IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

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

Plaintiff,

v.

PURDUE PHARMA L.P., *et al.*,

Defendants.

Case No. CJ-2017-816
Judge Thad Balkman

DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON AND JOHNSON'S MOTION TO ALLOW FULL CROSS-EXAMINATION OF STATE WITNESSES

The U.S. Supreme Court describes cross-examination as the "greatest legal engine ever invented for the discovery of truth." *Lilly v. Va.*, 527 U.S. 116, 123 (1999) (quoting *Cal. v. Green*, 399 U.S. 149, 158 (1970)). The pursuit of truth is hindered when cross-examination is unfairly limited. The State has succeeded in using scope objections to thwart cross-examination about the FDA-approved labeling for Janssen's medications and the DEA regulations governing Noramco and Tasmanian Alkaloids. It has strategically avoided federal regulatory action in its direct questioning—even where such action is plainly relevant to the subject matter discussed by its experts—because it shows the lawfulness and reasonableness of the Janssen Defendants' conduct.

The Court cannot allow the State's strategic omissions to prevent full and fair cross-examination. One of the primary points of cross-examination is to explore relevant questions that direct questioning has strategically ignored. Under Oklahoma law, therefore, cross-examination is not limited to the precise lines of questioning pursued on direct, but available to "develop

relevant truth related to matters covered on direct examination," *Ark. La. Gas Co. v. Bass*, 698 P.2d 947, 949 (Okla. Civ. App. 1985), and extends to any question that "tends to elucidate, modify, explain, contradict or rebut testimony given in chief by the witness," *Hardin v. State*, 1982 OK CR 124, 649 P.2d 799, 803. Federal regulation blessing the very actions State experts claim should subject the Janssen Defendants to billions of dollars in liability is unquestionably relevant and responsive to those experts' opinions. The Court should grant this motion and permit full cross-examination of State witnesses, including on federal regulatory actions that undermine their opinions.

I. BACKGROUND

Noramco's supply of API to manufacturers of opioid medications, particularly Purdue, was the centerpiece of Dr. Kolodny's testimony. In Kolodny's opinion, Noramco's supply of API was so beyond the pale as to make Johnson & Johnson a "kingpin" for "drug dealers"—that is, other pharmaceutical manufacturers:

> I believe that Johnson & Johnson was a major cause of our opioid crisis. It was Johnson & Johnson's opium that flooded—that flooded into the United States. I think it's fair to characterize Johnson & Johnson as a kingpin in our opioid crisis because it was their opium that they were selling and that other drug dealers or pharmaceutical companies were selling.[1]

This came at the conclusion of a three-day-long direct examination in which Kolodny provided ***over 50 pages*** of testimony about how the activities of Noramco and Tasmanian Alkaloids allegedly contributed to the opioid crisis. Kolodny also confirmed that it was his testimony that at some point after 1998, Noramco should have stopped supplied API to Purdue or its affiliates.[2]

But the activities of Noramco and Tasmanian Alkaloids are in no way wrongful, and cannot form the basis of any liability, because they were conducted under a strict regulatory regime with

[1] Ex. 1, June 13, 2019 (PM) Trial Tr. 21:15-21.
[2] *Id.* 30:13-17.

the blessing of the federal government. Noramco's supply of API to opioid manufacturers merely fulfilled the express directives of the DEA pursuant to DEA regulation. The DEA determined the *exact* amount of API that Noramco would produce, and the *exact* amount of API that manufacturers could buy, based on annual medical needs in this country. 21 C.F.R. §§ 1303.11-12. Tasmanian Alkaloids' transnational supply of narcotic raw material was also strictly regulated by the DEA and the International Narcotics Control Board.[3] Every gram of raw material those companies sold went to a buyer whom the DEA had expressly authorized to purchase it.

The State's decision to avoid discussing regulations was a strategic choice designed to obscure the full truth about Noramco and Tasmanian Alkaloids, and the State exploited that tactic to object to Janssen questioning that would have shown those companies' activities were not only lawful, but affirmatively blessed by federal authorities.

