IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

PART C

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

DEFENDANTS TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, AND ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.'S MOTION FOR SUMMARY JUDGMENT AND BRIEF IN SUPPORT

REDACTED VERSION

THIS DOCUMENT WAS FILED IN ITS ENTIRETY UNDER SEAL ON APRIL 23, 2019

EXHIBIT 10

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

Q. And you worked with them for many years?

A. Yes.

Q. Do you believe that had they known this, they would have wanted to engage with Janssen as a key opinion leader?

MR. EHSAN: Objection, calls for speculation.

THE WITNESS: I -- yeah, I don't know what they would do or what they were thinking.

BY MS. BALDWIN:

Q. If you turn to Page 8, it looks like they sampled consistent of the -- the sample of 1,000 physicians were from five different regions; correct?

MR. EHSAN: Objection to form.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. And they broke down the Respondents by specialty, and the majority were primary care physicians; is that correct?

A. Yes.

MR. EHSAN: Same objection.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. And then there's -- on the following page,

there is a table that shows the number and percentage of doctors by Duragesic decile in each region. Do you see that?

MR. EHSAN: Objection to form.

THE WITNESS: Yes. Can you tell me what a "Duragesic decile" means?

MR. ROBINSON: You can't ask questions.

THE WITNESS: Sorry.

BY MS. BALDWIN:

Q. Well, again, did you know -- you didn't know until I told you today that -- correct, that Janssen ranked physicians based on how often they prescribed their products; correct?

A. Correct.

MR. EHSAN: Objection to form.

BY MS. BALDWIN:

Q. And it's typically on a scale of 1 to 10?

A. Yes.

MR. EHSAN: Objection to form.

BY MS. BALDWIN:

Q. You didn't know that prior to today?

MR. EHSAN: Objection to form.

THE WITNESS: I think it was a scale of 1 to 7. On Page 6 it says 1 to 7, but I did not know that until today.

BY MS. BALDWIN:

Q. Yeah, 1 to 7 is the influence of a key opinion leader on prescribing.

A. Oh, I see. Got it.

MR. EHSAN: Objection to form.

BY MS. BALDWIN:

Q. This is a pretty --

A. Yeah, involved.

Q. This PowerPoint is a pretty involved analysis of the influence of key opinion leaders on physicians prescribing. Would you -- wouldn't you say?

MR. EHSAN: Objection to form.

MR. ROBINSON: Objection to form.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. If you turn to Page 12, do you see that they -- Janssen did a point allocation summary. "Each Respondent was asked to assign points based on the level of influence of these parameters on his prescribing. The most influential factor was assigned 100 points, and no two factors were to be assigned the same value by a Respondent. A summary of the response is as follows in the next two slides: First one with overall results, and the

second one by specialty group of Respondent"; correct?

MR. EHSAN: Objection to form.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. Give you an example of Question 10: "Please consider the following specific factors that may influence your prescribing of opioids. Of course many other factors will influence your prescribing, but we are interested in the relative influence of these particular factors"; correct?

MR. EHSAN: Objection to form.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. And these factors include peer interaction; correct?

A. Yes.

MR. EHSAN: Objection to form.

BY MS. BALDWIN:

Q. Availability of coupons and/or vouchers?

MR. EHSAN: Same objection.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. Patient request for specific drugs?

MR. EHSAN: Same objection.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. Sales representative messages?

MR. EHSAN: Same objection.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. Influence of opinion leaders?

MR. EHSAN: Same objection.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. Peer-reviewed journal articles or studies?

MR. EHSAN: Same objection.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. Medical education?

MR. EHSAN: Same objection.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. Formulary status?

MR. EHSAN: Same objection.

THE WITNESS: Yes.

BY MS. BALDWIN:

Q. Regulatory liability concerns?

A. Yes.

MR. EHSAN: Same objection.

used them before.

We didn't use them excessively in my practice, and we rarely use them at very high doses. So that's a long-winded yes.

You know, I think when I present, that would be the basis that I would come from, and no one would shift me, and some people disagreed with my positions and other people agreed.

In the long run, I believe that the work that I did would be embraced by pharmaceutical companies, because in the long run, pharmaceutical companies wouldn't have successful products unless they were used safely.

BY MR. ERCOLE:

Q. In fact, pharmaceutical companies did sponsor, indirectly at least, presentations that you've given on these very topics; correct?

MS. BALDWIN: Objection, leading.

THE WITNESS: I would say they sponsored the book Responsible Opioid Prescribing, which if you really read it, is basically a book that says be careful.

BY MR. ERCOLE:

Q. It's a book to physicians saying be careful, these are the risks associated with

opioids potentially; correct?

A. This is a dangerous group of drugs that we have to use carefully or we'll use the right to use them, which is something I say in the book.

Q. And the book you're referring to is Responsible Opioid Prescribing; is that correct?

A. Correct.

Q. Just we heard a lot of -- we'll get into some of the content of that book a little bit later, but we had a lot of questions about Responsible Opioid Prescribing. Just to clarify, the opinions expressed in that book are your independent opinions and your independent opinions only; correct?

MS. BALDWIN: Objection, leading.

THE WITNESS: They're my independent opinions, but with that said, I wrote the book as a commissioned production for the Federation of State Medical Boards to articulate what I thought was an important -- were important guiding principles from the model policy, which gave medical boards guidance on how to investigate physicians if they were called out for their prescribing. Does that make sense?

So with that, that was really my

framework, and I built it -- I built the Responsible Opioid Prescribing case out from there.

BY MR. ERCOLE:

Q. Understand, and we'll get into some of these topics a little bit later, but at least with respect to the views expressed in Responsible Opioid Prescribing, the book that you authored, is it fair to say that those views were developed by you independent from any pharmaceutical company influence?

MS. BALDWIN: Objection, leading.

THE WITNESS: Independent of any direct influence. Again, it's all an amalgamation of all the experiences and thoughts and ideas that I've had, but they were in my independent views.

BY MR. ERCOLE:

Q. And the book reflects your independent views; correct?

A. Correct.

MS. BALDWIN: Objection, leading.

THE WITNESS: I would say the book is consistent with my views throughout, throughout its evolution of editions.

BY MR. ERCOLE:

Q. There have been -- with respect to that

book and again we'll get into this a little bit, is it fair to say there have been two editions?

A. There have been three editions. The first two were called First and Second Edition. The third was called the Second Edition Expanded.

Q. Dr. Fishman, you understand this case was brought by the -- strike that. Let me go back.

You mentioned before that you have no direct knowledge, and I don't want to misquote you, but this is what I wrote down. You have no direct knowledge of how any company in this case marketed its drugs. Do you recall saying that?

MS. BALDWIN: Objection, leading.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. And is that accurate?

A. Yes.

Q. You understand that this case is -- strike that.

With respect to your reference to drugs, that would include opioid medicines; correct?

MS. BALDWIN: Objection.

THE WITNESS: Correct.

BY MR. ERCOLE:

Q. You understand this case is brought by the

Q. So about since say 1993 or so?

A. Correct.

Q. I'm not asking you an exact number, but since that time, do you have a sense of sort of how many pain management -- excuse me, how many patients you've treated for pain-management-related issues as a practicing physician on a weekly basis?

