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 William C. Hetherington Special Discovery Master

DEFENDANTS' MOTION TO EXCLUDE TESTIMONY OF DR. DANESH MAZLOOMDOOST AND BRIEF IN SUPPORT

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UNDER SEAL PER COURT ORDER DATED APRIL 16, 2018

Q. I'm sorry to interrupt you, Doctor. I'm sorry. It starts with, Duragesic can -- Duragesic can be abused?

A. "Can be abused in a manner similar to other opioid agonists, legal or illicit. This risk should be considered when administering, prescribing or dispensing Duragesic in situations where the health care professional is concerned about increased risk of misuse, abuse or diversion.

Q. That language suggests that one has to be careful of the risks of abuse and diversion of Duragesic in patients, correct.

MR. CUTLER: Object to the form.

A. So it's akin to saying you have to be careful when you drive, but if you drive recklessly or -- or -- or cautiously, yes, I -- I will agree that -- that it's giving a warning.

Q. (By Mr. Ehsan) And if it goes -- if you look at the next paragraph, states persons at risk -- or strike that.

It states persons at risk -- I will try again a third time.

"Persons at increased risk for opioid abuse include those with personal or family history of substance abuse." I'll pause there. Did I read that

correctly so far?

A. That's correct.

Q. Are -- do you agree, Doctor, that patients who have personal or family history of substance abuse have an increased risk for opioid abuse?

MR. CUTLER: Object to the form. Vague.

A. I think a personal history of trauma or family history of abuse or mental illness increases somebody's risks for abuse. However, it doesn't mean that people who don't have those elements are immune from abuse.

Q. (By Mr. Ehsan) Understood. What I read so far doesn't say others don't have a risk. It just says those who have these conditions are at an increased risk, correct?

A. No, but the reason I bring that up is that there's a notion within pharmaceutical marketing that as long as you do risk mitigation like using the opioid risk tool assessment -- assessment tool, that you can rest assured the patient doesn't have -- or has a sufficiently low risk for addiction, that it's safe to prescribe these opioids, and that's -- that's directly in conflict with what this labeling sales.

Q. The label goes on to say -- to define substance abuse as including drug or alcohol abuse or addiction, correct?

A. Yes.

Q. And it says another category of individuals are at increased risk are, quote, those who have a history of mental illness, example, major depression, correct?

A. That's right.

Q. And I think you just said if you have a family history of mental -- or personal history of mental illness, that puts you at an increased risk, correct?

A. And yet -- and yet, when they look at the studies of patients with mental illness who present for pain, a far greater percentage of those patients receive an opioid than they do counseling and antidepressant like an SSRI or SNRI, which underlies this notion that that -- that the -- in spite of these warnings, the marketing messages have -- have created environment which conflicts with these warnings.

Q. The box warning goes on to say, "Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids." Would you agree with that statement?

A. I agree with that.

Q. Good clinical practice?

MR. CUTLER: Object to the form.

A. I agree with that statement.

Q. (By Mr. Ehsan) Goes on to say, "All patients receiving opioids should be routinely monitored for sign of misuse, abuse or addiction." Do you agree with that statement?

A. I do. And -- and I think this brings up another point that when -- when patients are identified with risk of abuse or that they have a high likelihood of abusing the medications, what's typically done with those patients? Where is the pharmaceutical instructions on what to do with that patient? If you're putting out a medication that has that kind of a risk to it, shouldn't you have a contingency plan available to those clinicians?

Q. I'll --

MS. PATTERSON: Objection. Nonresponsive.

Q. (By Mr. Ehsan) I'll read you the next sentence. "Patients with increased risk of opioid abuse may still be appropriately treated with modified-release opioid formulations; however, these patients will require intensive monitoring for signs of misuse, abuse or addiction."

Do you agree with that statement?

A. I do.

MR. CUTLER: Object to the form. Outside the scope of his expert testimony.

Q. (By Mr. Ehsan) So at least as of 2005, would you agree that this package insert appropriately reflected the risk of -- of abuse, misuse and addiction with a -- with Duragesic?

MR. CUTLER: Object to the form. Vague. You've looked through two of -- of 30 pages of this document. He's also not here to opine on anything about the package insert, so it's outside the scope of his expert testimony.

A. Yeah, I refrain from making an opinion.

Q. (By Mr. Ehsan) Doctor, I'm not asking you what the rest of the label says, because I'm just -- just this portion we read, would that sufficiently form -- sufficiently inform someone of the risk of abuse, misuse and addiction with -- with Duragesic?

MR. CUTLER: Object to the form --

A. Like I said --

MR. CUTLER: -- calls for speculation. Vague. Outside the scope of his expert testimony.

A. Yeah, there's a lot more that goes into that and it would be difficult for me to assess that right now.

Q. (By Mr. Ehsan) Do you have an opinion of whether or not the rest of the label contradicts the material in the box warning?

MR. CUTLER: Same objection as being entirely outside the scope of his expert testimony.

Q. (By Mr. Ehsan) So just so I'm clear, is it your opinion that you're not an expert on package inserts?

A. I -- I understand the content of it. I would never claim to be an expert in it.

Q. You're also -- is it your testimony, Doctor, that you are not familiar -- you were not familiar with the content of this particular package insert for Duragesic?

MR. CUTLER: Object to the form. Mischaracterizes his testimony.

A. I have not read it line for line like we did right now in I don't know how long.

Q. (By Mr. Ehsan) Well, let me rephrase. Sitting here today, can you recall the content of the package insert for any Schedule II opioid?

MR. CUTLER: Object to the form. Vague.

A. Yeah, not in gross detail.

Q. (By Mr. Ehsan) How about the box warning for any of the Schedule II opioids?

MR. CUTLER: Objection. Form.

A. So far as that opioids are addictive and have risks for respiratory depression, I think that's pretty

universal across opioids.

Q. (By Mr. Ehsan) And it's your belief that the language contained in this package insert -- well, strike that. Let me ask it this way.

You believe that the -- do you believe that the package -- the language in this package insert would be informative to a prescribing physician about the risks and benefits of Duragesic for his or her particular patient?

MR. CUTLER: Object to the form. Vague. Calls for speculation as to unnamed other doctors. Outside of his expert testimony.

A. You know, if I saw a warning on the street "road closed, do not enter," how much risk there is to entering that, what the specific risks are, the details of that are not explicitly stated. So it's difficult to say if this is enough content for a physician to completely grasp the full risks and concerns.

Q. (By Mr. Ehsan) Do you know if patients receive any of this information when they -- when they fill the prescription for Duragesic?

MR. CUTLER: Object to the form. Calls for speculation.

A. I don't know.

Q. (By Mr. Ehsan) In the call logs you reviewed,

of this book chapter, there's a section B, Physical Dependence. Do you see that?

A. I do.

Q. And states, (As read) physiological state of adapt -- adaptation to a drug or class of drugs in which a withdrawal syndrome occurs in response to abrupt cessation or reduction of dose -- dose. Did I read that correctly, Doctor?

A. Yes.

Q. And you're familiar with the term physical dependence?

A. Yes.

Q. Do you consider physical dependence to be a distinct clinical entity versus addiction?

MR. CUTLER: Object to the form.

A. I think they -- they're on a continuum.

Q. (By Mr. Ehsan) Are you familiar with the current DSM-5 diagnostic criteria for opioid use disorder?

MR. CUTLER: Object to the form.

A. I'm aware of it. I don't -- I wouldn't be able to repeat it verbatim.

Q. (By Mr. Ehsan) Are you aware of the DSM-4 criteria for opioid dependence?

MR. CUTLER: Object to the form.

A. So I -- it's a little bit tangential to what I do, given that it's more of a psychiatric resource, and I do know that there's a difference in going from 4 to 5.

Q. (By Mr. Ehsan) Under the DSM-4 first, does the presence of physical dependence in and of itself sufficient to diagnose drug dependence in a patient?

MR. CUTLER: Object to the form.

A. Again, hard for me to answer that as it's a psychiatric. I -- I -- I really try to make the distinction that managing pain and managing addiction are two separate issues. And I think that's one of the mistakes that we're making is that we're trying to lump them all into one box.

My expertise is in managing pain. I have enough knowledge to identify concerns for a use disorder and I have resources to whom I refer to when I identify my concerns, but as far as the specific delineations of what defines DSM-4 or DSM-5 criteria or the specific treatments of addiction, I defer that to my colleagues.

Q. (By Mr. Ehsan) One of the advantages of having a multi -- multidisciplinary team treat the patient is that you can bring in experts in various conditions to simultaneously assess and manage the patient, correct?

MR. CUTLER: Object to the form. Vague. Also calls for testimony outside of his expert opinion.

A. Yeah, simultaneously is a -- is something I take issue with. I'm not sure that that's ...

Q. (By Mr. Ehsan) Okay. One of the advantages of a multidisciplinary team is that various experts can, in coordination, treat the patient and coordinate his or her care, correct?

MR. CUTLER: Same objections to form and scope.

A. What's interesting is multidisciplinary pain clinics were on the rise up until '90s, 2000, and then when marketing campaigns around opioids really got promoted, this is -- this is reflective of how influential the marketing campaigns were, that not only did they penetrate into academic settings where terms like pseudoaddiction are used in -- in support of other references for pseudoaddiction creating that echo chamber, but on top of that, you have insurances that start to shift away from a more robust approach to managing pain like multidisciplinary pain clinics and shifting more towards the short-sided interventions of using opioids.

As a result, you saw this dramatic reduction in the number of multidisciplinary pain clinics, because

medication is indicated for cancer pain, but anybody who has had cancer pain can also receive these medications, which is an off-label use of the medication.

Well, what I found was interesting when I reviewed the Oklahoma call logs is the call logs were very, very brief. They were very scant in the content when it comes to -- to Teva and -- and its affiliate companies, but there was one doctor in particular who had numerous contacts or evidence of contacts. This physician was a psychiatrist --

Q. Do you remember my question, by the way?

MR. CUTLER: Object to the form. He's --

Q. (By Ms. Patterson) Do you remember?

MR. CUTLER: Object to the interruption. You asked him a question. He's giving you an answer --

Q. (By Ms. Patterson) Yeah, you can answer.

MR. CUTLER: He's entitled to give it.

Q. (By Ms. Patterson) Go ahead.

A. So -- so this --

MR. LAFATA: I don't remember it.

Q. (By Ms. Patterson) go ahead.

A. So this physician was a psychiatrist, who I don't know of many psychiatrists who treat oncological pain, but he was visited quite regularly by representatives. So I'm not sure quite why, but you can

interpret that it wasn't specific to cancer pain. And this physician ultimately lost his license after having five overdoses in his clinic and -- and is no longer in practice.

So the -- the content coming out of your company is indeed attributable directly to the -- to the opioid epidemic. And your question to me earlier was about the validity of that statement, the opioid epidemic is strictly attributable to pharmaceutical marketing, and I'm just giving you examples of situations in where I've experienced it myself and I've seen Oklahoma physicians experience it as well.

Q. Are you finished?

A. Yes, ma'am.

MS. PATTERSON: I'll move to strike and object as nonresponsive, because that wasn't my question at all, but I'll -- I'll ask my question again.

Q. (By Ms. Patterson) Have you conducted any independent research to support your statement that the opioid epidemic is directly attributable to focused pharmaceutical marketing?

A. Other --

MR. CUTLER: Object -- object to the form. Asked and answered. He just testified that he reviewed Oklahoma data.

A. So your question about have I conducted research --

Q. (By Ms. Patterson) Yeah.

A. -- Is very vague.

Q. Okay.

A. Because it depends on how you define that research --

Q. Then that's watt you have to tell me, it's vague, and I'll try to -- I'll try to make it more clear for you. Okay? Let me do it this way.

You told me that you -- you've told us today that you've reviewed some call logs, right?

A. Yes, ma'am.

Q. Okay. And those call logs were provided to you by counsel for the state, correct?

A. I believe they were obtained from disclosures from you.

Q. Well, sure, but you didn't get them from me or from counsel from the other defendants, you got them from the lawyers for the state, correct?

MR. CUTLER: Object to the form.

Q. (By Ms. Patterson) Is that right?

MR. CUTLER: They're defendants' call logs.

Q. (By Ms. Patterson) Is that right, Doctor?

A. They're defendants' call logs.

Q. Sure. I'm not --

A. They're your call logs.

Q. -- I'm not disavowing the call logs. I'm just asking how you came into possession of them.

A. Yes, I -- I read them here.

Q. Okay. And the call -- how many call logs did you look at?

MR. CUTLER: Object to the form. Asked and answered.

A. Don't remember, but a number.

Q. (By Ms. Patterson) Fewer than 10?

MR. CUTLER: Object to the form.

A. Something in that ballpark.

Q. (By Ms. Patterson) Okay. And the call logs that you looked at, they were call logs from which companies?

A. From all three companies, from Teva, from Janssen, and from Purdue.

Q. How many Teva call logs did you look at?

A. I can't recall.

MR. CUTLER: Object to the form.

Q. (By Ms. Patterson) how many J&J call logs or Janssen call logs did you look at?

MR. CUTLER: Object to the form.

Q. (By Ms. Patterson) Don't recall?

A. I don't recall.

Q. And Same -- same would be for Purdue, you don't recall --

MR. CUTLER: Object to the form.

Q. (By Ms. Patterson) -- is that right?

A. No, ma'am.

Q. Okay. But you -- it's your testimony here that you looked at at least one call log and maybe more that referenced a -- some activity by a sales representative from Teva; is that right?

A. Yes, ma'am.

Q. Okay. Do you recall -- well, strike that.

And the call log that you recall looking at that referenced Teva, the one that you were speaking about a moment ago was a call log that referenced a psychiatrist here in the state of Oklahoma?