This follows earlier, similar scope objections by the State. For example, during the cross-examination of Dr. Danesh Mazloomdoost, counsel for the Janssen Defendants asked whether he could "identify ... any instance where a Janssen representative told [him] anything about Nucynta ER that [he] felt was false or misleading," Mazloomdoost cited the promotion of "long-acting opioids, including Nucynta ... [a]s an appropriate treatment for chronic non-malignant pain" at a dinner program he attended.[4] But when Janssen's counsel asked him if he understood that Nucynta ER's indication "for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time" had been

[3] International Narcotics Control Board, "Narcotic Drugs," International Narcotics Control Board, available at https://www.incb.org/incb/en/narcotic-drugs/index.html (last accessed May 20, 2019) ("The 1961 [UN] Convention establishes strict controls on the cultivation of opium poppy"); Janssen Trial Ex. J239, Keith Bradsher, *The New York Times*, "Shake-Up on Opium Island" (July 19, 2014) at 3-4 (the "entire process is tightly monitored by a United Nations-authorized board, which tracks production and requires strict security").
[4] Ex. 2, June 6, 2019 (AM) Trial Tr. 124:15-22.

approved by the FDA,[5] the State objected to what it characterized as "legal questions about a regulatory issue that isn't relevant to Dr. Mazloomdoost's testimony."[6] The Court "caution[ed]" Janssen's counsel "not to get into his knowledge about regulatory matters," and warned that it would "probably sustain the objection" as to similar lines of questioning.[7]

II. ARGUMENT

The State's scope objections represent an impossibly cramped vision of cross-examination having no support in Oklahoma law. By statute, the scope of cross extends to the "subject matter of the direct examination and matters affecting the credibility of the witness." 12 O.S. § 2611(C). Neither the "subject matter" nor "matters affecting the credibility of the witness" are limited to the precise, narrow lines of questioning pursued by the State on direct. To fall within the scope of direct, questioning need only be "responsive to testimony given on direct examination" or "tend[ ] to elucidate, modify, explain, contradict or rebut testimony given in chief by the witness." *Hardin v. State*, 1982 OK CR 124, 649 P.2d 799, 803.

There can be no doubt that the lines of questioning described above satisfy these standards. Kolodny argued that Noramco and Tasmanian Alkaloids' activities were egregious enough to make Johnson & Johnson akin to a "kingpin" atop a criminal drug network, and significant enough to make the Janssen Defendants a "major cause" of the entire opioid crisis. Questioning about the strict regulatory regime that authorized those entities' activity is directly responsive to Kolodny's incendiary claim that they amounted to criminal enterprises, and thus critical to developing the "relevant truth" about Dr. Kolodny's opinion. The same goes for questioning Mazloomdoost about Nucynta ER's FDA-approved label. It was plainly responsive and relevant to his testimony on

[5] *Id.* 127:11-128:21.
[6] *Id.* 129:5-11.
[7] *Id.* 132:1-8.

direct because it showed that the FDA authorized the very statement that Mazloomdoost insisted was misleading: that Nucynta was an "appropriate treatment for chronic non-malignant pain." The label rebutted his claim and impeached his credibility.

The State relies on a tortured analogy to argue that federal regulation of the conduct it challenges is irrelevant. "The government allows me to own a car. If I buy one I can get a license. It doesn't permit me to make the conscious choice to run people over in the street."[8] But supplying Purdue with API is *exactly* the conduct the DEA licensed Noramco to undertake, not some gross, unforeseeable misuse of its license. The DEA decided exactly how much API Noramco would make, and exactly how much Purdue would receive, based on its assessment of medical necessity in the United States.

Cars do, however, provide a useful analogy for why Janssen must be able to ask about relevant regulation on cross-examination of State experts. Just as the rules of the road are part of any discussion about fault for a car accident, FDA and DEA regulations are an inescapable part of discussing fault involving pharmaceutical marketing and API supply. No one can have a coherent opinion about whether someone is a safe driver without reference to speed limits, stoplights, and the like—whether or not they are an expert on traffic regulations. Likewise, a witness cannot credibly assert that marketing for a drug was inappropriate without reference to the FDA-approved indication for that drug. Nor can a witness know whether supply of API was wrongful without looking at how tightly the government regulated which companies received API and in what amount.