A. Well, it's varied on a weekly basis. I don't know if it's acceptable, but just I've treated thousands of patients over the years.

Q. Have you prescribed opioids for those patients?

A. For some.

Q. Yes. Have you prescribed long-acting opioids for some patients?

A. Again, for some.

Q. And have you provided -- prescribed short-acting opioids for some patients?

A. Yes.

Q. And have you prescribed opioids for noncancer pain?

A. Yes.

Q. And have you prescribed opioids for chronic pain?

A. Yes.

Q. Do you still prescribe opioids today?

A. I do.

Q. Is it fair to say that as a -- as the sort of trained medical professional, you are the person responsible for making a prescribing decision with respect to any particular patient?

A. It's true in respect to my patients.

Q. All I'm asking is about your patients; is that true?

A. Yes, if it's my patient, it's my decision.

Q. You have the responsibility for making that decision; correct?

A. Yes.

Q. You have -- as a trained medical professional, you have the obligation to exercise your independent medical judgment in making that prescribing decision; is that fair to say?

MS. BALDWIN: Objection, leading.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. With respect to prescriptions of opioids that you've written, have you always exercised your own independent medical judgment in deciding to prescribe that opioid for a particular patient?

A. Yes.

Q. Is it important for prescribers to exercise their own independent medical judgment when making a prescribing decision regarding opioids?

MS. BALDWIN: Objection to form.

THE WITNESS: It's not only important, it's -- it would be beneath the standard of care to do otherwise.

BY MR. ERCOLE:

Q. And with respect to your practice, have you ever -- strike that.

With respect to your pain management practice, have you ever interacted with pharmaceutical representatives who have come to your practice?

A. Yes.

Q. Did those -- did some of those pharmaceutical representatives ever detail you about particular medicines?

A. Yes.

Q. And in writing opioid prescription, did you ever rely blindly on anything a pharmaceutical representative might say about a particular product in that type of situation?

MS. BALDWIN: Object to form.

THE WITNESS: No.

BY MR. ERCOLE:

Q. Is it fair to say it would be beneath the standard of care to rely blindly on what a pharmaceutical representative might say to a particular physician at a particular time?

MS. BALDWIN: Object to form.

THE WITNESS: Sorry.

MS. BALDWIN: Objection to form.

THE WITNESS: I think that's a difficult question to answer because there are some circumstances where a industry representative might actually have the most critical information about delivering a drug, or in modern times today, on implanting a medical device, et cetera. So you can't say always, but we have to be very, very careful, you know, walking that road and that line, and I don't know that I've ever been in that line where I've needed an industry representative to help me.

But I know that right now in every hospital in America we're using new technologies that we have no experience with, and unless we have industry partners who are experienced because they developed the tools, we would be unsafe in

delivering those devices or those technologies.

BY MR. ERCOLE:

Q. With respect to opioid prescribing itself, did you ever prescribe a opioid medicine because of some marketing statement a pharmaceutical company made, as opposed to exercising your own independent medical judgment as to what was in the best needs of the patient?

MS. BALDWIN: Object to form.

THE WITNESS: I did not.

BY MR. ERCOLE:

Q. As a trained medical professional, did you ever prescribe opioid medicine because of some funding that you received indirectly from a pharmaceutical company concerning a publication, as opposed to making your own independent medical judgment?

MS. BALDWIN: Object to form.

THE WITNESS: No.

BY MR. ERCOLE:

Q. Did you ever write an opioid prescription because a pharmaceutical representative, for instance, dropped a lunch off in your office?

MS. BALDWIN: Object to form.

MR. ROBINSON: Object to form, foundation.

THE WITNESS: No.

BY MR. ERCOLE:

Q. How about ever write opioid prescription because were you invited for a dinner program by a pharmaceutical company?

MS. BALDWIN: Object to form.

THE WITNESS: No.

BY MR. ERCOLE:

Q. Were you ever -- did you ever write an opioid prescription because of some offer to sit on an advisory board by a pharmaceutical company?

MS. BALDWIN: Object to form.

THE WITNESS: Absolutely not.

BY MR. ERCOLE:

Q. In fact, all of these -- this notion of doctors exercising their own independent medical judgment to prescribe opioids safely is precisely what you've been teaching about since the late '90s; is that fair to say?

MS. BALDWIN: Objection, leading.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. How about was it even before the late '90s?

MS. BALDWIN: Same objection.

THE WITNESS: Yes. It's not about opioids, but it's the foundation of my training. You can't rely on any one piece of information, and you certainly can't rely on information that comes solely from conflicted sources.

I mean, it's ironic that that's, in fact, what we did in a field in many ways to get into the problems that we're in, but, yes, that's kind of where -- those are the foundations of my training.

BY MR. ERCOLE:

Q. When you say your "training," where would you have -- where did you learn those?

A. Well, I trained in internal medicine through the Yale system in Greenwich Hospital in Southern Connecticut, and then I trained and did my anesthesia subspecialty training at Mass General at Harvard, and my psychiatry training at Mass General at Harvard. I think those are particularly places that were grounded in that solemn role of a clinician to independently see each patient as an individual and treat them based on their presentation, rather than any other group of ideas or beliefs and datasets, et cetera.

Q. And, in fact, that's the standard of care that physicians are obligated to perform; is that

correct?

MS. BALDWIN: Objection, leading.

THE WITNESS: I believe that's true.

BY MR. ERCOLE:

Q. With respect to your teaching, have you always taught that type of standard of care?

A. Yes.

Q. And does that date back to 1993 when you first started teaching?

A. No, you know, I probably -- so the way that my lineage worked is that I graduated medical school in '90. And then from '90 to '92 and a half, I was doing internal medicine, and then it was back in the day when you could actually overlap different trainings. So I actually was a internal medicine resident, and went up to Boston, and I became actually an internal medicine resident and an anesthesia pain fellow at the same time doing electives in one and training in the other. And then actually there was a time where I was a psychiatry resident, internal medicine resident and an anesthesia fellow for six months. So, you know, that was -- so, really, I became faculty -- I technically became faculty at Harvard Medical School in my fellowship, but I became formal

faculty after my psychiatry residency, which was I think at the end in 1995. So that's really when my teaching career began.

Q. So I assume basically if you survived all of that, you could basically survive anything; is that fair to say?

A. I'm surprised I did it.

Q. At least since 1995 you've been teaching about -- about opioids; is that fair to say?

MR. ROBINSON: Objection, form.

MS. BALDWIN: Objection, form.

BY MR. ERCOLE:

Q. I'll reask it. You've been teaching students at least as of since 1995; correct?

MS. BALDWIN: Objection.

MR. ROBINSON: Objection.

THE WITNESS: Opioids have been an issue since then.

BY MR. ERCOLE:

Q. And pharmacovigilance has been an issue sense then; is that fair to say?

A. Yes.

Q. And at least since 1995, have you trained your students on the potential risks associated with opioid?

A. Yes.

Q. And since 1995, have you trained your students on the potential for a risk of addiction associated with opioids?

A. Yeah. You know, I have to say that I was in that last cohort that was trained that if you used opioid for pain, you had very minimal risk of addiction, and that had to be unlearned over many years. So I'm not sure I would want to use my training in 1995, my teaching in 1995 as a reference standard for that.