A. Yes, ma'am.

Q. And that psychiatrist here in the State of Oklahoma was being called on by a representative of Teva?

A. Yes, ma'am.

Q. Okay. Do you recall that psychiatrist's name?

A. I don't, but I'm sure a Google search would produce it.

Q. Okay. But you don't recall it as we sit here

today?

A. I don't.

Q. When did you first see that call log?

A. Yesterday.

Q. Okay. Had you seen any call logs prior to the time you prepared your disclosure which we've marked as Exhibit No. 6?

A. No, ma'am.

Q. Okay. Had you seen any call logs at all regarding this case prior to yesterday?

A. No, ma'am. I wouldn't be privy to those.

Q. Okay.

A. But you know, the similarities are uncanny about both the experience I've had as well as --

Q. And we're going to talk about that.

A. -- clinicians I've spoken with.

Q. We're going to talk about that, but you've not spoken to any clinicians in the state of Oklahoma, have you?

A. No.

Q. Okay. So I want to focus on the one call log that you saw yesterday for the first time that references a Teva representative calling on a psychiatrist in the State of Oklahoma.

MR. CUTLER: Object to the form.

Q. (By Ms. Patterson) What particular medication or drug was the sales representative in that particular call log talking to the psychiatrist about?

A. So there were two call logs for that one psychiatrist.

Q. Okay.

A. And it was both Fentora and Actiq.

Q. Okay. So two call logs but dealing with the same doctor?

A. Yes, ma'am.

Q. And -- and the sales representative spoke to the doctor at least -- at least based on the call log about both Fentora and Actiq, correct?

A. The content of the discussion was not disclosed, which -- which I thought was different than everybody else's.

Q. Okay. Well, that was kind of --

A. But there were -- there were multiple dates of contact with -- where I presume the conversation was about the medication. Why else would they be there?

Q. Okay. But let me -- let me very specific about this. You saw two call logs showing that a Teva sales representative had called on the same psychiatrist in the state of Oklahoma, correct?

A. Yes, ma'am.

understand the scope of what you know about it, so let me just do it this way and we'll move on.

You have some understanding based on discussions you had with colleagues that at some point in time there was some legal action that involved Teva with regard to either Actiq or Fentora; is that accurate?

MR. CUTLER: Object to the form. Mischaracterizes his testimony. Asked and answered. You can answer it one more time.

A. Yeah, I'm saying that the concerns that I had in my exposures with Actiq and Fentora were confirmed as being unethical and overreaches by the company when legal action was taken and they were -- they were deemed as culpable to those -- to those issues.

Q. (By Ms. Patterson) They were deemed as culpable? By whom?

A. So I --

MR. CUTLER: Object -- object to the form.

Q. (By Ms. Patterson) Do you know?

MR. CUTLER: He's not a legal expert. He's told you a couple of times now how he knows about this and now you're apparently asking him about legal questions.

MS. PATTERSON: He said deemed as culpable.

I'm just asking by whom.

A. So we can have a medical conversation and you can feel just as inaccurate or incapable of having that -- the accuracy of legal. I'm not sure what the terminology you use.

Q. (By Ms. Patterson) Okay.

A. But the fact that there was legal action taken and there was admission of guilt or at least a reflection of guilt that corroborates with the experiences that I've had, that corroborates with the -- the concerning ethics of interacting with an Oklahoma psychiatrist, you know, where I heard that information or the accuracy or the specific terminology of that, to me, is less relevant --

Q. Okay.

A. -- than the concern of guilt and admission of guilt.

Q. Okay. Thank you. So let's talk about your personal experiences that you refer to with sales representatives of Teva with regard to Actiq and Fentora. I think you said -- I think you referred to three different experiences you've had. Was I correct about that?

A. At least.

Q. Okay. Well, let's talk about the three that

you remember today. When was the first one? And I'm not -- I'm not asking for a specific date, but was it when you were in medical school? Was it when you were in residency?

A. The first that I recall would be during fellowship.

Q. During fellowship. All right. And where were you doing your fellowship? I don't have your CV handy.

A. MD Anderson.

Q. Okay. Houston, Texas. That's where I live. How did you like Houston?

A. Love Houston.

Q. It's a great place.

A. It is.

Q. All right. So you did fellowship at MD Anderson. What years was that?

A. 2009 to 2010.

Q. Okay. And you had -- again, we're talking about the three interactions you had with sales reps regarding those -- those two drugs. Were any of the other two at -- while you were at MD Anderson?

A. Which other two?

Q. I want to go through the three experiences you've had that you can remember right now where you were exposed to some sales rep regarding Actiq or

Fentora. You said the first one was when you were at MD Anderson, and then there were two others. Were they also at MD Anderson or were they later?

A. No, they were when I was in practice at Kentucky.

Q. Okay. Very good. Let's talk about the first one. You started to refer to it. You said an Actiq -- a representative came in and was talking about Actiq, correct?

A. Yeah, I don't remember if it was Actiq or Fentora.

Q. Okay. A sales rep came in when you were at fellowship at MD Anderson and spoke about one of those two medications and you think that would have been 2009 or 2010?

A. Sometime in that ballpark, yes, ma'am.

Q. I'm sure you don't remember the name of the rep, do you?

A. Not at this point.

Q. Okay. And were you -- were there other physicians present during that presentation?

A. Yes, ma'am. It was -- it was a drug-represented lunch, so they had brought us lunch.

Q. Okay.

A. And there was a presentation about the Risk

Q. Okay. Other than what you've mentioned, do you remember any of the other specifics statements that were made in that presentation at MD Anderson?

MR. CUTLER: Object to the form.

A. Yeah, it's -- I remember them talking about the medications, talking about the on-label indications for it, talking about areas where we can -- we can nudge the margin, like the example they have is -- is the patient I mentioned earlier from Oklahoma who had a history of breast cancer and months and months if not years after her care, she was continuing to take Actiq or Fentora. I don't remember which.

Q. (By Ms. Patterson) Right, but that's -- the drug rep who was visiting with you guys at that time at MD Anderson wasn't talking to you about this patient from Oklahoma?

A. Wasn't specifically --

Q. Because I'm going to ask you about the patient from Oklahoma --

A. Sure.

Q. -- separately. I do want to ask you some questions about that. I'm just focusing right now about on what the drug rep was saying in that meeting, that lunch meeting. Have you told me everything you can recall that the drug rep said in that meeting?

MR. CUTLER: Object to the form.

A. I -- no, I probably have things that I don't remember right now.

Q. (By Ms. Patterson) Okay.

A. And maybe at some point, it will come back to me.

Q. But you've told me everything you remember right now?

MR. CUTLER: Object to the form.

A. You know, if I were to sit here and think in more detail, I could probably come up with more details, but to the best of my recollection, that was the content that stood out to me.

Q. (By Ms. Patterson) Okay. And was part of the gist of what stood out to you is that you thought that the -- that the rep was suggesting off-label use of the medication?

MR. CUTLER: Object to the form.

A. I felt -- I remember feeling uncomfortable with the conversation. I remember feeling like I -- you know, there's a sense of peer pressure when your attendings are in the room, when your colleagues are there and everybody is -- is talking about the medication, the overreach on regulation, and that the representatives are not -- are not providing any ethical

guidance of, well, there's value to this. There's reason to this. There's purpose to it.

You're not getting that from your attendings either, so you're left to kind of continue on the same conversation. And I think that kind of peer pressure takes place on a regular basis across the board in health care. When it comes to opioids, the stigmatization of not prescribing, the stigmatization of quote, unquote allowing people to suffer when there's a tool that can help them, that -- that stigma is pretty profound.

So if I had never gone into greater detail about the medication what the specific on-label and off-label uses are, that very well could have stayed with me as far as being appropriate utilization of medication rather than recognizing it as inappropriate use of medication, as exemplified by the patient that I mentioned.

MS. PATTERSON: Objection, Doctor. Not responsive.

Q. (By Ms. Patterson) My question really -- I'm trying to be very simple here so I can get some answers and move on to something else.

Was part of what stood out from -- to you from that presentation at MD Anderson was that the rep was

suggesting an off-label use of the medication?

MR. CUTLER: Object to the form. Literally just asked and answered.

A. Yeah.

Q. (By Ms. Patterson) Was that a yes, that's what stood out to you?

MR. CUTLER: Object to the form. Asked and answered.

A. Yeah, I've answered that. If you want to strike it from the record, that's your prerogative.

Q. (By Ms. Patterson) Well, no, it's not my prerogative. That's -- I can make objections to it and I did and we'll take that up with the judge later. I'm just trying to get an answer to the question. Let me rephrase it. Okay?

Did the drug rep for Teva that visited you and your colleagues at MD Anderson in 2009 or 2010 suggest off-label use of either of the Actiq or Fentora products?

A. I don't remember specifically who mentioned it. I know that the conversation was had.

Q. Okay.

A. And I know that there were insinuations made that that's okay.

Q. Okay.

A. I mean, if -- if the representative was really doing what they were supposed to do, I would anticipate them to jump in and say, well, frankly, that's off-label use, in which case that would have stood out in my mind. That would have been a statement that I would say, huh, the rep is actually objecting to something my attending is doing. This is something I should probably take a closer look at. That never happened.

Q. Have you ever prescribed Actiq?

A. I have.

Q. Have you ever prescribed Fentora?

A. Well, so I know I've prescribed either or. I don't remember which and at what time.

Q. Okay. How many times have you prescribed either Actiq or Fentora do you know?

A. A small handful.

Q. Okay.

A. Because I think that it is a really niched drug.

Q. And when you say it's a really niched drug, what do you mean by that?

A. It's a small population that would benefit from medication like that.

Q. Okay.

A. It's not something that -- nor is it something

prescribed Actiq or Fentora for a patient who is in remission?

A. No, that would be off-label use and I've answered that.

Q. Okay. Fair enough. Thank you. Have you ever read the package insert for either Actiq or Fentora?

MR. CUTLER: Object to the form.

A. I'm not sure why you guys have this obsession with package inserts, but --

Q. (By Ms. Patterson) Just it's an easy question. I mean, have you ever read it?

A. I mean, I can't recall if I've read it in detail.

Q. Okay.

A. I'm sure that I've glanced through package inserts, but ...

Q. And, again, let me do it separately and just so it's clear on the record. Let me ask you about Actiq first.

Do you recall if you've ever read the package insert for Actiq?

A. So --

MR. CUTLER: Object to the form.

A. -- it's been such a long time that I've used Actiq or Fentora, they blend together for me.

Q. (By Ms. Patterson) Okay.

A. I don't remember which is which.

Q. Okay. And so you can't tell me whether you -- you can't -- strike that.

You don't have a specific recollection as we sit here today of reading the package insert for either one of them?

MR. CUTLER: Object to the form.

A. I imagine that I probably did since they were modes of delivery that were not -- not what we're used to prescribing. So I would say probably as a fellow, I did read through it, but we're talking about nine, 10 years ago.

Q. (By Ms. Patterson) Fair enough. Okay. And then have you now told me about every interaction you recall having had yourself with sales representatives from Teva?

A. As far as I recall, yes, ma'am.

Q. Okay. Have you ever had any interactions that you can recall with any -- anyone representing Watson Laboratories or Actavis Pharma regarding any medication?

MR. CUTLER: Object to the form.

A. Yeah, I don't -- I don't recall the specific companies. I remember the medications that were being represented or the category of medications represented,

but you know, we have generic name, brand name, company name, you know, it kind of --

Q. (By Ms. Patterson) Well, let me ask it this way. Do you know what -- do you know if Actavis or Watson manufacture or market any brand name opioids?

MR. CUTLER: Object to the form.

A. So there's been a lot of sales within that that arena, so I don't know who owned what medication --

Q. (By Ms. Patterson) Fair enough.

A. -- at what point, but that -- they were all consolidated under Teva.

Q. Who is "they"?

A. All those -- all those medications were at some point purchased and now or at some point belong to Teva or represented by Teva.

Q. All what medications?

A. Actiq and Fentora.

Q. Okay. All right. Okay. Thank you. Now, let's talk about Oklahoma for a second. Well, first of all let me ask you about that patient that you said that you saw when you were at MD Anderson who was from Oklahoma.

Do you know who -- do you know what doctor in Oklahoma prescribed Actiq or Fentora for that patient?

A. That patient would come to MD Anderson so that

we would prescribe that, because --

Q. Okay. So it wasn't prescribed by a doctor in Oklahoma?

MR. CUTLER: Object to the form.

A. I don't -- I don't recall. I think that the -- I know that the Actiq was prescribed by us, but it wasn't the only medication she was on, but Actiq was the only medication -- or Fentora, whichever one it was at the time --

Q. (By Ms. Patterson) Whichever?

A. -- was the only medication that we were prescribing --

Q. Okay.

A. -- as far as I recall. So I think that it was in coordination with whoever her local physician was.

Q. Okay. But as far as you recall, it was prescribed by physicians at MD Anderson in Texas?

A. Yes, ma'am.

Q. Okay. Have you ever -- I know you said in response to one of the questions earlier today that you've never spoken to or discussed anything about pharmaceutical marketing with any -- strike that. Let me ask it this way.

Have you ever talked with any doctor in the State of Oklahoma about the marketing materials or

information that they have personally be provided by any drug manufacturer?

MR. CUTLER: Object to the form.

A. So as a face-to-face conversation, I haven't, but when I've reviewed the senate finance records for the State of Oklahoma, I noticed that the volume of books by the Federation of State Medical Boards, the -- I don't remember the title of that book, but it was some opioid policy or guidance and the volume of books taken -- brought into Oklahoma was fairly large.

Q. (By Ms. Patterson) The volume of books, I'm not understanding what you're talking about.

A. So there's a book at the Federation of State Medical Boards put out about appropriate opioid prescribing. It's, again similar, to the -- Dr. Fishman's book, the Responsible Opioid Prescribing. And it was, again, sponsored by pharmaceutical companies. It conveyed information that was overreaches or inaccuracies about the safety or efficacy of opioids. The volume of those books, the number of --

Q. You mean the number of those books?

A. The number of those books that came to Oklahoma was a very high number. We saw the same books when I was in Maryland, when I saw -- when I was in Kentucky, when I was in Texas.

