IN THE DISTRICT COURT OF CLEVELAND COUNTY

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 TRIAL BRIEF

EXHIBIT H

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

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

Case Number
CJ-2017-816

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., f/k/a JANSSEN PHARMACEUTICALS, INC.;
(9) JANSSEN PHARMACEUTICA, INC., f/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, 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.

VIDEO DEPOSITION OF STEVEN ALAN CRAWFORD, M.D.
TAKEN ON BEHALF OF THE DEFENDANTS
ON FEBRUARY 13, 2019, BEGINNING AT 9:06 A.M.
IN OKLAHOMA CITY, OKLAHOMA

Reported by: Cheryl D. Rylant, CSR, RPR
Video Technician: Kaleb Pianalto
PAGES 1 - 360

comments. 09:38

Q. And that is true for almost every 09:38

prescription medication, correct? 09:38

MS. BALDWIN: Object to form. 09:38

Q. (By Mr. Ehsan) Well, let me ask the question 09:38

slightly better. 09:38

All prescription medications carry risks, correct? 09:38

A. Yes, sir, all medications, whether they're 09:38

prescription or not. 09:38

Q. That's true. You can potentially do a lot of 09:38

harm with over-the-counter medications as well, 09:38

correct? 09:38

A. Yes, sir. 09:38

Q. So when you prescribe any medication, you 09:38

engage in a risk and benefit an -- assessment for the 09:39

patient receiving the medication, correct? 09:39

A. Yes, sir. 09:39

Q. So for -- specifically focusing on opioids. 09:39

Opioids have risk of respiratory depression, correct? 09:39

A. Yes, sir. 09:39

Q. They carry the risk of constipation, correct? 09:39

A. Yes, sir. 09:39

Q. They carry the risk of mental confusion or 09:39

fogginess, correct? 09:39

A. Yes, sir. 09:39

Q. They carry the risk of potentially increasing intracranial pressure, correct? 09:39

A. Yes, sir. 09:39

Q. And they also carry the risk of potential addiction, misuse, or abuse, correct? 09:39

A. Yes, sir. 09:39

Q. Now, when -- when did you first start prescribing opioids in any clinical setting? 09:39

A. Again, it was a number of years ago, but I think it must have been during my residency. 09:39

Q. So some -- somewhere back in the '80s. Would that be fair? 09:40

A. '70s. '79 was when I started my residency. 09:40

Q. And at the time -- going back to '79 to present. Were you aware that opioids carried the risk of respiratory depression? 09:40

A. Yes, sir. 09:40

Q. When did you first become aware of that risk? 09:40

A. Probably during medical school, but, again, that's been a number of years ago. 09:40

Q. And that is an understanding you've held consistently to present? 09:40

A. Yes, sir. 09:40

Q. Focusing on the risk of constipation with opioids. When did you first understand that opioids 09:40

carry the risk of constipation? 09:40
A. Again, probably during medical school. 09:40
Q. And you've consistently held that view to 09:40
present? 09:40
A. Yes, sir. 09:40
Q. How about the risk of opioids for addiction, 09:40
abuse, or misuse, when did you first become aware of 09:40
that risk? 09:40
A. During medical school. 09:40
Q. And that -- 09:40
A. Or --
Q. Go ahead. 09:40
A. Sorry.
Q. I'm sorry. 09:40
A. During medical school. 09:40
Q. And have you had -- and have you held that 09:40
understanding to present? 09:40
A. No. 09:40
Q. Okay. How -- how has your understanding of 09:41
the risk of -- of the fact that opioids have a risk 09:41
of abuse and misuse -- let me strike that and ask the 09:41
question differently. 09:41
Has there ever been a point in time where you 09:41
believed that opioids didn't cause or didn't carry 09:41
the risk of abuse or misuse? 09:41

oxycodone, and oxymorphone have the highest potential for abuse and associated risk of fatal overdose due to respiratory depression. Fentanyl can be abused and is subject to criminal diversion. The high content of fentanyl in the patches called Duragesic may be a particular target for abuse and diversion." 02:09 02:09 02:09 02:09 02:09 02:09

Q. In representing to you that this was a 2005 label, would the language in the bolded box warning adequate -- well, strike that. 02:09 02:09 02:09

Would you agree with me, Dr. Crawford, that the language you just read from this box warning convey a message that this drug carries a risk of abuse, misuse, or addiction? 02:09 02:09 02:09 02:09

A. Yes. 02:09

Q. And it states it quite plainly, correct? 02:10

A. Yes, sir. 02:10

Q. So if this is the 2005 label for Duragesic, a doctor who would have read this label in 2005 would have been able to understand that this meant that all Schedule II opioids carry a significant risk of addiction and criminal diversion, correct? 02:10 02:10 02:10 02:10 02:10

A. That's what it says. 02:10

Q. And when you prescribe Duragesic to your patients today, are you aware that there's a risk of addiction and abuse associated with the fentanyl, 02:10 02:10 02:10

which is the active ingredient in Duragesic? 02:10
A. Yes, sir. 02:10
Q. Now, I think you mentioned that one of the 02:10
sources of information you rely in assessing the risk 02:11
and benefit of a medication was the drug label. Do 02:11
you recall that testimony? 02:11
A. Yes, sir. 02:11
Q. And I just wanted to make sure I heard you 02:11
when -- when we had this discussion correctly. But 02:11
is it your practice to make sure you are familiar 02:11
with the prescribing information or label for a drug 02:11
if you're going to prescribe it to a patient? 02:11
A. Yes, sir. 02:11
Q. And would you agree with me, Doctor, that you 02:11
would never disregard the information -- or strike 02:11
that.
Would you agree with me, Doctor, that you never 02:11
disregarded information in a product label based on 02:11
something a pharmaceutical representative told you; 02:11
is that correct? 02:11
MS. BALDWIN: Object to the form. 02:11
THE WITNESS: I don't recall ever doing 02:11
that, no. 02:11
Q. (By Mr. Ehsan) Could yourself -- see 02:11
yourself doing that? 02:12

MS. BALDWIN: Object to the form. 02:12
THE WITNESS: To re -- to -- 02:12
Q. (By Mr. Ehsan) Let me -- 02:12
A. -- believing a -- what a pharmaceutical rep says and they're saying, "No, this drug is safe," is what you're -- 02:12
Q. Yes, sir. 02:12
A. If a -- if a drug rep came and told me this is a safe medicine, to give as high a dose as I wanted, I think it's poppycock, but. 02:12
Q. So if a -- a pharmaceutical representative or detailer came to you and told you Duragesic is not addicting, despite the bold information that's in this label, you would defer to the bolded information in the label, correct? 02:12
MS. BALDWIN: Object to the form. 02:12
THE WITNESS: In the issue of current, yes. In the mid '90s, which this wasn't part of, I had that belief challenged. 02:12
Q. (By Mr. Ehsan) Understood. And that's the article we talked about, correct? 02:12
A. Yes, sir. 02:12
Q. Understood. 02:12
And the -- the science has continued to -- to -- strike that. 02:12

specific instance where you didn't make a prescribing decision in the best interest of your patient?

MS. BALDWIN: Object to form.

THE WITNESS: If I know what I do today, I probably would not have accelerated many of my patients with their opioid prescribing and tried my best to limit those, particularly to less than 90 MME, or even less, 50 MME.

Q. (By Mr. Ercole) Are you aware of any instance -- well, can you -- can you -- are you aware of any instance where you did not make a prescribing decision that was in the best interest of the patient based upon the science available at that time?

MS. BALDWIN: Objection to form.

THE WITNESS: Based on what I knew at the time, I thought I made the right decision at the time.

Q. (By Mr. Ercole) Have you ever heard of the company Cephalon?

A. I've heard of it.

Q. Do you know whether that company manufactures opioid medicines?

A. I think I am now. I wouldn't -- if you had asked me, you know, a year ago, I probably wouldn't. It's a relatively smaller company from what I know,

but don't know much more about it than that. 04:49

Q. Sure. 04:49

So is it -- is it -- is it fair to say, then, that 04:49

you were -- you never -- since you didn't know of 04:49

Cephalon until about a year ago, you never interacted 04:49

with any Cephalon sales representative? 04:50

A. Not -- not that I'm aware of. I can't 04:50

remember any Cephalon sales reps. 04:50

Q. And it's fair to say that you're not aware of 04:50

any false or misleading statements that -- that any 04:50

representatives of Cephalon ever made to you? 04:50

A. At the time, no. I don't know if -- if I -- 04:50

anyway, no, not at the time. 04:50

Q. Well, I guess, sitting here today, can you -- 04:50

can you identify -- 04:50

A. Even -- even today, I don't know of any 04:50

specific Cephalon-related materials that would be 04:50

considered something that would be out of the pail as 04:50

it were. 04:50

Q. Sitting here today, are you aware of any 04:50

Cephalon-related materials that you would have 04:50

received? 04:50

MS. BALDWIN: Object to form. 04:50

THE WITNESS: No. 04:50

Q. (By Mr. Ercole) Sitting here today, are you 04:51

aware of any statements made by Cephalon to any prescribers in Oklahoma? 04:51

MS. BALDWIN: Object to form. 04:51

THE WITNESS: I'm -- I'm not aware of any, but I -- that's -- yes. Don't know. Have no idea. 04:51

Q. (By Mr. Ercole) You mentioned before that within the last 10 years, you've had limited, if any, interactions with pharmaceutical representatives; is that fair to say? 04:51

A. That is correct. 04:51

Q. And do you recall any interactions with pharmaceutical sales representatives within the last 10 years? 04:51

A. Vaguely, yes. 04:51

Q. And do you recall the companies for which any of those sales representatives worked? 04:52

A. The most recent were vaccine manufacturers reps, science representatives, not marketing representatives, Sanofi Pasteur and Pfizer. I'm trying to think of the other. GSK. I give talks on vaccines and like to know what they're coming up with, with new products. So I do meet with the science reps, but not with the marketing reps. 04:52