Q. Whatever teaching that you would have done in 1995, would have been teaching that you sort of independently developed; is that fair to say?

MS. BALDWIN: Objection, leading.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. And since 1995, have you taught your students that before prescribing a particular medicine, they should read the label table of the medicine?

A. I don't know that I could tell you that that's a specific thing I've advised students to do.

Q. Is it self-evident that before --

A. Yes.

Q. Let me just finish before you respond.

A. Sorry.

Q. Thank you. Is it self-evident that before prescribing a medicine, a provider needs to and should understand the contents of the label of that medicine?

MS. BALDWIN: Objection, form, leading.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. And is it fair to say that before writing a prescription of a medicine, that a provider should understand the risks associated with that medicine?

MS. BALDWIN: Object to form, leading.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. And whether implicitly or explicitly, are those concepts that have been made clear in teaching that you've done since 1995?

MS. BALDWIN: Object to form.

THE WITNESS: They're consistent.

BY MR. ERCOLE:

Q. Is it fair to say that with respect to the labels of medicines, including opioids, the labels

MS. BALDWIN: Object to form.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. And would that apply to opioids as well?

MS. BALDWIN: Objection, same objection.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. And does the -- that training begins in medical school; is that fair to say?

MS. BALDWIN: Same objection.

THE WITNESS: The training should begin in medical school.

MS. BALDWIN: Same objection in case you didn't hear me.

THE WITNESS: Sorry.

BY MR. ERCOLE:

Q. Since 1995, have you trained your students to obtain informed consent from a patient before writing opioid prescription?

MS. BALDWIN: Objection, leading.

THE WITNESS: You know, I don't think that we emphasized that -- I emphasized that or we as a field emphasized that as much as we should and do now.

BY MR. ERCOLE:

Q. When you say "we as a field," what field are you referring to?

A. Pain medicine.

Q. That is -- that's the medical community; is that correct?

A. Yes.

Q. And we'll get into some of these documents, but at least in the 1990s you were publishing articles about opioid contracts; is that fair to say?

A. That's right.

Q. What is an opioid contract?

A. An opioid contract is a bilateral agreement between a patient and a prescriber that outlines the expectations and the procedure for receiving an opioid and can serve as an informed consent process.

Q. Do you know, do you recall when you first started using opioid contracts in your particular practice, if you've done at all?

A. Oh yeah. From the beginning they were used in my training.

Q. And what -- when you say "from the beginning," are you referring to 1995, for

instance?

A. Probably 1993 I think we were using opioid contracts when I started my pain fellowship.

Q. And those opioid contracts would have disclosed the risks associated with using opioids; is that fair to say, to the patient?

MS. BALDWIN: Objection.

THE WITNESS: So you seem to know about the paper that I did. We actually did a survey of opioid contracts and most of them didn't and most of them really didn't meet informed consent criteria. So I don't think in the early days it did. The contracts in the early days was really to benefit the prescriber at the -- and putting the patients in kind of the one-down position.

BY MR. ERCOLE:

Q. With respect to the opioid contracts that you utilized in your practice, did those contracts disclose the risks associated with opioids?

MS. BALDWIN: Objection.

THE WITNESS: They ultimately did -- sorry, they ultimately did as they evolved in my practice, but probably didn't in the early days.

BY MR. ERCOLE:

Q. And you as a physician or your practice

would have controlled what went into an opioid contract and what didn't go into an opioid contract; is that fair to say?

MS. BALDWIN: Objection, leading.

THE WITNESS: Yes, yes.

BY MR. ERCOLE:

Q. The pharmaceutical companies did not -- did not control what you as a physician decided to put or not put into a particular opioid contract; correct?

MS. BALDWIN: Objection, leading.

THE WITNESS: Well, I don't think they had any binding input. I do vaguely recall that some companies actually, to be helpful, came up with agreement language that they would put forward for some period of time, but they didn't influence what I put in my contract or we put in our contract in my clinic.

BY MR. ERCOLE:

Q. Is it fair to say that since 1995 you've trained your students to utilize the opioid contracts in connection with their contract?

A. Yes.

MS. BALDWIN: Objection, leading.

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

say I have a history with Cephalon in that they made misleading statements about me.

BY MR. ERCOLE:

Q. Okay. With respect to making misleading statements about you, do you recall what that issue was?

A. The issue was that I agreed to do a public service announcement, and I think it was Cephalon at the time, and then it became Teva, and I signed an agreement that said that I wasn't getting paid, and it would only be for public service, public education. It was actually a commentary that I made at a professional meeting about the risk of addiction and abuse in children. They wound up putting it up on their marketing website, unbeknownst to me, something that they later took off and apologized for.

Q. So is it fair to say when that issue was brought to your attention, that they immediately took off the video from the website?

A. Yes.

MS. BALDWIN: Object to form.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. You said Cephalon also apologized to you.

risks of opioids.

BY MR. ERCOLE:

Q. And then Cephalon went and put that, actually, on its website; is that correct?

MS. BALDWIN: Objection, leading.

THE WITNESS: That is correct, or Teva did. I'm not sure.

BY MR. ERCOLE:

Q. Fair enough. Once you said, Hey, could you take that down because there was an incorrect attribution of some payment to you in there, they immediately did that; is that fair to say?

MS. BALDWIN: Objection, leading.

THE WITNESS: They took it down because it was never intended to be used in their marketing, and there was also an inaccurate attribution of payment to me.

BY MR. ERCOLE:

Q. In connection with that particular video, was there anything false or misleading other than the attribution of payment to you that was associated with that?

MS. BALDWIN: Object to form.

THE WITNESS: No.

BY MR. ERCOLE:

Q. Other than that medication attribution of you receiving a payment, anything false or misleading that you can recall Cephalon making about opioids?

MS. BALDWIN: Object to form.

THE WITNESS: No.

BY MR. ERCOLE:

Q. With respect to the misattribution of payment that you just described, that was disclosed as part of the video; is that correct?

MR. ROBINSON: Object to form.

MS. BALDWIN: Objection.

THE WITNESS: I actually don't know. It was somehow transmitted to media sources that I was paid, so Cephalon made a statement that I wasn't -- in fact, reproduced this document I had them sign that stated that I would not be paid. These were my own ideas. This would only be used for a public service announcement, and it would not be used for marketing purposes or for corporate purposes.

BY MR. ERCOLE:

Q. So we looked at and I asked you to look at Exhibit 1 in your CV. There are a number of different categories in this particular document,

it's very extensive, very impressive. If you look to, it looks like it's Bates marked as FISH 8; do you see that on the bottom right-hand corner? There is a section that says, "Teaching Lectures and Presentations"; do you see that?

A. Yes.

Q. And it looks like there are -- if you scroll through, it looks like there are 566 of them; do you see that?

A. Yes, as of August 2017.

Q. Sitting here today with respect to those lectures and presentations, could you identify a single one of those lectures or presentations that did not reflect your own independent medical opinion?

A. No.

Q. Because they all did reflect your own --

MS. BALDWIN: Object to form.

BY MR. ERCOLE:

Q. They all did reflect your own independent medical opinion?

MS. BALDWIN: Objection, leading.

THE WITNESS: They did.