Q. I just want to make it clear. This is just -- this is a book. It's not a bunch of different volumes of a book. It's just a book that you're talking about?

A. It's one book --

Q. Okay.

A. -- but the number of copies of that book --

Q. I gotcha. I'm with you.

A. -- was a sizable number.

Q. Right. And -- and You based that on some senate document --

MR. CUTLER: Hold on. Counsel, let him finish his question. You keep speaking over him. I'm sorry, are you --

Q. (By Ms. Patterson) I'm just trying too get through this so we can finish up.

A. Sure. I -- I can appreciate that. It's been a long day. The number of those books --

Q. Right.

A. -- that came into Oklahoma was very, very high. It felt -- it seemed like it was a disproportionately high number, and I'm familiar with the content of that book, which was --

Q. And respectfully, I'm not --

A. -- again you're over --

Q. -- asking you about the content.

do you plan to testify in this case as an expert on the cause or causes of the opioid epidemic?

MR. CUTLER: Object to the form.

A. So I have experience in the arena of opioid and pain management. I've seen the mismanagement. I have clinical experience managing patients who were mismanaged and getting them to a better -- better state. I've reviewed the literature around opioids. I've reviewed the literature around how this epidemic evolved and how there is -- the campaigns of misinformation using key opinion leaders, misrepresenting data, capitalizing on vulnerable population, stigmatizing and diverting attention away from the -- the more concerning or pressing issues, such as the neurophysiologic changes around opioids, so yeah, I have some background around this topic and how it's evolved over time.

MS. PATTERSON: Objection. Nonresponsive.

Q. (By Ms. Patterson) Are you planning to testify as an expert on that in this case?

MR. CUTLER: Object to the form.

A. So --

MR. CUTLER: Speaks for itself.

A. -- yeah, the fact that my disclosure reflects all of that, it's not inclusive of everything that I would -- I would testify to or discuss, but it includes

the content that I'm presenting as concerns.

Q. (By Ms. Patterson) Is it your testimony, Doctor -- and again, I'm referencing back to this particular bullet in your disclosure that we were looking at a moment ago. Is it your testimony that the opioid epidemic has been caused solely by focused pharmaceutical marketing?

MR. CUTLER: Object to the form. Vague. In part calls for testimony outside of his disclosure. To the extent you can answer it.

A. So it would be a speculation as to all of the responsible parties.

Q. (By Ms. Patterson) Okay.

A. But I can say with confidence that the manufacturers and the marketers of opioids had a very, very heavy hand in it.

Q. What are the other causes --

MR. CUTLER: Counsel, you can ask one more question. We're after six hours, so you can ask one more and then we're done.

MS. PATTERSON: Well, respectfully, Counsel, I'm not finished with questioning. If you want to cut it off, I can understand that. We can approach the judge about it. I'm happy to do that.

MR. CUTLER: Yeah, we've got I think rules in

this state about how long and you-all are over your time, so --

MS. PATTERSON: I understand --

MR. CUTLER: -- one more question.

MS. PATTERSON: -- I understand your position and I'm just making clear my position.

MR. CUTLER: Sure.

Q. (By Ms. Patterson) Do you believe there are causes for the opioid epidemic other than focused pharmaceutical marketing?

MR. CUTLER: Object to the form. Vague. Calls for testimony outside of his expert testimony. Asked and answered.

A. Yeah, I agree with my lawyer that this is -- that question is outside of my area of expertise. I can say with confidence specific parties, but yeah.

Q. (By Ms. Patterson) So it would be outside of your area of expertise --

MR. CUTLER: We're done. It's over six hours.

Q. (By Ms. Patterson) -- to -- it would be outside of your area of expertise to discuss other causes for --

MR. CUTLER: I'm going to instruct you not to answer that. You're over your -- the time allowed by Oklahoma rules of deposition. I told you you got one

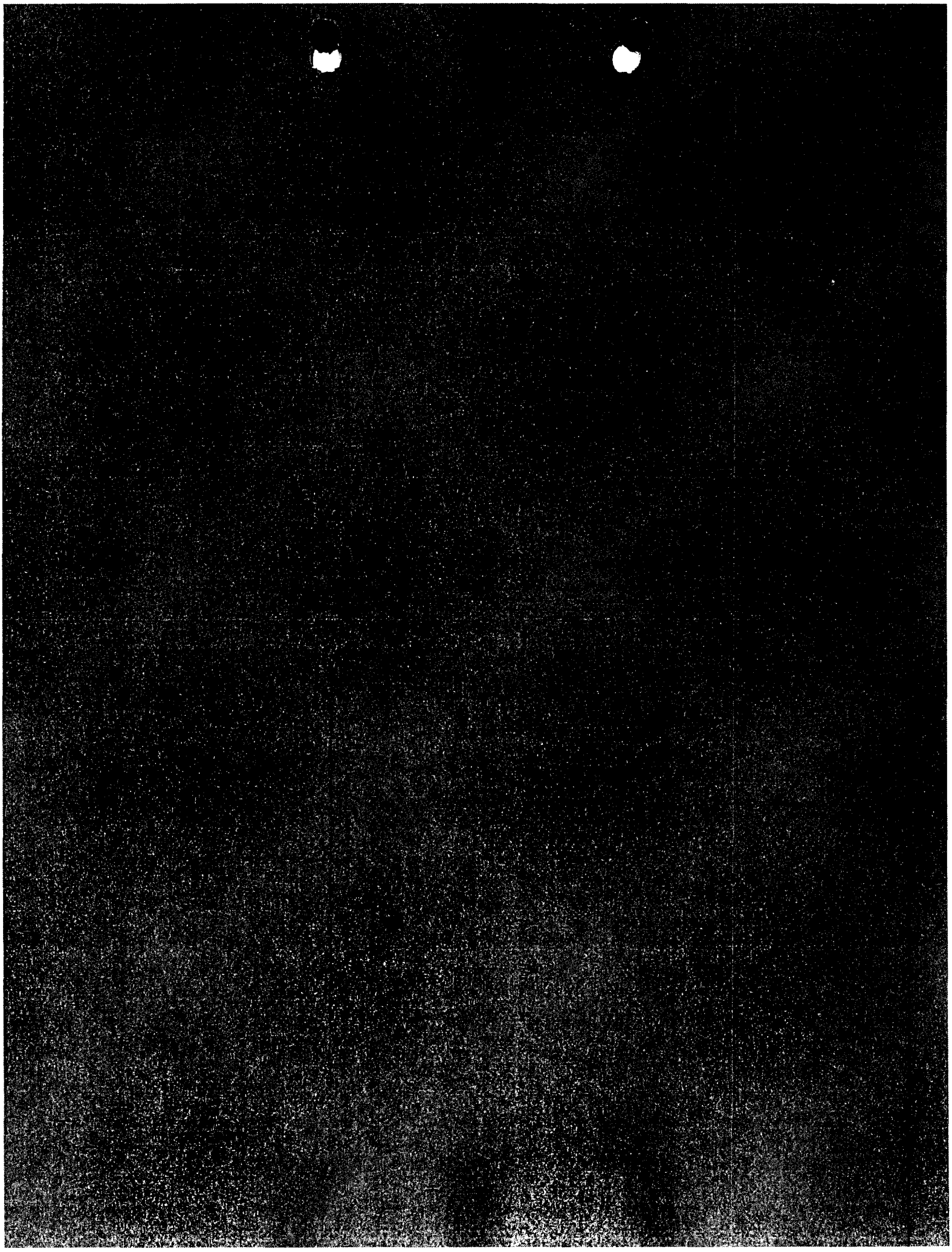

EXHIBIT C

2018 WL 6681223
Only the Westlaw citation is currently available.
United States District Court, N.D. Oklahoma.

Arlon SHANK, Plaintiff,
v.
WHITING-TURNER CONTRACTING COMPANY, Defendant.

Case No. 17-CV-446-JED-FHM
|
Signed 12/19/2018

Attorneys and Law Firms

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OPINION & ORDER

JOHN E. DOWDELL, UNITED STATES DISTRICT JUDGE

*1 Before the Court is Defendant Whiting-Turner Contracting Company ("Whiting-Turner")'s *Daubert* Motion to Exclude Plaintiff's Lost Earnings Opinions. (Doc. 53). Plaintiff has submitted a response (Doc. 56), and Whiting-Turner has submitted a reply (Doc. 60).

I. Background

This is a slip and fall case in which Plaintiff alleges that he sustained serious injury after tripping at his work site on May 5, 2015. Plaintiff has retained an expert, Dr. Ralph D. Scott, Jr., to testify as to the economic losses suffered by Plaintiff as a result of his injury. Dr. Scott, an economist, calculated that Plaintiff suffered a past loss of $233,420.53 and will suffer a loss in earning capacity in the range of $534,160.29 to $632,469.86. (Doc. 53-4 at 2). He further calculated that Plaintiff suffered a past loss of fringe benefits of $98,469.80 and will suffer a future loss of fringe benefits in the range of $283,154.69 to $335,267.92. (*Id.* at 6). In total, Dr. Scott concluded that Plaintiff's overall economic loss would be between $1,149,205.32 and $1,299,628.11. (*Id.* at 1, 6).

II. Standards Governing Expert Testimony

Rule 26(a)(2) of the Federal Rules of Civil Procedure describes the mandatory disclosures parties must make concerning expert testimony. Under Rule 26(a)(2)(A), a party must disclose to the other parties the identity of any expert witness it may use at trial. Rule 26(a)(2)(B) then describes the written report that must accompany any Rule 26(a)(2)(A) disclosure. This written report must contain:

> (i) a complete statement of all opinions the witness will express and the basis and reasons for them;
>
> (ii) the facts or data considered by the witness in forming them;
>
> (iii) any exhibits that will be used to summarize or support them;
>
> (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years;
>
> (v) a list of all other cases in which, during the previous 4 years, the witness testified as an expert at trial or by deposition; and
>
> (vi) a statement of the compensation to be paid for the study and testimony in the case.

Fed. R. Civ. P. 26(a)(2)(B).

A district court may only allow evidence violating Rule 26(a) if the violation was justified or harmless. *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 953 (10th Cir. 2002). In determining whether a violation was justified or harmless, courts should consider the following factors: "(1) the prejudice or surprise to the party against whom the testimony is offered; (2) the ability of the party to cure the prejudice; (3) the extent to which introducing such testimony would disrupt the trial; and (4) the moving party's bad faith or willfulness." *Woodworker's Supply, Inc. v. Principal Mut. Life Ins. Co.*, 170 F.3d 985, 993 (10th Cir. 1999).

Moving beyond procedural requirements, Rule 702 of the Federal Rules of Evidence provides important substantive requirements for the admissibility of expert testimony. Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> *2 (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589, 597 (1993), the Supreme Court held that district courts act in a "gatekeeping role" to ensure that scientific expert testimony is relevant and reliable. An expert's opinion must be based on "more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. The applicability of *Daubert* was later expanded to apply to the opinions of all experts, not just scientific experts. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) ("We conclude that *Daubert's* general holding—setting forth the trial judge's general 'gatekeeping' obligation—applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge.").

The Supreme Court set forth several non-exclusive factors that a court may consider in making its determination whether proposed expert testimony will assist the trier of fact: (1) "whether it can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) the "known or potential rate of error" of a technique; and (4) whether the theory or technique has "general acceptance," which is an important consideration because " 'a known technique which has been able to attract only minimal support within the community' may properly be viewed with skepticism." *See Daubert*, 509 U.S. at 593-94. The inquiry into these factors is "a flexible one," and the focus is "on principles and methodologies, not on the conclusions that they generate." *Id.* at 593.

In *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227 (10th Cir. 2005), the Tenth Circuit discussed the role of district courts when considering a *Daubert* challenge. The court should make a preliminary finding whether the expert is qualified, by determining "if the expert's proffered testimony ... has 'a reliable basis in the knowledge and experience of his [or her] discipline.' " 400 F.3d at 1232-33 (quoting *Daubert*, 509 U.S. at 592). The proponent of expert testimony must establish that the expert used reliable methods to reach his conclusion and that the expert's opinion is based on a relevant factual basis. *See id.* at 1233. "[A] trial court's focus generally should not be upon the precise conclusions reached by the expert, but on the methodology employed in reaching those conclusions." *Id.* However, an impermissible analytical gap in an expert's methodology can be a sufficient basis to exclude expert testimony under *Daubert*. *See id.; see also Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005). "Neither *Daubert* nor the Federal Rules of Evidence 'require[ ] a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert.' " *Norris*, 397 F.3d at 886 (quoting *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

II. Analysis

*3 It is clear from the tables included as part of Dr. Scott's report that he utilized historical data showing Plaintiff's income from shortly after Plaintiff's injury to the present in order to estimate Plaintiff's projected income until retirement. (*See* Doc. 53-4 at 4). Because Plaintiff only made approximately $26,000 from June 1, 2017, to May 31, 2018, Dr. Scott assumes Plaintiff will only make $26,000 per year—much less than his projected annual income of approximately $85,000 as a union electrician—for the rest of his working life. (*Id.*). Because the post-injury historical data shows no earned fringe benefits, Dr. Scott assumes that Plaintiff will continue to earn no fringe benefits. (*Id.* at 5). In other words, a basic assumption of Dr. Scott's opinions is that Plaintiff is permanently impaired—that his limited earnings from the past few years since his injury can be extrapolated into the future until retirement.