Q. Fair enough. 04:52

How about since 2011, are you aware of any 04:52

interactions you've had with any representatives of pharmaceutical companies concerning its opioid medicine? 04:52 04:52 04:52

A. No, sir. 04:53

Q. And have you ever heard of the company Teva Pharmaceuticals? 04:53 04:53

A. Yes. 04:53

Q. And I assume, since 2011, you're not aware of any interactions you've had with any representative of Teva Pharmaceuticals, correct? 04:53 04:53 04:53

MS. BALDWIN: Object to form. 04:53

THE WITNESS: No, sir. 04:53

Q. (By Mr. Ercole) Do you -- sitting here today, do you recall any interactions that you've ever had with a representative of Teva Pharmaceuticals? 04:53 04:53 04:53 04:53

A. I think when we had reps coming, I believe Teva had a PPI drug -- I think that's right. You know what I mean by a PPI? 04:53 04:53 04:53

Q. And, now, please feel free to enlighten us. 04:53

A. Proton pump inhibitor. 04:53

Q. Okay. 04:53

A. And which one it is, I don't know. It's like a Prilosec. It wasn't a Prilosec, but something like that. I think that they were one of the 04:53 04:53 04:53

manufacturers of one of those drugs. That's the -- the only thing I vaguely recall of Teva. 04:53 04:53

Q. And just so my notes are clear, that's -- sitting here, that's the only product you ever recall being discussed with you by any representative of Teva; is that correct? 04:54 04:54 04:54 04:54 04:54

A. That's all that I can vaguely recall, and it's a distant memory. 04:54 04:54

Q. And that -- that particular PPI product may have been actually manufactured by a -- a different company? 04:54 04:54 04:54

A. Could. Could. But I -- I don't know. I wouldn't put a lot of money on my memory on that one. 04:54 04:54

Q. And it's -- it's been some time, correct? 04:54

A. Yes. 04:54

Q. Can you -- 04:54

MR. ERCOLE: Can we go off the record for one minute? 04:54 04:54

VIDEO TECHNICIAN: We're going off the record at 4:55 p.m. 04:54 04:54

(Break was taken.) 04:54

VIDEO TECHNICIAN: We're back on the record at 5:02 p.m. 05:02 05:02

Q. (By Mr. Ercole) Doctor, we were talking about the PPI inhibitor. Do you recall that? 05:02 05:02

A. Yeah. 05:02

Q. And I guess you recall sort of one 05:02

interaction with, perhaps, a Teva representative 05:02

regarding a PPI inhibitor, correct? 05:02

A. Right. 05:03

Q. Any statements from Teva Pharmaceuticals 05:03

regarding opioids that you ever recall receiving? 05:03

A. No, sir. 05:03

Q. Any statements regarding opioids that you -- 05:03

from Teva Pharmaceuticals that you recall being 05:03

disseminated in Oklahoma at all? 05:03

MS. BALDWIN: Object to form. 05:03

THE WITNESS: I don't recall any. 05:03

Q. (By Mr. Ercole) So sitting here today, you 05:03

can't identify any, correct? 05:03

A. No, sir. 05:03

MS. BALDWIN: Object to form. 05:03

Q. (By Mr. Ercole) Doctor, sitting here today, 05:03

are you aware of any false or misleading statement 05:03

any sales representative for any drug manufacturer 05:03

ever made to you or -- strike that. Let me rephrase. 05:03

Sitting here today, are you aware of any false or 05:03

mislead -- misleading statement any sales 05:03

representative for any drug manufacturer ever made to 05:03

you? 05:04

MS. BALDWIN: Object to form, asked and answered. 05:04

THE WITNESS: As I said, I think, from what I know now, there were manufacturers' reps that encouraged the use of opioids in chronic severe nonmalignant pain. 05:04

Q. (By Mr. Ercole) Okay. 05:04

A. And I -- to say -- to state the exact person that did that, no, I can't tell you that. But I do believe I remember that there was encouragement of that. 05:04

Q. Sure. 05:04

So you mentioned -- you used the words manufacturer reps that encouraged the use of opioids, correct? 05:04 05:05

A. Yes. 05:05

Q. Okay. My question is a little bit different than that. 05:05

Sitting -- 05:05

A. Okay. 05:05

Q. -- here today, can you recall any false or misleading statement that any sales representative for any drug manufacturer ever said or made to you? 05:05

MS. BALDWIN: Objection, asked and answered multiple times. 05:05

comfortable with now. 05:10

Q. (By Mr. Ercole) And you say "higher dose," 05:10
right? 05:10

A. Higher and longer, yes, sir. 05:10

Q. When you say -- so higher, is that -- just so 05:10
that my notes are clear, higher and longer. What do 05:11
you mean by "higher and longer"? 05:11

A. Higher, greater than 90 MME -- 05:11

Q. Uh-huh. 05:11

A. -- for a definite, but even greater than 50, 05:11
which I have some patients on, and continuing to 05:11
help -- to have to follow those patients. And 05:11
longer, that the longer you have somebody on it, the 05:11
harder it is to have them reduce those doses. 05:11

Q. Sitting here today, though, can you actually 05:11
say that you would not have written a particular 05:11
opioid prescription for a particular patient based 05:11
upon your medical assessment? 05:11

MS. BALDWIN: Object to form, asked and 05:11
answered multiple times. 05:11

THE WITNESS: I would probably use much 05:11
less of a strength and escalating that dose, as I've 05:11
said before. 05:11

Q. (By Mr. Ercole) Sure. 05:11

And -- and fair enough with respect to strength. 05:11

But at least with respect to the opioid -- initial opioid prescription itself? 05:12

A. I -- I -- 05:12

Q. Is it -- I mean, you've been talking about -- about strength -- 05:12

A. Right. 05:12

Q. -- and -- and the -- the dose of the opioid prescription, correct? 05:12

My question is a little bit different, which is, sitting here today, can you identify any particular patient for -- for which you would not have written an opioid prescription that you actually did write a prescription for? 05:12

MS. BALDWIN: Object to form, asked and answered. 05:12

THE WITNESS: At this point, no, I can't -- I -- I don't recall any particular patient. There's patients that came to me who were already on opioids that I would attempt more aggressively to reduce their dose, but -- and that I've continued on that -- the higher dose that I'm now trying to reduce because of the change in belief of the use of chronic long-term high-dose opioids. 05:13

Q. (By Mr. Ercole) And, again, your -- the answer that you just gave deals with sort of moving 05:13

from a higher dose of opioids to a lower dose of opioids, correct? 05:13

A. And shorter -- 05:13

MS. BALDWIN: Object to form. 05:13

THE WITNESS: -- duration. 05:13

Q. (By Mr. Ercole) Sure. 05:13

The -- you mentioned the labels of -- we talked about the labels of -- of opioids and what they disclose, correct? 05:13 05:14 05:14

A. Yes, sir. 05:14

Q. And the -- is it fair to say that the -- do you have any reason to doubt that the labels of opioid medicines over the last three decades disclosed the risk of -- of abuse and addiction with respect to those medicines? 05:14 05:14 05:14 05:14 05:14

MS. BALDWIN: Object to form. 05:14

THE WITNESS: So 30 years ago would have been 1998; is that right? Or 1988? '88. 05:14 05:14

Q. (By Mr. Ercole) '88. Your -- your math is better than mine, but -- 05:14 05:14

A. It's late in the day. I'm trying to think. It's '88. I have no idea, in 1988, what the drug insert said. Show me one. 05:14 05:14 05:14

Q. Give me one second. 05:15

A. Sure. 05:15

EXHIBIT I

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
(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.	)

PORTIONS OF THE TRANSCRIPT ARE COVERED UNDER THE PROTECTIVE ORDER

TRANSCRIPT OF MOTIONS HEARING
HAD ON THE 11TH DAY OF APRIL, 2019,
BEFORE THE HONORABLE
THAD BALKMAN, DISTRICT JUDGE
AND WILLIAM C. HETHERINGTON, JR.,
RETIRED ACTIVE JUDGE AND SPECIAL DISCOVERY MASTER

REPORTED BY: Tanya Burcham, CSR, RPR

it is carried forward to this very day. It's always been that way.

The defendant J & J cited something in their brief that there's another statute that talks about if you have a claim for money, then that might mean you have a right to a jury trial. If you just read that, you might believe that they're right. In fact, when I read it I was thinking to myself, wow, maybe they're right. But as I learned in the two years of dealing with all of the drug companies in the case, what they say and what's actually correct unfortunately are widely varied. That is not the law in Oklahoma. We didn't think it was the law in Oklahoma. We know it's not the law in Oklahoma. What that statute deals with is if you have a case that's primarily about money, i.e. legal damages, that's -- you get a right to a jury trial. That's pretty simple. We all know that. That's not the case when the thrust of your case is about equity, as an abatement case is.

Now, let's just stop there for a second. If you'll remember, when I first started this morning, I talked about the three prongs of nuisance law available to the attorney general. Statutes exist for a reason. And when you have one that divides it up into indictment, civil action, and abatement, that's not a

meaningless or superfluous list there. Abatement is listed as a standalone on its own. It exists that way because it is something unique and different from a civil action for damages. That has always been the case.

So we can turn to the idea of what a nuisance case is in Oklahoma and how it works. When we talk about abatement, let's just start with what happens in a nuisance case and what you have to show. It's a critical point that's been made in front of Judge Hetherington on some issues for discovery. In a nuisance case, on a public nuisance case, when you look at this first prong about did the defendant unlawfully act or omit to perform a duty -- it's very critical -- that does not mean that you have to show the defendant was negligent. It does not mean you have to show something like approximate cause. None of our nuisance laws found in the torts or negligence or approximate cause or foreseeability. I'll read to you from a North Dakota case defining their statute, which is where ours comes from. This is the *Knoff v American Crystal Sugar* mal. 380 N.W.2d 313. It's a 1986 Supreme Court case on nuisance out of North Dakota. It deals with wastewater lagoons and how they affected agricultural property.

