer being distributed; its CME activity expired in March 2012.

The expanded 2012 edition of the book is closely aligned with two important federal initiatives: the U.S. Food and Drug Administration (FDA) proposed Risk Evaluation and Mitigation Strategies (REMS) for Long-Acting/Extended-Release Opioid Class-Wide content guidelines for prescriber education[10] and the ONDCP's action plan to address the national prescription drug abuse epidemic, adopted in 2011.[11] Among its recommended strategies, the ONDCP's action-plan calls for a collaborative effort with state medical boards to raise awareness of the safe and appropriate use of opioids to treat pain, while minimizing the risk of addiction and substance abuse, as a part of continuing medical education and instruction in health professional schools. Recommendations in the book are designed to address the key elements of these federal initiatives, including support of prescription drug monitoring programs (PDMPs), more effective disposal methods of unused medications, improved education for healthcare providers and patients, and reducing the prevalence of "pill mills" and doctor shopping through enforcement efforts.

Responsible Opioid Prescribing: A Clinician's Guide reminds physicians that they have vitally important duties when prescribing: to become well versed in the latest guidance on how to evaluate and select patients for whom opioids are appropriate, and to monitor carefully their treatment. It provides a renewed warning to physicians that opioids are potentially dangerous, that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society, and that such medications must be used with great caution. The book is a key supporting resource for the educational efforts of state medical boards as they seek to raise awareness of the risks associated with prescribing opioids.

The Online Prescriber Education Network (OPEN)

In 2006, the FSMB became one of 24 recipients of the Attorney General Consumer and Prescriber Education Grant Program, designed to provide physicians with tools for accessing unbiased sources of information about drugs and to help them recognize improper pharmaceutical industry marketing practices.

As a part of the FSMB's overall efforts to ensure the highest standards of prescribing behavior, the FSMB developed and implemented an internet-based portal, the Online Prescriber Education Network (OPEN). OPEN provides accredited CME courses developed by universities and other educational institutions. Among the nearly 50 CME courses available at the site are modules on clinical practice guidelines for drug therapy, evidence-based medicine, and pharmacologic management of acute pain, as well as modules designed to help physicians recognize improper pharmaceutical marketing practices.

In addition, the portal provides access to relevant state and federal statutes, unbiased databases of information about the safety and efficacy of prescription medicines, and tools and strategies for evidence-based prescribing.

Since its inception in 2006, OPEN has provided guidance to physicians on how to be safer, more responsible prescribers, and how to recognize improper marketing of drugs by pharmaceutical companies. Since 2008, the OPEN modules have been accessed by approximately 10,745 learners with 5,260 completing one or more activity for CME credit.

Policy Brief on Balance, Uniformity and Fairness in Law Enforcement

The FSMB co-produced a policy brief with the Center for Practical Bioethics and the National Association of Attorneys General (NAAG) in 2009, aimed specifically at the issue of prescription drug diversion, titled: "Balance, Uniformity and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice."[12]

The brief summarized discussions of the Balanced Pain Policy Initiative Law Enforcement Roundtable, made up of leaders from the law enforcement and health care communities focused on ensuring that patients who need pain medications have access while preventing these drugs from becoming a source of harm and abuse.[13] The FSMB played a key role as one of the convening organizations, with the goal of helping foster stronger working partnerships between law enforcement and health care on these issues. Among the participants were: Mark Caverly, Chief, Liaison & Policy Section, U.S. Drug Enforcement Administration; Myra Christopher, President and CEO, Center for Practical Bioethics; Adam Clark, PhD, Director of Health Policy, Lance Armstrong Foundation; Drew Edmonson, Attorney General, State of Oklahoma; Cathy Gallagher, Associate Section Chief, Liaison & Policy Section, U.S. Drug Enforcement Administration; Richard Roper, U.S. Attorney, Northern District of Texas; William Sorrell, Attorney General, State of Vermont; Charles Cichon, Executive Director, National Association of Drug Diversion Investigators; Craig Watkins, District Attorney, Dallas County, Texas; and others.

Roundtable participants agreed on six strategies intended to seek balance as law enforcement agencies focus on sources of illegal drug diversion – to ensure that these efforts do not negatively impact appropriate medical practice and patient care. The strategies, ranging from distinguishing between criminal behavior and medical negligence to promoting the use of PDMPs, were publicly distributed in February 2009.

Roundtable participants agreed that the FSMB's *Model Policy for the Use of Controlled Substances for the Treatment of Pain* forms a strong foundation for educating health-care providers about issues related to opioid diversion and that "state boards in all states should learn, study, adopt and promote this Model Policy."[14] Moreover, the brief declared: "the short primer on record keeping and other aspects of pain medicine in Scott Fishman's book, Responsible Opioid Prescribing: A Physician's Guide, is another excellent resource for doctors."[15]

National Collaboration to Better Utilize Health Information Technology Related to Prescribing

In 2012, the FSMB announced a collaborative effort with the Office of the National Coordinator for Health Information Technology, ONDCP, SAMHSA, major pharmacy chains and other stakeholder organizations to promote the use of health information technology to reduce prescription drug abuse. Under this project, the FSMB will work with partner organizations to improve access to database information on prescribers and dispensers of controlled substances found in PDMPs. The project will put an emphasis on increasing timely access to PDMP data at the point of care, at the point of dispensing, and in hospital emergency departments.[16]

Initiatives with Federal Agencies and Other Organizations

An integral component of the FSMB's efforts related to opioid prescribing and the under-treatment of pain is its collaboration with various government agencies and other stakeholder organizations. Among the organizations the FSMB has worked with are SAMHSA's Center for Substance Abuse Treatment, the Drug Enforcement Administration (DEA), the FDA, ONDCP, and the National Institute on Drug Abuse – all of whom are helping the FSMB update and revise its *Model Policy for the Use of Controlled Substances for the Treatment of Pain*.

FSMB leaders continue to meet with their counterparts in federal agencies to assist with the development of national policy, including the ONDCP's new prescription drug abuse plan. Among the FSMB's recent outreach activities:

- In December 2010, FSMB leaders met with Dr. Janet Woodcock, Director, and Douglas Throckmorton, Deputy Director of the FDA's Center for Drug Evaluation and Research (CDER) to discuss REMS, CME, and the FSMB's efforts on behalf of responsible opioid prescribing as they relate to state medical and osteopathic boards.

- In March 2011, the FSMB representatives were invited by U.S. Surgeon General Regina Benjamin, MD, MBA, to participate in the Summit on Prescription Drug Abuse in Youth. Following the conference, the FSMB submitted comments to the U.S. Surgeon General's Office, which sought additional input on ways to reduce prescription drug abuse in the nation's youth population.

- In June 2011, the FSMB participated in the White House Summit on Health Information Technology and Prescription Drug Abuse. The roundtable, hosted by the Office of the Vice President of the United States, ONDCP, Office of the National Coordinator for Health Information Technology, and the Office of Science and Technology Policy, engaged approximately two dozen leaders across the public safety, healthcare, and technology sectors to address a variety of topics, ranging from use of PDMP data at the point of care to facilitate appropriate prescribing to leveraging PDMP data in emergency rooms through health information exchanges. The FSMB is currently serving on the Office of the National Coordinator for Health Information Technology's Law and Policy Work Group for the Enhancing Access to Prescription Drug Monitoring Programs (PDMPs) Project.

- In July 2011, the FSMB CEO met with Thomas Frieden, MD, MPH, Director, Centers for Disease Control and Prevention (CDC) and Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR), in Atlanta, GA. Among items for discussion were opportunities for the CDC and the FSMB to collaborate on opioid prescribing education. Following the meeting with Dr. Frieden, the FSMB's CEO met with other CDC senior leaders to continue the discussion, exploring ways in which the CDC and FSMB can collaborate to address prescription drug abuse, including opportunities available with the promotion of provider and patient education, PDMPs, and identifying state disciplinary trends for opioid prescribing.

- Also in July 2011, the FSMB's senior staff attended a meeting of the FDA Industry Working Group (IWG), which includes the branded and generic manufacturers charged by the FDA to develop REMS for long acting and extended release opioids. As a key component of the REMS, the IWG is required to develop an educational program for prescribers and patients and provide the educational materials either directly or through accredited continuing medical education (CME) providers. In November 2011, the IWG submitted a REMS draft blueprint for prescriber education, to which the FDA requested stakeholder input. The FSMB submitted comments in support of the REMS blueprint.

- In November 2011, FSMB leaders met with ONDCP Director Gil Kerlikowske at the 2011 American Medical Association (AMA) Interim Meeting in New Orleans, LA. ONDCP requested the meeting in order to identify ways in which state medical and osteopathic boards can serve as an education resource to the physician community regarding responsible opioid prescribing. In addition, ONDCP sought to explore mechanisms whereby state boards can be of assistance in monitoring prescribing patterns to identify fraudulent providers and patients who are 'doctor shopping.'

- In March 2012, FSMB senior staff served as faculty for a DEA training program, Pharmaceutical Investigations and Prosecution Seminar, in Philadelphia, PA.

- In 2011-2012, the FSMB continued to participate in SAMHSA's Center for Substance Abuse Treatment Open Dialogue Meetings, a forum to discuss the non-therapeutic use of prescription medications, and

strategies to reduce their misuse. Among the participants are experts from the medical community, federal agencies, consumer organizations, and the pharmaceutical industry.

- The FSMB continued to serve as a member of the FDA Opioid Patient Prescriber Pain Treatment Agreement Working Group, assisting with the development of model provider patient agreements for long-term opioid therapy as well as other prescriber resources.