One of the primary arguments in Defendant's Motion to Exclude is that Plaintiff's expert lacks a foundation to assume permanent disability. In response, Plaintiff points to five pieces of evidence that, he asserts, serve as the foundation for Dr. Scott's economic calculations of diminished wages and fringe benefits:

- A July 15, 2016, order by an administrative law judge (ALJ) of the Oklahoma Workers' Compensation

Commission authorizing medical treatment for Plaintiff (Doc. 56 at 15-18) ("Exhibit 1");

- A July 3, 2017, pleading submitted to the Workers' Compensation Commission by Plaintiff's employer, P1 Group, Inc. (*id.* at 19) ("Exhibit 2");

- Reports from June and July 2017 by Antoine Jabbour, M.D., an independent medical examiner appointed by the Workers' Compensation Commission (*id.* at 20-24) ("Exhibit 3");

- October 11, 2017, post-operation notes by Jason Joice, M.D. (*id.* at 25-31) ("Exhibit 4"); and

- A Joint Petition for Settlement of Plaintiff's workers' compensation claim filed on March 2, 2018 (*id.* at 32) ("Exhibit 5").

Plaintiff claims that "[f]rom these facts and records and summaries thereof, Dr. Scott knew that [Plaintiff] had been unable to work ... for the two years following June 15, 2015 (the date of [Plaintiff's] first shoulder surgery)." (Doc. 56 at 7-8). Plaintiff goes on to state that "[f]rom these facts and records, Dr. Scott knew that Plaintiff has only worked intermittently during the third and fourth years post-injury." (*Id.* at 8). According to Plaintiff, Dr. Scott also "knew that the workers' compensation commission had entered an order fixing the degree of Plaintiff's permanent partial disability at 30.5% to the 'whole person.' " (*Id.*). Therefore, Plaintiff asserts, "Dr. Scott had sufficient basis to make lost wage calculations based on the likelihood that Mr. Shank will never work as a union electrician again." (*Id.*).

Yet, these materials identified in Plaintiff's response brief were not cited anywhere in Dr. Scott's written report. On the first page of his report, Dr. Scott states that "[b]ecause of his injury, [Plaintiff] has been deprived of a flow of income that he could have otherwise generated." (Doc. 53-4 at 1). He then goes on to describe the mathematical calculations he used—all of which depend on the assumption that Plaintiff has a permanent impairment. If Dr. Scott relied on the aforementioned materials to inform his opinions concerning Plaintiff's economic losses, these materials needed to be identified in his written report pursuant to Rule 26(a)(2)(B).

"Before an attorney can even hope to deal on cross-examination with an unfavorable expert opinion he must have some idea of the bases of that opinion and the data relied upon." *Smith v. Ford Motor Co.*, 626 F.2d 784, 794 (10th Cir. 1980) (quoting Jack H. Friedenthal, Discovery and Use of an Adverse Party's Expert Information, 14 Stan. L. Rev. 455, 485 (1962)). The federal rules regarding expert witness designations are meant "to take the guesswork out of expert testimony for all parties involved in litigation." *Addleman v. Keller Transp., Inc.*, No. 13-CV-230-S, 2014 WL 10222534, at *3 (D. Wyo. Dec. 9, 2014). "Parties are entitled to a *timely* and *detailed* description of what the witnesses relied upon in forming *each* particular opinion so the opposing party may adequately prepare discovery for the deposition and cross-examination of the witness at trial." *Id.* (emphasis in original). In this case, Plaintiff's own response brief suggests that Dr. Scott considered a lot of material that is not cited in his report.

*4 Typically, the Court would conduct an analysis using the *Woodworker's Supply* factors to determine whether Dr. Scott's testimony should be allowed despite his incomplete report. *Jacobsen*, 287 F.3d at 953. However, in this case, the Court finds that such an analysis is unnecessary because Dr. Scott's opinions must be excluded under Fed. R. Evid. 702 and *Daubert*. Pursuant to Rule 702, an expert witness's testimony must be "based on sufficient facts or data." Fed. R. Evid. 702(b). Here, even if the Court assumes Dr. Scott considered the facts and data identified in the Plaintiff's response brief, these facts and data are insufficient to serve as a foundation for his opinions.

Exhibit 1, the order authorizing medical treatment, merely shows that a motion by Plaintiff's employer before the Workers' Compensation Commission to terminate Plaintiff's *temporary total* disability benefits was denied and the employer was mandated to provide medical treatment, including surgery, for Plaintiff's right shoulder. (Doc. 56 at 17). This order does not provide any information as to whether Plaintiff's injury is permanent and will limit his earning capacity indefinitely. Exhibit 2, the Workers' Compensation pleading, also only concerns *temporary total* disability benefits. (*Id.* at 19).

The medical reports by Dr. Jabbour, Exhibit 3, discuss whether or not Plaintiff needed to have a third surgery on his right shoulder. (*Id.* at 20-24). Ultimately, in a letter dated July 6, 2017, Dr. Jabbour expressed his opinion that Plaintiff should undergo "a third and hopefully final shoulder surgery." (*Id.* at 24). Dr. Jabbour does

not give an opinion on whether Plaintiff will suffer a permanent disability as a result of the initial injury. Exhibit 4, the post-operation notes, state that Plaintiff's work status is "light work/activity," but that his status is "improving." (Doc. 56 at 27). The "Work Status Report" restricts Plaintiff from using his right shoulder and arm, but an end date of November 11, 2017, is provided for those restrictions. (*Id.* at 26).

The only exhibit to mention permanent disability is Exhibit 5, the Joint Petition for Settlement. This document, filed with the Workers' Compensation Commission, states that Plaintiff's employer and/or the employer's insurance carrier will pay $34,513.50 "for permanent partial disability (aprx 30.5%)." (*Id.* at 32). However, this document merely represents the settlement terms agreed to by Plaintiff, his employer, and the employer's insurance carrier. *See Okla. Stat.* tit. 85A, § 115(A) ("If the employee and employer shall reach an agreement for the full, final and complete settlement of any issue of a claim pursuant to this act, a form designated as 'Joint Petition' shall be signed by both the employer and employee, or representatives thereof, and shall be approved by the Workers' Compensation Commission or an administrative law judge, and filed with the Commission."). The Court finds that this settlement agreement alone is not sufficient to support Dr. Scott's crucial assumption that Plaintiff's recent earnings represent the limit of his earning capacity for the rest of his career. [1] Without a proper basis for that assumption, Dr. Scott's opinions are too speculative to pass muster under *Daubert. See McClain v. Metabolife Int'l,* 401 F.3d 1233, 1237 (11th Cir. 2005) ("*Daubert* requires the trial court to act as a gatekeeper to insure that speculative and unreliable opinions do not reach the jury.").

*5 For the foregoing reasons, Defendant Whiting-Turner's Motion to Exclude is **granted**. Dr. Scott will be excluded from testifying at trial.

SO ORDERED this 19th day of December, 2018.

All Citations

Slip Copy, 2018 WL 6681223

Footnotes

1 Plaintiff also points to Whiting-Turner's experts' findings as supporting the conclusion of permanent impairment. (Doc. 56 at 8-9). However, Plaintiff does not suggest that Dr. Scott was provided these materials in advance of preparing his own report. As such, the Court is unable to treat these findings as bases of Dr. Scott's opinions.

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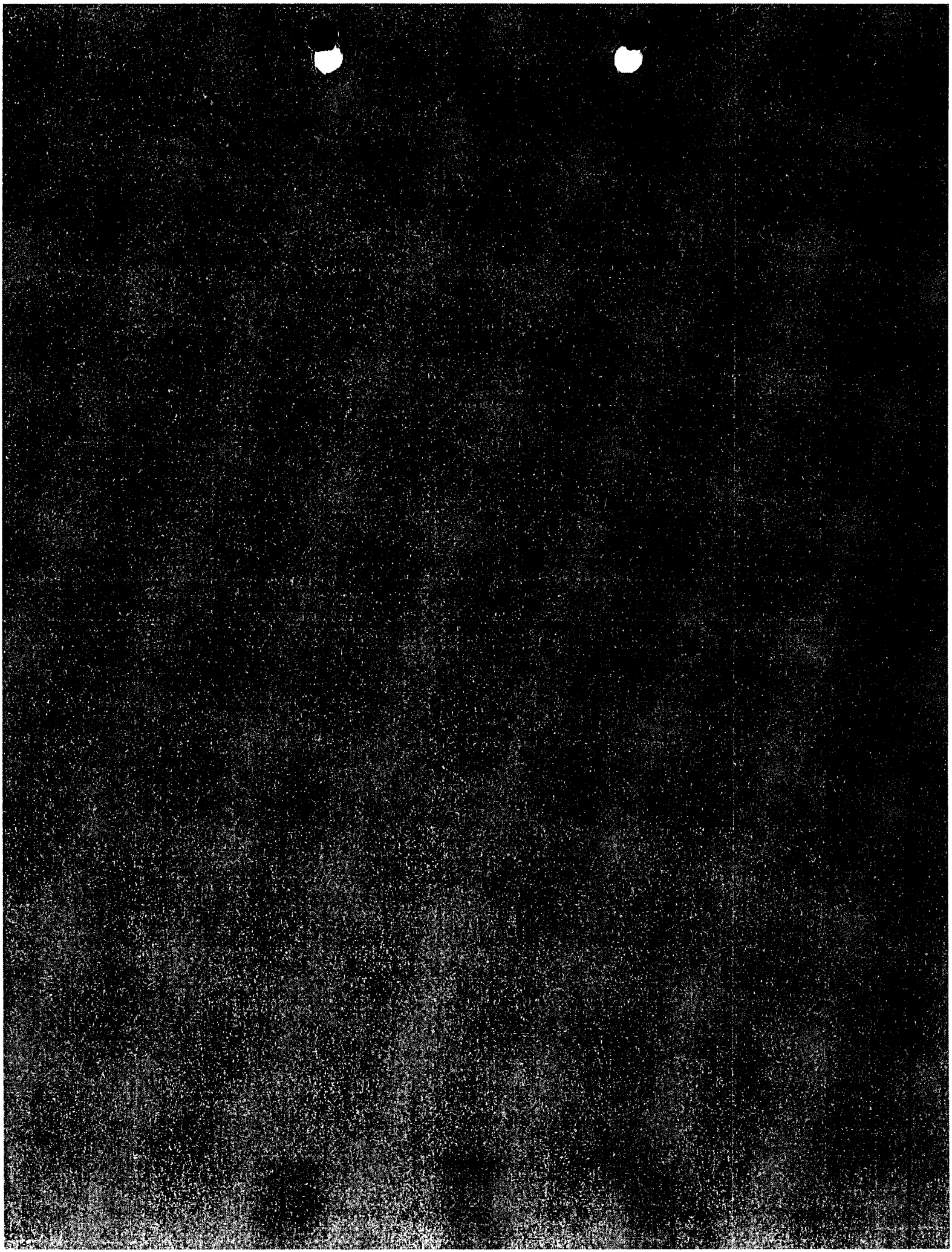

EXHIBIT D

2005 WL 782809
Only the Westlaw citation is currently available.
United States District Court, D. Delaware.

ADVANCED MEDICAL OPTICS, INC., a Delaware corporation, Plaintiff,
v.
ALCON INC., a Swiss corporation, and Alcon Laboratories, Incorporated, a Delaware corporation. Defendants.

No. Civ.A. 03–1095–KAJ.
|
April 7, 2005.

Attorneys and Law Firms

Richard L. Horowitz, and David E. Moore, Potter Anderson & Corroon LLP, Wilmington, Delaware, for plaintiff.

A. James Isbester, and Gillian W. Thackray, Isbester & Associates, Berkeley, California, of counsel.

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Robert G. Krupka, and Erica S. Olson, Kirkland & Ellis, LLP, Los Angeles, California, of counsel.

MEMORANDUM OPINION

JORDAN, J.

I. INTRODUCTION

*1 This is a patent infringement case. Presently before me are two *Daubert* motions [1] filed by defendants Alcon Laboratories, Inc. and Alcon Manufacturing, Ltd. (collectively, "Alcon") seeking to exclude the testimony of two experts, Dr. Randall Olson (*see* Docket Item ["D.I."] 156) and Mr. Harold Walbrink (*see* D.I. 160), offered by Advanced Medical Optics, Inc. ("AMO") pursuant to Federal Rule of Evidence 702. Jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338. For the reasons that follow, Alcon's motions will be granted in part and denied in part.

II. BACKGROUND

The background related to the patents in suit is set forth in the Opinion construing the disputed claim terms. (D.I. 238 at 1–5.)

III. STANDARD OF REVIEW

Motions to exclude evidence are committed to the court's discretion. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir.1994) (on a motion to exclude proffered expert testimony, the trial court's inquiry is a flexible one, and its decision to admit or exclude expert testimony is reviewed under an "abuse of discretion" standard) (internal citations omitted). [2] "[W]hen the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment," the Court of Appeals will give those rulings "a 'hard look' to determine if a district court has abused its discretion in excluding evidence as unreliable." *Id.* at 750.

IV. DISCUSSION

Federal Rule of Evidence 702 obligates judges to ensure that any scientific testimony or evidence admitted is relevant and reliable. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). Rule 702 provides that "if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise...." The party offering the expert testimony has the burden of proving admissibility. *See Daubert,* 509 U.S. at 592 n. 10 (citation omitted). The subject of an expert's testimony must be grounded in the methods and procedures of science and based on more than a subjective belief or speculation. *Id.* at 589–90. Further, Rule 702 requires that expert testimony assist the trier of fact, in other words, it must "fit" the issues in the case by having a "valid scientific connection to the pertinent inquiry." *Id.* at 591–92.

In determining "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact," the court must assess whether the methodology underlying the testimony is scientifically valid and whether it can properly be applied to the facts at issue. *Id.* at 592–93. As part of that inquiry, the court "must examine the expert's conclusions in order to determine whether they could reliably follow from the facts known to the expert and the methodology used." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 153 (3d Cir.1999).