But in the question before the Court on

whether the plaintiff had to show negligence or anything like that, the Court said we have previously distinguished between nuisance and negligence principles. And it is well settled that a nuisance may be created wholly without negligence. Negligence may or may not result in the creation of a nuisance, and on the other hand a nuisance may be created wholly without negligence. The court goes on to say that proof of absence of negligence is not a defense to an action grounded in nuisance because the focus is upon the condition created and not upon the exercise of care or skill by the defendant. It goes on to say that the statute defines nuisance, in part, of omitting to perform a duty, which is what you see before you. And the type of duty which gives rise to claim of nuisance may differ from the duty implicated in a negligence action. And I'm reading from the court, quote, to render a person liable on the theory of either nuisance or negligence, there may be some breach of duty on his part, but liability for negligence is based on a want of proper care, while ordinarily a person who creates or maintains a nuisance is liable for the resulting injury to others regardless of the degree of care or skill exercised to avoid the injury. The creation or maintenance of a nuisance is a violation of an absolute

duty. The doing of an act, which is wrongful in itself, where negligence is a violation of a relative duty, the failure to use a degree of care required under particular circumstances in connection with an act or omission which is not of itself wrongful. It goes on to say, nuisance is a condition and not an act or failure to act so that a wrongful condition exists. The person responsible for its existence is liable for resulting damage to others.

Why did I read all that? Well, a couple of reasons. One, much of the case that the defendants have tried to put on through discovery deals with their claims that they're not at fault, but the State of Oklahoma is. Somehow we don't make drugs but we're responsible for the worst public health crisis in US history.

We talked about this with Judge Hetherington, and I explained this issue to Judge Hetherington. There are no negligence claims here. Johnson & Johnson stood up in court and said yes there is. There's a negligence claim, there's a negligence claim. I invited them to read our petition. They had to come back and write a letter to Judge Hetherington apologizing for making that statement and admitting that there is no negligence in this case. And because

there's no negligence in this case, there's no contribution claim against the State, which will come up in just a minute on why that's important.

But the other reason that I'm reading this is that when you're talking about nuisance, as you see the North Dakota court do here and we've got tons of Oklahoma law on this, you're dealing with a condition. The condition is the problem. And when you go back to the statute of what empowers the attorney general to do, in this case, his job, he's called upon to choose certain remedies. One of them is abatement. In here we're talking about abatement to remedy the condition. That's what this case is about. That's why we don't have a jury trial. That is what we're asking Your Honor to do.

So words matter. The lawyers in this case know that I'm very fond of a dictionary because I was told by one of the lawyers in a deposition that words matter. So I started using a dictionary quite a bit in cases. Mr. Merkley doesn't like it. He's tried to ask us to actually use our phones where we pulled dictionaries up and leave them in the record. And we've objected to that because we need them. So today, actually instead of my phone, I brought a hard copy of the dictionary. But this isn't just any dictionary,

titled Costs to the State of Oklahoma of Abating the Opioid Crisis. And because that is central here, under 12 OS 556, Janssen is entitled to a jury trial on the State's public nuisance claim.

Now, you know, we heard about joint and several liability. We will have the -- certainly have the opportunity to, I am sure, to brief the impact of the amendments to, I believe it's 21 OS 15(B) on an action brought -- maybe it's 15 OS. But we'll have the opportunity to brief that to explain how the amendments to the joint and several liability statute merely mean that we revert to the common law in this case. That's not at issue right now. I assume they will argue it again when we get to the severance portion of this, and Mr. McCampbell will be addressing that primarily on our side. We'll address that as well. That has nothing to do with the issue before the Court, which is again very simple: Does Section 556 give Janssen a right to jury trial on the claim as it stands now before the Court. And on that question, the answer is yes. Thank you.

THE COURT: Thank you, Mr. Brody.

Mr. McCampbell, did you have something to add?

MR. MCCAMPBELL: Very briefly, Your Honor. Brad, I'll go next and then you can go.

MR. BECKWORTH: Certainly. I was assuming

you were agreeing with us.

MR. MCCAMPBELL: I think I am. Let's talk about that. As the Court will recall, I want to make sure we've got a good, clear understanding about what this trial will be at -- will be about, and with that understanding we would be ready to go forward in a non jury context.

Mr. Beckworth has explained this morning that they're not asking for future damages, they're not asking for punitive damages, and that solves two out of the three clarifications. The third clarification is related to the issue Mr. Brody addressed, which is the difference between a permanent and a temporary nuisance. And by definition, a temporary nuisance is one that can be abated. A permanent nuisance is a nuisance that can not be abated. So money addressing permanent nuisance would be damages. Abating a temporary nuisance, that's an abatement remedy, and I understand the State says sometimes that would include money to abate it, and I understand that. I also understand -- Brad will want to listen to this part.

MR. BECKWORTH: I'm ready.

MR. MCCAMPBELL: I also understand Mr. Beckworth and I may have some disagreements about whether a particular item is that of permanent nuisance

or a temporary nuisance. We can talk about that and if we can't resolve it the Court can resolve it. The framework I'm looking for, though, is I think we're all agreeing what we're looking at here are temporary nuisances that can be abated. And that's the third clarification we need to go forward and say, yeah, we're ready to go without a jury on this.

THE COURT: Thank you, Mr. McCampbell.

MR. BECKWORTH: Were you done or do you just want me to agree?

MR. MCCAMPBELL: If you're in a position to agree then we can make progress.

MR. BECKWORTH: I don't disagree with any of it.

MR. MCCAMPBELL: That being the case, Your Honor, we would be willing to go forward in a non jury context and in a non jury trial.

I do want to state, this is not based on my analysis of the law whether a jury trial is required or not. And as between Mr. Beckworth and Mr. Brody, I haven't done that analysis. Our analysis was, if that's what we're talking about, then it makes sense to go forward in a non jury context, and that's what we'd like to do. These abatement remedies, particularly appropriate for the Court to look at it, and also, of

course, it's a way more efficient proceeding. It can go much faster. And we're just agreeing with the State that would be the logical way to go about that. Thank you.

THE COURT: Thank you. Mr. Beckworth, I'll give you five minutes to respond to Mr. Brody.

MR. BECKWORTH: Judge Hetherington usually limits me to one, but thank you. And I'm glad -- you may not know this, but we've got Teva's national inhouse general counsel -- inhouse general counsel here today and there are outside counsel too. It's good everybody is here and Mr. McCampbell and I came to the agreement and I think that's right. I can do it in five or less, Your Honor.

First, General Hunter wrote me a note. Let me read it. I agree with it, but I'll read it anyway. It says, Not an action for the recovery of money. I have said that over and over today. Let's address this again. We're not seeking future damages. We're not seeking past damages. We're seeking an abatement of a nuisance, and that's it. And that happened, the first case that I read to you earlier, let's just go into this real quick. There was a nuisance. The Court said there was an injunction to stop conduct, and an abatement order to order the defendant to pay the cost of cleaning

CERTIFICATE

STATE OF OKLAHOMA)
COUNTY OF CLEVELAND)

I, Tanya Burcham, a Registered Professional Reporter within and for the State of Oklahoma, do hereby certify that I was present at the proceedings had April 11, 2019; that I recorded in stenotype notes all of said proceedings, that I thereafter transcribed my notes so taken and reduced same to typewritten form, and that the foregoing Transcript of Proceeding is full, true, correct and complete, to the best of my skill and ability.

I further certify that I am not an attorney for nor relative of any of said parties or otherwise interested in the outcome or event of said action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal this 13th day of April, 2019.

_____
Tanya Burcham, CSR, RPR

EXHIBIT J

STATE OF NORTH DAKOTA **IN DISTRICT COURT**

COUNTY OF BURLEIGH **SOUTH CENTRAL JUDICIAL DISTRICT**

State of North Dakota Ex Rel. Wayne Stenehjem, Attorney General,

Plaintiff,

v.

Purdue Pharma L.P.; Purdue Pharma, Inc., The Purdue Frederick Company, Inc., and Does 1 through 100, inclusive,

Defendants.

Case No. 08-2018-CV-01300

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

INTRODUCTION

[¶1] This matter is before the Court on the Defendants', Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc. (collectively "Purdue"), Motion to Dismiss for failure to state a claim. The State has sued Purdue in this matter seeking to essentially hold it liable for the impact of opioid overuse and addiction in North Dakota. The State asserts claims for alleged violations of the North Dakota Unlawful Sales or Advertising Practices statute, N.D.C.C. § 51-15-01 *et seq.* (Consumer Fraud law) (Counts 1 & 2) and the nuisance statute, N.D.C.C. § 42-01-01 *et seq.* (Count 3).

[¶2] In its Motion, Purdue argues the present case should be dismissed on the pleadings for various reasons, including the following:

1. The State's claims fail as a matter of law because it seeks to impose liability for Purdue's lawful promotion of FDA-approved medications for an FDA-approved use, i.e. the claims are preempted by federal law.
2. The State does not plead the essential elements of causation.
3. The State's statutory public nuisance claim fails because North Dakota

courts have not extended that statute to cases involving the sale of goods, and, even it did apply, the State does not allege that Purdue unlawfully interfered with a public right in North Dakota.

[¶3] The Plaintiff, the State of North Dakota ex rel. Wayne Stenehjem, Attorney General ("the State"), resists the Motion arguing they have sufficiently pled their claims and Purdue's arguments mischaracterize the claims.

[¶4] A hearing was held on the Motion on February 26, 2019. Parrell Grossman and Elin Alm appeared on behalf of the State. Will Sachse appeared and argued on behalf of Purdue. Robert Stock also appeared on behalf of Purdue.

[¶5] The Court has extensively reviewed the parties' briefing on the present Motion, on more than one occasion, and has reviewed the oral arguments presented by both parties. The Court has also extensively reviewed the State's Complaint in this matter, paying careful attention to the allegations detailed therein, following oral argument.

FACTS

[¶6] The facts underlying this Action are detailed at length in the Complaint [DE 2], and in the parties' respective briefing on the present Motion to Dismiss [DE 13 & DE 34]. The Court will not restate the facts as outlined by the parties, but incorporates those facts by reference into this Order.