- The FSMB is a sponsor of the DEA's National Prescription Drug Take-Back Day program, promoting the safe disposal of pain medications among state medical and osteopathic boards.

Throughout the last year, the FSMB also maintained an ongoing dialogue and partnership activities regarding prescription drug abuse with a wide variety of other stakeholders, including the National Council of State Boards of Nursing (NCSBN), the National Association of Boards of Pharmacy (NABP), the National Association of State Controlled Substances Agencies (NASCA), the National Council on Patient Information and Education (NCPIE), the Alliance of States with Prescription Drug Monitoring (ASPDM), and the American Pain Society (APS).

Additional Information Regarding the *Responsible Opioid Prescribing* book and the FSMB's Model Policies

As noted earlier, the book *Responsible Opioid Prescribing* educates physicians about FSMB policy on the use of controlled substances for the treatment of pain, seeking to reduce the risk of diversion and abuse of prescription opioids while balancing the need for patient access to these medications. The book distills the principles of FSMB's *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, which were adopted by the FSMB in 2004. The guidelines offer a balanced approach to opioid prescribing, acknowledging the legitimate medical uses of controlled substances for patients in need, while stressing the critical responsibility that physicians have in safeguarding against abuse and diversion.

The first edition of *Responsible Opioid Prescribing* was one of the first books to not only highlight the heightened risks of opioids, but to call upon physicians to measure the efficacy and safety of opioid therapy against tangible and measurable functional outcomes in addition to the subjective feedback of their patients.

The book's title emphasizes the need for prescribers to act responsibly – to educate themselves about the risks of opioids, to focus on their patients' behaviors and risk factors, and to monitor carefully and document the success or failure of treatment to achieve functional outcomes.

The book was recently revised, with a new title (Responsible Opioid Prescribing: A Clinician's Guide) and new information about the risks associated with opioids as well as safety and risk management. The new information and additional sections support the original – and still-central – theme of the book, which continues to be that the use of opioids must be grounded in solid risk-management and caution by prescribers.

The FSMB firmly stands behind the integrity of the book, the development of which was overseen by an advisory board of respected medical and policy experts and which presents an unbiased and impartial view of opioid prescribing. All revenue generated from the sale of the FSMB's *Responsible Opioid* guides was dedicated to support the development and distribution of these materials. Funding contributors had no input or influence on its content.

It is important to note that contributions and support for the book have come from non-industry sources, such as the Lance Armstrong Foundation and the Mayday Fund, and that a wide variety of not-for-profit organizations have supported the book's distribution through their independent purchases of it. Examples include SAMHSA, the American Academy of Family Physicians, Kaiser Permanente, the American Cancer Society, the New Jersey

Academy of Family Physicians, the Pennsylvania Medical Society, Vanderbilt University Center for Professional Health and the U.S. Department of Veterans Affairs.

The Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (1998), *the Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office* (2002), *the Model Policy for the Use of Controlled Substances for the Treatment of Pain* (2004), and the two editions of *Responsible Opioid Prescribing* provide guidance for physicians to ensure that a balance is struck between the dual realities of opioid misuse, abuse and diversion and the legitimate medical needs of millions of Americans who suffer from pain. The FSMB believes the appropriate role for the regulatory community is to ensure that, in seeking this balance, physicians are apprised of their responsibility to manage the inherent risks of opioids and to remain in full compliance with laws and regulations governing their use, should they choose to prescribe them. While there can be divergent views within the medical community on the best way forward in this area of medical practice, as in others, we believe the guidelines, policies, and books we have developed, with consensus from stakeholders, provide a prudent framework for patient safety as our understanding of pain management and opioid use continues to evolve.

Turning to the questions in the May 8, 2012 Senate Finance Committee letter, to the best of our knowledge, after reasonable due diligence and good faith efforts and to comply with the information requested, the following is provided in response to the questions contained in that letter.

Question 1:

Provide a detailed account of all payments/transfers received from all organizations that develop, manufacture, produce, market, or promote the use of opioid-based drugs from 1997 to the present. For each payment identified, provide:

i. Date of payment
ii. Payment description (CME, royalty, honorarium, research support, etc.)
iii. Amount of payment
iv. Year end or year-to-date payment total and cumulative total payments for each organization or individual.
v. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.

Answer 1:

The requested payments/transfers received by the Federation of State Medical Boards (FSMB) and the Federation of State Medical Boards Research and Education Foundation (FSMB Foundation) from 1997 to the present are:

Payer Organization	Date	FSMB Fiscal Year (5/1 – 4/30)**	Payment Description	Amount of Payment	Percent of Total Revenue (Consolidated)
		Total for FY 1997		$0.00	0.00%
		Total for FY 1998		$0.00	0.00%
		Total for FY 1999		$0.00	0.00%

		Total for FY 2000		**$0.00**	**0.00%**
Purdue Pharma	7/14/2000	2001	Purchase of Copies of FSMB Pain Model Guidelines	$28,324.56	
Pfizer Corp.	8/4/2000	2001	Support for the FSMB National Clearinghouse on Internet Prescribing	$50,000.00	
Purdue Pharma	9/27/2000	2001	Support for the FSMB National Clearinghouse on Internet Prescribing	$10,000.00	
		Total for FY 2001		**$88,324.56**	**1.09%**
Purdue Pharma	1/29/2002	2002	Support for the FSMB National Clearinghouse on Internet Prescribing	$10,000.00	
Pfizer Corp.	2/6/2002	2002	Support for the FSMB National Clearinghouse on Internet Prescribing	$10,000.00	
		Total for FY 2002		**$20,000.00**	**0.23%**
Purdue Pharma	1/24/2003	2003	Purchase of Copies of FSMB Pain Model Guidelines	$25,180.50	
Purdue Pharma	3/26/2003	2003	Grant in Support of 2003 FSMB Annual Meeting Session	$60,000.00	
		Total for FY 2003		**$85,180.50**	**0.76%**
Purdue Pharma	4/27/2004	**Total for FY 2004**	Grant for Project to Update *FSMB Model Guidelines for the Use of Controlled Substances in the Treatment of Pain*; Educate FSMB Member Boards; and Assess Changes in Knowledge and Attitudes of FSMB Member Boards, as Assessed by Surveys (5 Total Payment Installments)	**$87,895.00**	**0.53%**
Purdue Pharma	11/24/2004	2005	Grant for Continued Support of Aforementioned Project	$112,000.00	

Purdue Pharma	3/31/2005	2005	Grant for Continued Support of Aforementioned Project	$132,000.00	
		Total for FY 2005		**$244,000.00**	**1.50%**
Purdue Pharma	7/29/2005	2006	Grant for Continued Support of Aforementioned Project	$132,000.00	
Purdue Pharma	12/13/2005	2006	Grant for Continued Support of Aforementioned Project	$75,000.00	
		Total for FY 2006		**$207,000.00**	**1.05%**
Endo Pharmaceuticals	6/22/2006	2007	Grant in Support of *FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management*	$40,000.00	
Purdue Pharma	7/6/2006	2007	Grant in Support of *FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management*	$50,000.00	
Abbott Laboratories	8/16/2006	2007	Support of *FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management*	$30,000.00	
Cephalon	9/5/2006	2007	Donation	$30,000.00	
		Total for FY 2007		**$150,000.00**	**0.75%**
Alpharma	8/28/2007	2008	Grant to Support the Distribution of *Responsible Opioid Prescribing* to State Medical Boards (SMBs)	$100,000.00	
Endo Pharmaceuticals	9/11/2007	2008	Grant to Support the Distribution of *Responsible Opioid Prescribing* to SMBs	$100,000.00	
Cephalon	9/11/2007	2008	Grant to Support the Distribution of *Responsible Opioid Prescribing* to SMBs	$100,000.00	
Purdue Pharma	11/8/2007	2008	Grant to Support the Distribution of *Responsible Opioid Prescribing* to SMBs	$100,000.00	

		Total for FY 2008		**$400,000.00**	**2.10%**
King Pharmaceuticals	6/17/2008	2009	Grant to Support the Distribution of *Responsible Opioid Prescribing* to SMBs	$100,000.00	
Endo Pharmaceuticals	12/4/2008	2009	Grant to Support the Distribution of *Responsible Opioid Prescribing* to SMBs	$100,000.00	
Alpharma	1/15/2009	2009	Purchase of 20 Copies of *Responsible Opioid Prescribing*	$238.23	
		Total for FY 2009		**$200,238.23**	**1.18%**
King Pharmaceuticals	12/15/2009	**Total for FY 2010**	Support for the Distribution of *Responsible Opioid Prescribing* to SMBs	**$75,000.00**	**0.32%**
Mallinckrodt* (*a Covidien Company)	8/18/2010	2011	Grant to Support the Distribution of *Responsible Opioid Prescribing* to SMBs	$100,000.00	
Cephalon	11/10/2010	2011	Donation to Support the Distribution of *Responsible Opioid Prescribing* to SMBs	$50,000.00	
Endo Pharmaceuticals	1/28/2011	2011	Grant for Proposed CME Activity Related to FDA Opioid REMS	$125,000.00	
Covidien	4/15/2011	2011	Grant for Proposed CME Activity Related to FDA Opioid REMS	$85,000.00	
		Total for FY 2011		**$360,000.00**	**1.60%**
Endo Pharmaceuticals	7/1/2011	**Total for FY 2012**	Purchase of 6,000 Copies of *Responsible Opioid Prescribing*	**$46,620.00**	**0.24%**
Totals		**Total for FY 1997 – 2012**		**$1,964,258.29**	**0.81%**

**The FSMB's Fiscal Year was changed in 1999 from *Dec 1 – Nov 30* to *May 1 – April 30.*

Question 2:
Identify any grants or financial transfers used to fund the production of the book, "Responsible Opioid Prescribing" by Dr. Scott M. Fishman. Provide the date, amount, and source of each grant.