*2 Expert testimony can only be received from someone who has specialized knowledge or training sufficient to qualify him to opine on an issue within his field of expertise, and the expert's opinion must be confined to that field. *See Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1179 (4th Cir.1997) (metallurgist not qualified to testify about industry standards for safes); *Barrett v. Atl. Richfield Co.*, 95 F.3d 375, 382 (5th Cir.1996) (expert not qualified to testify about correlation of chemical effects on rats and on humans). Moreover, testimony of an expert that constitutes mere personal belief as to the weight of the evidence invades the province of the fact-finder. *See McGowan v. Cooper Indus., Inc.*, 863 F.2d 1266, 1273 (6th Cir.1987) (expert permitted to testify as to the customary duty of factory representatives in the air compressor industry, but should not have been permitted to opine on breach of such duty because the jury was equally qualified to make that determination); *S.E.C. v. Lipson*, 46 F.Supp.2d 758, 763 (N.D.Ill.1998) ("Expert testimony may not be used merely to repeat or summarize what the jury independently has the ability to understand.").

A. Dr. Olson

Pursuant to Federal Rule of Evidence 702, Alcon seeks to preclude Dr. Olson from testifying in regard to four categories of issues (D.I.156), each of which will be discussed in turn.

1. General sales and market analysis

Alcon seeks to preclude Dr. Olson from testifying in regards to a general sales and market analysis of phacoemulsification devices. (D .I. 157 at 7–11.) Specifically, Alcon notes four opinions rendered by Dr. Olson on this topic:

(1) "In regards to companies selling phacoemulsification equipment, I believe there is a competitive disadvantage for any company that does not have Occlusion Mode on its equipment. (D.I. 158, Ex. 1 at A019, Dr. Olson's Revised Expert Disclosure at 18.)

(2) "I think that [if] that information [on Occlusion Mode were] out there and appropriately marketed [it] would produce a huge competitive advantage for whoever had occlusion mode." (D.I. 158, Ex. 3 at A172, Dep. of Dr. Olson at 58:14–17, Oct. 11, 2004.)

(3) "Fluidics drives sales, because removing the air reduces the post-occlusion surge and therefore allows high aspiration levels to be used safely." (D.I. 158, Ex. 1 at A022, Dr. Olson's Revised Expert Disclosure at 21.)

(4) General comments on Alcon's financial size and market strength. For example, "[t]hey're the 800 pound gorilla," (D.I. 158, Ex. 3 at A134, Dep. of Dr. Olson at 8:25, Oct. 11, 2004), "they're the biggest. They're the strongest." (*Id.* at A138, 12:12.)

(D.I. 157 at 8.) Alcon asserts that "[t]hese opinions venture outside Dr. Olson's general area of cataract surgery because they require specific knowledge about how the phacoemulsification market has responded to Occlusion Mode and the '765 patent, and should be excluded for that reason." (*Id.*) In support of its position, Alcon argues that Dr. Olson admitted during his deposition that he lacks specialized training in analyzing sales or market trends for phacoemulsification machines:

*3 Q. You don't claim to have any special knowledge or training in the analysis of sales and market trends for phacoemulsification machines, right?

A. *I'm not in sales and marketing,* but I do see sales and marketing figures, ... I think I have an interest, *but I don't claim any special expertise.*

(D.I. 158, Ex. 3 at A206–07, Dep. of Dr. Olson at 173:21–174:4, Oct. 11, 2004 (emphasis added).)

In response, AMO argues that Dr. Olson, as an "expert consumer" of phacoemulsification products, should be permitted to address the jury in regards to the competitive advantage that a phacoemulsification machine having the invention of each of the two patents in suit would have in the market. (D.I. 185 at 6.) For support, AMO asserts that Dr. Olson is a sophisticated consumer of phacoemulsification machines because he is familiar with various phacoemulsification machines, has been performing cataract surgery for thirty years, and because he approves all purchases by his department at the Moran Eye Center. (*Id.*) Additionally, AMO asserts that Dr. Olson provided four reasons why he believes Occlusion Mode offers a competitive advantage:

> 1) Alcon would not have added it to its systems if Alcon did not believe it was important to do so, 2) his conversations and interactions with leading surgeons such as Bruce Wallace and Howard Fine led him to conclude that some surgeons would not purchase equipment that did not have occlusion mode, ... 3) [his] review of the trade literature regarding occlusion mode suggests that occlusion mode is an important feature to a number of leading surgeons, and 4) [his] own study of the problem of thermal injury leads him to conclude that the use of occlusion mode can reduce thermal injury eight fold.

(*Id.* at 8–9.)

Because Dr. Olson lacks expertise in the analysis of sales and market trends for phacoemulsification machines, he will be precluded from testifying on this topic. He has admitted that he has no expertise in this particular area. Being an "expert consumer," as AMO puts it, does not remedy this deficiency. Further, the "main basis" for Dr. Olson's opinions are "[t]he fact that Alcon decided to put occlusion mode on its latest equipment." (D.I. 158, Ex. 3 at A169, Dep. of Dr. Olson at 55:12, 1–2, Oct. 11, 2004.) That reason, as AMO admits, is "more a matter of plain common sense than special expertise." (*See* D.I. 185 at 9.)

Additionally, Dr. Olson's opinion regarding the general preferences of other surgeons is speculative and not supported by reliable data. The basis for his opinion on this point is that two of his collegues have preferences for devices with Occlusion Mode, and even as to them, he testified that he could only be certain one of them would actually insist on buying a machine with Occlusion Mode. Dr. Olson testified during his deposition as follows:

Q. Is there any other basis for your statement?

A. I do feel there are people out there who use occlusion mode and feel its important, and I think that they—I mean, the Alcon people know. You could ask them, but I'm sure they have surveys. And I'm sure there are people who would not buy the equipment without it, so I think that that's got to be it as well. But my main basis is the fact that Alcon put it in their equipment.

*4 Q. You say that you're sure that there were people who would not buy the equipment without it having occlusion mode. *Why are you sure that there are people who would not buy a phacoemulsification system if it didn't have occlusion mode?*

A. Because there are people talking about occlusion mode and how you should have it. There are many names listed there, Bruce Wallace most recently in the meeting I was just at, *so I know one, Bruce Wallace.* I mean, from what he said, I don't think Bruce Wallace would buy anything without an occlusion mode. He talked about the fact that occlusion-mode phaco was important. *So there have to be others. If there were none, why would Alcon add it to their equipment in face of a patent? It makes no sense.*

Q. Other than Bruce Wallace, can you identify anyone else who you believe would not purchase a phacoemulsification system if it didn't have occlusion mode?

A. *Not without talking to them.* There's others, who talk about it here, but I—the only one I'm aware who's talked to very recently is Bruce Wallace. Whether Howard Fine still thinks it's important or not, he certainly in there will say he feels it's very important.

Q. And when you're saying in there, you're referring to the articles that Ms. Thackray sent to you, right?

A. Yes, that you now have, yes.

(D.I. 158, Ex. 3 at A169–70, Dep. of Dr. Olson at 55:6–56:13, Oct. 11, 2004 (emphasis added).)

In that testimony, Dr. Olson admits that he has not talked to any other surgeons, besides Bruce Wallace, about whether they would only buy machines with Occlusion Mode. The articles to which he refers do not support his opinion in this regard either, because as he admits, he cannot tell without talking to those surgeons whether they would only buy machines with the occlusion mode feature. His comments also reveal that he does not know whether other surgeons agree with Bruce Wallace's view, nor has

he conducted a survey to find out. Thus, his testimony on the viewpoints of other surgeons is purely speculative.

Lastly, Dr. Olson testified that his opinion on the sales and marketing aspects of Occlusion Mode were based on extrapolations from a survey he conducted on wound burns. That survey, however, which was unpublished and not peer reviewed, did not ask its respondents whether Occlusion Mode was enabled during the surgery, and did not even mention the Occlusion Mode feature. (D.I. 158, Ex. 6 at A341–56, Wound Burn Survey Questionnaire; *see* D.I. 158, Ex. 3 at A190–91, Dep. of Dr. Olson at 97:25–98:6, Oct. 11, 2004 ("Q. Now, the survey didn't ask whether the occlusion mode feature was active, correct? A. [It d]id not. Q. So it could be that occlusion mode was enabled during some of the wound burns that the ... study found? A. It's possible.").) Thus, it is not a reliable basis from which an opinion on the general market and physician preferences could be based.

Therefore, because Dr. Olson does not have sufficient expertise in the sales and marketing of phacoemulsification devices, and his opinion on such matters is not supported by reliable bases, he will be precluded from testifying to any sales and market analysis of phacoemulsification devices, including testimony addressing the economic advantages of phacoemulsification devices incorporating Occlusion Mode and the '765 patent as they pertain to the market. Dr. Olson will be permitted, however, to testify about his own preferences for certain features in phacoemulsification machines and what he considers advantageous from his perspective, based on his many years of experience using such machines in the performance of cataract surgery, to the extent such opinions were disclosed in his expert report.

2. Infringement by Alcon of the '240 or '765 patent

*5 Alcon seeks to preclude Dr. Olson from offering testimony relating to whether Alcon infringes either the '240 patent or the '765 patent. (D.I. 157 at 11–12.) According to Alcon, "Dr. Olson implied at numerous times throughout his deposition that Alcon's phacoemulsification systems infringed the '240 and '765 patents, and that Alcon's alleged infringement was knowing and deliberate." (*Id.* at 11.) Alcon argues that Dr. Olson "lacks the expertise that would enable him to perform a claim construction analysis of the patents to determine whether they are infringed by the Infiniti system ... [because he] admitted that he lacks specialized training in engineering and patents." (*Id.* (citing D.I. 158, Ex. 3 at A141, Dep. of Dr. Olson at 18:11–13, Oct. 11, 2004.))

AMO asserts that "Dr. Olson has not done an element-by-element analysis of the patents against the accused products and AMO has no intention of asking him to do so...." (D.I. 185 at 9.) Rather, AMO argues that Dr. Olson's view that Alcon's device is so similar to AMO's device that it appears to have been copied is both competent and pertinent. (*Id.* at 10.)

Dr. Olson will not be permitted to testify in regards to infringement of either patent. Federal Rule of Civil Procedure 26(a)(2)(B) states, in relevant part, that "[t]he [expert] report shall contain a complete statement of all opinions to be expressed...." Dr. Olson did not disclose an opinion on infringement of either patent in his expert report, and as such he may not offer one at trial. *See* Fed.R.Civ.P. 26(a)(2)(B). Additionally, in its Answering Brief in Opposition to Alcon's Motion, AMO lists six things upon which Dr. Olson has been asked to opine, not one of which concerns infringement or copying.[3] (*See* D.I. 185 at 3.) Thus, it is clear that Dr. Olson may not properly offer an opinion on infringement, and it is equally clear that AMO did not intend for him to do so. Therefore, Dr. Olson will not be permitted to offer testimony relating to whether Alcon infringes either patent in suit.

3. Occlusion Mode and Safety of Phacoemulsification

Alcon seeks to preclude Dr. Olson from offering testimony "relating to his opinion that Occlusion Mode made phacoemulsification safer, and consequently a mainstream procedure in cataract surgery because it enabled surgeons to rely on the Occlusion Mode feature to prevent the occurrence of thermal injury to the eye." (D.I. 156 at 1.) More specifically, Alcon objects to five opinions on this topic offered in Dr. Olson's report: (i) that the invention of Occlusion Mode "solves this problem [of thermal injury] by automatically shifting the parameters so that the surgeon can no longer use the ultrasound to a dangerous level" (D.I. 158, Ex. 1 at A018, Dr. Olson's Revised Expert Disclosure at 17); (ii) that "Occlusion Mode is one of the safety features that many feel should be standard with modern phacoemulsification equipment" (*id* . at A019); (iii) that "[t]he overall

effect of the Occlusion Mode invention described in the ['240] patent was to make phacoemulsification safer and therefore more mainstream (*id.* at A018); and, in the same vein, (iv) that "Occlusion Mode is one of the breakthroughs that have made phacoemulsification widely available and used by most cataract surgeons in the United States today" (*id.* at A019); and again (v) that "[Occlusion Mode] put the phacoemulsification technology in the hands of surgeons who previously were afraid of using phacoemulsification, and so has made cataract surgery available for more patients" (*id.*).