[¶7] The State of North Dakota filed this action against drug manufacturer, Purdue Pharma, alleging the opioid epidemic and a public health crisis in North Dakota were caused, in large part, by a fraudulent and deceptive marketing campaign intended by Purdue to increase sales of its opioid products. The State alleges it has paid and will continue to pay expenses for the medical care and law enforcement response of North Dakota's population due to overuse, addiction, injury, overdose, and death. The State

seeks damages, injunctive relief, and civil penalties.

[¶8] The State's Complaint asserts three causes of action: (1) violations of North Dakota's Consumer Fraud Law – Deceptive Practices (N.D.C.C. 51-15-01 et seq.); (2) violation of North Dakota's Consumer Fraud Law – Unconscionable Practices (N.D.C.C. 51-15-01 et seq.); and (3) statutory public nuisance.

[¶9] Purdue now seeks to dismiss the State's claims as a matter of law.

LEGAL STANDARD

[¶10] A motion to dismiss a complaint under N.D.R.Civ.P. 12(b)(6) test the legal sufficiency of the statement of the claim presented in the complaint. *Ziegelmann v. Daimler Chrysler Corp.*, 2002 ND 134, ¶ 5, 649 N.W.2d 556. "Because determinations on the merits are generally preferred to dismissal on the pleadings, Rule 12(b)(vi) motions are viewed with disfavor." *Id.* A complaint "should not be dismissed unless it is disclosed with certainty the impossibility of proving a claim upon which relief can be granted." *Id.* A court's scrutiny of the pleadings should be deferential to the plaintiff. *Id.*

[¶11] The Court notes at the outset that Purdue filed the present Motion as a Motion to Dismiss under Rule 12(b)(6). However, both parties have cited to multiple documents and sources outside of the pleadings and each relies heavily on these sources in their briefing. "When a motion to dismiss for failure to state a claim upon which relief can be granted is presented before the court and 'matters outside the pleadings are presented to and not excluded by the court, the motion should be treated as one for summary judgment and disposed of as provided in Rule 56.'" *Podrygula v. Bray*, 2014 ND 226, ¶7, 856 N.W.2d 791 (quoting *Livingood v. Meece*, 477 N.W.2d 183, 187 (N.D. 1991)).

[¶12] The Court does not intend to ignore or exclude the materials cited by the parties and incorporated in their briefing, which are technically outside the pleadings. Based on the parties framing of the issues, both in their briefing and at the hearing on the present Motion, and based upon Purdue's reliance on matters technically outside the pleadings, the Court will treat Purdue's Motion as a motion for summary judgment.

[¶13] Rule 56(c) of the North Dakota Rules of Civil Procedure directs a trial court to enter summary judgment "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law."

[¶14] The standard for summary judgment is well established:

> Summary judgment is a procedural device for the prompt resolution of a controversy on the merits without a trial if there are no genuine issues of material fact or inferences that can reasonably be drawn from undisputed facts, or if the only issues to be resolved are questions of law. A party moving for summary judgment has the burden of showing there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. . . . [W]e must view the evidence in the light most favorable to the party opposing the motion, and that party will be given the benefit of all favorable inferences which can reasonably be drawn from the record.

Golden v. SM Energy Co., 2013 ND 17, ¶ 7, 826 N.W.2d 610, 615 (quoting *Hamilton v. Woll*, 2012 ND 238, ¶ 9, 823 N.W.2d 754.

[¶15] "Although the party seeking summary judgment bears the initial burden of showing there is no genuine issue of material fact, the party opposing the motion may not simply rely upon the pleadings, but must present competent admissible evidence which raises an issue of material fact." *Black v. Abex Corp.*, 1999 ND 236, ¶ 23, 603 N.W.2d 182. "Summary judgment is appropriate against a party who fails to establish

the existence of a factual dispute on an essential element of her claim and on which she will bear the burden of proof at trial." *Id.*

ANALYSIS

A. Federal Preemption

[¶16] Purdue first argues the State's claims are improper because they seek to impose liability for lawful promotion of FDA-approved medications for an FDA-approved use. Specifically, Purdue argues that the FDA has approved opioid medications for long-term treatment of chronic non-cancer pain, and Purdue's promotion is consistent with the FDA-approved indications and labeling decisions. Because their promotion/marketing is consistent with FDA-approved labeling decisions and because the FDA has previously declined to alter the labeling and/or warnings, Purdue argues the State's claims are preempted.

[¶17] The Supremacy Clause of the United States Constitution makes federal law the supreme law of the land, and state law that conflicts with federal law is without effect. *Home of Economy v. Burlington N. Santa Fe R.R.*, 2005 ND 74, ¶ 5, 694 N.W.2d 840. Whether claims are preempted is a question of law that may be resolved at the pleading stage. *See NoDak Bancorporation v. Clarkson*, 471 N.W.2d 140, 142 (N.D. 1991). The North Dakota Supreme Court has described when federal law preempts state law under the Supremacy Clause:

> First, Congress can define explicitly the extent to which its enactments pre-empt state law. Pre-emption fundamentally is a question of congressional intent, and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one.
>
> Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. Such an intent may be

> inferred from a "scheme of federal regulation ... so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," or where an Act of Congress "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." Although this Court has not hesitated to draw an inference of field pre-emption where it is supported by the federal statutory and regulatory schemes, it has emphasized: "Where ... the field which Congress is said to have pre-empted" includes areas that have "been traditionally occupied by the States," congressional intent to supersede state laws must be "'clear and manifest.'"
>
> Finally, state law is pre-empted to the extent that it actually conflicts with federal law. Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements, or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Home of Economy v. Burlington N. Santa Fe R.R., 2005 ND 74, at ¶ 5.

[¶18] "The United States Supreme Court's framework for analyzing preemption claims starts with the assumption that Congress does not intend to displace state law." *Id.* at ¶ 6. "The assumption that Congress did not intend to displace state law is not triggered when a state regulated in an area where there has been history of significant federal presence." *Id.* (citing *United States v. Locke*, 529 U.S. 89 (2000)).

[¶19] Although there are three established types of federal preemption as detailed above, the parties in this case agree that "conflict preemption" is the only potential basis for preemption in this case. Conflict preemption exists where state law has not been completely displaced but is superseded to the extent that it conflicts with federal law. *Lefaivre v. KV Pharmaceutical Co.*, 636 F.3d 935, 939 (8th Cir. 2011). There are two types of conflict preemption, impossibility preemption and obstruction preemption. *Id.* "Impossibility preemption arises when compliance with both federal and state regulations is a physical impossibility. *Id.* (internal quotations omitted). "Obstruction

preemption exists when a state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.*

[¶20] "[T]he FDCA's treatment of prescription drugs includes neither an express preemption clause (as in the vaccine context, 42 U.S.C. § 300aa-22(b)(1)), nor an express non-preemption clause (as in the over-the-counter drug context, 21 U.S.C. §§ 379r(e), 379s(d))." *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 493 (2013). "In the absence of that sort of 'explicit' expression of congressional intent, we are left to divine Congress' will from the duties the statute imposes." *Id.*

[¶21] In determining whether the State's claims against Purdue in this case are preempted in this case, the Court must review Congress' purpose and intent in enacting the Federal Food, Drug, and Cosmetic Act (FDCA). This was succinctly summarized by the 10th Circuit in *Cereveny v. Aventis, Inc.*, 855 F.3d 1091, 1096 (10th Cir. 2017):

> The Federal Food, Drug, and Cosmetic Act has long required a manufacturer to obtain approval from the FDA before the manufacturer can introduce a new drug in the market. 21 U.S.C. § 355(a). For brand-name drugs, a manufacturer must submit an application. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 133 S.Ct. 2466, 2470–71, 186 L.Ed.2d 607 (2013). The application must include the proposed label, "full reports of investigations which have been made to show whether such drug is [safe and effective]," comprehensive information of the drug's composition and the "manufacture, processing, and packing of such drug," relevant nonclinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source." 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50(c)(2)(i), (d)(1), (2), (5)(iv).
>
> If the FDA approves the application, the manufacturer generally is restricted from changing the label without advance permission from the FDA. 21 U.S.C. §§ 331(a), (c), 352; 21 C.F.R. § 314.70(a), (b). But an exception exists, allowing a manufacturer under certain circumstances to change the label before obtaining FDA approval. 21 C.F.R. § 314.70(c).4 But even when this exception applies, the FDA will ultimately approve the label change only if it is based on reasonable evidence of an

> association between the drug and a serious hazard. 21 C.F.R. §§ 201.80(e), 314.70(c)(6)(iii).

Cereveny v. Aventis, Inc., 855 F.3d 1091, 1096 (10th Cir. 2017).

[¶22] Purdue argues the FDCA "preempts state-law claims that seek to impose a duty to alter FDA-approved labeling or to market FDA-approved prescription medications in a way that conflicts with federal law." [DE 13 (Purdue's Brief in Support of Motion to Dismiss) at ¶ 20. Specifically, Purdue argues the State's claims are preempted because they require Purdue to include, either in the label for opioids or in its marketing of the opioids, a more extensive warning of the risks and benefits of Opioids than what has been approved by the FDA. Purdue contends federal law preempts such state law claims where they would require a pharmaceutical manufacturer to make statements about safety or efficacy that are inconsistent with what the FDA has required after it evaluated the available data.

[¶23] Similar issues were addressed by the United States Supreme Court in *Wyeth v. Levine*, 555 U.S. 555 (2009). At issue in *Levine* was the label warning and accompanying use instructions for Phenargen, an antihistamine approved by the FDA for the intravenous treatment of nausea. *Id.* at 559. The plaintiff argued the manufacturer violated its common law duty to warn of the risks associated with the injection of Phenargen, including the manner in which it is injected. *Id.* at 559-60. The manufacturer argued the claim was preempted because the FDA had previously approved the warning and use instructions for the drug's label. *Id.* at 560.