Answer 2:

Payment Description	Payer Organization	Date	Amount of Payment
Grant to Support the *FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management*	Endo Pharmaceuticals	6/22/2006	$40,000.00
Grant to Support the *FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management*	Purdue Pharma	7/6/2006	$50,000.00
Payment to Publisher, Waterford Life Sciences	FSMB Foundation	7/10/2006	$40,000.00
Payment to Publisher, Waterford Life Sciences	FSMB Foundation	7/18/2006	$50,000.00
Support for *FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management*	Abbott Laboratories	8/16/2006	$30,000.00
Payment to Publisher, Waterford Life Sciences	FSMB Foundation	9/20/2006	$25,000.00

Question 3:
How much revenue was generated by sales of "Responsible Opioid Prescribing?" Provide amounts by year, state, and total.

Answer 3:

Revenue from sales includes a combination of retail, in-house and external bulk orders, online sales, and royalties. The following chart reflects revenue based on retail, in-house sales and bulk orders. It should be noted that the amounts listed below are not necessarily an indication of where the books were distributed. For example, JBS International, based in Maryland, is a contractor for SAMHSA, and purchased thousands of copies of the book to distribute at SAMHSA/CSAT educational workshops around the country. The revenue provided by state is based on the origin of the payment.

State & Year	Revenue
Alabama	
2008	$38.85
2009	$42.95
Arizona	
2008	$217.45
2010	$16.80
California	
2009	$1,541.35
2010	$1,213.80
Colorado	
2011	$111.00
Connecticut	
2010	$16.80
Delaware	
2010	$572.74
Florida	
2008	$142.45
Georgia	
2008	$25.90
2009	$621.15
Illinois	
2008	$55.00
2010	$16.80
Indiana	
2009	$149.00
Iowa	
2009	$260.44
Kansas	
2008	$383.47
2009	$4,678.00
2010	$137.80
Kentucky	
2008	$12.95
2009	$245.80
Maine	
2009	$270.35
2011	$137.80
Maryland	
2008	$35,799.44

2009	$787.12
2010	$9,547.51
2011	$5,379.80
Massachusetts	
2008	$25.90
Michigan	
2010	$16.80
Minnesota	
2008	$51.80
2009	$3,133.25
2010	$1,560.91
2011	$1,932.00
Missouri	
2008	$38.85
Nebraska	
2008	$12.95
New Hampshire	
2008	$51.80
2010	$264.12
New Jersey	
2009	$3,368.20
2010	$17.24
2012	$16.80
New York	
2008	$103.60
2010	$287.47
North Carolina	
2008	$29.75
2010	$90.02
Ohio	
2008	$38.85
2009	$16.70
Oklahoma	
2008	$30,000.00
2009	$6,300.00
2011	$137.01
Oregon	
2009	$16.80
Pennsylvania	
2010	$1,165.87

2011	$47,595.66
Rhode Island	
2010	$70.00
South Carolina	
2008	$12.95
Tennessee	
2008	$12.95
2009	$1,054.36
2011	$306.30
Texas	
2009	$3,750.00
Utah	
2008	$25.90
Virginia	
2008	$729.99
2009	$332.75
2010	$15,455.47
Washington	
2008	$12.95
Wisconsin	
2008	$77.70
2009	$97.60
2010	$33.80
2012	$16.80
Wyoming	
2010	$14,825.07
Total (2008-2012):	**$195,509.46**

Additional Sales

Year	Revenue
2008	$262.95
2009	$7,875.16
2010	$657.60
2011	$137.80
Total (2008-2011):	**$8,933.51**

The following chart provides online sales of *Responsible Opioid Prescribing* through Midpoint National, an online order fulfillment company, and includes advanced purchases for the 2nd edition of the book. The sales revenue listed below accounts for the charges deducted by Midpoint National for its fees.

Year	Total Revenue
2009	$11,469.80
2010	$14,352.50
2011	$14,715.29
2012	$12,557.73
Total (2009-2012):	**$53,095.32**

The following chart provides royalties received from the *Responsible Opioid Prescribing* publication:

Year	Total Revenue
2008	$13,437
2009	$4,779
2011	$3,629
Total (2008-2011):	**$21,845**

Question 4:

List each state that has distributed copies of "Responsible Opioid Prescribing" and the number of copies distributed.

Answer 4:

The following is a chart of state-level distributions of *Responsible Opioid Prescribing*. Books were distributed directly by state medical boards or in conjunction with and support from state/federal health departments and agencies, and non-profit organizations.

State	# Books Distributed
Alabama	**450**
Arizona	**100**
Connecticut	**1,130**
District of Columbia	**4,140**
Florida	**9,100**
Georgia	**18,121**
Illinois	**500**
Iowa	**1,550**
Maine	**3,840**
Michigan	**42,366**
Minnesota	**900**
Montana	**1,800**
New Hampshire	**4,100**
New Mexico	**4,500**

North Carolina	**2,000**
North Dakota	**300**
Oklahoma	**6,000**
Pennsylvania	**601**
Rhode Island	**6,006**
South Carolina	**8,070**
Vermont	**4,412**
Virginia	**20,000**
Washington	**15,395**
West Virginia	**5,200**
Wyoming	**2,550**
Total:	**163,131**

Question 5:

Provide the names of any people or organizations, other than Federation of State Medical Boards employees or Dr. Scott M. Fishman, involved in writing or editing the content of "Responsible Opioid Prescribing."

i. For each person or organization identified, list any financial transfers between the identified person or organization and the Federation of State Medical Boards.

ii. For each individual or organization identified, provide a description of the involvement.

Answer 5:

The following individuals participated in advising, writing, and/or editing the content of the first or second edition of *Responsible Opioid Prescribing*. The job title presented below corresponds with the participant's position held at the time of the production of each edition of *Responsible Opioid Prescribing*.

The following individuals did not receive monetary compensation or an honorarium from the FSMB or its Foundation for their participation in the production of *Responsible Opioid Prescribing*.

Several individuals serving on the Advisory Board, including then FSMB Chair and current U.S. Surgeon General Regina M. Benjamin, MD, MBA, and William L. Harp, MD, Executive Director of the Virginia Board of Medicine, have served the FSMB and its Foundation in various capacities (i.e. Board and Committee leadership, workgroups, educational faculty, etc.), and some may have received travel reimbursements and/or stipends in connection with other FSMB-related activities. Such financial transfers were not related in any way to the production of the book.

***Responsible Opioid Prescribing*: A Physician's Guide (2007)**

Advisory Board:

Upon the author's completion of the manuscript of 'Responsible Opioid Prescribing', the Advisory Board was *charged with reviewing content and making recommendations as deemed necessary.*

Regina M. Benjamin, MD, MBA
Bayou Clinic
Bayou La Barre, AL
Chair, FSMB Board of Directors

Anton C. Bizzell, MD
Immediate Past Medical Officer
Center for Substance Abuse Treatment
Division of Pharmacologic Therapies
Substance Abuse & Mental Health Administration

Myra Christopher
President/CEO
Center for Practical Bioethics

Perry G. Fine, MD
Professor of Anesthesiology
University of Utah, School of Medicine

Rollin M. Gallagher, MD, MPH
Director, Center for Pain Medicine, Research & Policy
University of Pennsylvania

Aaron Gilson, PhD
Co-Director for U.S. Policy Research
Pain & Policy Studies Group/WHO Collaborating Center
University of Wisconsin-Madison

William L. Harp, MD
Executive Director
Virginia Board of Medicine

Rebecca A. Kirch
Associate Director of Policy
American Cancer Society

Michael Moskowitz, MD
Assistant Professor, Anesthesiology and Pain Medicine,
School of Medicine, University of California, Davis

David Thornton
Immediate Past Executive Director
Medical Board of California

Medical Writer:
The medical writer assisted the author with writing and editorial support.

Stephen Braun

Associate Editors
The Associate Editors reviewed the full manuscript and offered suggested edits and identified any content concerns.

Perry G. Fine, MD
Rollin M. Gallagher, MD, MPH
Aaron Gilson, PhD

Michael Moskowitz, MD, MPH

***Responsible Opioid Prescribing*: A Clinician's Guide (2012)**

Advisory Board

Roger Chou, MD
Associate Professor, Departments of Medicine and Medical Informatics & Clinical Epidemiology
Oregon Health & Science University School of Medicine, Portland, OR

Rollin M. Gallagher, MD, MPH
Clinical Professor of Psychiatry and Anesthesiology
Director, Center for Pain Medicine, Research & Policy University of Pennsylvania
Deputy National Program Director for Pain Management, Veterans Affairs Health System

Marc B. Hahn, DO
Dean and Senior Vice President for Health Affairs, University of New England, Biddeford & Portland, Maine, College of Osteopathic Medicine, Biddeford, ME

William L. Harp, MD
Executive Director, Virginia Board of Medicine, Perimeter Center, Henrico, VA

Scott G. Kirby, MD
Medical Director, North Carolina Medical Board, Raleigh, NC

Sandrine Pirard, MD. PhD, MPH
Medical Officer, Division of Pharmacologic Therapies, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Administration, Rockville, MD

Janelle Rhyne, MD, MA, MACP
FSMB Chair, Medical Director, Cape Fear Health Net, Health Net Clinic, Wilmington, NC

Medical Writer

Stephen Braun

Question 6:

Please identify the name, job title, job description, and dates employed of any Federation of State Medical Boards employees who worked on distributing this book.