It is easy to understand why the State is fighting to keep obviously relevant FDA and DEA regulations out of the case. The State's experts are far outside the medical mainstream. They have

[8] Ex. 1, June 13, 2019 (PM) Trial Tr. 32:13-16.

fought in the regulatory arena to have their restrictive view of opioid prescribing adopted by the federal government—and lost. Now, as the State takes these outliers' crusade to the judiciary, it would prefer to distract from the inconvenient fact that expert regulators not only disagree with their fringe views, but also authorized the exact conduct they challenge. Oklahoma law does not allow the State to insulate its witness's opinions from that directly relevant impeachment through strategic omissions on direct examination. The Court should therefore allow questioning on regulatory matters that directly "contradict[s] or rebut[s] testimony given in chief by the witness." *Hardin*, 1982 OK CR 124, 649 P.2d 799, 803.

III. CONCLUSION

The Court should grant this motion and permit full cross-examination of State witnesses, including on federal regulatory actions that are relevant to their opinions.

Dated: June 14, 2019

Respectfully submitted,

By: _____

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CERTIFICATE OF MAILING

Pursuant to OKLA. STAT. tit. 12, § 2005(D), this is to certify on June 14, 2019, a true and correct copy of the above and foregoing has been served via email to the following:

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EXHIBIT 1

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) JOHNSON & JOHNSON; (2) JANSSEN PHARMACEUTICALS, INC.; (3) ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS; (4) JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;	)	
Defendants.	)	

TRANSCRIPT OF PROCEEDINGS
HAD ON THE 13TH DAY OF JUNE, 2019 (AFTERNOON SESSION)
BEFORE THE HONORABLE
THAD BALKMAN, DISTRICT JUDGE

REPORTED BY: Tanya Burcham, CSR, RPR

Q. What is that opinion?

A. They did.

Q. Dr. Kolodny, do you have an opinion as to whether the acts or omissions of these defendants injured or endangered the comfort or repose of Oklahomans?

A. I do.

Q. What is that opinion?

A. They did.

Q. Dr. Kolodny, do you have an opinion as to whether the acts and omissions of these defendants offend decency -- and let me phrase what that means here -- with respect to how opioids should be prescribed in a community like this. Do you have an opinion?

A. I do.

Q. What is that opinion?

A. They did.

Q. Do you have an opinion whether defendants' acts or omissions rendered Oklahomans insecure in life here in Oklahoma?

A. I do.

Q. What is that opinion?

A. They did.

Q. Do you have an opinion, Dr. Kolodny, as to whether all of these things that you've just opined about, the conduct of the defendants and the result of that conduct, have impacted

a considerable number of persons in Oklahoma at the same time?

A. I do.

Q. What is that opinion?

A. They did.

Q. Now, Dr. Kolodny, those effects, is that what we've referred to or you've referred to as the opioid epidemic or crisis?

A. Yes.

Q. Dr. Kolodny, I want you listen very carefully. Do you have an opinion as to whether the conduct of these defendants that you've just talked about was a cause of the opioid epidemic and crisis we have in Oklahoma?

A. I do.

Q. Please tell the Court what your opinion is.

A. I believe that Johnson & Johnson was a major cause of our opioid crisis. It was Johnson & Johnson's opium that flooded -- that flooded into the United States. I think it's fair to characterize Johnson & Johnson as a kingpin in our opioid crisis because it was their opium that they were selling and that other drug dealers or pharmaceutical companies were selling.

Johnson & Johnson was aware of the 2003 GAO report that faulted Purdue Pharma for promoting OxyContin aggressively and mentioned, in particular, the unbranded campaign to increase opioid prescribing as a class of drug outlined in that GAO

report. Despite reading that report, reading that the federal government was criticizing Purdue Pharma, Johnson & Johnson continued to sell opium and oxycodone to Purdue Pharma. And Johnson & Johnson did exactly what was described in that report, also promoted an unbranded campaign to increase opioid prescribing.

In 2007, when Purdue Pharma was convicted criminally of claiming that OxyContin was less addictive because of its extended-release formulation, Johnson & Johnson continued to sell opium and oxycodone to Purdue Pharma and continued to do exactly what Purdue -- Purdue Pharma was convicted criminally of doing. They promoted their products as having lower abuse potential.