[¶24] The United States Supreme Court held that the state failure to warn claim was not preempted by FDA regulations. *Id.* at 581. The Court rejected the manufacturer's argument that, once a label is approved by the FDA, the manufacturer is not obligated

to seek revision of its contents. *Id.* at 570-71. The Court outlined that FDA regulations permit a drug manufacturer, without first obtaining FDA approval, to strengthen a warning contained in a label already approved by the FDA, if the manufacturer has evidence to support an altered warning. *Id.*

[¶25] The *Levine* Court established a "clear evidence" standard of proof required to support a claim of conflict preemption based on FDA labeling regulations. *Id.* at 571-72. *Levine* did not hold that impossibility preemption based on FDA labeling regulations is precluded in all cases. Rather, *Levine* established that the FDA labeling regulations do not preempt state law claims unless the manufacturer presents "clear evidence that the FDA would not have approved a change" to the drug's label or warning, thereby making it "impossible" for the manufacturer to comply with "both federal and state requirements." *Levine*, 555 U.S. at 571.

[¶26] The *Levine* Court did not define "clear evidence," and it did not establish the level of proof required to constitute such evidence. The Court simply held that in the circumstances of that case, there was no evidence that the manufacturer tried to alter the label to include additional warnings, and, therefore, the state law claims were not preempted by FDA regulations.

[¶27] In this case, the Court concludes the marketing practices of Purdue that the State claims are improper – including claims relating to OxyContin's appropriateness for long-term treatment of chronic pain [DE 2 (Complaint) at ¶¶107-08], maximum dosing [Complaint at ¶¶ 95, 115-16], and the use of screening tools [Complaint at ¶¶ 85-89], were consistent with the FDA-approved product labeling. *See generally* [DE 14-16 (Exhibits 1-3 to Purdue's Brief)].

[¶28] The State claims it is not pursuing an inadequate labeling theory, but simultaneously argues Purdue could have, and should have, strengthened its labeling and warnings to include additional risk information without prior FDA approval. [DE 34 (State's Opposition Brief) at 26-27]. The Complaint, however, contains no allegations of newly acquired information that could provide a basis for Purdue to change its labeling without prior FDA approval. Instead, consistent with the Supreme Court's decision in *Levine*, there is "clear evidence" that the FDA would not have approved changes to Purdue's labels to comport with the State's claims.

[¶29] In 2013, the FDA addressed the same issues raised by the State, and concluded that no modification to the product labeling was necessary. [DE 14-16 (Exhibits 1-3)]. In response to a 2012 citizen's petition from PROP, the FDA studied the available scientific evidence and concluded that it supports the use of ER/LA opioids to treat chronic non-cancer pain. [DE 17 (Exhibit 4)]. Therefore, the FDA has communicated its disagreement with the State's specific contention that Purdue "falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence," and therefore that it was improper to promote OxyContin for chronic pain. PROP and other commentators raised these same concerns as a reason to limit the indication for opioid medications, but the FDA rejected the request. [DE 17 (Exhibit 4) at 5]. Nor did the FDA direct Purdue to stop marketing the medications for long-term use. *Id.* at 14 ("FDA has determined that limiting the duration of use for opioid therapy to 90 days is not supportable.").

[¶30] As to certain risks that were already included in the labeling for Purdue's opioid medications, the FDA required Purdue to conduct additional studies and further assess those risks along with the benefits of use before any changes or additional warnings would be included. *Id.* at 11. The FDA is awaiting any new evidence to determine whether the medications' labeling should be revised to provide any different or additional information about those risks and benefits to physicians.

[¶31] The following allegations made by the State in its Complaint similarly conflict with statements the FDA has specifically approved:

[¶32] **Oxy Contin and 12-hour relief**: The State alleges "Purdue misleadingly promoted OxyContin as . . . providing 12 continuous hours of pain relief with one dose." [DE 2 (Complaint) at ¶ 115]. The FDA specifically addressed and rejected this claim. In a January 2004 citizen's petition, the Connecticut Attorney General requested labeling changes for OxyContin, asserting that OxyContin is not a true 12-hour drug and that using it on a more frequent dosing schedule increases its risk for diversion and abuse. In September 2008, the FDA denied the petition, and concluded the evidence failed to support that using OxyContin more frequently than every 12 hours created greater risk. *See* [DE 18 (FDA's September 2008 letter to Richard Blumenthal, Attorney General, State of Connecticut) at 14-17; cited by Complaint at ¶ 117). Since then, the FDA continues to approve OxyContin as a 12-hour medication. [DE 14 (Exhibit 1)].

[¶33] **Higher Doses**: The State alleges Purdue misrepresented the safety of increasing opioid doses. [DE 2 (Complaint) at ¶¶ 94-100]. This allegation is contrary to the FDA's labeling decision in response to the PROP Petition, which denied a request to limit the

dose of opioids. The FDA concluded "the available information does not demonstrate that the relationship [between opioid dose and risk of certain adverse events] is necessary a causal one." [DE 17 (Exhibit 4)].

[¶34] **Pseudoaddiction**: The State claims Purdue falsely promoted the concept of "psuedoaddiction" – drug seeking behavior that mimics addiction, occurring in patients who receive adequate pain relief – to diminish addiction concerns by implying this concept is substantiated by scientific evidence. [DE 2 (Complaint) at ¶¶ 77-84]. However, the FDA has approved labeling for Purdue's medications that embody this concept, both before and after the FDA's evidentiary review in response to the PROP petition. The FDA-approved labeling for extended-release opioid medications discusses "[d]rug-seeking behavior" in "persons with substance use disorders[,]" but also recognizes that "preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control." *See* FDA REMS, FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics at 3.

[¶35] **Manageability of Addiction Risk**: The State alleges Purdue misrepresented that addiction risk screening tools allow prescribers to identify and safely prescribe opioids to patients predisposed to addiction. [DE 2 (Complaint) at ¶¶ 85-89]. However, again, the State ignores that the FDA-approved REMS for Purdue's medications directs doctors to use screening tools and questionnaires to help mitigate opioid abuse. [DE 14 (Exhibit 1 - Oxy Contin Labeling)]. The FDA's response to the PROP Petition also clarified this distinction between physical dependence and addiction. [DE 17 (Exhibit 4) at 16 n.64 (the DSM-V "combines the substance abuse and substance dependence categories into a single disorder measured on a continuum, to try to avoid an

inappropriate linking of 'addiction' with 'physical dependence,' which are distinct issues.")].

[¶36] **Withdrawal**: The State alleges Purdue falsely claimed that "opioid withdrawal is not a problem." [DE 2 (Complaint) at ¶ 90]. The State contends symptoms associated with withdrawal can "decrease the likelihood that . . . patients will be able to taper or stop taking opioids." *Id.* However, the FDA approved Purdue's labeling, which informs doctors that physically dependent patients can be withdrawn safely by gradually tapering the dosage, and that addiction is "separate and distinct from physical dependence." [DE 14 (Exhibit 1 - Oxy Contin Labeling)].

[¶37] **Abuse-Deterrent Formulations**: The State alleges Purdue deceptively claimed that abuse-deterrent formulations of its opioid medications could "deter abuse," and "create false impressions that" abuse-deterrent formulations could "curb addiction and abuse." [DE 2 (Complaint) at ¶ 101]. The FDA-approved Oxy Contin labeling states that "OXYCONTIN is formulated with inactive ingredients intended to make the tablet more difficult to manipulate for misuse and abuse." [DE 14 (Exhibit 1 – OxyContin Labeling)]. Therefore, statements that abuse-deterrent formulations are designed to reduce the incidence of misuse, abuse, and diversion, [Compl. At ¶¶101-106], are consistent with the FDA-approved labeling and FDA policies. The State's allegations are also inconsistent with the FDA's 2013 "extensive review of the data regarding reformulated OxyConin" and the FDA's conclusion that reformulated Oxy Contin is "expected" to "make abuse via injection difficult," "reduce abuse via the intranasal route," and "deter certain types of misuse in therapeutic contexts." 78 Fed. Reg. 23273-01, 2013 WL 1650735 (Apr. 18, 2013).

[¶38] In other words, when presented with many of the same concerns the State alleges against Purdue in its Complaint regarding the enhanced risks of using opioids in high doses and for long durations, and with inadequate or misleading warnings, the FDA chose neither to impose those limits on opioid use nor to add warnings about those risks. The Court concludes this is "clear evidence" under *Levine* that the FDA would not have approved the changes to Purdue's labeling that the State contends were required to satisfy North Dakota law.

[¶39] "[T]he Court in *Levine* did not say that for evidence to be clear it must result from a formal procedure of approval or disapproval." *Rheinfrank v. Abbott Laboratories, Inc.*, 680 Fed. Appx. 369, 386 (6th Cir. 2017). The *Levine* Court concluded the claims were not preempted in that case because there was "no evidence in [the] record." *Wyeth*, 555 U.S. at 572. However, the Court noted that the claims in *Levine* "would have been preempted upon clear evidence that the FDA would have rejected the desired label change." *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1098 10th Cir. 2017). "*Levine* did not characterize the proof standard as requiring a manufacturer in every case to prove that it would have been impossible to alter the drug's label." *Dobbs v. Wyeth Pharmaceuticals*, 797 F. Supp.2d 1264, 1279 (W.D. Okla. 2011). "[T]his court does not interpret *Levine* as imposing upon the drug manufacturer a duty to continually 'press' an enhanced warning which has been rejected by the FDA." *Id.*

[¶40] In this case, the Court concludes Purdue has met its burden under *Levine's* clear evidence standard. "[A] court cannot order a drug company to place on a label a warning if there is clear evidence that the FDA would not approve it." *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010). Given that the FDA

does not yet believe the state of the data supports additional warnings or altered labeling when presented with the issues asserted by the State in this case, it would have been impossible for Purdue to comply with what the State alleges was required under North Dakota law while still respecting the FDA's unwillingness to change the labeling and warnings, both on its labels for opioids and in its advertising.