BY MR. ERCOLE:

Q. And if you turn to the next category, it

EXHIBIT 11

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

MS. COATES: -- -ject.

MR. BIERIG: -- form of the question.

MR. BRODY: Object to form.

THE WITNESS: No. Pharmaceutical companies -- in my understanding, they are for-profit companies.

BY MS. BALDWIN:

Q Okay. And a for-profit company's goal is to generate profits; isn't that true?

MR. BRODY: Object to form.

MR. BIERIG: Same objection.

THE WITNESS: I am sorry. I've really not thought about that as the goals of -- of companies or corporations. Their goal is, I would say not, solely to -- for profit, but I don't know. I'm not in that space.

BY MS. BALDWIN:

Q So the FSMB has taken millions -- at least close to $2 million from opioid manufacturers to carry out various activities without any knowledge of the goals of those pharmaceutical companies?

MR. EISENBERG: Objection --

MR. BIERIG: Object to --

MS. COATES: Objection --

MR. BIERIG: -- the form --

MS. COATES: -- lack of --

MR. BIERIG: -- of the --

MS. COATES: -- foun- --

MR. BIERIG: -- question --

MS. COATES: -- -dation.

MR. BIERIG: -- and statement of facts not in evidence.

MR. EISENBERG: Objection: form.

BY MS. BALDWIN:

Q Is that your testimony?

A The Federation of State Medical Boards has applied for grants from pharmaceutical company education who have grant programs and education staff that offer -- that support CME in many areas, and they are unrestricted educational grants that are apart from any influence on content.

MS. BALDWIN: Okay. I'm going to object to that answer as nonresponsive and repeat the question.

BY MS. BALDWIN:

Q The FSMB has taken close to $2 million from opioid manufacturers to carry out various activities without any knowledge of the goals of

those pharmaceutical companies?

MR. BIERIG: And I'm --

MS. COATES: Same --

MR. BIERIG: -- going to --

MS. COATES: -- objection.

MR. BIERIG: -- again object to the form of the question, the inclusion of facts not in evidence, and the leading nature of the question.

MR. BRODY: Objection: asked and answered.

THE WITNESS: The Federation of State Medical Boards applied for and received educational -- unrestricted educational grants. The financial goals of the grantors was never discussed in my recollection.

BY MS. BALDWIN:

Q So when the FSMB applies for a grant, it doesn't take into any consideration what the -- who the grantor is, what their motives are, what their products are, what kind of company they are; is that what you're saying?

MR. BIERIG: Object to the form of the ques- --

MR. EISENBERG: Objec- --

MR. BIERIG: -- -tion.

MR. EISENBERG: -- -tion: form.

THE WITNESS: No.

BY MS. BALDWIN:

Q If you look back at this slide, it states, Competing goals may produce conflicts of interest where primary clinical responsibility is eroded.

Is that right?

A That's what the slide says, and -- yes.

Q So, in other words, when the best interest of the patient or clinical comp- -- competence is eroded, that could present a conflict of interest?

MR. BIERIG: Object.

MR. EISENBERG: Objection: form.

MR. BIERIG: The document speaks for itself.

THE WITNESS: There could be a conflict of interest as this states.

BY MS. BALDWIN:

Q If you turn to the next slide, this slide states that a conflict of interest arises when judgment regarding patients, integrity of research, profession is unduly influenced either

you're going to have to clarify the question for me.

BY MS. BALDWIN:

Q Okay. Do you think that receiving close to $2 million from opioid (indiscernible) fact [verbatim] -- that a medical nonprofit whose job or goal is to regula- -- support the regulatory medical community, that nonprofit receiving close to $2 million from opioid manufacturers presents a conflict of interest?

MR. BIERIG: Asked and answered.

MS. COATES: Same objection.

THE WITNESS: There was no influence or conflict of interest for these projects.

BY MS. BALDWIN:

Q So your answer to my question is no?

A If you're asking for the Federation of State Medical Boards. If you're asking for the universe of medical associations, I cannot answer --

Q What do you --

A -- that.

Q What do you think?

MR. BRODY: Objection: asked and answered.

THE WITNESS: You -- personally --

BY MS. BALDWIN:

Q Yeah.

A -- my opinion?

Q Uh-huh.

A My opinion is there was no conflict of interest, and that these -- the guidelines that were developed were developed from a grant from Robert Wood Johnson, and that there was -- it was a consensus document, as were all of them, and there were -- there was no influence from the pharmaceutical companies.

Q So you disagree with the slide that was -- in the CM [verbatim] activities sponsored on the open network that receiving money -- significant amounts of money does not influence the influential?

MR. BRODY: Object --

THE WITNESS: No --

MS. COATES: Object to --

THE WITNESS: -- I --

MR. BRODY: -- to the --

THE WITNESS: -- don't disa- --

MR. BRODY: -- form.

THE WITNESS: -- -gree.

MR. BRODY: It misstates --

THE COURT REPORTER: Wait.

MR. BRODY: -- the document.

BY MS. BALDWIN:

Q You don't disagree with that slide?

A This slide is a program appropriately set for the potential conflicts of interest. I can only speak to the projects that the Federation of State Medical Boards was involved with.

Q So you're saying if other medical nonprofits received millions of dollars from pharmaceutical companies, that could pre- -- present a potential conflict of interest?

MR. BIERIG: Asked and answered --

MR. BRODY: Object --

MR. BIERIG: -- and object --

MR. BRODY: -- to --

MR. BIERIG: -- to the --

MR. BRODY: -- form.

MR. BIERIG: -- form of the question.

MR. BRODY: Join.

THE WITNESS: My opinion is that as was stated; that there was potential if -- there's potential areas of conflict of interest that people should be wary of.

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to the Senate, did that respond fully to the question that was posed by the Senate?

A Yes, sir.

Q And in -- in the response which takes the form of the chart which extends from page 10 to page 14 -- to page 13, excuse me --

A Yes, sir.

Q -- of the letter, are there any payments from Janssen Pharmaceuticals?

A (Witness reviews document.)

No, sir.

Q The Senate asked FSMB to indicate for each year that a payment was received, the percentage of funding from pharmaceutical manufacturers relative to total revenue; correct?

A Correct.

Q And is that what appears in the final column?

A Yes, sir.

Q And for the total, which is on page 13, what was the percentage of a total revenue that those payments constituted?

A .81 percent.

Q If you turn to page 14, you'll see the second question posed in the Senate query, and

Page

that asks FSMB to identify any grants or financial transfers used to fund the production of the book Responsible Opioid Prescribing by Dr. Scott M. Fishman and ask THAT FSMB provide the date, amount and source of each grant.

Did FSMB respond fully to that question from the Senate?

A Yes, sir.

Q Were there any payments from Janssen Pharmaceuticals?

A No.

Q With respect to the various projects that are identified in the chart at pages 11 to 13, you indicated that the money received from pharmaceutical manufacturers did not present a conflict of interest for FSMB.

Do you recall that testimony from this morning?

A Yes, sir.

Q Why is that?

A Because these were unrestricted gant -- grants. There were -- they were free of -- of influencing the content. They were -- our projects were based on policy developed through our policy development as -- with the

Page

participation of a wide variety of stakeholders that we, by the way, do for every topic that we address. This is only one of many.