We've seen Johnson & Johnson promote opioids in this unbranded campaign, funding front groups, patient groups meant to look like grassroots organizations that promoted opioids, funding professional groups that were promoting opioids. We know that Johnson & Johnson participated in the Pain Care Forum, a group that I have referred to as the opioid mafia, working to protect their stake in the opium supply into the United States. We know that Johnson & Johnson didn't simply fund an unbranded campaign but they also directly promoted their own opioids in ways that were improper. We know that their sales reps downplayed the addiction potential of Duragesic. We know that they promoted their products

International Narcotics Control Board, which monitors global opioid consumption, and what we're looking at is oxycodone by weight of consumption in the United States. And my understanding is that more than 60 percent of that oxycodone is Johnson & Johnson's product.

Q. (By Mr. Yoder) I am not asking you about the ultimate supply. Do you agree, Doctor, that OxyContin is made by Purdue Pharma?

A. Yes.

Q. Do you agree that neither Johnson or Johnson Janssen Pharmaceutical manufactures a prescription opioid product that has oxycodone in it?

A. They manufacture the active ingredient.

Q. That's not my question, Doctor. I'm talking about the actual prescription opioid. We'll get to the raw material, we will get to the active pharmaceutical ingredient. But I would ask you to answer my question.

I'm talking about the actual prescription opioid that is manufactured and that is marketed. Okay? Do we have an understanding of that?

A. It -- yes.

Q. Okay. And do you agree that neither Johnson & Johnson or Janssen Pharmaceuticals manufactures and markets a prescription opioid that has as its active pharmaceutical ingredient, oxycodone?

A. I would agree that they don't market an oxycodone-containing product. I'm not sure I can completely agree they don't manufacture because I think they're part of the manufacturing. But I would definitely agree with you that they don't market an oxycodone-containing product.

Q. OxyContin is marketed, let's use your term, by Purdue Pharma. Correct?

A. Yes.

Q. All right. Now, you have offered some criticisms that Johnson & Johnson or Janssen Pharmaceutical -- actually, it's really Noramco. Noramco is the entity that has the contractual relationship in supplying active pharmaceutical agreement to Purdue Pharma or one of its affiliates. Correct?

A. Noramco has been supplying active -- has been supplying opioids to many different manufacturers, including generic.

Q. Okay. Not my question. I'm talking specifically about Noramco and the agreement that you referenced in your testimony, with Purdue Pharma, were one of its affiliates. Correct?

A. Yes.

Q. And that was in 1998, if I recall correctly?

A. There was an agreement in 1998, that's correct.

Q. Right. Now, your criticism is, at some point thereafter, Noramco should have made a decision to stop doing

business with Purdue Pharma or one of its affiliates.

In particular, they should have no longer supplied the active pharmaceutical ingredient. Is that your testimony? It either is or it isn't, Doctor?

A. No, I'm -- you were asking me a question. I want to think about that a little bit. I want to make sure I understand your question.

Are you asking me what I believe Noramco should have done when it became clear that we had a problem with OxyContin in the United States?

Q. No. I'm asking you to answer my question.

A. Okay. I'm going to -- I'm going to try.

Q. My question is, is it your testimony that at some point after 1998, Noramco should have stopped supplying active pharmaceutical ingredients to Purdue Pharma or one of its affiliates?

A. Yes.

Q. Okay. See, we're moving now. Okay. Isn't it the responsibility of the government to decide which drug companies are allowed to manufacture and sell prescription opioids in this country?

MR. BECKWORTH: Objection, Your Honor. It's beyond the scope of the direct. He's not here to talk about what the government allows in terms of supply. That's not what he's testified to. It's not part of his testimony.

MR. YODER: Your Honor, I think it's highly relevant to the opinions that he's come into court trying to offer about the supply of this material which is highly regulated.

MR. BECKWORTH: Your Honor, the --

MR. YODER: And again -- and if I may make an offer. The facts are that, as we will show, that this is all done in a regulated and lawful manner. And I think it's very important for the Court to hear from this witness whether he understands that or not. And if he wants to testify that he doesn't, so be it. But if he does, then I'm entitled to question him about his understanding of this regulatory scheme that deals with these materials.

MR. BECKWORTH: Your Honor, if I may respond. The government allows me to own a car if I buy one, and I can get a license. It doesn't permit me to make the conscious choice to run people over in the street. The questions that he was asked were about their choices to supply and continue to supply. It has nothing to do with whether the federal government allowed it. It's just like their own false and misleading statement chart.