[¶41] Accordingly, federal law preempts the State's state-law claims, which are based on the marketing of Purdue's medications for their FDA-approved uses, including for treatment of chronic, non-cancer pain. Those claims necessarily "conflict[] with the FDA's jurisdiction over drug labeling, and specifically its approval of" those indications. *Prohias v. Pfizer, Inc.*, 490 F.Supp.2d 1228, 1234 (S.D. Fla. 2007). Because Purdue has met its burden under *Wyeth v. Levine*, the court concludes the state law claims asserted by the State are preempted in this matter by federal law.

B. Consumer Fraud Law Claims

[¶42] In addition to the preemption arguments detailed above, Purdue also argues the State's Consumer Fraud Law claims (First and Second Causes of Action) should be dismissed because the State has failed to plead the essential element of causation. The State argues it is not required to allege causation to prevail under the Consumer Fraud Law.

[¶43] The Unlawful Sales or Advertising Practices Act prohibits deceptive or fraudulent conduct in the sale or advertising of merchandise:

> The act, use, or employment by any person of any deceptive act or practice, fraud, false pretense, false promise, or misrepresentation, with the intent that others rely thereon in connection with the sale or advertisement of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is declared to be an unlawful practice. The act, use, or employment by any person of any act or

> practice, in connection with the sale or advertisement of any merchandise, which is unconscionable or which causes or is likely to cause substantial injury to a person which is not reasonably avoidable by the injured person and not outweighed by countervailing benefits to consumers or to competition, is declared to be an unlawful practice.

N.D.C.C. § 51-15-02.

[¶44] Purdue relies on *Ackre v. Chapman & Chapman, P.C.*, 2010 ND 167, 788 N.W.2d 344, for the argument that causation is an element the State must plead and prove to support its cause of action under the Consumer Fraud Law. *Ackre* involved a lawsuit brought under the private right of action in N.D.C.C. § 51-15-09. Because of this, the State argues "[w]hen the Court stated that the Plaintiff was required 'to show the putatively illegal action caused some threatened or actual injury to his or her legal rights and interests,' the Court was referring to what is required for a private plaintiff to have standing to bring a private right of action under N.D.C.C. § 51-15-09." [DE 34 (State's Response Brief) at ¶ 66]. Specifically, the State asserts "Consumer Fraud Actions brought by the Attorney General are civil law enforcement actions, not civil tort actions, and causation, and requirements applied to tort actions are, therefore, inapplicable to consumer fraud claims." [DE 34 (State's Response Brief) at ¶ 65].

[¶45] These arguments blatantly ignore the State's own Complaint and the types of damages it is seeking in this lawsuit.

[¶46] The State specifically alleges that "Purdue's conduct has resulted in a financial burden on the State of North Dakota." [DE 2 (Complaint) at ¶ 15]. It goes on to allege that the State and its Departments have "spent millions of dollars on opioid prescriptions for chronic pain and addiction treatment – costs directly attributable to the opioids Purdue unleashed on the State." *Id.* "Purdue's deceptive marketing of opioids

and the resulting opioid epidemic also has caused the State to incur additional cost for law enforcement, North Dakota Workforce Safety and Insurance, Department of Corrections, North Dakota Department of Human Services, and North Dakota Behavioral Health and other agencies." *Id.* at ¶ 16. "The State seeks injunctive relief, disgorgement and restitution for amounts the State's Medicaid program and other State agencies have paid for excessive opioid prescriptions." *Id.* at ¶ 17. The State also clearly asserts it is seeking "restitution for North Dakota consumers who, like the State, paid for excessive prescriptions of opioids for chronic pain." *Id.*

[¶47] The State's Complaint clearly includes requests for money damages for purported violations of the Consumer Fraud Law. For additional examples, the Complaint requests the Court to "restore any loss suffered by persons as a result of the deceptive acts or practices of Defendants as provided in N.D.C.C. § 51-15-07." [DE 2 (Complaint) at ¶ 186(d) (emphasis added)]. The State also alleges "Purdue is responsible for the claims submitted and the amount the State's Medicaid program and other State agencies spent on its opioids." *Id.* at ¶ 182. The Prayer for Relief also requests "[t]hat Purdue be ordered to pay restitution to the State, [and] State agencies, including the Department of Human Services." [DE 2 (Complaint – Prayer for Relief (E)].

[¶48] The plain language of § 51-15-07 requires proof that the money to be restored was acquired "by means of" the allegedly deceptive act. Whether styled as a claim for money damages or for restitution pursuant to § 51-15-07, the requirement is the same: The State must plead and prove causation, i.e. the loss of money occurred "by means of" the alleged deception. *Compare* N.D.C.C. § 51-15-09 (allowing claim "against any

person who has acquired any moneys or property by means of any practice declared to be unlawful un this chapter") (emphasis added) *with* N.D.C.C. § 51-15-07 (allowing restitution of money "that may have been acquired by means of any practice in this chapter . . . declared to be unlawful") (emphasis added).

[¶49] When the State makes a claim under the Consumer Fraud Law for out-of-pocket losses, it is no different than a private plaintiff's claim to recover actual damages suffered "by means of" the deception. *See* N.D.C.C. § 51-15-09. There is simply no basis in North Dakota law to conclude the "by means of" language in the private consumer section of the Consumer Fraud Act (51-15-09) has a different meaning than the "by means of" language in § 51-15-07.

[¶50] The State's Complaint fails to identify which losses occurred "by means of" – i.e., because of – any specific alleged deception or misrepresentation on the part of Purdue. The State does not allege that every opioid prescription in North Dakota was unlawful. In fact, the State expressly acknowledges that it does not seek an outright ban on the sale of opioids. [DE 34 (State's Response Brief) at 25]. The State acknowledges that "not every sale" of opioids "contributed" to the public health problem. *Id.* at 49. To put it succinctly, the State essentially alleges that there is an opioid problem in North Dakota that has caused the State and its citizens great "financial burden", and that the problem was the fault of Purdue and its marketing, but then completely fails to allege how Purdue's allegedly deceptive marketing actually caused the alleged great "financial burden."

[¶51] The State does not identify any North Dakota doctor who ever received any specific purported misrepresentation made by Purdue, or who wrote a medically

unnecessary prescription because of those alleged statements. The State also does not allege any false statement caused the State to reimburse prescriptions it otherwise would not have reimbursed. Under the State's theory, it can recover for reimbursements under the Consumer Fraud Act even if the State fails to show any such reimbursements were caused by a deception, and even when the State continued to pay for reimbursements with knowledge of the alleged deception.

[¶52] Rather than plead the requisite specifics, the Complaint offers only conclusory allegations that Purdue had "a marketing campaign" since the 1990s, which was "designed to convince prescribers and the public that its opioids are effective for treating chronic pain" and allegedly resulted in the routine prescription of opioids for long-term use. [DE 2 (Complaint) at ¶ 4]. These allegations are unconnected to any particular North Dakota doctor or prescription. Additionally, the State fails to plead how the alleged misstatements, most of which are alleged to have occurred over a decade ago, could have caused specific prescribing decisions to this day.

[¶53] A generalized "fraud-on-the-market" theory does not suffice to establish causation. In cases that assert claims for fraudulent or deceptive pharmaceutical marketing, "a fraud-on-the-market theory cannot plead the necessary element of causation because the relationship between the defendants' alleged misrepresentations and the purported loss suffered by the patients is so attenuated . . . that it would effectively be nonexistent." *In re Actimmune Mktg. Litig.*, 614 F.Sup.2d 1037, 1054 (N.D. Cal. 2009), aff'd, 464 F.App'x 651 (9th Cir. 2011).

[¶54] The State acknowledges that patients may not lawfully obtain Purdue's opioid medications without a valid prescription. [DE 2 (Complaint) at ¶ 11]. The State also

recognizes that doctors themselves have many resources available about Purdue's products, including FDA-approved labeling that discloses the risks Purdue allegedly concealed. *Id.* at ¶¶ 69-70, 72-73, 75-76, 83-84, 88, 93, 97-100, 104, 111-12, 117.

[¶55] Even assuming, for purposes of argument only, that Purdue had failed to disclose these risks, such a failure would not be the "proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004) (internal quotations and citations omitted) (concluding North Dakota would adopt the "learned intermediary" doctrine). The State's theory in this case depends on an extremely attenuated, multi-step, and remote causal chain. The State's claims – no matter how styled – have to account for the independent actor (i.e. doctors) who stands between Purdue's alleged conduct and the alleged harm. *Id.* In the face of information available to physicians, the State has not pleaded facts showing that Purdue's alleged misrepresentations – as opposed to the undisputed multiple layers of individualized decision-making by doctors and patients or other possible intervening causes – led to any relevant prescribing or reimbursement decision.

[¶56] A defendant is not liable for alleged injuries that either result from a superseding, intervening cause, or "if the cause is remote" from the injury. *Moum v. Maercklein*, 201 N.W.2d 399, 403 (N.D. 1972); *see also Price v. Purdue Pharma Co.*, 920 So.2d 479, 485-86 (Miss. 2006) (observing lack of proximate cause for claims of opioid addiction brought against Purdue, because injuries were the result of illegally obtained and improper use of opioids). "A superseding cause is an act of a third person or other force which by its intervention prevents the actor from being liable for harm to

another which his antecedent negligence is a substantial factor in bringing about." *Leistra v. Bucyrus-Erie Co.*, 443 F.2d 157, 163 n.3 (8th Cir. 1971) (internal quotations omitted).

[¶57] *Ashley County, Ark. v. Pfizer, Inc.*, 552 F.3d 659 (8th Cir. 2009), which was decided under analogous facts, is instructive. In *Ashely County*, Arkansas counties brought claims against pharmaceutical companies for, *inter alia*, public nuisance and deceptive trade practices, seeking "compensation to recoup the costs expended by the counties in dealing with the societal effects of the methamphetamine epidemic in Arkansas, with liability premised on the use of the Defendants' products in the methamphetamine manufacturing process. *Id.* at 663. The Eighth Circuit affirmed the dismissal of the complaint for failure to state a claim, and determined that "[p]roximate cause seems an appropriate avenue for limiting liability in this context . . . particularly 'where an effect may be a proliferation of lawsuits not merely against these defendants but against other types of commercial enterprises – manufacturers, say, of liquor, anti-depressants, SUVs, or violent video games – in order to address a myriad of societal problems regardless of the distance between the 'causes' of the 'problems' and their alleged consequences.'" *Id.* at 671-72 (quoting *Dist. of Columbia v. Beretta, U.S.A., Corp.*, 872 A.2d 633, 651 (D.C. 2005)).