*6 Alcon asserts that these opinions rendered by Dr. Olson are "inadmissible because they lack adequate foundation, and therefore fail to 'assist the trier of fact.' " (D.I. 157 at 13.) Specifically, Alcon asserts that they are based in large part on "(1) biased information supplied almost exclusively by AMO attorneys, (2) materials that Dr. Olson himself labels as 'scanty,' (3) a partial analysis of an unpublished survey, and (4) unsupported assumptions that are speculative at best." (*Id.*)

AMO argues in response that Dr. Olson reviewed whatever publications were available, not merely those provided by AMO, concerning the use of Occlusion Mode in phacoemulsification, and that "Dr. Olson did not rely on peer-reviewed articles on occlusion mode because none existed." (D.I. 185 at 10, 12.) AMO asserts that reliance on peer-reviewed journals is not a prerequisite to admissibility and that the articles on which Dr. Olson relied were "written by respected and well-known practitioners in the field." (*Id.*) Further, AMO argues that "Dr. Olson is well qualified to survey fellow practitioners on the incidence of wound burn, and to opine on the value of occlusion mode in reducing it." (*Id.*)

"The trial judge in all cases of proffered expert testimony must find that it is properly grounded, well-reasoned, and not speculative before it can be admitted." Fed.R.Evid. 702 advisory committee's note. The main issue raised by Alcon is the reliability of the opinions offered by Dr. Olson. Alcon does not challenge Dr. Olson's expertise to offer such opinions, but rather challenges the bases upon which he relies to render them. (*See* D.I. 207 at 5.) Each challenged opinion is discussed below.

a. That the invention of Occlusion Mode "solves this problem [of thermal injury] by automatically shifting the parameters so that the surgeon can no longer use the ultrasound to a dangerous level"

Alcon challenges Dr. Olson's opinion that the invention of Occlusion Mode "solves this problem [of thermal injury] by automatically shifting the parameters so that the surgeon can no longer use the ultrasound to a dangerous level." (D.I. 158, Ex. 1 at A018, Dr. Olson's Revised Expert Disclosure at 17.) Dr. Olson testified at his deposition that "occlusion mode *could* dramatically decrease wound burn...." (D.I. 158, Ex. 3 at A183, Dep. of Dr. Olson at 77:5–6, Oct. 11, 2004 (emphasis added).) In his report, Dr. Olson was more emphatic, stating that Occlusion Mode actually did have that effect. (D.I. 158, Ex. 1 at A018, Dr. Olson's Revised Expert Disclosure at 17.) Dr. Olson indicated that his opinion in this regard is largely based upon his survey. (*See* D.I. 158, Ex. 3 at A182–83, Dep. of Dr. Olson at 76:21–77:6, Oct. 11, 2004.) As discussed earlier, however, *see supra* Part IV.A.1., Dr. Olson's survey did not inquire whether Occlusion Mode was enabled during the procedures being reported, nor did it mention Occlusion Mode at all. (D.I. 158, Ex. 6 at A341–56, Wound Burn Survey Questionnaire; *see* D.I. 158, Ex. 3 at A190–91, Dep. of Dr. Olson at 97:25–98:6, Oct. 11, 2004.) Thus, it is not a reliable basis of support for the type of definitive conclusion rendered in Dr. Olson's report. Dr. Olson will be permitted to testify as to whether he thinks Occlusion Mode "could" decrease wound burn, based on his years of experience[4] and the various articles he has reviewed, but he cannot testify that Occlusion Mode in fact decreases instances of wound burn because his survey does not provide a reliable basis for such a conclusion, and because, as he admits, "there's basically no studies on this subject or anything." (D.I. 158, Ex. 3 at A145, Dep. of Dr. Olson at 26:24–25, Oct. 11, 2004.)

b. "Occlusion Mode is one of the safety features that many feel should be standard with modern phacoemulsification equipment."

*7 Alcon challenges Dr. Olson's opinion that "Occlusion Mode is one of the safety features that many feel should be standard with modern phacoemulsification equipment." (D.I. 158, Ex. 1 at A019, Dr. Olson's Revised Expert Disclosure at 18.) Alcon asserts that Dr. Olson lacks a reliable basis to conclude what "many" feel about modern phacoemulsification equipment. (D.I. 157 at 18.) At his deposition, however, Dr. Olson testified that he based his opinion on the articles he reviewed in which various experts have stated preferences for

Occlusion Mode. Although Dr. Olson has testified that he considers these articles to be "throw-away" articles, in that "you usually look at them, and [then] you throw them away" (D .I. 158, Ex. 3 at A146, Dep. of Dr. Olson at 27:11–12, Oct. 11, 2004), they do provide an adequate basis for this specific opinion. Alcon's citation to *Tuman v. Genesis Associates,* 935 F.Supp. 1375, 1385 (E.D.Pa.1996), is unavailing because, as that court held, the expert's opinion was not "fundamentally unsupported." Neither is Dr. Olson's in this instance, and, as such, Alcon's objections go to the weight of Dr. Olson's opinion, not its admissibility.

c. "The overall effect of the Occlusion Mode invention described in the ['240] patent was to make phacoemulsification safer and therefore more mainstream."

Alcon's next challenge is to Dr. Olson's opinions that "[t]he overall effect of the Occlusion Mode invention described in the ['240] patent was to make phacoemulsification safer and therefore more mainstream." (D.I. 158, Ex. 1 at A019, Dr. Olson's Revised Expert Disclosure at 18.) Alcon's main objection is that this particular conclusion is misleading "because he overstates his propositions." (D.I. 157 at 18.)

I agree with Alcon that, in light of his deposition testimony, Dr. Olson has perhaps overstated this conclusion in his report. When asked about his basis for concluding that Occlusion Mode is one of the breakthroughs that have made phacoemulsification widely available and used by most cataract surgeons in the United States today, Dr. Olson replied, "I think its one of the steps that has made the procedure safer. *There's others,* but in totality, *all of those different steps are the reason why it's the predominant procedure today.*" (D.I. 158, Ex. 3 at A167, Dep. of Dr. Olson at 53:10–13, Oct. 11, 2004 (emphasis added).) Dr. Olson clarifies that it is the totality of "all of those different steps" that has led to phacoemulsification being the predominant procedure today, not just Occlusion Mode.

In light of that qualification, I do not believe that his testimony will mislead the jury. He will be subject to cross-examination by Alcon, whose efforts will no doubt highlight the limitations Dr. Olson admitted on this point in his deposition. Alcon has not demonstrated that this opinion is inadmissible under Federal Rule of Evidence 702 and, therefore, he will not be precluded from giving it at trial.

d. "Occlusion Mode is one of the breakthroughs that have made phacoemulsification widely available and used by most cataract surgeons in the United States today."

*8 Alcon makes the same challenge to Dr. Olson's opinion that "Occlusion Mode is one of the breakthroughs that have made phacoemulsification widely available and used by most cataract surgeons in the United States today." (D.I. 158, Ex. 1 at A019, Dr. Olson's Revised Expert Disclosure at 18.) Again, I agree with Alcon that Dr. Olson has perhaps overstated this conclusion in his report. When asked about his basis for concluding that Occlusion Mode made phacoemulsification safer and put the technology in the hands of surgeons who were previously afraid of using phacoemulsification, Dr. Olson replied that "... it is *one of many* features that have made phaco safer...." (D.I. 158, Ex. 3 at A165, Dep. of Dr. Olson at 51:11–12, Oct. 11, 2004 (emphasis added).) Dr. Olson's testimony indicates that there are other features which contributed to the safety of phacoemulsification as well. However, for the same reasons discussed, *supra* Part IV.A.3.c., Alcon has not demonstrated that this opinion is inadmissible under Federal Rule of Evidence 702 and, therefore, he will not be precluded from giving it at trial.

e. "[Occlusion Mode] put the phacoemulsification technology in the hands of surgeons who previously were afraid of using phacoemulsification, and so has made cataract surgery available for more patients."

Dr. Olson also opined that Occlusion Mode "put the phacoemulsification technology in the hands of surgeons who previously were afraid of using phacoemulsification, and so has made cataract surgery available for more patients." (D.I. 158, Ex. 1 at A019, Dr. Olson's Revised Expert Disclosure at 18.) When asked whether he was aware of any surgeons who were previously afraid of using phacoemulsification before they could use occlusion mode, Dr. Olson relied: "I don't have any survey. There's no study or published [sic], so this was just my opinion. I don't have anything other specifically than my opinion for that statement ... if there was scientific literature, if we had studies, if we had—we don't. I mean, all we have is a few opinions, so therefore, when you have nothing else to depend upon, then you can only use your opinion." (D.I. 158, Ex. 3 at A166–67, Dep. of Dr. Olson at 52:12–53:3,

Oct. 11, 2004.) Furthermore, Dr. Olson testified that he believes Occlusion Mode is not used by most surgeons (*id.* at A167, 53:20), but that, in fact, he doesn't "know how many use it and how many do not" (*id.* at A168, 54:17–18). Thus, Dr. Olson admits that he has no reliable basis for this opinion, and, he will be precluded from testifying to it at trial.

4. Maximizing Air Removal

Alcon seeks to preclude Dr. Olson from offering testimony "related to his opinion that [the '765 patent] disclosed a method and apparatus that maximized air removal from the fluidics system of phacoemulsification devices and enabled phacoemulsification devices incorporating its claims to reach, for the first time, aspiration levels of 500 mmHg or higher while maintaining chamber stability." (D.I. 156 at 2.) Alcon asserts that Dr. Olson's opinions on the '765 patent are based on unsupported suppositions as opposed to facts (D.I. 157 at 19), and that he lacks the necessary experience to offer expert testimony on fluidics devices (D.I. 207 at 10–11).

*9 In response, AMO asserts that Dr. Olson's opinions are based on his knowledge and experience of using phacoemulsification devices in the field of opthalmological surgery. (D.I. 185 at 12–13.) Thus, AMO argues that Dr. Olson's testimony meets the threshold of admissibility. (*Id.* at 13.)

In *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 324 (3d Cir.2003), the Third Circuit noted that although a proffered expert has "extensive experience with jet skis," his testimony on the safety of an accelerating mechanism was properly excluded because the expert "had no education or experience in product design of jet skis or accelerating mechanisms; nor did he provide scientific, statistical or other evidence evaluating the relative safety of different jet ski models or the accelerating mechanisms." Similarly, Dr. Olson's qualifications as a renowned ophthalmologist are not questioned, but he is not qualified to render an opinion on fluidics systems or chamber stability. He is not an engineer and has not conducted any studies to analyze whether different systems can achieve an aspiration level of 500 mmHg while maintaining excellent chamber stability. (D.I. 158, Ex. 3 at A203, Dep. of Dr. Olson at 136:15, Oct. 11, 2004.) Thus, like the expert in *Calhoun*, Dr. Olson would be outside his area of expertise if permitted to testify in this regard. Accordingly, he will be precluded from so testifying. "While [his] ... background, education, and training may provide [him] with general knowledge to testify about general matters, more specific knowledge is required to support more specific opinions." *Calhoun*, 350 F.3d at 322.

B. Mr. Walbrink

Alcon seeks to exclude three discrete areas of testimony by Mr. Walbrink. (D.I.160.)

1. Infringement Opinions

Alcon asserts that Mr. Walbrink should be precluded from offering testimony on infringement of the '240 and '765 patents by Alcon's phacoemulsification systems, the Legacy with Advantec and the Infiniti. (D.I. 160 at 1.) Alcon argues that Mr. Walbrink's testimony contravenes Rule 702 because his opinions on infringement "are pulled directly from litigation positions crafted by AMO's attorneys, as opposed to conclusions drawn from his own independent assessment of the claims at issue." (D.I. 161 at 6.)

In response, AMO asserts that Federal Rule of Civil Procedure 26(a)(2)(B) "does not preclude counsel from providing assistance to experts in preparing [the expert's] report." (D.I. 186 at 4 (quoting Fed.R.Civ.P. 26(a)(2)(B) advisory committee's note).) Furthermore, AMO argues that Mr. Walbrink did not merely adopt the opinions of AMO's counsel, but rather "engaged in extensive telephone conversations with AMO counsel regarding claim interpretation" (*id.* at 13) and "participated in the compilation, drafting, editing, and organization of his report" (*id.* at 15).

Alcon's position is untenable. It admits that Rule 26 does not preclude counsel from assisting an expert in preparing a report, but it argues that Mr. Walbrink's report merely represents the substantive conclusions of counsel. (D.I. 161 at 5–6.) Alcon's citations to cases in which expert reports were excluded are distinguishable from the facts of this case because Mr. Walbrink did contribute his expertise to the drafting of the report. *See Crowley v. Chait*, 322 F.Supp.2d 530, 543 (D.N.J.2004) (noting that counsel may not draft the entire report without prior "substantive input" from the expert); *Stein v. Foamex Int'l, Inc .*, No. CIV A. 00–2356, 2001 WL 936566, at *5 (E.D.Pa. Aug. 15, 2001) (the rules do not permit "blanket adoption of reports prepared by counsel")

(internal citation omitted). Mr. Walbrink testified at his deposition as follows:

*10 Q. Would you describe for me the process that you went through to develop the report that we've marked as Exhibit 179.

A. First, we discussed the issues at hand.

Q. And when you say "we," you mean you and Ms. Thackray?

A. And Jamie Isbester, as well, collectively. *I drafted some of it, worked on claim construction with one of their other associates*—I believe his name is Bob —then met with Gillian, Ms. Thackray, and Jamie Isbester at their facility in Berkeley, and worked for a day, I think, further drafting and pulling it together. And then over the course of several days after that, there were multiple drafts and revisions, and then we submitted it.

Q. Now, you said you drafted some of it. What parts did you draft?

A. That would be hard because, I mean, *I was involved in most of it.* The claim construction was primarily done by—I believe it was Bob. But as far as the content of the body of the report, it was a collaborative effort. It would be hard to single out what I did versus someone else.

(D.I. 162, Ex. 3 at A131–32, Dep. of Mr. Walbrink at 22:8–23:5, Oct. 19, 2004 (emphasis added).) The foregoing testimony supports AMO's contention that Mr. Walbrink collaborated with AMO's counsel and was involved in the creation of his expert report. Thus, Mr. Walbrink's testimony on intringement cannot be excluded as simply reflecting the opinions or work product of AMO's counsel.

2. Commercial success of AMO's systems

Alcon asserts that Mr. Walbrink should be precluded from offering testimony on the commercial success of AMO's two phacoemulsification systems, the Diplomax and the Sovereign, because his opinion is based solely on what AMO's counsel has told him and is therefore unreliable. (D.I. 161 at 9.) Further, Alcon argues that Rule 26(a)(2)(B) requires that an expert's report "contain a complete statement of all opinions to be expressed *and the basis and reasons thereof.*" (D.I. 208 at 9 (quoting Fed.R.Civ.P. 26(a)(2)(B)) (emphasis added).) Thus, Alcon asserts that the four new bases for his opinion identified in the declaration he submitted after his deposition and after the close of discovery should not be considered because those reasons were not presented in his Rebuttal Report. (*Id.* at 9.)