MR. YODER: Your Honor --

MR. BECKWORTH: They can sell the drugs, but they can't do it deceptively. So we did not ask him about regulations at all. It's what they can do within the confines of being a supplier. I think it's completely outside the

scope. It's an improper question.

MR. YODER: And they absolutely didn't ask because they don't want to get into the area because they know this is all highly regulated and that this supply was lawful. And if this witness is going to come into court and use terms like kingpin --

MR. BECKWORTH: Your Honor, he just said we can ask.

MR. YODER: -- then -- then we should be able to question him as to whether he is aware of the regulatory scheme that governed the lawful supply of these materials.

THE COURT: It is outside the scope of the direct examination. I sustain the objection.

MR. YODER: Okay.

Q. (By Mr. Yoder) Let me ask it this way, without asking you about the law then, Dr. Kolodny.

Are you aware of the fact that the government entered into a corporate integrity agreement with Purdue Pharma?

A. I believe so, yes.

Q. Okay.

MR. YODER: Your Honor. If I may approach, Your Honor?

THE COURT: Yes.

MR. YODER: We have a lot of documents, Your Honor, so if you'll just give us a moment.

THE COURT: All right. Sure.

EXHIBIT 2

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER ATTORNEY GENERAL OF OKLAHOMA,	)	
Plaintiff,	)	
VS	)	Case No. CJ-2017-816
(1) JOHNSON & JOHNSON; (2) JANSSEN PHARMACEUTICALS, INC.; (3) ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS; (4) JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;	)	
Defendants.	)	

TRANSCRIPT OF PROCEEDINGS
HAD ON THE 6TH DAY OF JUNE, 2019 - (MORNING SESSION)
BEFORE THE HONORABLE
THAD BALKMAN, DISTRICT JUDGE

REPORTED BY: *Tanya Burcham, CSR, RPR*

Q. I'm not asking about any particular one, I'm just asking, do you have a memory of ever prescribing Nucynta ER?

A. And I -- and I'm saying I don't recall because it wasn't a medication that I prescribed a tremendous amount. So I don't recall if I prescribed the ER version or the regular version.

Q. We know you weren't visited by Janssen representatives about Duragesic. Were you ever, after you went into practice, visited by Janssen sales representatives about Nucynta or Nucynta ER?

A. Yes, sir. And I remember attending one of the representative dinners as well.

Q. With Janssen?

A. Yes, sir.

Q. Okay. Now, in your medical clinic, you're the boss. Right?

A. I'd like to think it's a team approach.

Q. Okay. But you're the director. Right?

A. Correct.

Q. And you also manage your time. Right?

A. Yes, sir.

Q. And with any Janssen sales representative, you're not required to see them, are you?

A. No, sir.

Q. You make a choice to see them. Right?

A. Correct. So I can keep tabs on the misinformation they're providing.

Q. Whatever your purpose is, you don't have to meet with them, do you?

A. No, sir.

Q. And that's true with respect to any other sales representative for any other company. Correct?

A. Yes, sir. Except when I go to conferences.

Q. All right. And that's true for other doctors. Right?

A. Correct.

Q. Okay. So can you prescribe Nucynta ER if you don't meet with a sales representative?

A. Yes, sir.

Q. Can you identify for me any instance where a Janssen representative told you anything about Nucynta ER that you felt was false or misleading?

A. Yes. I believe during the dinner program that I attended, I was in disagreement with the utilization of long-acting opioids, including Nucynta which they were advocating is an appropriate treatment for chronic non-malignant pain.

Q. I mean, interesting, you didn't say anything about that in your direct testimony. But what was the name of the representative?

A. I have a hard time recalling names, sir, and especially representatives.

Q. And after that statement was made, did you refuse to ever see another sales representative?

A. No, sir.

Q. Did you refuse to see that sales representative?

A. I don't recall.

Q. Did you ever register any complaint to anyone at Janssen that you felt somebody was providing misinformation?

A. I didn't know that was an option.

Q. Did you ever look into whether it would be?

A. No, sir. I have not.

Q. You're passionate about this stuff. Right?

A. I'm passionate about my patients. Yes, sir.

Q. And you're passionate about how people generally are treated for chronic pain. Right?

A. I believe they deserve the proper treatment for pain. Correct.

Q. So what you're saying is, somebody made a statement to you that you felt was false and misleading, and yet you didn't register any complaint at the time or take action. Is that what you are saying?