Answer 6:

The following employees of the Federation of State Medical Boards (FSMB) served in some capacity in the development and/or distribution of the *Responsible Opioid Prescribing* publication.

Last Name	First Name	Job Title	Job Description	Dates of Employment
Alfred	Kelly	FSMB Director, Education Services	Under the supervision of the Chief Advocacy Officer, the Director of Education Services manages all functions of the Education Department. This includes the development and delivery of educational services, programs and products, providing educational assistance to state medical boards, and collaborating with external entities in the interest of state medical boards.	3/2/98-present
Austin	Dale	FSMB Senior Vice President and Chief Operating Officer (Interim Executive Vice President 2001-2002)	Reporting directly to the President as Chief Executive Officer (CEO), the Senior Vice President serves as the Federation's Chief Operating Officer (COO). Under guidelines and parameters established with the President, the Senior Vice President is responsible for management and oversight of all internal operations of the Federation's national office, both administrative and programmatic. This person maintains a cohesive work force in an effective organizational structure based on teamwork and accountability. Through appropriate executive and management staff, the Senior Vice President oversees implementation of new and enhanced work processes and resource allocations that more efficiently and effectively accomplish the mission, goals and objectives of the Federation and promote a positive working environment for all employees.	2/20/95-11/30/08
Bransford	Denise	Manager, IMIS Solutions	The Manager of IMIS Services plans, maintains and ensures the accessibility of the FSMB's member services database and member services products to the FSMB and our member boards. Responsibilities include collecting dues, subscriptions and orders; invoicing; ensuring data integrity and accessibility; internal and external user support; managing customer relationships with member boards; data gathering; and meeting internal customer reporting requests.	5/5/97-present
Chaudhry, DO, FACP	Humayun	FSMB President and Chief Executive Officer	Under the general direction of the Board of Directors, the President/CEO for the Federation of State Medical Boards (FSMB) is responsible for the overall leadership and corporate direction of the organization's activities. The President/CEO serves as the primary spokesperson and represents the FSMB to the leadership of other organizations as the premier organization concerned with medical licensure and discipline. The President/CEO has the ultimate responsibility for carrying out the mission of the FSMB and achieving all of its	10/19/09-present

			goals in a manner that is in keeping with the core values of the organization. Key partnerships include those with the National Board of Medical Examiners, the Education Commission for Foreign Medical Graduates, the American Medical Association, the Association of American Medical Colleges, and the American Osteopathic Association.	
Jagoda	Jonathan	Director, Federal Government Relations	The Director of Federal Government Relations is a position within the Federation of State Medical Boards (FSMB) Washington, D.C. Advocacy Office that reports directly to the Chief Advocacy Officer. The position contributes to the overall success of the FSMB's Washington, D.C. Advocacy Office in achieving advocacy and policy goals.	7/28/10 – present
McCullough	Randy	Senior Director, Finance	The Sr. Director of Finance is responsible for presenting and analyzing all pertinent financial information in an accurate and understandable format. This information is reported directly to the executive staff and includes the preparation of financial statements, quarterly variance reports, and the tracking of investments. In addition, the Sr. Dir of Finance is heavily involved in the budgeting process for the Federation.	1/11/88- present
Paxton	Bill	Director, Legislative Services	The Director of Legislative Services has responsibility for the management of all functions of the organization's legislative services and government relations, including: research, review, and monitoring of federal and state legislation and regulations relating to FSMB policies and medical licensure and regulation; communicating with and providing assistance to state medical boards on legislative issues and strategies; coordinating operation of the Internet Clearinghouse; coordinating interaction with government relations firms and legislative tracking service. The Director works closely with senior staff and provides administrative support to special committees and workgroups in developing policy. The Director develops relationships and seeks to collaborate with external entities on issues that affect medical regulation and impact public health and safety.	7/12/04- 12/1/06
Robin	Lisa	FSMB Chief Advocacy Officer	The Chief Advocacy Officer (CAO) directs the FSMB's Washington, DC advocacy office and directly oversees and manages a wide range of services on behalf of and promoting state medical and osteopathic boards and the FSMB. These include: state and federal legislative services, advocacy and outreach activities, public policy, education, and public affairs and other projects as	8/24/94 – present

			assigned by the President/CEO. The CAO oversees the FSMB federal and state public policy strategy, which entails formulating and implementing the FSMB's legislative and regulatory agenda on behalf of FSMB member boards and the FSMB.	
Schneidman, MD	Barbara	FSMB President	Under the general direction of the Board of Directors, the President/CEO for the Federation of State Medical Boards (FSMB) is responsible for the overall leadership and corporate direction of the organization's activities. The President/CEO serves as the primary spokesperson and represents the FSMB to the leadership of other organizations as the premier organization concerned with medical licensure and discipline. The President/CEO has the ultimate responsibility for carrying out the mission of the FSMB and achieving all of its goals in a manner that is in keeping with the core values of the organization. Key partnerships include those with the National Board of Medical Examiners, the Education Commission for Foreign Medical Graduates, the American Medical Association, the Association of American Medical Colleges, and the American Osteopathic Association.	1/1/09-10/16/09
Still	Sheila	Administrative Assistant, Education	The Administrative Assistant for Education Services is a shared position of responsibilities that consists of administrative duties relating to the functions of the Education department and the Director of Education Services, and the FSMB Librarian. The Administrative Assistant will perform a variety of complex administrative duties requiring a thorough knowledge of office procedures and will possess the ability to work independently as well as the ability to interact with FSMB executive leadership and staff.	6/5/00 - present
Thompson, MD	James	FSMB President and Chief Executive Officer	Under the general direction of the Board of Directors, the President/CEO for the Federation of State Medical Boards (FSMB) is responsible for the overall leadership and corporate direction of the organization's activities. The President/CEO serves as the primary spokesperson and represents the FSMB to the leadership of other organizations as the premier organization concerned with medical licensure and discipline. The President/CEO has the ultimate responsibility for carrying out the mission of the FSMB and achieving all of its goals in a manner that is in keeping with the core values of the organization. Key partnerships include those with the National Board of Medical Examiners, the Education	3/4/02-10/31/08

			Commission for Foreign Medical Graduates, the American Medical Association, the Association of American Medical Colleges, and the American Osteopathic Association.	
Turner	Michelle	FSMB Director, Professional Development and Member Data Services	The Director is responsible for the design, development, and implementation of educational programs for the professional growth and development of FSMB's leadership and support staff.	7/16/99-present
Winn, MD	James	Executive Vice President	Under the general direction of the Board of Directors, the President/CEO for the Federation of State Medical Boards (FSMB) is responsible for the overall leadership and corporate direction of the organization's activities. The President/CEO serves as the primary spokesperson and represents the FSMB to the leadership of other organizations as the premier organization concerned with medical licensure and discipline. The President/CEO has the ultimate responsibility for carrying out the mission of the FSMB and achieving all of its goals in a manner that is in keeping with the core values of the organization. Key partnerships include those with the National Board of Medical Examiners, the Education Commission for Foreign Medical Graduates, the American Medical Association, the Association of American Medical Colleges, and the American Osteopathic Association.	10/1/94-9/11/01

Conclusion

The FSMB, and the state medical boards it represents, are committed to helping address the nation's dual public health issues of under-treated pain and opioid prescription misuse, abuse and diversion. The FSMB shares the Committee's concern over the problems stemming from addiction to opioid medications. The FSMB has launched a wide range of activities in response, ranging from educational initiatives for physicians to close collaboration with federal health care and law enforcement agencies and strong efforts to expand tools such as prescription drug monitoring programs.

At the center of the FSMB's work is the belief that the prescribing of medications that are FDA-approved for pain management, such as long-acting and extended release opioids, should involve a careful balance by physicians between the benefits of these medications to control pain and suffering, and the rising concerns associated with their misuse, abuse and diversion.

The FSMB supports educating physicians about these concerns and emphasizing responsible and appropriate prescribing when a decision is made to use this class of drugs.

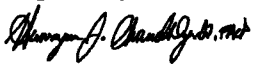
The FSMB and state medical boards' efforts to educate physicians about the responsible prescribing of opioids do not advocate for opioid therapy; but rather, ensure that those who do choose to prescribe FDA-approved pain medications do so in a medically appropriate way that properly manages risk and reduces adverse outcomes.

The FSMB's efforts give physicians the knowledge and understanding of best practices and guidelines so they have the confidence to prescribe in a manner that ensures patient safety and is in compliance with federal regulations. This is in direct alignment with the FSMB's mission and purpose of protecting the public and the integrity of medical practice while ensuring access to medical treatment.

The FSMB joins other medical organizations in acknowledging the need for more robust data on opioid use and effectiveness. Until more data is available, we must ensure that physicians fully understand and adhere to best-practice guidelines for the proper prescribing of these drugs. In a major report on pain in 2011, the IOM concurred, writing: "Health professions education and training programs, professional associations, and other groups that sponsor continuing education for health professionals should develop and provide educational opportunities for primary care practitioners and other providers to improve their knowledge and skills in pain assessment and treatment, including safe and effective opioid prescribing."[17] The FSMB is committed to filling this vital need as a part of its service to the nation.