And, so, I am -- was involved at the federation at this point in time, and I am very confident that -- that this was -- that it was free of influence and that it was used exactly as -- as stated here.

Q You said a wide variety of stakeholders --

A Yes.

Q -- were involved.

Can you describe generally the different kinds of stakeholders who were involved in that process?

A Well, there were -- for instance, I know after the -- the symposium that we had on the -- our first guidelines, which we do that on many topics, to get a broad -- broad consensus, it's important that our -- our documents be consensus documents.

And, so, there would be many medical organizations. The very large ones would include the American Medical Association, the American Osteopathic Association, many others. We also

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

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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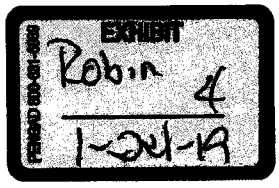

Physicians must constantly weigh these dual realities as they consider treatment options for their patients in pain. Similarly, the nation's state boards of medicine must also weigh the risks and advantages of opioid prescribing as they establish the rules and regulations under which medicine is practiced 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 FSM B 's Fiscal Y ear 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:

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

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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 12

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

plus having the patient in front of you?

MR. BECKWORTH: Objection.

MS. SPENCER: You may answer.

THE WITNESS: Yes, I agree with that.

BY MR. EHSAN:

Q. And it's also true, doctor, that the individual risk profile of a patient can oftentimes outweigh the general risk profile of any particular intervention?

A. You're going to have to clarify what you mean by that question.

Q. Sure. So I think what we -- what Mr. Beckworth spoke with you about was the fact that there's a variability within the population about the risk of addiction with long-term opioid use in a noncancer setting and the numbers I believe you said ran from less than 1 percent to significantly higher. And the average, I think in your last paper, was 4.7 percent; is that correct?

MR. BECKWORTH: Objection. That's not his testimony.

MS. SPENCER: You can answer.

THE WITNESS: Yes. The last systematic review and metaanalysis of studies that looked at patients without a prior history of substance abuse

found an incidence of addiction of 4.7 percent.

BY MR. EHSAN:

Q. So that 4.7 percent is a general number. But if you then know, for example, that that patient is, for whatever reason, genetically susceptible, that may override any consideration of that 4.7 percent because the individual patient risk profile is such that it completely reshuffles or recalibrates, to use your words, the risk/benefit analysis of the prescriber; is that fair?

A. Yeah. I don't think that the general number, what you called a general number before, is clinically appropriate to make decisions on. It may be appropriate to consider a range of therapies based on -- based on a balance between expected benefit and expected risk in a population of patients.

I think physicians make those judgments about all sorts of interventions every day. But the decision to take a specific therapy and administer it requires a benefit-versus-risk analysis of the individual that has to consider a whole range of considerations of the type that you mentioned before.

Q. And likewise, the risk of addiction or

abuse or misuse of an opioid is not the only risk that these medications carry; is that correct?

A. That's correct.

Q. And sometimes the other risk of these medications -- for example, increased intracranial pressure -- could be significantly more important to a particular prescribing decision than the potential risk of addiction; is that fair?

A. We wouldn't usually worry about increased intracranial pressure during chronic therapy, but we would worry about things like cognitive impairment, the risk of falls, severe constipation, those kinds of risks.

Q. Certainly those risks are separate and apart from the addiction risk; is that fair?

A. Yes, that's true.

Q. And someone may be susceptible to a different side effect of the medication irrespective of where they sit on the abuse or addiction potential; is that fair?

A. That is fair to say, yes.

Q. So when you -- do you still prescribe opioids today?

A. Yes. I have a small -- a small practice at this point.

BY MR. EHSAN:

Q. Let me break it out. So -- one second and I'll focus you on something. One moment.

Well, before I get there, let me ask you something because I'm trying to follow your declaration so that you can follow along.

If you look at paragraph 5 of your declaration, which is also on page 4, you state that, "I have observed" -- and it's the second sentence -- "I have observed and treated numerous patients with chronic pain, including those with diverse noncancer disorders and those with cancer or other life-limiting illnesses."

Do you see that?

A. Yes.

Q. So would it be fair to say you have chronic pain patients whose diagnoses varied significantly once you put cancer aside?

A. Yes.

Q. And have you had occasion to treat patients with opioids for a variety of underlying diagnoses for the cause of the chronic pain?

A. Yes.

Q. Do you think it would be appropriate -- it would be appropriate for someone to decide that

only certain diagnoses should be entitled to opioid therapy and all other diagnoses should not?

A. I don't believe that that's the right medical practice, no.

Q. Would you feel that it would be an intrusion on the practice of medicine by a doctor to restrict opioid medications, for example, to certain categorical lists of diagnoses?

A. Yes, I would.

Q. Do you think it would be an intrusion on the practice of medicine to say that a prescription above a certain morphine milligram equivalent is de facto unnecessary?

MR. BECKWORTH: Objection.

MS. SPENCER: You may answer.

THE WITNESS: Yes. I agree that it would be inappropriate to do that.

BY MR. EHSAN:

Q. Ultimately, as we talked about, the best people to make a decision about what's right for a particular patient is -- are the doctor and that patient sitting in that room with the most information about the risks and the benefits to that particular patient, correct?

A. Correct.

Q. If you were asked to assess whether or not a colleague's prescription of an opioid to a patient was medically necessary or not, could you do that without looking at the medical record?

A. No.

Q. Could you do it -- Would you prefer to see the patient?

A. I think that's a complex question. It depends on what specific question is being asked. I think evaluating a medical record and determining that a physician is repeatedly assessing for analgesia, for side effects, for functional outcomes, and for aberrant drug-related behaviors over time and reacting to the information that he or she is collecting over time would be, to me, very reassuring that the patient is being properly managed.

I think if the question was more challenging, like whether or not some aberrant drug-related behaviors that were occurring that the physician was trying to deal with -- whether or not those behaviors represented the disease of addiction or some comorbid psychiatric disorder, that sort of subtle diagnostic challenge would require seeing the patients.

1990, which may be very different because -- than the statement you would make today because the science has changed, correct?

A. Correct.

MR. BECKWORTH: Objection.

BY MR. EHSAN:

Q. That doesn't make either statement false. It just makes them appropriate for the time that they were given, correct?

A. Yes.

MR. BECKWORTH: Objection.

BY MR. EHSAN:

Q. So when you were talking to folks in the context of discussions you had about chronic long-term opioid use, you always gave them fair and balanced information; is that correct?

A. Yes. I tried to.

Q. And you've given those -- I just want to separate two separate topic areas. Because I think there was some conflation here between CMEs, which are continuing medical education events; is that correct?

A. Yes.

Q. And promotional speaking engagement, okay?

A. What are now called that.

Q. What are now called that?

A. What are now called those.

Q. Names change. But we'll stick with the CME first.

A. Yes.

Q. In the context of a CME, who had control over the content?

A. The speaker.

Q. So if it was you who was speaking, it would have been you, correct?

A. Yes.

Q. Now, is it possible for a pharmaceutical company to directly or indirectly provide financial support for a CME?

A. Yes.

Q. In your experience, has a pharmaceutical company ever dictated to you the content of a CME where you disagreed about a particular point?