In response, AMO asserts that "counsel for Alcon failed to develop further testimony regarding the content of Mr. Walbrink's discussions with AMO's counsel and failed to acknowledge the further bases set forth in Mr. Walbrink's Rebuttal Report...." (D.I. 186 at 17.) AMO points to Mr. Walbrink's statement in his Rebuttal Report that "it would appear to me, as discussed in my opening report on infringement, that the Advantec upgrade to Alcon's Legacy model and the Infinity model of phacoemulsification machines have adopted the exact same technology" (D.I. 162, Ex. 2 at A99–100, Rebuttal Report of Mr. Walbrink at 14–15) as a basis for his opinion on commercial success. (D.I. 186 at 17–18.) Additionally, AMO notes that Mr. Walbrink's declaration further discusses the bases for his opinion. (*Id.* at 18.)

*11 Under Rule 26(a)(2)(B), an expert's report must contain "the basis and reasons" for the expert's opinions. It is clear that none of Mr. Walbrink's Reports submitted during discovery contains the challenged reasons on which he now seeks to rely for his opinion on commercial success attributable to Occlusion Mode. Thus, based on Rule 26(a)(2)(B), Mr. Walbrink's Rebuttal Report is critically deficient in this regard. At his deposition, Mr. Walbrink testified as follows:

Q. Sure. It's at the bottom of page 14. You say, "[i]t is my understanding that the occlusion mode has been an important feature of two successful phacoemulsification machines sold by AMO, the Diplomax line and the Sovereign line." Did I read that correctly?

A. Yes.

Q. What is the basis for that statement?

A. *Discussions with counsel. And I can't tell you what else may have been considered in that.*

Q. So the only basis, as you sit here today, that you can identify is that AMO's counsel told you that, right?

A. *That's all I can identify today, yes.*

D.I. 162, Ex. 3 at A163–64, Dep. of Mr. Walbrink at 197:19–198:7, Oct. 19, 2004 (emphasis added).) The foregoing shows that the only disclosed basis Mr. Walbrink had for this opinion was the "discussions [he had] with [AMO's] counsel." (*See id.*) Therefore, Mr. Walbrink's deposition cannot cure the deficiency of his Rebuttal Report.[5] If there were other bases for Mr. Walbrink's opinion, they were not disclosed as required. Simply claiming to have an understanding, without providing the bases for that understanding, fails to meet the disclosure requirements of the Federal Rules of Civil Procedure.

Mr. Walbrink's last ditch declaration (D.I.189) does not remedy this deficiency, for at least two reasons. First, it was submitted long after the close of discovery, as an exhibit to AMO's Answering Brief on this motion. (D.I.186.) I agree with Alcon that acceptance of such a late submission would be unfairly prejudicial and would make "a mockery of the Rules' requirements for discovery and expert disclosure." (*See* D.I. 208 at 9.) Second, Mr. Walbrink has admitted that he is "not versed in the financial aspects of these products," yet he purports to offer four reasons for his opinion, each of which relate to the financial aspects of AMO's products. He cannot disclaim expertise in an area and then opinion on it. Thus, for these independent reasons, Mr. Walbrink will be precluded from testifying on the issue of commerical success.

3. The '765 patent and the achievement of an aspiration level of 500 mmHg while maintaining chamber stability

Alcon asserts that Mr. Walbrink should be precluded from testifying that "[t]he Sovereign fluidics system, incorporating the invention of the '765 patent, was the first phacoemulsification system to achieve the 500 mg [sic] Hg aspiration level while maintaining excellent chamber stability" because his opinion is based solely on AMO's brochures and promotional materials and Dr. Olson's opinion. (D.I. 161 at 9–10.)

*12 In response, AMO asserts that Mr. Walbrink's opinion was based on his review of product brochures and promotional materials, the expert report of Dr. Olson, his background and experience, many hours of deliberation, and his examination of Alcon's Infiniti system. (D.I. 186 at 19.) AMO argues that these matters are the proper subject of cross-examination before the jury, not "the basis for a motion to exclude." (*Id.* at 21.) I disagree.

First, Alcon correctly notes that Mr. Walbrink's opinion is directed to AMO's Sovereign system, not Alcon's Infiniti system, and that Mr. Walbrink's examination of the Infiniti system does not provide a reliable basis for his conclusions regarding the Sovereign system. Second, Mr. Walbrink admitted in his deposition testimony that he "has not used the Sovereign." (D.I. 162, Ex. 3 at A154, Dep. of Mr. Walbrink at 142:6, Oct. 19, 2004.) Third, he testified that he only has "incidental knowledge" of the Sovereign system, which he gained by reading Dr. Olson's expert report and "brochures or promotional materials" provided exclusively by AMO. (*Id.* at A154, 142:13, 19.) But as earlier discussed, *supra* Part IV.A.4., Dr. Olson will be precluded from testifying about the invention in the '765 patent achieving an aspiration level of 500 mmHg while maintaining chamber stability. Thus all that remains as Mr. Walbrink's basis for his opinion are the brochures or promotional materials provided exclusively by AMO. As noted in *Tuman,* an expert's testimony may be unreliable if the expert "relied almost exclusively on information from one source who was clearly biased." *Tuman,* 935 F.Supp. at 1385 (internal citations omitted). This is such a case. The only remaining basis for this opinion from Mr. Walbrink is information that was provided exclusively by AMO, a party to the case. Thus, Mr. Walbrink will be precluded from testifying with regard to the achievement of an aspiration level of 500 mmHg while maintaining chamber stability.

V. CONCLUSION

Based on the foregoing reasons and authorities, Alcon's motion to exclude the testimony of Dr. Olson (D.I.156) will be granted in part and denied in part, and Alcon's motion to exclude the testimony of Mr. Walbrink (D.I.160) will be granted in part and denied in part. An appropriate order will follow.

ORDER

For the reasons set forth in the Memorandum Opinion issued in this matter today, IT IS HEREBY ORDERED that the Defendants' motion to exclude the testimony of Dr. Olson (D.I.156) is GRANTED IN PART, to the extent that Dr. Olson will not be permitted to

offer testimony on the analysis of sales and market trends for phacoemulsification machines, infringement by Defendants of the '240 or '765 patent, that Occlusion Mode in fact decreases instances of wound burn, that "[Occlusion Mode] put the phacoemulsification technology in the hands of surgeons who previously were afraid of using phacoemulsification, and so has made cataract surgery available for more patients," and that the '765 patent disclosed a method and apparatus that maximized air removal from the fluidics system of phacoemulsification devices and enabled phacoemulsification devices incorporating its claims to reach, for the first time, aspiration levels of 500 mmHg or higher while maintaining chamber stability, and DENIED IN PART, as to the remainder of Dr. Olson's opinions which have been challenged by Defendants.

***13** Further, IT IS ORDERED THAT Defendants' motion to exclude the testimony of Mr. Walbrink (D.I.160) is GRANTED IN PART, to the extent that Mr. Walbrink will not be permitted to offer testimony on the issue of commercial success and the achievement of an aspiration level of 500 mmHg while maintaining chamber stability, and DENIED IN PART, as to the remainder of Mr. Walbrink's opinions which have been challenged by Defendants.

All Citations

Not Reported in F.Supp.2d, 2005 WL 782809

Footnotes

1 The motions are based upon Federal Rule of Evidence 702 and the Supreme Court's direction in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993), and later cases that district court judges are to perform a "gatekeeping" function when considering the admissibility of expert testimony. (D.I. 156; 160.)

2 The Federal Circuit applies the law of the regional circuit in reviewing decisions on whether to admit expert testimony, and, therefore, the Third Circuit's holdings on the issue are binding precedent. *Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1390–91 (Fed.Cir.2003) ("Whether proffered evidence should be admitted in a trial is a procedural issue not unique to patent law, and therefore we ... [apply] the law of the regional circuit....").

3 AMO asserts that it asked Dr. Olson to provide expert testimony in the following six areas: "(i) a tutorial into the physiology and treatment of cataracts; (ii) the importance, from the surgeon's point of view, of each of the patents in suit; (iii) the problem of thermal injury; (iv) the difficulty in manual detection of occlusion; (v) the increased safety of the automatic response to occlusion of the system described in the '240 patent; and (vi) the inapplicability of the Shimizu reference to [the] invention of the '240 patent." (D.I. 185 at 3.)

4 Dr. Olson's experience with Occlusion Mode is apparently limited, however, because, as he admits, he does not use Occlusion Mode himself. (D.I. 158, Ex. 3 at A173–74, Dep. of Dr. Olson at 59:25–60:2, Oct. 11, 2004.)

5 This is not meant to say that if Mr. Walbrink had testified to other bases, such testimony would necessarily have been sufficient under Rule 26(a)(2)(B) to remedy his deficient expert report.

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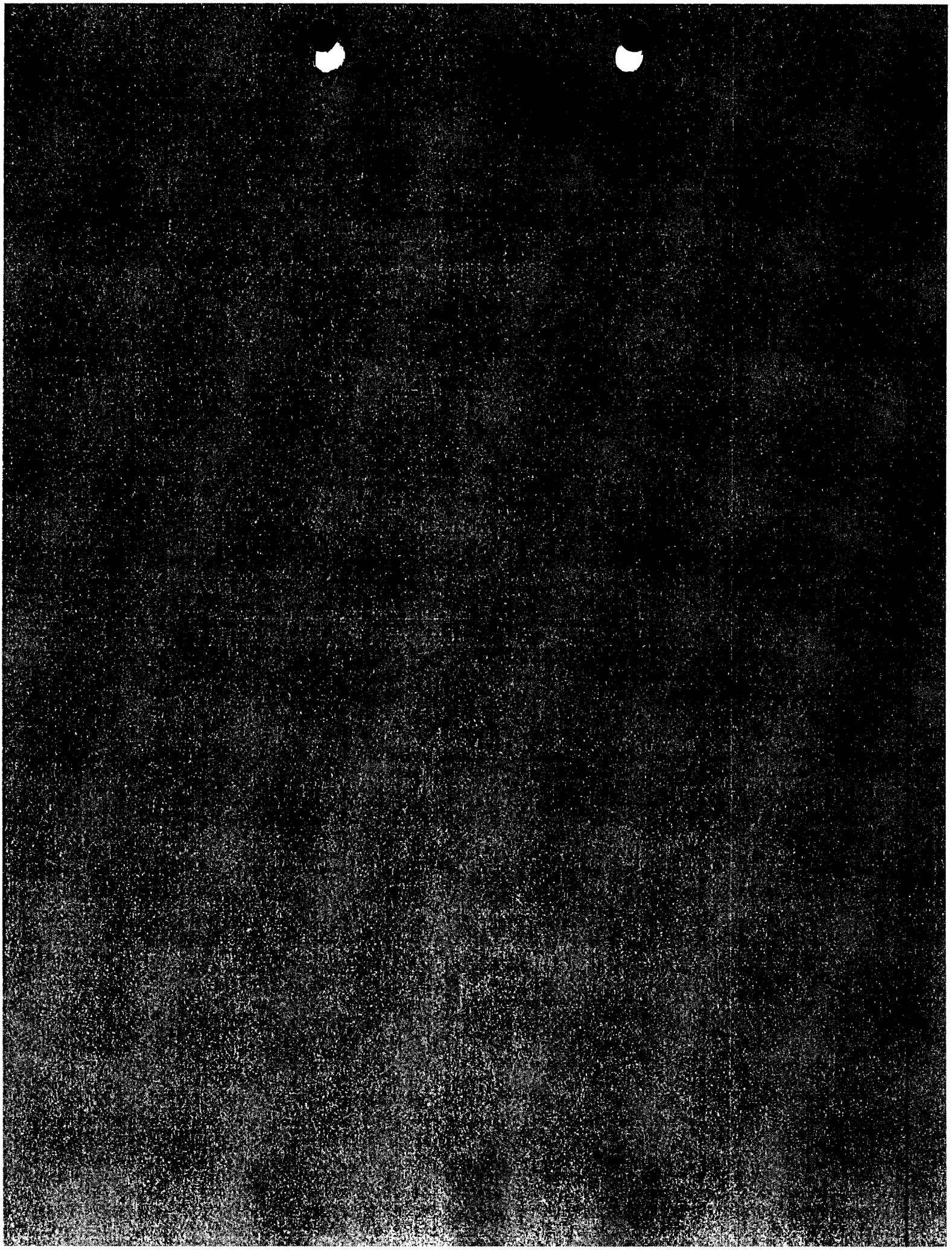

EXHIBIT E

2013 WL 7208221
Only the Westlaw citation is currently available.
United States District Court,
W.D. Oklahoma.

Jessica WELLS, individually and as
next friend of J.W., a minor, Plaintiffs,
v.
ALLERGAN, INC., Defendant.

No. CIV–12–973–C.
|
Feb. 4, 2013.

Attorneys and Law Firms

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ORDER

ROBIN J. CAUTHRON, District Judge.

*1 Now before the Court is "Defendant Allergan, Inc.'s Motion to Exclude Expert Testimony of David A. Kessler, M.D." (Dkt. No. 92). Defendant argues for the exclusion of Dr. Kessler's testimony on the grounds that it offers impermissible legal conclusions, will not assist the trier of fact, is speculative, and is unfairly prejudicial. Defendant does not challenge Dr. Kessler's qualification as an expert on FDA regulation of the pharmaceutical industry. *

Federal Rule of Evidence 702 states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion ... if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Thus, to be admissible under Rule 702, the witness must be qualified as an expert, the testimony must be reliable, and the testimony must be relevant, meaning it would assist the trier of fact. *See Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1232 (10th Cir.2004) (noting testimony must be both reliable and relevant); *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993). Defendant's challenge centers on whether Dr. Kessler's testimony would be helpful to the jury.