We urge you to read these documents in their entirety and full medical context. We stand ready to provide any additional information, if needed, and welcome the opportunity to discuss these questions further with you personally. We would also be pleased to engage in a full discussion with you regarding the FSMB Model Policies and our publication, *Responsible Opioid Prescribing*.

Respectfully,



Humayun J. Chaudhry, DO, FACP
President and CEO

Enclosures

1) *The Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (1998)
2) *The Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office* (2002)
3) *The Model Policy for the Use of Controlled Substances for the Treatment of Pain* (2004)
4) *Balance, Uniformity and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice*. (2009)
5) *Responsible Opioid Prescribing*: A Clinician's Guide (2012)

References

1. American Medical Association. *AMA Policy H-120.944: Standards, Laws, and Regulations Addressing Pain Medications and Medical Practice.* https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-120.944.HTM. Accessed May 30, 2012.

2. Gil Kerlikowske, Director of the Office of National Drug Control Policy. From a speech delivered at the Federation of State Medical Boards Annual Meeting, Forth Worth, Texas, April 26, 2012. Mr. Kerlikowske's full comment: "There's a real gap in the amount of education and training that is provided around pain management, addiction, treatment, tolerance, dependence, etcetera. We know that that's an important issue... and I am going to talk about that in particular. Because I could not be more pleased, frankly, and I could not be more proud of the work that you all have done in this area... I was just given the latest edition of the Clinician's Guide for Responsible Opioid *Prescribing* by Dr. Fishman, boy, I could not be more proud of what you are doing with that. The second edition of this, being distributed across literally by the tens of thousands, I'm sure, is just a wonderful, wonderful step in the right direction of putting something that is so well written in the hands of very busy professionals that need that information. I commend you and my hat is off to you for doing that... So we could not be more pleased or proud of the cooperation and collaboration that we have with all of you. I am truly in awe of the work that you have done and the way you have taken this on."

3. Centers for Disease Control and Prevention. *Prescription Painkiller Overdoses in the U.S.* November, 2011. http://www.cdc.gov/Features/Vitalsigns/PainkillerOverdoses/. Accessed May 22, 2012.

4. Institute of Medicine of the National Academies. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*; June 2011.

5. Federation of State Medical Boards of the United States. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*; May 1998.

6. Federation of State Medical Boards of the United States. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*; May 2004.

7. William L. Harp, MD, Executive Director, Virginia Board of Medicine. Letter of endorsement to the Federation of State Medical Boards, July 29, 2011.

8. Janet Mills, Attorney General, State of Maine. Remarks to the Maine Medical Association Practice Education Seminar, June 3, 2009. http://www.mainemed.com/spotlight/2009/AttorneyGeneral_Speech_PracticeEducationSeminar.pdf. Accessed May 22, 2012.

9. Gil Kerlikowske, Director of the Office of National Drug Control Policy. From a speech delivered at the Federation of State Medical Boards Annual Meeting, April 26, 2012.

10. United States Food and Drug Administration. *Draft Blueprint for Prescriber Education for the Long-Acting/Extended-Release Opioid Class-wide REMS.* November 4, 2011. http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM277916.pdf. Accessed May 22, 2012.

11. United States Office of National Drug Control Policy. Epidemic: Responding to America's Prescription Drug *Crisis*. 2011.

12. Federation of State Medical Boards of the United States, Center for Practical Bioethics, National Association of Attorneys General. *Balance, Uniformity and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice*. February 2009.

13. Ibid.

14. Ibid., p. 11

15. Ibid.

16. Federation of State Medical Boards of the United States. "FSMB Announces Opioid Prescribing Initiative." News release, Feb. 17, 2012. http://www.fsmb.org/pdf/nr-opioid.pdf. Accessed May 22, 2012.

17. Institute of Medicine of the National Academies. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*; June 2011.

EXHIBIT 1-J

IN THE DISTRICT COURT OF CLEVELAND COUNTY

STATE OF OKLAHOMA

No. CJ-2017-816

- - - - - - - - - - - - - - - - - - - X

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER, ATTORNEY GENERAL
OF OKLAHOMA,

Plaintiff,

v.

(1) PURDUE PHARMA, L.P., et al.,

Defendants.

- - - - - - - - - - - - - - - - - - - X

COMPLETE CAPTION ON PAGE 2

- - - - - - - - - - - - - - - - - - - X

VOLUME I Pages 1-542

DEPOSITION OF RUSSELL PORTENOY, M.D.

Thursday, January 24, 2019, 10:49 a.m.

Shaheen & Gordon, P.A.

107 Storrs Street

Concord, New Hampshire 03301

-- Reporter: Kimberly A. Smith, CSR, CRR, CRC, RDR --

Realtime Systems Administrator

U.S. Legal Support

Would you agree that opioid manufacturers are not all the same?

A. I'm going to ask you to clarify when you say "not all the same." In what context?

Q. Sure. There are different manufacturers of opioids, correct?

A. Correct.

Q. And those companies manufacture different opioid medicines, correct?

A. Yes.

Q. And those companies sell different opioid medicines, correct?

A. Yes.

Q. And some of those medicines may be generic opioids; is that fair?

A. Yes.

Q. And some of those medicines may be brand medications; is that fair?

A. Yes.

Q. And is it also fair to say that different opioid companies engage in different types of marketing?

A. I don't -- I can't answer specifically, but I think that that's a fair statement.

Q. Sure. And is it fair to say that different

opioid manufacturers may say different things about their medicines?

A. That's a fair statement too.

Q. And is it fair to say that with respect to opioid medicines, that they differ?

A. Yes.

Q. Some are long-acting opioids?

A. Yes.

Q. Some are short-acting opioids?

A. Yes.

Q. And there are other differences as well, correct?

A. Yes.

Q. Different delivery systems, for instance?

A. That's right.

Q. Dr. Portenoy, have you ever heard of Watson Laboratories, Inc.?

A. Yes.

Q. And have you heard about Watson Laboratories, Inc. in connection with this case?

A. I --

MS. SPENCER: When you say "this case," you mean the State of Oklahoma versus these companies involved here today, or do you mean --

MR. ERCOLE: I mean -- Sorry. I didn't

mean to cut you off.

MS. SPENCER: -- the more general opioid litigation that is pending, you know, here and elsewhere?

MR. ERCOLE: Sure.

BY MR. ERCOLE:

Q. I mean this particular case, the State of Oklahoma versus the pharmaceutical manufacturers, the reason why you're here today.

A. Yeah. I'm not aware that I heard about Watson Laboratories in this context.

Q. Do you recall any communications that you've had with Watson Laboratories, Inc.?

A. I don't.

Q. Are you aware of any marketing that Watson Laboratories, Inc. has done?

A. I'm not.

Q. Are you aware of any funding that Watson Laboratories, Inc. has given to you or any of your employers?

A. Not that I recall.

Q. Dr. Portenoy -- and just to clarify, going forward, when I refer to "this case," I'm referring to the State of Oklahoma case --

MS. SPENCER: Thank you.

BY MR. ERCOLE:

Q. -- and if you do have a question or you're not understanding what I'm saying, please just raise that issue --

A. Sure.

Q. -- and I'll clarify for you.

A. Thank you.

Q. Dr. Portenoy, are you familiar with the entity Actavis LLC?

A. Not specifically.

Q. Are you aware of any communications that you've ever had with Actavis LLC?

A. I'm not.

Q. Are you aware of any marketing ever done by Actavis LLC?

A. Not that I'm aware of.

Q. Are you aware of any funding Actavis LLC has ever given to you or any of your employers?

A. Not that I recall.

Q. Dr. Portenoy, are you familiar with the entity Actavis Pharma, Inc.?

A. Not that I recall, no.

Q. Are you aware of -- Strike that.

Have you had any communications with Actavis Pharma, Inc.?

A. No.

Q. Are you aware of any marketing of any products that Actavis Pharma, Inc. has done?

A. Not that I'm aware of.

Q. Are you aware of any funding that Actavis Pharma, Inc. has given to you or any of your employers?

A. No.

Q. Are you aware of any of the products that Actavis Pharma, Inc. manufactures?

A. I'm not. But I have to say that, as you know, in the pharmaceutical industry, names change and companies are acquired by other companies. And it's possible that I've lost track of what products have been sold to other companies.

So I don't have a recollection about Actavis. But if I found out, for example, that they were a manufacturer of one of the drugs involved in the litigation, it wouldn't surprise me. It means that they just acquired that product and I wasn't aware of it.

Q. Sir, sitting here today, you're not aware of any products that Actavis Pharma, Inc. manufactures, correct?

A. I am not aware, no.

Q. And you're not aware of any products that Actavis Pharma, Inc. has manufactured in the past --

A. No.

Q. -- correct?

A. That's correct.

Q. Would the same apply to Actavis LLC?

A. Yes.

Q. Would the same apply to Watson Laboratories?

A. Yes.

Q. Dr. Portenoy, if you can pull up your declaration. I think it's Exhibit 2.

A. I have it, yes.

Q. Great. You agree, I think you testified before, that this case is a very serious case, correct?

A. Yes.

Q. And is it fair to say that the assertions made in your declaration are serious too, correct?

A. I think that's true.

Q. Sure. If you turn to paragraph 30 of your declaration --

A. Um-hum.

MS. SPENCER: Page 19.

BY MR. ERCOLE:

Q. Yes. Take your time to get there.

A. Um-hum.

Q. The State asked you some questions earlier about paragraph 30. Do you recall that?

A. Yes.

Q. And by "the State" -- and I mean --

MS. SPENCER: We know.