A. No.

Q. And there are strict rules and regulations about disclosures when it comes to a CME, correct?

A. Yes. And as I mentioned before, those too have been evolving over the years. Now they're quite strict. They were less strict in the '80s and '90s.

Q. I'm sorry. Please finish.

A. I think that was the statement I wanted to make. Thank you.

MR. EHSAN: And just to kind of drive this point . . .

MS. SPENCER: Are we done with the 1986 article?

MR. EHSAN: For now, yes.

(Portenoy Exhibit 32 was marked for identification.)

BY MR. EHSAN:

Q. Doctor, the reporter has handed you what's been marked as 32, I believe?

A. Yes.

Q. Exhibit 32. I'll give you as much time as you like to look at it. But just looking at the cover, do you recognize what it is?

A. Yes.

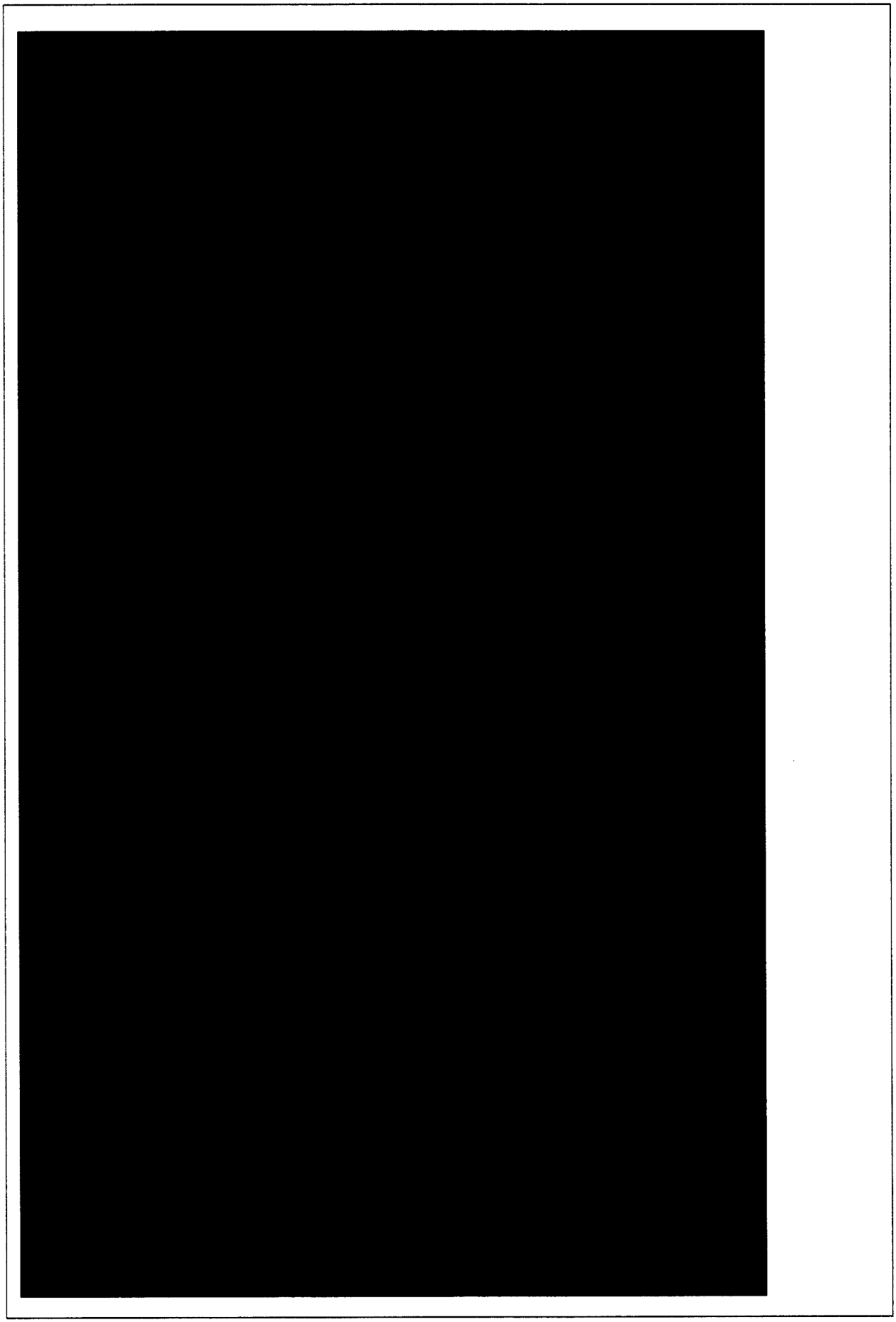
Q. And what is your recollection of what it is.

MS. SPENCER: I would give -- give me a second to look at it and give him a moment to familiarize himself with it.

MR. EHSAN: Sure.

MS. SPENCER: Thanks.

THE WITNESS: Yes.



Q. Now, doctor, we've gone through a whole lot of science nerdy stuff, so I will try to distill some of that down because sometimes I get into that conversation and now it's just the two of us talking and no one else understands what we're saying. But maybe others do.

MR. BECKWORTH: Objection. Disrespectful to the 12 people in the jury box.

BY MR. EHSAN:

Q. Doctor, would it be fair to say that at all times, you provided the best possible and most accurate information in your speaking -- Strike that. Let me start more broadly.

You received money from opioid manufacturers, correct?

A. Yes.

Q. It never influenced anything you said with respect to saying something you didn't believe was

accurate, correct?

A. Correct.

Q. You also received funding for publications, correct?

A. When you say "publications," you need to be more specific.

Q. Sure. You received funding for studies, correct?

A. Yes. Research studies.

Q. Research studies. And those fundings never dictated to you anything about the conclusions or your findings, correct?

A. That's correct.

Q. You gave a significant number of talks related to opioid use; is that correct?

A. Yes.

Q. And in all of those talks, you tried to present a fair and balanced presentation of the science as we understood it at the time, correct?

A. Yes.

Q. Likewise, you never attended any speaking engagement regardless of the context in which a speaker provided information related to the use of opioids that you did not find -- that you found to be problematic or inappropriate or inaccurate,

correct?

A. I don't recall any.

Q. You have, in fact, given talks about addiction, abuse, and diversion, correct?

A. I have given talks that have included information about those areas, yes.

Q. Well, you have put on talks or conferences that address abuse, addiction, and diversion, correct?

A. Yes.

Q. And some of those talks were funded by opioid manufacturers, correct?

A. Yes.

Q. As best as you recall, the labeling for opioid medications included a section on the risks and the benefits of the medication, correct?

A. Yes.

Q. And those included, at least in the 2000s time period that we specifically talked about, a discussion about addiction, diversion, and abuse, correct?

A. Yes.

Q. And at least in the couple of instances that you recalled, in a boxed warning, correct?

A. Yes.

Q. And as you testified, you encourage your residents when you teach them to read the labeling information for the medication they're prescribing, correct?

A. No, I don't think I said that. When I educate, whether it's residents or fellows, which is a more common trainee level that I educate at -- these are people who have finished their residency and getting extra training in pain medicine or in palliative care, when I educate trainees or educate colleagues, the emphasis is always on needing to know what -- what -- needing to know the information necessary to make judgments about what's safe and effective for patients based on the specific characteristics of the patient.