[¶58] Similarly, in this case, the connection between the alleged misconduct and the prescription depends on multiple, independent, intervening events and actors. These intervening events and actors include: the doctor's independent medical judgment, the patient's decision whether and how to use the medication, the patient's response to the medication, and the State's own decision to reimburse the prescriptions. Additionally,

it is nearly impossible to trace any of the harms the State alleges back to solely Purdue's own medications, as opposed to other manufacture's opioids and other unlawful opioids. Holding Purdue solely responsible for the entire opioid epidemic in North Dakota is difficult to comprehend, especially given Purdue's small share of the overall market for lawful opioids. It is also difficult to comprehend given the large market for unlawful opioids.

[¶59] The State's claims that Purdue can, should, or should have in the past, "changed the message" regarding opioids to include stronger warnings and labeling is not taken well by the Court. Even if Purdue can and does "change the message," Purdue has absolutely no control over how doctors prescribe the drug and how patients choose to use the drug. Purdue also has no control over how other manufacturers of opioids promote the drugs. Doctors can be loose with their prescribing practices, and patients do not always follow their doctor's orders. The Court does not mean to suggest this is the sole cause of the opioid crisis in North Dakota. But the State has failed to allege facts which, if true, show that Purdue, alone, caused the opioid crisis for which the State seeks compensation. The causal chain the State attempts to allege is simply too attenuated.

[¶60] The State seems to acknowledge its attenuated theory of causation in its Complaint by identifying a number of behaviors that contribute to the opioid crisis, such as "doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment." [DE 2 (Complaint) at ¶ 151]. The State also clearly acknowledges the "high statistic of people that first get addicted after obtaining opioids free from a friend or relative." *Id.* at ¶ 145. These are not Purdue's

acts or misrepresentations, yet the State seeks to hold Purdue solely liable. The State's effort to hold one company to account for this entire, complex public health issue oversimplifies the problem.

[¶61] The Court concludes the State's causal theory is too attenuated and requires *dismissal of the State's Consumer Fraud Law Claims as a matter of law.* If the State can proceed on the causation it has alleged in this lawsuit against Purdue, it begs the question of how far the causal chain can go. There are a seemingly limitless number of actors who could have "tried harder" under the State's theory and claims. Purdue is no higher up in the causal chain under the facts alleged by the State than any other actor who could be held liable. The State has not pleaded facts that Purdue's alleged misrepresentations caused North Dakota doctors to write medically unnecessary prescriptions or that Purdue's alleged misrepresentation caused the State to reimburse prescriptions.

[¶62] Because the State has failed to adequately plead causation, its Consumer Fraud Law claims fail as a matter of law and must be dismissed.

C. Public Nuisance

[¶63] Purdue additionally argues the State's Third Cause of Action for public nuisance must be dismissed because no North Dakota court has extended the public nuisance statutes to cases involving the sale of goods. Because the State's nuisance claim in this case revolves around the effects of a product (opioids) sold and used in North Dakota, Purdue argues the State's public nuisance claim fails.

[¶64] The State's claim for public nuisance is brought under N.D.C.C. § 42-01-01 *et seq.* (nuisance) and 42-02-01 *et seq.* (abatement of common nuisance). A nuisance is defined by N.D.C.C. § 42–01–01, which provides:

> A nuisance consists in unlawfully doing an act or omitting to perform a duty, which act or omission:
>
> 1. Annoys, injures, or endangers the comfort, repose, health, or safety of others;
>
> 2. Offends decency;
>
> 3. Unlawfully interferes with, obstructs or tends to obstruct, or renders dangerous for passage, any lake, navigable river, bay, stream, canal, basin, public park, square, street, or highway; or
>
> 4. In any way renders other persons insecure in life or in the use of property.

N.D.C.C. § 42-01-01.

[¶65] "A public nuisance is one which at the same time affects an entire community or neighborhood or any considerable number of persons, although the extent of the annoyance or damage inflicted upon the individuals may be unequal." N.D.C.C. § 42–01–06. The N.D.C.C. § 42–01–01 definition of nuisance applies to public nuisance claims. *Kappenman v. Klipfel*, 2009 ND 89, ¶ 36, 765 N.W.2d 716.

[¶66] In response to Purdue's argument on this issue, the State attempts to characterize its claims as focusing only on Purdue's marketing conduct, and not on the actual sale of opioids. The State alleges "[t]he Complaint does not identify Purdue's sale of the opioids as the public nuisance; instead, the nuisance is Purdue's misrepresentations and deceptive promotion of their risks and benefits." [DE 34 (State's Response Brief) at ¶ 73]. This argument, again, ignores the clear allegations in the State's Complaint.

[¶67] The State specifically alleges a public nuisance in this case in that "Purdue's conduct unreasonably interfered with the public health, welfare, and safety of North Dakota residents by expanding the opioid market and opioid use through an aggressive and successful marketing scheme that relied on intentional deception and misrepresentation regarding the benefits, safety and efficacy of prescription opioids." [DE 34 (State's Response Brief) at ¶ 72; and DE 2 (Complaint) at ¶¶ 4, 7, & 9]. The State further alleges that Purdue's conduct "caused and maintained the overprescribing and sale of opioid for long-term treatment of chronic pain at such volumes and degrees as to create an epidemic." [DE 2 (Complaint) at ¶ 201].

[¶68] The State cannot escape the true nature of the nuisance claim it has pleaded. The "overprescribing and sale" of opioids manufactured by Purdue are directly at the heart of the State's nuisance claim, regardless of how it otherwise now tries to characterize its claim.

[¶69] Purdue is correct, as the State concedes, that North Dakota courts have not extended the nuisance statute to cases involving the sale of goods. [DE 34 (State's Response Brief) at ¶ 74; DE 13 (Purdue's Brief in Support of Motion) at ¶ 45]. Such a situation was addressed by the Eighth Circuit Court of Appeals in *Tioga Pub. Sch. Dist. No. 15 of Williams Cty. State of N. Dakota v. United States Gypsum Co.*, 984 F.2d 915, 920 (8th Cir. 1993). Although *Tioga* was a federal case, in the absence of binding North Dakota Supreme Court decisions interpreting North Dakota law, federal court decisions are given deference. *N. Dakota Fair Hous. Council, Inc. v. Peterson*, 2001 ND 81, ¶¶ 20-24, 625 N.W.2d 551, 559 (N.D. 2001).

[¶70] In *Tioga*, the 8th Circuit concluded that the North Dakota Supreme Court would not extend the nuisance doctrine to cases involving the sale of goods. *Tioga*, 984 F.2d at 920. The Court reasoned:

> Tioga has not presented us with any North Dakota cases extending the application of the nuisance statute to situations where one party has sold to the other a product that later is alleged to constitute a nuisance, nor has our research disclosed any such cases. North Dakota cases applying the state's nuisance statute all appear to arise in the classic context of a landowner or other person in control of property conducting an activity on his land in such a manner as to interfere with the property rights of a neighbor

Id. (emphasis added).

[¶71] The State urges this Court to distinguish *Tioga* "because it does not arise from a direct injury to a private individual from the use of the product purchased, and it's not a *product liability or warranty type claim.*" [DE 34 (State's Response Brief) at ¶ 74]. However, the statutory definition of nuisance applies equally to public and private nuisances. Additionally, as the Eighth Circuit warned in *Tioga*:

> [T]o interpret the nuisance statute in the manner espoused by Tioga would in effect totally rewrite North Dakota tort law. Under Tioga's theory, any injury suffered in North Dakota would give rise to a cause of action under section 43–02–01 regardless of the defendant's degree of culpability or of the availability of other traditional tort law theories of recovery. Nuisance thus would become a monster that would devour in one gulp the entire law of tort, a development we cannot imagine the North Dakota legislature intended when it enacted the nuisance statute.

Tioga, 984 F.2d at 921.

[¶72] This Court agrees with the reasoning of the Eighth Circuit in *Tioga*. The State is clearly seeking to extend the application of the nuisance statute to a situation where one party has sold to another a product that later is alleged to constitute a nuisance. *Id.* at 920 *(emphasis added)*. The reality is that Purdue has no control over its product after it

is sold to distributors, then to pharmacies, and then prescribed to consumers, i.e. after it enters the market. Purdue cannot control how doctors prescribe its products and it certainly cannot control how individual patients use and respond to its products, regardless of any warning or instruction Purdue may give.

[¶73] No North Dakota court has extended the public nuisance statutes to cases involving the sale of goods. The Eighth Circuit Court of Appeals, while applying North Dakota law, expressly declined to do so, and this Court declines to do so in this case. The State does not have a cause of action for nuisance against Purdue since its nuisance claim arises from the "overprescribing and sale" of opioids manufactured by Purdue. Therefore, the State's claim for public nuisance must be, and is, dismissed.

CONCLUSION

[¶74] Based upon the foregoing, the Court concludes that the State has not adequately pleaded its causes of action against Purdue. Therefore, for all the reasons stated above, Purdue's Motion to Dismiss is, in all respects, hereby **GRANTED.**

[¶75] Counsel for Purdue is tasked with the responsibility of drafting a judgment consistent with this memorandum.

IT IS SO ORDERED.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated this 10th day of May, 2019.

BY THE COURT:

James S. Hill

James S. Hill, District Judge
South Central Judicial District

cc:

EXHIBIT K

IN THE DISTRICT COURT OF CLEVELAND COUNTY

STATE OF OKLAHOMA

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

vs. Case No. CJ-2017-816

PURDUE PHARMA, 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

mentioned earlier, it was your belief in some instances pharmaceutical companies may not like some of your opinions regarding opioids; is that correct?