BY MR. ERCOLE:

Q. -- Mr. Beckworth, who's representing the State here.

A. Yes.

Q. And Mr. Beckworth walked you through some of the examples from (a) to (p) in that declaration, correct?

A. Yes.

Q. So if you can turn to paragraph 30(c), do you see that?

A. Yes.

Q. And it refers to, in paragraph 30(c), a seminar titled "Breakthrough pain curriculum development workshop"?

A. Yes.

Q. And in there, it says, "I believe this was financed ultimately by Cephalon, Inc. related to its

EXHIBIT 1-K

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

= =

STATE OF OKLAHOMA, ex rel,
MIKE HUNTER, ATTORNEY GENERAL
OF OKLAHOMA,

Plaintiff,

-vs- Case No. CJ-2017-816

PURDUE PHARMA, LP,
et al.,

Defendants.

= =

Videotaped Deposition of:

KENNETH J. MOUNT

Madison, Wisconsin
December 19, 2018

Reporter: Taunia Northouse, RDR, CRR, CRC

Q Has that funding ever influenced any publications by PPSG?
A Not that I am aware of.
Q Has that funding ever influenced how PPSG thinks about opioids?
A Not that I am aware of.
Q Has any pharmaceutical manufacturer, including the defendants here, ever directed or controlled PPSG?
A Not that I'm aware of.
Q PPSG stopped accepting funding from manufacturers in 2011; correct?
A Correct.
Q This was because of a change in the University of Wisconsin's conflict policies; correct?
A I'm not sure I can say that was the exact cause, but it does correlate with that, yes.
Q Did the fact that funding from manufacturers stopped in 2011 alter PPSG's primary purpose?
A No.
Q Did the fact the funding from manufacturers stopped in 2011 affect PPSG's views on opioid use?
A Not that I know of, no.
Q After funding stopped in 2011, did PPSG continue its efforts to promote the medically appropriate use of opioids to treat pain?

A Yes.
Q And the State didn't mention the Actavis or Watson entities today; correct?
A I do not recall that being mentioned.
Q Are you aware of any funding from these entities?
A No, other than what was reported.
Q And are you aware of any communication between these entities and PPSG?
A No.

MS. LEIBELL: That's all I have.

RE-EXAMINATION

By Ms. Baldwin:
Q I have some additional questions.
A Okay.
Q Teva's attorney just asked you some questions about whether or not you are aware of whether the pharmaceutical funding that PPSG influenced the opinions of PPSG, affected their advocacy in any way, affected their work product. You testified that you weren't aware of that occurring; is that correct?
A Correct.
Q But you don't know one way or the other, do you?

MR. SPARKS: Object to the form.

MS. LEIBELL: Object to the form.

MR. McANANEY: Object to the form.

A I did not participate in their actual intake/outputs, so no, I did not have firsthand knowledge of that.

Q Now, Mr. Sparks, the attorney for Janssen, asked you several questions about the spreadsheet that you created.

A Yes.

Q I have some follow-up questions about that. If you turn to page 4, Mr. Sparks asked you some questions about the University of Texas's funding of PPSG; is that correct?

A Yes.

Q And some general questions about the university itself; is that correct?

A Yep. Yes.

Q Does the University of Texas manufacture opioids?

A Not to my knowledge.

Q Does the University of Texas make the active pharmacal ingredients in opioid products?

A Not to my knowledge.

Q Does -- did the University of Texas give a scientist an award for accomplishing engineering the opioid poppy for the purpose of proliferating

I assume you can't add in your head.

A In this case --

Q It's the total.

A -- 1.78 million plus 707,000 and change.

Q From pharmaceutical manufacturers?

A Yes.

MR. SPARKS: Object to the form.

Q Mr. Sparks, Janssen's counsel, asked you some questions about the UW Foundation. Do you recall that?

A Yes.

Q And I believe you testified that the UW Foundation funding that it provides to PPSG actually comes from other donors?

A Yes.

Q Is that correct? Do you know who those donors are?

A I do not.

Q Do you know if any of those donors are pharmaceutical companies?

MR. SPARKS: Objection. Form.

A I do not specifically.

Q Teva's attorney asked you some questions; is that correct?

A Yes.

Q She asked you if you received any money from the Actavis defendants, didn't she?

MR. SPARKS: Object to the form.

A Yes.

Q And you testified that, no, that PPSG had not received any money from the Actavis defendants; is that correct?

A I believe I stated they were not on the list, that I'm not aware of any funding.

Q But she was not honest with you, was she?

MR. SPARKS: Objection to form.

MS. LEIBELL: Objection to form.

MR. McANANEY: Object to the form.

Q Because PPSG received money from King Pharmaceuticals, didn't it?

A King -- we did --the group did receive funding from King Pharmaceuticals.

Q And King Pharmaceuticals made a drug called Kadian; are you aware of that?

A I am not.

Q And she didn't tell you that King Pharmaceuticals sold that drug to her client Actavis, did she?

MR. SPARKS: Object to the form.

MS. LEIBELL: Object to the form.

MR. McANANEY: Object to the form.

A No.

MS. BALDWIN: I have no further questions.

MR. McANANEY: I have one -- I have a couple questions.

RE-EXAMINATION

By Mr. McAnaney:

Q You just noted that attorneys for Janssen, Teva, and Purdue objected to a lot of the State's questions; correct?

A Yes.

Q And your lawyer objected to a lot of the State's questions; right?

A Correct.

Q Your lawyer didn't object to any of Purdue's questions; correct?

A No.

Q Your lawyer didn't object to any of Janssen's questions; correct?

A Correct.

Q Your lawyer didn't object to any of Teva's questions; correct?

A Correct.

Q Is your lawyer in cahoots with lawyers for Purdue,

Teva, and Janssen?
A Not to my knowledge.
MR. McANANEY: No further questions.
MS. LEIBELL: One follow-up. Sorry.

RE-EXAMINATION

By Ms. Leibell:
Q Is King Pharma the same as Actavis?
A I am not aware of that specifically.
MS. LEIBELL: That's all I have.

RE-EXAMINATION

By Mr. Sparks:
Q Sir, have we ever spoken today -- before today?
A Prior to today? No.
Q Do you know if I've ever spoken with your lawyers prior to today?
A Not that I'm aware of.
Q Do you know if you or your lawyers have ever spoken to plaintiff's counsel prior to today?
A I do not. I know they've had to communicate with various attorneys to comply with the process, but I don't know specifically.

Q Prior to today, if I told you prior to today your lawyers had communicated with the lawyers for plaintiff, not defendants, do you have any reason not to believe that?

A No.

MR. SPARKS: Thank you.

THE VIDEOGRAPHER: Going off the record at 4:48, media 3 of 3. End of deposition. Microphones are off.

(adjourning at 4:48 p.m.)

EXHIBIT 1-L

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
MACON DIVISION

PATRICIA FAYE ALLEN, Individually and as the Administrator of the Estate of Tracy Faye Edge, *Plaintiff,* **v.** **VINTAGE PHARMACEUTICALS LLC d/b/a PAR PHARMACEUTICAL; ENDO HEALTH SOLUTIONS, INC.; and RHODES PHARMACEUTICALS LP,** *Defendants.*	**CIVIL ACTION NO. 5:18-cv-00329-TES**

ORDER GRANTING MOTIONS TO DISMISS AND DENYING MOTION TO AMEND

There are five motions presently pending in this case: Defendants' Motions to Dismiss [Docs. 4, 13]; Defendant Rhodes Pharmaceuticals' ("Rhodes") Motion Seeking Judicial Notice [Doc. 5]; Rhodes's Motion to Strike Plaintiff's Amended Complaint [Doc. 17]; and Plaintiff's Motion to Amend her Complaint [Doc. 19]. As discussed below, Rhodes's Motion to Dismiss, Motion Seeking Judicial Notice, and Motion to Strike are **GRANTED**; Defendant Vintage Pharmaceuticals, LLC d/b/a Par Pharmaceutical's ("Par") Motion to Dismiss is **GRANTED**; and Plaintiff's Motion to Amend is **DENIED as futile**.

FACTUAL BACKGROUND[1]

On April 20, 2016, Plaintiff's daughter, Tracy Faye Edge, died from "Morphine and Amitriptyline toxicity" and "opioid toxicity" after being prescribed the two medications less than one month apart. [Doc. 19-1, ¶¶ 4, 8–10, 41, 56]. According to Plaintiff, Rhodes, who manufactured the morphine prescribed to Ms. Edge, and Par, who was a manufacturer of amitriptyline, knew or should have known of the danger posed by combining the two drugs but "failed to exercise ordinary care" and "issued no warnings regarding the toxicity." [*Id.* at ¶¶ 2, 5, 21–23]. Plaintiff also alleges that both Defendants "knew or should have known . . . that Plaintiff should have never been prescribed, dispensed, marketed or sold the prescription drugs that caused Plaintiff's death." [*Id.* at ¶ 33]. Moreover, Plaintiff claims that "opioid manufacturers such as Rhodes and [Par] market and claim in literature that opioids are safer than a Tylenol" and "encourage doctors to write prescriptions for opioids . . . [by] touting [them] as safe, and non-habit forming," even though such marketing is "false, misleading and causes harm," including the harm that befell Ms. Edge. [*Id.* at ¶¶ 59–62]. According to Plaintiff, Defendants had a duty to market "dangerous drugs" (presumably including morphine and amitriptyline) as "dangerous drugs of last resort." [*Id.* at ¶ 67]. In addition to marketing to doctors, Plaintiff claims that Defendants deliberately marketed to Ms. Edge by mail. [*Id.* at ¶ 17].