It hasn't been my practice to recommend to everyone to read the package label. That has never been an educational meme of mine, if you will.

However, including in my education information about the pharmacology, how to optimize the analgesic outcomes, what expectations should be made for side effect monitoring and how to treat side effects, and then to be aware of the risk of abuse and addiction and in recent years how to actually assess and manage that, that's always been

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

drug Fentora"; do you see that?

A. Yes.

Q. Are you aware of anything false or misleading in that seminar, "Breakthrough pain curriculum development workshop"?

A. I don't have a specific recollection of that workshop. As a general rule, I would say no, there was nothing false or misleading in workshops like that.

Q. And why would you say that as a general rule?

A. I participated in a number of educational programs devoted to breakthrough pain. Breakthrough pain was a specific interest of mine. I developed the first measurement tool for that type of pain and was involved in designing the research protocols that demonstrated how the short-acting drugs work for breakthrough pain. So it was a specific area of interest.

So I participated in a number of those kinds of programs. And all the programs that I participated in were CME programs that -- for which I created my own messages, used my own slides. There was never any effort on the part of a funding company, the sponsor, to change my messages or ask

me to use specific slides.

Q. And paragraph 30(c) indicates that you were compensated $3,000 by Advanced Strategies in Medicine.

Do you see that?

A. Yes.

Q. Was there anything wrong with being compensated for putting together a seminar that was neither false nor misleading?

A. No, I don't think so.

Q. If you turn to paragraph 30(e) -- Strike that. The next sort of bullet down, paragraph 30(d), do you see that?

A. Yes.

Q. It says, "On May 15, 2007, I worked on an advisory board for Cephalon, Inc. concerning the drug Fentora, for which I was compensated $3,500"?

A. Yes.

Q. Did I read that correctly?

A. Yes.

Q. And are you aware of anything false or misleading that was discussed at that advisory board meeting on May 15, 2007?

A. I'm not aware of anything.

Q. Was there anything inappropriate about

being compensated for your work in connection with that advisory board meeting?

A. No.

Q. And is it fair to say that that advisory board meeting was an internal meeting at Cephalon? Strike that. That's a bad --

MS. SPENCER: I was going to say, he can answer if he recalls.

MR. ERCOLE: Fair enough.

BY MR. ERCOLE:

Q. In connection with that advisory board meeting, was there any marketing done external in connection with that?

MS. SPENCER: Objection.

You can answer if you recall.

THE WITNESS: Yeah. I don't recall this specific meeting in 2007. So I really can't answer that.

BY MR. ERCOLE:

Q. As a general matter, did advisory boards engage in marketing?

A. No. As a general matter, the advisory boards did not discuss marketing.

Q. And sitting here today, with respect to the May 15, 2007 advisory board meeting for Cephalon,

you're not aware of any marketing that was done in connection with that particular meeting?

A. I'm not aware of any, no.

Q. And you're not aware of anything false or misleading said during that meeting, correct?

A. That's correct.

Q. Paragraph -- turn to the next paragraph, paragraph 30(e). It says, "On November 6, 2007, I presented a continuing medical education program, 'Meet the patients: Individualizing therapy for persistent and breakthrough pain.'"

Do you see that?

A. Yes.

Q. Are you aware of anything false or misleading -- Strike that.

In connection with that CME program, did you independently develop the content of that program?

A. I don't remember the specific program, but I'll answer yes to that because I developed the content for all of the educational programs that I did.

Q. And with respect to any CME programs you did for -- Strike that.

With respect to any CME programs that

were sponsored by Cephalon, is it fair to say that Cephalon never controlled the content of those programs?

A. That I was involved with?

Q. Yes.

A. Yes, it's fair to say that.

Q. And to the best of your recollection, the November 6, 2007 CME program was no exception?

A. That's -- To the best of my recollection, that's true.

Q. And it indicates in that paragraph that you were compensated $2,000 by Advanced Strategies in Medicine; do you see that?

A. Yes.

Q. Anything improper about you being compensated for your work in creating that CME?

A. I don't think so, no.

Q. If you go down to paragraph 30(j) --

A. Yes.

Q. -- it says, "On April 1, 2009, I participated in a Fentora medical scientific advisory board meeting"?

A. Yes.

Q. Do you see that?

A. Yes.

Q. And is the medical scientific advisory board meeting referenced there the same type of advisory board meeting that you've talked about already?

A. I don't remember this specific meeting. I remember, for example, participating in a meeting in which we designed a new research protocol for studying Fentora in -- as a repeated dose administration.

So the answer is, it could have been on a research protocol, or it could have been of the type I mentioned before where we were talking about the role of treating breakthrough pain as part of pain medicine.

Q. Anything inappropriate that you recall taking place on April 1, 2009?

A. No, not that I recall.

Q. Anything inappropriate or wrong from your perspective in connection with participating in an advisory board meeting for Fentora?

A. No.

Q. If you turn to paragraph 30(m), it says, "In May 2010, I moderated an online program called 'Medico-legal issues, clinical guidelines and opioid dose conversions.'"

Q. Are you aware of any marketing that Teva USA has done?

A. No, I'm not.

Q. Are you aware of anything false or misleading that Teva USA has said about any of its products?

A. No.

Q. Can we turn to paragraph 32 of your declaration, sir. Do you see that?

A. Yes.

Q. And if you turn -- it starts on page 21 and goes to page 22.

A. Yes.

Q. And it says in here, "A responsible company" -- Do you see the sentence that starts, "A responsible company should disclose relevant risks when communicating with the public"?

MS. SPENCER: It's on the next page.

BY MR. ERCOLE:

Q. Sorry, it goes to paragraph --

A. Yes.

MS. SPENCER: I'm just facilitating.

MR. ERCOLE: Thank you.

THE WITNESS: Yes.

BY MR. ERCOLE:

Q. Are you aware of Cephalon not disclosing any relevant risks when communicating with the public of its medicine?

A. I'm not aware of communications to the public from Cephalon.

Q. And it goes on to say, "the risks associated with opioid abuse and addiction were known at that time."

Do you see that?

A. Yes.

Q. That would have been in 2004?

A. Yes.

Q. So in 2004, in your declaration, you're confirming that the risks associated with opioid abuse and addiction were known, correct?

A. Correct.

Q. And they would have been known within the medical community, correct?

A. Yes.

Q. If you turn to paragraph 34 of your declaration, I believe it's page 23.

A. Yes.

Q. It says, "I believe that, over the years, some defendant drug companies have used my work to

promote opioids by referencing the positive statements that I made repeatedly without providing the background, analysis of the literature, and cautions that accompanied these positive statements."

Do you see that?

A. Yes.

Q. Are you aware of any instances where Cephalon did that?

MS. SPENCER: All you can answer is what you know.

THE WITNESS: Yes. So I'm not aware of an example where Cephalon has done that, no.

BY MR. ERCOLE:

Q. And you're not aware of an example of Teva USA doing that?

A. No.

Q. If you turn to paragraph 35 of your declaration. Do you see that, sir?

A. Yes.

Q. And I think it may be the fourth sentence down. It says, "Although I personally was never influenced to say things I did not believe," do you see that?