A. No representative ever told me that was an option.

Q. Did you ask?

A. No, sir.

Q. Did you ask anyone at Janssen?
A. Again, I wouldn't even think of that.
Q. And what was the false statement?
A. That long-acting opioids have a role in chronic non-malignant pain, and that they benefit the patients over the long-term.
Q. Would you agree that the FDA has approved the use of Nucynta ER for moderate and severe chronic pain?
A. Sir, that's outside my expertise. I don't know if the FDA approves or disapproves.
Q. Do you know what a warning label is?
A. Yes, sir.
Q. And do you know that for any Schedule II drug there has to be a warning label?
A. Yes, sir.
Q. And do you understand that that is something that's approved by the FDA?
A. Again, if you're referring to the drug inserts, you know, up until this trial, I really hadn't taken a close look at any one of them.
Q. You're registered with the DEA to prescribe prescription opioids. Right?
A. Correct. Which I base upon my training.
Q. And you know that Schedule II prescription opioids are addictive. Right?

A. Yes, sir.

Q. You know they can be abused. Right?

A. Yes, sir.

Q. And you know that because they are a Schedule II opioid they have to have a warning with any literature describing the risk of using the drug. Correct?

A. Correct. Yes, sir.

Q. Okay.

MR. YODER: If I may approach, Your Honor.

THE COURT: Yes, you may.

Q. (By Mr. Yoder) I'm going to hand you what's been marked as Exhibit J-2783. So if you take a look --

MR. YODER: May we publish, Your Honor?

THE COURT: Has it been admitted already?

MR. YODER: Yes.

THE COURT: Yes.

Q. (By Mr. Yoder) So this is the -- the warning label and product literature approved by the FDA for Nucynta ER. If you'd just take a look at the first page, you'll see in the top left-hand corner it shows the initial U.S. approval in 2011. Do you see that?

A. Yes, sir.

Q. And that's consistent with your memory of when you learned that Nucynta ER was available?

A. Something in that ballpark, yes, sir.

Q. And -- so -- and this was after you had started your pain management practice in Lexington. Correct?

A. I had taken over my parents' practice, yes, sir.

Q. All right. So if you take a look at page 3. Right?

A. Yes, sir.

Q. And you will see that down at the bottom there's an Item 1, Indications and Usage. Do you see that?

A. Correct.

Q. And it states, Nucynta ER is an extended-release formulation of tapentadol --

You understand that's the active pharmaceutical ingredient in Nucynta ER?

A. Yes. I've heard it pronounced tapentadol.

Q. -- indicated for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. Do you see that?

A. Yes, sir. I see that.

Q. And you understand that is indication and usage for Nucynta ER that's approved by the federal Food & Drug Administration. Correct?

A. Yes, sir.

MR. DUCK: Your Honor?

THE COURT: Mr. Duck?

MR. DUCK: I'm sorry to interrupt. I'm going to

object to too much questioning about Nucynta, period. I think he should have some leeway on asking questions about Nucynta. I don't believe I asked any questions about it on direct examinations. I'm not trying to cut off any questions about Nucynta. They are opioids and this case is about opioids. But when we start getting into regulatory questions of Dr. Mazloomdoost, after he said that's not his area of expertise, related to a specific opioid that I didn't ask him about on direct, we just ask that Mr. Yoder, while he can ask about Nucynta, not go down this regulatory path that he seems to want to go down.

MR. YODER: Your Honor, he just testified -- if we can pull that up -- that a sales representative in this meeting made false and misleading statement. And I asked him what it was, and he said it was their statement that Nucynta ER was proper for the treatment of long-term chronic pain. The FDA has approved -- and I can read it, actually, here.

You were (indistinguishable) as an appropriate treatment for the --

MR. DUCK: Your Honor, may we approach the bench for this?

MR. YODER: -- chronic non-malignant pain.

THE COURT: Mr. Duck wants to approach the bench. So let's do that. Step over here. Thanks.