[1] The following facts are taken from Plaintiff's amended complaint and proposed amended complaint, which are identical.

With regard to Rhodes in particular, Plaintiff claims it knew or should have known "of the danger of opioid toxicity" and "that any opioid drugs prescribed to any patient . . . could prove fatal" but "continued to market and encourage doctors to prescribe opioids such as [m]orphine" anyway. [*Id.* at ¶¶ 24, 25]. Plaintiff also charges Par with failing to warn Ms. Edge[2] of the adverse effects associated with combining morphine and amitriptyline, even though it had a duty to issue such a warning under the Omnibus Budget Reconciliation Act of 1990. [*Id.* at ¶¶ 26, 27]. Plaintiff conclusorily and repeatedly alleges that these acts and omissions were the proximate cause of Ms. Edge's death and Plaintiff's injuries. [*Id.* at ¶¶ 35, 36, 40–42, 44, 47–49, 62, 64, 71].

PROCEDURAL HISTORY

Plaintiff filed her original complaint on September 10, 2018. [Doc. 1]. Rhodes filed its motion to dismiss on November 9, 2018 [Doc. 4], and Par filed its motion to dismiss on November 30, 2018 [Doc. 13]. On December 3, 2018—24 days after Rhodes filed its motion to dismiss and three days after Par filed its motion to dismiss—Plaintiff filed an amended complaint [Doc. 16], which Rhodes moves to strike as untimely [Doc. 17]. Fourteen days later (and likely in response to Rhodes's motion to strike), Plaintiff moved

[2] The amended complaint actually claims that Par should have warned "Plaintiff about the adverse effects associated with the Plaintiff's prescribed [m]orphine . . . combined with [a]mitriptyline . . . ." [Doc. 19-1, ¶ 26]. Because Patricia Faye Allen is a plaintiff to this action in her individual capacity as it relates to her wrongful death claim and there are no allegations that she took the drugs in question, the Court assumes Plaintiff intended to claim that Par failed to warn Ms. Edge of the adverse effects of mixing her prescriptions.

to amend her complaint and attached a proposed amended complaint identical to her previously-filed amended complaint. [Doc. 19].

As discussed herein, Rhodes' motion to strike is granted, as is its motion to dismiss. Par's motion to dismiss is likewise granted. Plaintiff's motion to amend is denied as futile.

DISCUSSION

A. Standard of Review

When ruling on a 12(b)(6) motion, the Court must accept the facts set forth in the complaint as true. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 572 (2007). A complaint survives a motion to dismiss only if the plaintiff alleges sufficient factual matter to state a claim for relief that is plausible on its face, and he must state more than "unadorned, the-defendant-unlawfully-harmed-me accusations." *McCullough v. Finley*, 907 F.3d 1324, 1333 (11th Cir. 2018) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009)). He must also "plead more than labels and conclusions or a formulaic recitation of the elements of a cause of action," *id.*, such that the factual allegations contained in the complaint are "enough to raise a right to relief above the speculative level," *Twombly*, 550 U.S. at 555.

When assessing a motion to dismiss for failure to state a claim, the Court employs a two-step framework. *McCullough*, 907 F.3d at 1333. First, the Court identifies and disregards allegations that are "no more than mere conclusions," since "[c]onclusory allegations are not entitled to the assumption of truth." *Id.* (quoting *Iqbal*, 556 U.S. at 679).

Second, the Court "assume[s] any remaining factual allegations are true and determine[s] whether those factual allegations 'plausibly give rise to an entitlement to relief.'" *Id.* (quoting *Iqbal*, 556 U.S. at 679).

Under Federal Rule of Civil Procedure 15(a)(2), the Court should freely grant leave to amend when justice so requires. However, the Court may deny leave to amend "(1) where there has been undue delay, bad faith, dilatory motive, or repeated failure to cure deficiencies by amendments previously allowed; (2) where allowing amendment would cause undue prejudice to the opposing party; or (3) where amendment would be futile." *Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001). An amendment is futile, for example, "when the complaint as amended is . . . subject to dismissal because . . . it fails to state a claim for relief." *Chang v. JPMorgan Chase Bank, N.A.*, 845 F.3d 1087, 1094 (11th Cir. 2017) (quoting *Hall v. United Ins. Co. of Am.*, 367 F.3d 1255, 1262–63 (11th Cir. 2004)).

B. Rhodes's Motion to Strike Plaintiff's Amended Complaint

As a preliminary matter, Rhodes has moved to strike Plaintiff's Amended Complaint [Doc. 16] as untimely. The Federal Rules of Civil Procedure allow a party to amend a pleading once as a matter of right within either (a) 21 days after serving the original pleading; or (b) 21 days after the other party files a responsive pleading or a motion to dismiss the original pleading under Rule 12(b), (e), or (f), whichever is earlier. Fed. R. Civ. P. 15(a)(1). Once a party can no longer amend as a matter of right, it must

obtain the other party's consent or leave of court before amending its pleading. *Id.* at (a)(2).

Plaintiff filed her original complaint on September 10, 2018. Rhodes filed its Rule 12(b)(6) Motion to Dismiss on November 9, 2018 and has not yet filed an answer. Par filed its Rule 12(b)(6) Motion to Dismiss on November 30, 2018 and has also not filed an answer. Plaintiff filed her Amended Complaint on December 3, 2018. Therefore, Plaintiff filed her Amended Complaint 24 days after Rhodes filed its motion to dismiss and three days after Par filed its motion to dismiss.[3] While it is clear that the Court must strike the Amended Complaint as to Rhodes, it is unclear whether the Amended Complaint is binding on Par.

Courts differ on when the clock starts for amending as a matter of right in cases where there are multiple defendants who have filed responsive pleadings or Rule 12(b), (e), or (f) motions. For example, the District Court for the District of Columbia held that an amended complaint filed as a matter of right is effective on all defendants who have not filed a responsive pleading or defensive motion more than 21 days prior to the day the plaintiff filed the amended complaint.[4] *Villery v. District of Columbia*, 277 F.R.D. 218,

[3] On December 3, 2018, Plaintiff requested and received a 14-day extension of time to file responses to Defendants' motions to dismiss pursuant to Local Rule 6.2. [Doc. 14]. The extension applied only to Plaintiff's briefs in response to the motions to dismiss and not to any time to amend as a matter of right. LR 6.2, MDGa ("In civil cases, the clerk of the court and his deputies are authorized to permit extensions of time to a date not to exceed fourteen (14) days for the filing of *briefs*.") (emphasis added).

[4] Thus, if Defendant A files an answer on Day 1, Defendant B files a motion to dismiss on Day 12, Defendant C files a motion to dismiss on Day 14, and Plaintiff files an amended complaint on Day 30, the amended

219 (D.D.C. 2011). However, other courts have held that an amended complaint filed as a matter of right is ineffective as to *all* defendants if it is filed more than 21 days after the *first* responsive pleading or defensive motion is filed.[5] *See, e.g., Rubenstein v. Keshet Inter Vivos Tr.*, No. 17-61019-Civ-WILLIAMS/TORRES, 2017 WL 7792570, at *3 (S.D. Fla. Oct. 18, 2017); *Williams v. Black Entm't Television, Inc.*, No. 13-CV-1459(JS)(WDW), 2014 WL 585419, at *3–4 (E.D.N.Y. Feb. 14, 2014).

Given the unqualified language of the advisory committee notes to the latest version of the Rule, the Court agrees with the latter rationale that the ability to amend as a matter of right concludes 21 days after the first defendant files a responsive pleading or a motion under Rule 12(b), (e), or (f). *See* Fed. R. Civ. P. 15(a) advisory committee's note to 2009 amendment ("The 21-day periods to amend once as a matter of course after service of a responsive pleading or after service of a designated motion are not cumulative. If a responsive pleading is served after one of the designated motions is served, for example, there is no new 21-day period.").[6] In light of this standard, Plaintiff's

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complaint is not binding on Defendant A but is binding on Defendants B and C, who filed their motions to dismiss less than 21 days prior to the date Plaintiff filed her amended complaint.

[5] That is, if Defendant A files an answer on Day 1, Defendant B files a motion to dismiss on Day 12, Defendant C files a motion to dismiss on Day 14, and Plaintiff files an amended complaint on Day 30, the amended complaint must be stricken as to all Defendants because Plaintiff filed it more than 21 days after the first responsive pleading in the case was filed.

[6] But even if the Court were to agree with the *Villery* court and find that the amended complaint is binding on Par (who filed its motion to dismiss just three days prior to Plaintiff filing her amended complaint), the claims against Par as alleged in the untimely-filed amended complaint are just as deficient as those in the original complaint and the proposed amended complaint attached to Plaintiff's motion to amend, and the Court would have dismissed the claims sua sponte after giving Plaintiff notice of its intent to do so. *See*

amended complaint has no bearing on either Defendant since Rhodes filed its Rule 12(b)(6) motion to dismiss more than 21 days prior to Plaintiff amending as a matter of right, and Par's motion to dismiss did not commence a new 21-day amendment period. Therefore, the Court will consider both Defendants' motions to dismiss and Plaintiff's motion to amend to determine if either the original complaint or the proposed amended complaint states a claim.