A. Yes.

Q. What did you mean by that?

A. Essentially what we were saying before. That in the funding that I received for educational programs or in the funding that I received for research projects, I personally was never asked to craft a specific message or not -- not convey a message that I originally put into some educational materials or to do a specific kind of research or change my research methodology. I haven't personally experienced that.

Q. And if you keep going where there's a reference to "they used the positive statements that I made about opioids to portray opioid treatment as safe and effective without the accompanying discussion of risk that I included in the papers, chapters, and lectures I produced beginning in the 1980s."

Do you see that?

A. Yes.

Q. Are you aware of any instance where Cephalon did that with respect to opioids?

A. Yeah. I don't have any specific recollection of that -- of those materials from Cephalon.

Q. About Teva USA?

A. No.

Q. If you turn to paragraph 36.
A. Yes.
Q. It says -- last sentence there -- "I believe that the drug companies created material that narrowly focused on the potential for safe and effective treatment of chronic noncancer pain, some of which was attributed to my work, but failed to include an adequate and balanced discussion of the limitations in the relevant science and the risks as they were then known."
Do you see that?
A. Yes.
Q. Any instances where Cephalon did that?
MR. BECKWORTH: Objection.
MS. SPENCER: You can answer to the extent that you know.
MR. BECKWORTH: Yeah. That's my objection. Are you asking him if he remembers or if there are, in fact, any?
MR. ERCOLE: Well, I appreciate the objection. So I'll let the question stand.
BY MR. ERCOLE:
Q. And you can answer the question if --
A. Yeah. I don't recall any.
Q. So sitting here, you don't recall any

instances where that happened with respect to Cephalon?

A. That's correct.

Q. Would the same hold true with respect to Teva USA?

A. Yes.

MR. BECKWORTH: Same objection.

BY MR. ERCOLE:

Q. If you turn to paragraph 38, do you see that?

A. Yes.

Q. It's a reference to the American Pain Foundation?

A. Yes.

Q. And was the American Pain Foundation formed to help patients -- Strike that.

Was the American Pain Foundation formed to help patients?

A. Patients, families, and the lay public.

Q. Do you think it did?

A. Yes.

Q. And how do you think it did?

A. It did a variety of programs that accomplished a lot of good. For example, it had a hotline that patients in distress or family members

would call. And the hotline received thousands of calls from distressed patients asking for information. It created educational materials at a patient reading level that it distributed about pain management. Those kind of materials weren't available anywhere else.

Q. And if you go down -- And the American Pain Foundation is no longer in existence today, correct?

A. That's correct.

Q. If you go down to the sentence that begins, "Although management and board members were never induced to create specific messages or change a message that was proposed as part of any project," do you see that?

A. Yes.

Q. What do you mean by that, sir?

A. I'm not aware of any time that a project that was funded by a pharmaceutical company as part of a grant request was needed to be changed, needed to be modified because the drug company wasn't comfortable with the project and requested specific changes in the messages.

I think that all these grants were considered to be unrestricted grants that would fund the project that would be under the control of the

management of the APF.

Q. And would it be fair to say that to the best of your knowledge, none of the pharmaceutical companies that have been sued in this case controlled the content of any product put out by the American Pain Foundation?

A. To the best --

MR. BECKWORTH: Objection.

THE WITNESS: To the best of my knowledge, that's true.

BY MR. ERCOLE:

Q. Would that hold true for the other third-party societies that you were involved with?

A. Yes. To the best of my knowledge, that's true.

Q. If you turn to paragraph 40 of your declaration.

A. Yes.

Q. Do you see that? It says, "I understand that pharmaceutical companies assisted in publicizing these guidelines and relied on them in marketing of publications."

Do you see that?

A. Yes.

Q. Are you aware of Cephalon ever doing that?

MR. BECKWORTH: Objection.

THE WITNESS: I don't have any --

MS. SPENCER: You can answer.

THE WITNESS: I don't have any specific information about Cephalon.

BY MR. ERCOLE:

Q. Are you aware of Teva USA ever doing that?

MR. BECKWORTH: Same objection.

THE WITNESS: No.

BY MR. ERCOLE:

Q. And I assume certainly you were never aware of Cephalon and Teva USA doing anything like that in Oklahoma, correct?

MR. BECKWORTH: Objection.

THE WITNESS: Correct.

BY MR. ERCOLE:

Q. If you turn to paragraph 42 of your declaration.

A. Yes.

Q. The first paragraph talks about opioid therapy being an appropriate first-line therapy for some types of -- for different types of pain; do you see that?

A. Yes.

Q. And there's a reference there to, "Opioid

MR. ERCOLE: So just to get on the record as you're --

MS. SPENCER: Yes, go ahead.

MR. ERCOLE: -- Dr. Portenoy, as your counsel knows, Judge Hetherington indicated that the State would have four hours, the defendants would have six hours. Now, I appreciate it was a recommendation, and I appreciate we've --

MS. SPENCER: That's not --

MR. ERCOLE: -- made that --

MS. SPENCER: I'll object. That's not what the order provided.

MR. ERCOLE: Well, we --

MR. BECKWORTH: Told you.

MR. ERCOLE: -- we may disagree on that. But fair enough. The request is obviously that I'd like maybe 15 more minutes or so and we'll -- I'll wrap up then.

MS. SPENCER: I will absolutely grant you 15 more minutes. My understanding of the order, and what my agreement is, is that you will have equal time. So along those lines, I will also permit Attorney Beckworth to ask 15 more minutes -- 15 minutes' worth of questioning as well. And that's equal time.

MR. ERCOLE: Sorry, sir. Before I was interrupted by the back-and-forth here, I need to go back and check where I was. I apologize for that interruption.

MR. BECKWORTH: And while you're doing that, just to be fair, to respect Amy's wishes, if you don't go that long, that's fine. If you stop now, I'll take the three or whatever we're over, to be fair to everyone --

MR. ERCOLE: Thank you.

MR. BECKWORTH: -- meaning equal time.

BY MR. ERCOLE:

Q. So let me -- so my question is, are you aware of any false or misleading statement said by Teva USA that has caused any particular prescriber to write an opioid prescription that was inappropriate?

MR. BECKWORTH: Same --

THE WITNESS: No, not to my knowledge.

BY MR. ERCOLE:

Q. And certainly not in Oklahoma; is that fair to say?

MR. BECKWORTH: Same objection.

THE WITNESS: Correct.

BY MR. ERCOLE:

Q. Are you -- Dr. Portenoy, are you aware that Cephalon manufactures a drug by the name of Actiq?

A. Yes.

Q. And are you aware that Cephalon manufactures a drug by the name of Fentora?

A. Yes.

Q. Have you ever prescribed Actiq or Fentora?

A. Yes.

Q. Have you ever prescribed Actiq or Fentora for breakthrough pain in patients who do not have cancer?

A. Yes.

Q. Can you describe some of those circumstances where you've done that.

MS. SPENCER: Again, within the confines of HIPAA, yes.

BY MR. ERCOLE:

Q. And I apologize. Yes. I don't need you to disclose names or specific information. Just --

A. Yes.

Q. -- some examples where that has happened.

A. Well, I recall one patient who has a diagnosis of a condition called medullary sponge kidney. This patient makes kidney stones and has