MS. BALDWIN: Objection, leading.

THE WITNESS: Well, I think at some times.

You know, my overall opinion is that I've never been a proponent of opioids. I've not been an opponent of them. You know, I don't think anybody should be for or against them. Personally, I think we should be for them when the benefits outweigh the risks, and against them otherwise. Sometimes people have different views on, you know, when that is and isn't. But I've always been clear, that's -- that's where I take a stand, that opioids are just one tool, and they've been excessively used because we've lost sight of that risk benefit analysis largely because we -- the big "we," you know, the education hasn't been there, and other things have happened to drive this.

But in my presentations I feel like I've always anchored in exactly that position, that you need to understand the risks and the benefits to know whether a treatment's appropriate, and if you do that, you won't have used opioids like people

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

EXHIBIT L

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER, ATTORNEY GENERAL
OF OKLAHOMA,
Plaintiff,
vs. 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., n/k/a JANSSEN
PHARMACEUTICALS, INC.;
ALLERGAN, PLC, f/k/a
ACTAVIS 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 JESSICA HAWKINS
TAKEN ON BEHALF OF THE DEFENDANTS
ON MARCH 6, 2019, BEGINNING AT 9:03 A.M.
IN OKLAHOMA CITY, OKLAHOMA

VIDEOTAPED BY: Gabriel Pack
REPORTED BY: Lacy Antle, CSR, RPR

A Can you repeat your question?

MS. BALDWIN: Object to the form.

Q (BY MR. PINKER) What documentation did you provide to him that enabled him to calculate a $5 million amount for early intervention?

A So what we provided him was our estimation of the number of people who would require these services multiplied by the cost of those services to our agency.

Q What document did you provide him that estimated the cost per person?

A The cost per person is based off of our cost per services, per person, for the same types of services at the Department of Mental Health and Substance Abuse Services.

Q What document did you provide him that gave him the estimated cost per person?

MS. BALDWIN: Object to the form. Repetitive.

THE WITNESS: I mean, I think I answered that question. It's a document that has the rate of pay for that service, times the number of people estimated to need that service for this Abatement Plan.

Q (BY MR. PINKER) What's that document

called?

A I don't recall that it has a name.

Q Did you prepare it for this particular Abatement Plan exercise?

A Staff within the Department of Mental Health and Substance Abuse Services provided him with that document.

Q Okay. So this was not an existing or historical document within your agency correct?

MS. BALDWIN: Object to the form.

THE WITNESS: The information contained within the document represents the rates that are paid for these services, so those were not new or original for this Abatement Plan, but the rationale of this particular service is related to the persons in Oklahoma who require these services for opioid use disorder treatment and so those costs that already exist for the Department of Mental Health and Substance Abuse Services were applied to those numbers of persons.

MR. PINKER: Move to strike, nonresponsive.

Q (BY MR. PINKER) I'm not asking about rationales. I'm trying to understand where the numbers on this piece of paper came from and how I

can investigate those numbers. Okay?

MS. BALDWIN: Object to the form. Repetitive.

THE WITNESS: So, as I said --

Q (BY MR. PINKER) So let me ask the question, I'm trying to frame for you what I'm trying to understand.

MS. BALDWIN: Let her finish because you just interrupted her.

Q (BY MR. PINKER) No, we need to understand one another. And I'll let you -- I'll let you say what you want, it's not responsive but I'll let you say. I'm trying to understand numbers, not rationales, not what the services are right now, simply where these numbers are coming from.

So you can say what you want now, it's not going to be responsive, but go ahead and say what you want.

MS. BALDWIN: I object to commentary by counsel.

Did you have -- were you in the middle of saying something, Ms. Hawkins?

THE WITNESS: You're asking me where these numbers come from. The numbers are rates that are paid for by the Department of Mental Health and

to what extent, with what resources and how fully each one of those things have been implemented.

Q (BY MR. PINKER) Do you believe that the State has made a good faith effort to adopt and implement the CDC guidance?

MS. BALDWIN: Object to the form. Outside the scope.

THE WITNESS: Are you speaking to the whole universe of guidance from the CDC or are you talking about the guidelines?

Q (BY MR. PINKER) The guidelines as it relates to opioid use disorder.

A Are you talking about the guidelines for pain management released by the CDC in 2016 or are you talking about guidance that the CDC has provided about this crisis?

Q You're the one that began by citing the CDC to me as being an entity that provides guidance that gives you comfort that the Abatement Plan is effective, right?

A Uh-huh.

Q Right?

A And you just called them guidelines which is a different thing.

Q Okay. So using the guidance?

A Uh-huh.
Q Which is the term you used?
A Uh-huh.
Q Has the State made a good faith effort to implement the existing CDC guidelines?
MS. BALDWIN: Object to the form.
THE WITNESS: The guidance provided by the CDC --
Q (BY MR. PINKER) The guidance.
A Yes.
Q And it has done that already?
A I can't --
MS. BALDWIN: Object to the form.
THE WITNESS: My same answer, I'm not going to speak to what level of implementation has been done. For example, there are many areas in which, due to resources, where we are simply responding as fast and as effectively as we can to this crisis, but lack the resources to do something, for example, statewide. But absolutely I believe the State has taken many of those actions and has undertaken good faith effort.
Q (BY MR. PINKER) Has the State tried to, in good faith, adopt the guidance provided by the CDC?
MS. BALDWIN: Object to the form.

THE WITNESS: I think I just answered that.

Q (BY MR. PINKER) Is that yes?

A Yes.

Q You think the State's obligated to do that, don't you?

MS. BALDWIN: Object to the form.

THE WITNESS: What do you mean by obligated?

Q (BY MR. PINKER) You think it has a responsibility to the citizens of this state to adopt that guidance, don't you?

MS. BALDWIN: Object to the form. Outside the scope of the witness's expert testimony.

THE WITNESS: So having not prepared for that topic in my testimony today, but telling you as a professional who works in this field for the State, yes, I believe the State has made tremendous efforts to implement that guidance.

Q (BY MR. PINKER) Well, one of the topics on which you have been designated is the programs and services that the State has implemented to address what you called the opioid crisis, right?

MS. BALDWIN: Object to the form.

Q (BY MR. PINKER) It's on the top of page 2.

So I'll focus on Department of Mental Health where I'm most familiar. I would say, as general categories these fit -- these are pretty consistent with what continues to occur in Oklahoma. There are some numbers in here that likely have increased, for example, the number of people who have been treated with opioid use disorder. In addition to that, there have been some initiation of an Opioid Overdose Fatality Review Board.

Also, I'm looking for, in particular, reference to practices that have been enrolled in practice dissemination programs in the last several months that has -- that has expanded slightly.

Q (BY MR. PINKER) Let me just say, I understand that the number of persons served and dollars spent will have gone up in the months between late 2018 and today. What I'm really asking is whether there are additional programs, services or interventions, in addition to the one that you've mentioned for me, which is the Opioid Overdose Fatality Review Board?

MS. BALDWIN: Object to the form.

THE WITNESS: I have no doubt that there are additional interventions that have begun or commenced since the time that I developed this chart

by other agencies. I can't speak to specifically, and I don't want to misspeak, but there is a lot of activity in the State of Oklahoma related to addressing the opioid crisis and I would expect that there would be additional items on here from other agencies if I were to create this today.

Q (BY MR. PINKER) Okay. But all I can do is ask you for your testimony now.

Do you know of specific services, programs or interventions that the State is implementing in addition to those which are listed on Exhibit 2?

MS. BALDWIN: Object to the form.

THE WITNESS: There have been receipt of new grants during this time, for example, I believe the Bureau of Narcotics and Dangerous Drug Control, during this time, has received -- a new opioid related grant has initiated new work in that area.

Q (BY MR. PINKER) Do you know what the grant relates to?

A It's related to opioids.

Q More specifically, do you know what it relates to?

A No, I don't have that information with me.

Q Do you know how much the grant was for?

A I don't. There have been additional

continuing medical education courses, and I would say, generally speaking, a lot of these interventions continue to be implemented.

Q I had assumed that.

Okay. You've gone through it?

A I have.

Q Okay. Other than the Opioid Overdose Fatality Review Board and the grant that you mentioned to me, you're not presently aware of anything else that would need to be added in terms of a line item to Exhibit 2, right?

A Well, those are the -- I'm sorry.

MS. BALDWIN: Object to the form.

THE WITNESS: Those would be the two things I would identify that I'm aware of.

Q (BY MR. PINKER) Yeah, that's what I asked.

A And I'm --

Q Okay.

A -- also trying to recall the month that I completed this. But yeah, it would have been the last couple of months.

Q Do you know the total cost of the actions that are listed in Exhibit 2 to the State of Oklahoma?

MS. BALDWIN: Object to the form. Outside

the scope of Ms. Hawkins' expert testimony. We actually have an expert testifying on past damages to the State of Oklahoma and it's not Ms. Hawkins.

THE WITNESS: I don't have that information.

MR. PINKER: All right. I'm going to pass the witness. I know some other people have questions. I want to note that I am specifically reserving some time. We will be filing a motion to compel with regard to some of the topics that answers were not given on.

MS. BALDWIN: Okay. Exactly what topics do you believe answers were not given on? I disagree. You've had ample time to depose Ms. Hawkins, so can you -- can you tell me --

MS. BALDWIN: No, it's in the record.

MS. BALDWIN: -- tell me specifically what you believe is deficient?

MR. PINKER: There are a host of things on which she declined to answer.

MS. BALDWIN: She answered all of your questions.

MR. PINKER: That's factually false.

MS. BALDWIN: There's not one question this witness has been directed not to answer, so I'm

CERTIFICATE

I, Lacy Antle, Certified Shorthand Reporter, do hereby certify that the above-named JESSICA HAWKINS was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth, in the case aforesaid; that the above and foregoing deposition was by me taken in shorthand and thereafter transcribed; and that I am not an attorney for nor relative of any of said parties or otherwise interested in the event of said action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal this 8th day of March, 2019.

Lacy Antle, CSR RPR