C. Negligent Manufacturing Claim

From what the Court can glean from the complaints, Plaintiff seeks to state a claim for negligent manufacturing against both Defendants, despite there being no separate cause of action stated for such a claim. *See* [Doc. 19-1, ¶ 28] ("Rhodes and [Par] negligently marketed, manufactured, distributed, dispensed and prescribed the prescription drugs that caused the death of Tracy Faye Edge."). To succeed on a claim for negligent manufacturing, a plaintiff "must come forward with evidence that, among other things, there was a defect in the product when it left the manufacturer that was caused by the manufacturer's negligence." *Miller v. Ford Motor Co.*, 653 S.E.2d 82, 84 (Ga. Ct. App. 2007); *see also Sheats v. Kroger Co.*, 784 S.E.2d 442, 446 (Ga. Ct. App. 2016). Here, Plaintiff merely asserts that "opioids are not safe" and that Defendants' drugs are "dangerous," but the Court cannot find a single allegation in either the original complaint or the proposed

Surtain v. Hamlin Terrace Found., 789 F.3d 1239, 1248 (11th Cir. 2015) (per curiam) ("Prior to dismissing an action on its own motion, a court must provide the plaintiff with notice of its intent to dismiss and an opportunity to respond.").

amended complaint that specifically identifies the dangerous qualities that were *inherent* in the drugs that killed Ms. Edge at the moment they left Defendants' facilities. At most, Plaintiff's complaints allege that an intervening factor made the drugs dangerous (e.g. overuse and/or taking them with certain other drugs). In the absence of an allegation of an inherent defect in her complaints, Plaintiff fails to allege facts to support the essential elements of a negligent manufacturing claim and, in doing so, fails to state a claim.

D. Failure-to-Warn Claim

In her complaints, Plaintiff also alleges that Defendants failed to warn of their drugs' adverse effects and of opioid toxicity in general. Defendants argue that this failure-to-warn claim is preempted by federal law and cite *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). In *Mensing*, the Supreme Court held that federal law requires manufacturers of generic prescription drugs to ensure that their drug labels are identical to those of the name-brand drugs from which the generics are derived, and it prohibits those manufacturers from unilaterally changing existing, approved labels. 564 U.S. at 613–17. Thus, federal law preempts state-law failure-to-warn claims against generic drug manufacturers because manufacturers would be incapable of complying with federal law if their warnings—or lack thereof—were considered inadequate under state law. *Id.* at 618.[7]

[7] The Court reiterated the *Mensing* holding in *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013).

Rhodes's morphine and Par's amitriptyline are both generic medications covered by the federal laws discussed in *Mensing*.[8] Nevertheless, Plaintiff alleges in her proposed amended complaint that Defendants "cannot preempt liability by merely claiming generic status" and that generic medications "are not allowed to hide under the auspices of generic status for liability." [Doc. 19-1, ¶¶ 52, 53]. Plaintiff offers no legal support for her contentions, and in the absence of some basis for her claims, the Court agrees with Defendants that, no matter how artfully pled, Plaintiff fails to state a claim for failure to warn because such a claim is preempted by federal law.

E. Fraud Claim

Plaintiff also seeks to state a claim for fraud or negligent misrepresentation against Defendants by alleging that they "directly marketed to spread false and deceptive statements about the risks and benefits of opioid use," "claim in literature that opioids are safer than a Tylenol," "encourage doctors to write prescriptions for opioids . . . [by] touting the opioids as safe and non-habit forming," and "deceptively marketed the opioids as being less addictive and safer," even though such "medical marketing . . . is false, misleading and causes harm." [*Id.* at ¶¶ 16, 59–61]. Pretermitting whether Plaintiff

[8] Plaintiff does not allege that the drugs at issue in this case were generics, but the Court obtained this information from photos attached to Defendants' motions to dismiss. The Court may consider documents not attached to the complaint without taking judicial notice of them and without converting the motion into one for summary judgment if the documents are "(1) central to the plaintiff's claim, and (2) [their] authenticity is not challenged." *U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 811 (11th Cir. 2015). Plaintiff does not dispute the generic status of Rhodes's morphine and Par's amitriptyline, and that status is central to the determination of the duties owed by Defendants to the public.

has pled the fraudulent/negligent misrepresentations with particularity as required under Federal Rule of Civil Procedure 9 is Plaintiff's failure to even plead the essential elements of either a fraud or negligent misrepresentation claim, which both require proof of justifiable or reasonable reliance and causation. Plaintiff has not pled any facts showing that Ms. Edge or her doctors relied on any representations made by Defendants in taking or prescribing morphine and amitriptyline. But even if she had done so, her conclusory statements that "[t]he false medical marketing and advertising by [Defendants] caused harm to [Ms.] Edge" and that "[b]ut for . . . [Defendants'] deceptive and false marketing of the generic opioids, [Ms.] Edge suffered damages and death" are factually insufficient to allege the essential element of causation. As such, Plaintiff has failed to state a claim for either fraud or negligent misrepresentation in either of her complaints.

F. RICO, Controlled Substances Act, and OBRA

To the extent Plaintiff seeks to allege any claims under the Racketeer influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961–1968 ("RICO"); the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*; or the Omnibus Budget Reconciliation Act of 1990, Pub. L. 101–508, 104 Stat. 1388 ("OBRA 90"), the Court has previously explained to Plaintiff that such claims are untenable. *See Allen v. Endo Pharm., Inc.*, No. 5:18-cv-00132-TES, ECF No. 74 (M.D. Ga. Aug. 23, 2018).[9]

[9] The Court may take judicial notice of its prior orders without converting a motion to dismiss into one for summary judgment. *Universal Express, Inc. v. SEC*, 177 F. App'x 52, 53 (11th Cir. 2015) (per curiam). The

CONCLUSION

For the reasons stated above, Plaintiff's original complaint is binding on Defendants, and Plaintiff was required to seek the Court's approval before amending her claims against them. By filing her Amended Complaint [Doc. 16] without such approval, Plaintiff did not comply with the requirements to amend as a matter of right under Federal Rule of Civil Procedure 15, and the Court therefore **GRANTS** Rhodes's Motion to Strike [Doc. 17].

The Court also finds that Plaintiff's original complaint fails to state a claim and that the proposed amended complaint attached to Plaintiff's Motion to Amend is likewise deficient. Accordingly, Defendants' Motions to Dismiss [Docs. 4, 13] are **GRANTED**, and Plaintiff's Motion to Amend [Doc. 19] is **DENIED as futile**. Plaintiff's Complaint [Doc. 1] is therefore **DISMISSED without prejudice**.

SO ORDERED, this 11th day of February, 2019.

s/Tilman E. Self, III
TILMAN E. SELF, III, Judge
UNITED STATES DISTRICT COURT

Court therefore **GRANTS** Rhodes's Motion Seeking Judicial Notice [Doc. 5], relating to the Court's prior orders and to which Plaintiff filed no response.

EXHIBIT 2

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,

Plaintiff,

vs.

(1) PURDUE PHARMA L.P.;
(2) PURDUE PHARMA, INC.;
(3) THE PURDUE FREDERICK COMPANY,
(4) TEVA PHARMACEUTICALS USA, INC.;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC,
(8) ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS;
(9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS LLC; and
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,

Defendants.

For Judge Balkman's Consideration

Case No. CJ-2017-816
Honorable Thad Balkman

William C. Hetherington
Special Discovery Master

DECLARATION OF JOHN HASSLER

I, John Hassler, declare as follows:

1. I am Senior Vice-President and General Manager of CNS, Sales and Marketing, at Teva Pharmaceuticals USA, Inc. ("Teva USA"). I have held this position since January 2015. I have worked for Teva USA since 2001.

2. I have personal knowledge of the facts set forth herein or have acquired such knowledge from my review of documents and conversations with relevant employees for Teva USA and Watson Laboratories, Inc. ("Watson Labs"), Actavis LLC ("Actavis LL"), and Actavis Pharma, Inc. ("Actavis Pharma"). I could and would competently testify to the facts stated herein if called to do so.

3. Prior to 2011, Teva USA did not manufacture or sell any branded opioid medicines.

4. Teva USA has never promoted the safety, efficacy, or therapeutic value of its generic medicines, including its generic opioids. As a general matter, Teva USA has never used continuing medical education ("CME"), speaker programs, or other third-parties to promote its generic opioids.

5. Actavis LLC sells only generic medicines, including only generic opioids.

6. Actavis LLC has never promoted the safety, efficacy, or therapeutic value of its generic medicines, including its generic opioids. As a general matter, Actavis LLC has never used continuing medical education ("CME"), speaker programs, or other third-parties to promote its generic opioids.

7. Actavis Pharma sells only generic medicines, including only generic opioids.

8. Actavis Pharma has never promoted the safety, efficacy, or therapeutic value of its generic medicines, including its generic opioids. As a general matter, Actavis Pharma has

never used continuing medical education ("CME"), speaker programs, or other third-parties to promote its generic opioids.

9. Watson Labs sells only generic medicines, including only generic opioids.

10. Watson Labs has never promoted the safety, efficacy, or therapeutic value of its generic medicines, including its generic opioids. As a general matter, Watson Labs has never used continuing medical education ("CME"), speaker programs, or other third-parties to promote its generic opioids.

I STATE UNDER PENALTY OF PERJURY UNDER THE LAWS OF OKLAHOMA THAT THE FOREGOING IS TRUE AND CORRECT.

Dated this 15th day of March, 2019.

By: _____
JOHN HASSLER
SVP & GM, Teva CNS
Teva Pharmaceuticals USA, Inc.
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