(The following bench conference was had:)

MR. DUCK: It seems like he's going down legal questions about a regulatory issue that isn't relevant to Dr. Mazloomdoost's testimony. Now, maybe I shouldn't have given him the leeway. He was asking questions about Nucynta. I know I hadn't asked about Nucynta. I think he should get to ask some questions. But to try to use questions about regulation and what the FDA did in the legal capacity after he said that's not his area of expertise, we take issue with.

And again, ask some questions about the medicine, ask questions about the pain treatment, ask questions about addiction and opioids. Questions about regulation, that's not what he's here for. They've got experts for that.

Honestly, it's probably better legal argument for closing argument than to put a pain expert up on the stand and ask whether or not the FDA regulated something in a certain way. We've always said this is not what this case is about, that's not what this case is about. They want to make it about that. This just isn't the witness to do that with. So we'd object to the entire line of questioning about FDA decision-making. Etcetera.

MR. YODER: This doctor has offered a testimony that my clients' representatives made a false and misleading statement, that these drugs can be used for treatment of long-term chronic pain. I'm entitled to probe his opinion in that regard and whether he's aware that they're approved for

that very use by the FDA. He can either say he is, he can say he's not aware of that, he can say whatever he wants to say, but I am absolutely entitled to probe his opinion. And I'm not limited to just ask questions that they choose to ask him. They didn't go into details, Your Honor. There's a reason why they didn't go into details. We're entitled to defend our clients by doing that and by showing that there is no basis for that opinion.

MR. DUCK: I just don't think -- I don't disagree that they're entitled to try to defend themselves with this FDA stuff. This just isn't the witness for it. We're in our case in chief. There are other witness that they'll call their own witnesses. They can talk about the FDA all they want to during their case in chief. With the pain physician who's here to talk about issues that have nothing to do with regulations. We spent a lot of time with Mr. Yoder's questioning on regulations, DEA, FDA, registry, etcetera. None of that came up with direct examination. And I don't think Your Honor wants to abandon the procedure that cross-examination is to be limited to the scope of direct examination. And hopefully that's not what's being suggested, but we just ask to -- to move on from this line of questioning.

MR. YODER: Your Honor, he's offered an opinion that a statement was made that's false and misleading. We're entitled to probe now.

THE COURT: I agree that you can -- you can ask Dr. Mazloomdoost about the statements that were made to him. I would caution you not to get into his knowledge about regulatory matters. Certainly, he may have knowledge of his own personal experience as a doctor. You're free to ask him those questions. But if I think you're getting into his opinions about regulations related to Nucynta ER, then I'll probably sustain the objection.

MR. YODER: But it's his understanding, Your Honor. I mean, he's offering an opinion that's really based on his understanding that somebody is inappropriate.

MR. DUCK: His medical understanding.

MR. YODER: Well, and it's not just for the use of the product, it's also for the statements made about the product, because he knows, or maybe he doesn't know, but I'm entitled to find out whether these are regulated or not and whether they're approved or not as part of that regulation. I mean, that's critical to the underpinnings of his opinion. And so I don't plan to ask him questions as if he's a regulatory expert. It's his understanding and his knowledge of these things.

THE COURT: I will overrule the objection to the extent that Mr. Yoder can proceed with his line of questioning with the understanding that you're not going to get into matters beyond the scope of his personal knowledge as a doctor.

Thank you.

MR YODER: Thank you.

MR. DUCK: Thank you, Judge.

(The following transpired in open court:)

Q. (By Mr. Yoder) So, Doctor, we were on exhibit J-2783. We were looking at the bottom of page 3. And we were looking at Item 1, Indications and Usage, that reads, Nucynta ER is an extended-release formulation of tapentadol indicated for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended time.

And my question is: Is it your understanding that that is an FDA-approved indication and usage for Nucynta ER?

A. Yes, sir. Your representatives were not speaking off label. My issue is with the --

Q. Sir, you're not -- I'm sorry. You're not answering my question.

A. I thought I did. I said yes, sir.

Q. No. Let me try again. Okay? Again, I understand you have strong feelings. I understand there's things you would like to say. Your counsel will give you a chance to do it. I get to ask questions and hopefully get answers to my questions.

A. Yes, sir.

Q. My question is pretty simple. Okay? Is it your