Defendant first asserts that Dr. Kessler will "usurp the role of the Court" by "instruct[ing] the jury on a litany of legal issues." (Def.'s Br., Dkt. No. 92, at 6.) To the extent Allergan seeks to preclude Dr. Kessler from testifying about FDA regulatory requirements and procedures or offering his opinion as to Allergan's compliance therewith, the motion is DENIED. Defendant is correct that the Tenth Circuit prohibits experts from testifying so as "to direct the jury's understanding of the legal standards upon which their verdict must be based." *Specht v. Jensen*, 853 F.2d 805, 810 (10th Cir.1988). However, in *Specht*, the court cautioned that it was drawing a narrow line and did not intend to "exclude all testimony regarding legal issues," as "a witness may refer to the law in expressing an opinion without that reference rendering the testimony inadmissible." *Id.* at 809. In this case, the Court disagrees with Allergan that Dr. Kessler's testimony about FDA regulations would "usurp" the role of the trial judge because this case is "not governed by federal regulations but by state law theories of negligence and strict liability." *In re Fosamax Prods. Liab. Litig.*, 645 F.Supp.2d 164, 191 n.16 (S.D.N.Y.2009). Dr. Kessler's testimony is admissible to assist the lay jury in " 'understand[ing] the complex regulatory framework that informs the standard of care in the pharmaceutical industry.' " *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, Case No. 3:09–MD–02100–DRH, 2011 WL 6302287, at *12 (S.D.Ill.Dec. 16, 2011) (*quoting Foxamax,*

645 F.Supp. at 191). Dr. Kessler may *not* testify as to the elements of a strict liability or negligence claim under Oklahoma law but *may* testify as to the law governing FDA regulations, Allergan's compliance with those regulations, and the relationship between FDA regulations and state tort liability. *See id.* at *11 ("The Supreme Court made clear in *Wyeth* that federal law does not prevent judges and juries in failure to warn cases from considering a drug companies [sic] compliance with FDA regulations."). Cross-examination and competing expert testimony will ensure that the jury carefully weighs Dr. Kessler's testimony. In addition, the Court will instruct the jury that the Court, not Dr. Kessler or any other witness, will inform the jury of the law applicable to this case.

**2 Allergan also challenges Dr. Kessler's testimony as having an improper basis. According to Defendant, Dr. Kessler's expert opinion "amounts to mind-reading," to the extent he "seeks to offer testimony about the knowledge, motivations, intent, state of mind, and purposes of Allergan, the FDA, and Dr. Wright." (Def.'s Br. at 10–11.) The Court agrees with Defendant that "mind-reading is not the type of 'specialized knowledge' contemplated by Rule 702" and that Dr. Kessler cannot be permitted to speculate as to the intent or state of mind of Allergan, the FDA, or Dr. Wright. (*Id.*) However, although Dr. Kessler cannot testify as to intent, Dr. Kessler can testify about facts from which the jury can infer intent. *See, e.g., DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 720 (7th Cir.1998) (holding an engineer could testify *as an expert* "that reducing the padding saved a particular mount of money ... [and] that [the manufacturer's] explanation for the decision was not sound (from which the jury might infer that money was the real reason); but he could not testify *as an expert* that [the manufacturer] had a particular motive"). Thus, Defendant's motion with respect to state of mind testimony is GRANTED IN PART and DENIED IN PART. If Defendant feels that Dr. Kessler has departed from an analysis of the facts and entered the realm of speculation during his testimony, Defendant may object at trial.

Finally, Defendant contends that Dr. Kessler "improperly assumes the role of Plaintiffs' advocate and invades the province of the jury" by " 'regurgitat [ing]' the evidence through various factual narratives." (Def.'s Br. at 13.) To the extent the facts relied upon by Dr. Kessler in forming his opinions are relevant and not cumulative, Dr. Kessler may include them in his testimony. However, Dr. Kessler may not "simply rehash[ ] otherwise admissible evidence about which he has no personal knowledge." *Highland Capital Mgmt ., L.P. v. Schneider,* 379 F.Supp.2d. 461, 468–69 (S.D.N.Y.2005). An expert must do more than simply "constructing a factual narrative based upon record evidence" or "address[ ] 'lay matters which a jury is capable of understanding and deciding without the expert's help.' " *Id.* at 469 (*quoting In re Rezulin Products Liab. Litig., 309 F.Supp.2d 531* (S.D.N.Y.2004)). Thus, Defendant's Motion is GRANTED IN PART and DENIED IN PART. Defendant may object at trial if Dr. Kessler appears to be simply regurgitating facts, rather than using relevant facts as context for his expert opinions.

Accordingly, for the reasons and to the extent stated above, "Defendant Allergan, Inc.'s Motion to Exclude Expert Testimony of David A. Kessler, M.D" (Dkt. No. 92) is hereby GRANTED IN PART and DENIED IN PART.

IT IS SO ORDERED.

All Citations

Not Reported in F.Supp.2d, 2013 WL 7208221

Footnotes

* Dr. Kessler earned a medical degree from Harvard Medical School and a law degree from the University of Chicago Law School, worked on food and drug issues for the United States Senate, served as Commissioner of the FDA under both President George H.W. Bush and President Clinton, served as the dean of two medical schools, taught drug regulation, consulted with private firms about drug regulation and FDA procedures, and has written and published numerous books and articles about the regulation of drugs and other public health topics.

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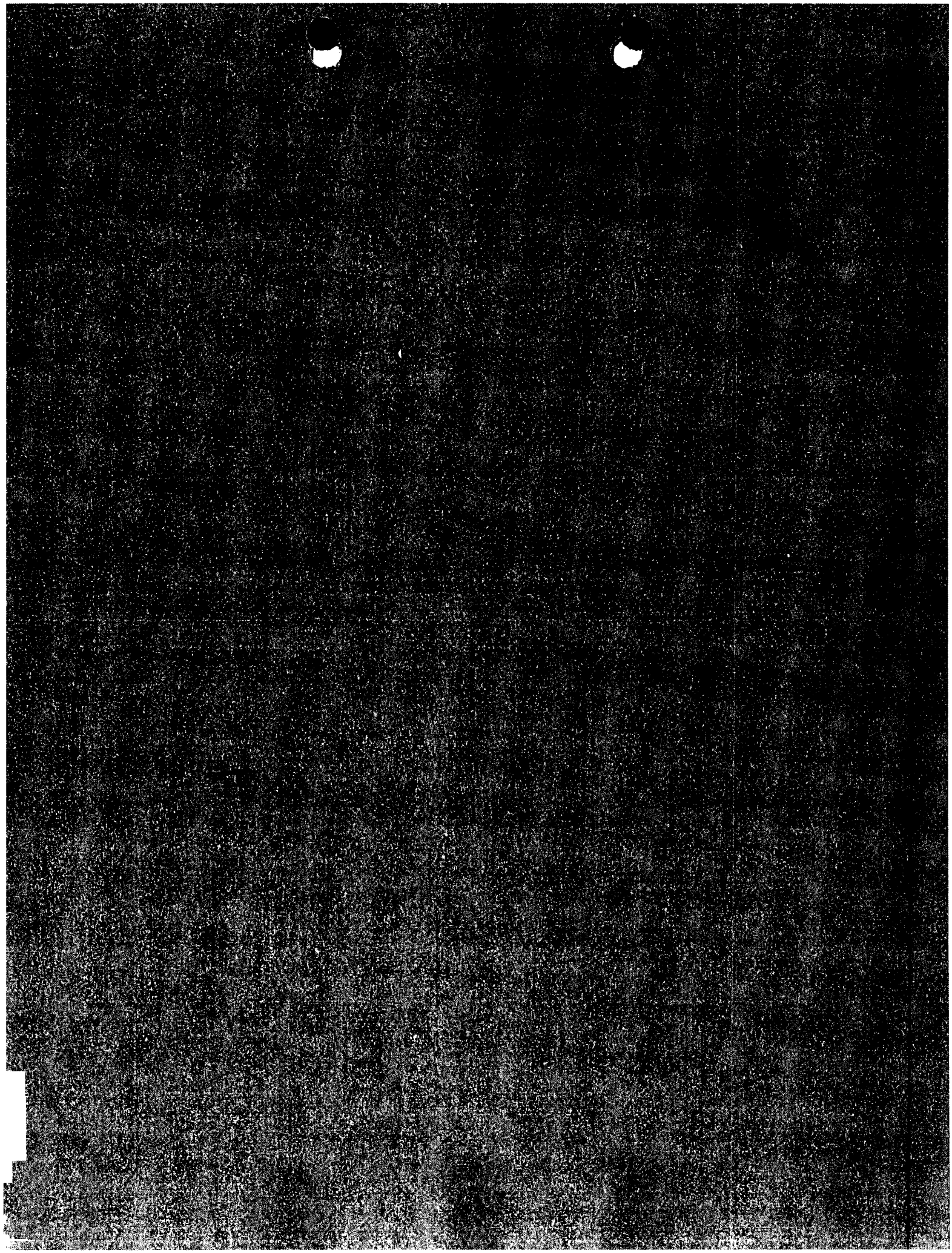

EXHIBIT F

2012 WL 1802066
Only the Westlaw citation is currently available.
United States District Court,
N.D. Illinois,
Eastern Division.

Jo Belle BALDONADO, Plaintiff.
v.
WYETH and its division, Wyeth Pharmaceuticals, Inc., Defendant.

No. 04 C 4312.
|
May 17, 2012.

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Judge.

*1 Defendant Wyeth moves *in limine* to exclude the anticipated expert testimony of two of Plaintiff's designated marketing experts—Dr. Matthew F. Hollon and Dr. Adriane J. Fugh–Berman. *See* Fed.R.Evid. 702; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). As explained below, Defendant's motion is granted in part, and denied in part.

BACKGROUND

Plaintiff Jo Belle Baldonado was diagnosed with breast cancer while she was taking Prempro, a prescription hormone therapy ("HT") medication that Defendant Wyeth designed, manufactured, and marketed. Plaintiff's prescribing physicians were Dr. Teresita D. Avila, M.D. and Dr. Mani Akkineni, M.D. Alleging that Prempro caused her breast cancer, Plaintiff filed the present civil action against Defendant and others. Trial is scheduled for October 9, 2012.

In advance of trial, Defendant moves to exclude the testimony of Dr. Matthew Hollon and Dr. Adriane Fugh–Berman, both of whom Plaintiff has designated as experts on Wyeth's marketing practices for its hormone therapy medications. The witnesses are "general liability experts" who have not filed case-specific expert reports. (R. 131, Pl's Resp. at 1.)

I. Expert Qualifications

Defendant does not challenge the qualifications of either Dr. Hollon or Dr. Fugh–Berman to offer expert opinions on Defendant's marketing practices. *See* Fed.R.Evid. 702(a) (stating that an expert may by qualified by "knowledge, skill, experience, training, or education"). For purposes of context, however, the Court briefly summarizes each expert's professional background.

A. Dr. Matthew F. Hollon, M.D., MPH

Dr. Hollon is a Board-certified physician of Internal Medicine at the University of Washington in Seattle ("UW"). (R. 131, Ex. 13, Expert Report of Dr. Hollon ("Hollon Report"), at 1.) He graduated from the UW School of Medicine in 1994, and thereafter completed a medical residency and fellowship in Internal Medicine at UW. (*Id.*) During his fellowship, Dr. Hollon attended classes at the UW School of Public Health and Community Medicine and received a Masters of Public Health. (*Id.*) Currently, Dr. Hollon is the Director of Evidence–Based Medicine for the Internal Medicine Residency Program at the UW Department of Medicine and an Assistant Professor in the Division of General Internal Medicine. (*Id.*) Dr. Hollon has been an active member in numerous professional organizations, and has published extensively in the area of pharmaceutical marketing. (*Id.* at 1–2.) He has also consulted on this topic for the Canadian government. (*Id.*)

B. Dr. Adriane J. Fugh–Berman, M.D.

Dr. Fugh–Berman is an associate professor in the Department of Physiology and Biophysics at Georgetown University Medical Center, where she teaches "graduate courses in the history of medicine and critical assessment of medical literature, including a module on clinical trial methodology and assessment of adverse events." (R. 131, Ex. 15, Expert Report of Dr. Fugh–Berman ("Fugh–Berman Report"), at 1.) She also lectures about "pharmaceutical company influence on physician prescribing practices." (*Id.*) For more than twenty-five years, Dr. Fugh–Berman has "worked in the field of women's health and corporate influence on healthcare," and has published numerous articles in that regard, including articles "on the culture of gynecology and the effect of drug company promotion on prescribing habits." (*Id.*) Dr. FughBerman previously practiced

general medicine with a focus on women's health. (*Id.*) After leaving clinical practice in 2001, Dr. Fugh–Berman has, among other professional pursuits, "been a consultant, scientific reviewer, working group member, or speaker on women's health issues for the National Institutes of Health, the Federal Trade Commission, the Centers for Disease Control, the Agency for Health Care Research and Quality, the Department of Defense, the National Security Agency, and the Institute of Medicine." (*Id.* at 1–2.)

II. Anticipated Expert Testimony

***2** Plaintiff seeks to call either Dr. Hollon or Dr. Fugh–Berman as a general liability expert on Defendant's marketing practices. [1] If permitted to testify, according to Plaintiff, the experts would opine that Defendant's marketing of HT products including Prempro fell below the standard of care that a pharmaceutical company should exercise. (R. 131, Pl.'s Resp. at 5–6, 8.) The experts in their respective reports offer extensive detail about Defendant's marketing practices and opine on the impact of those practices on patients and physicians. (*Id.*)

Plaintiff offers the experts to establish "key elements in Plaintiff's negligence and punitive damages claims." (R. 131, Pl.'s Resp. at 3.) Plaintiff contends that the experts "will serve to educate the jury on the nature and purpose of the marketing materials seen by Mrs. Baldonado and her physicians" (*id.* at 8), thereby "provid[ing] context for Wyeth's breach of its duty to the physicians and patients...." (*Id.* at 3.)

LEGAL STANDARD

"The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and the Supreme Court's opinion in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993)." *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir.2009). "The district court functions as a gatekeeper with respect to testimony proffered under Rule 702 to ensure that the testimony is sufficiently reliable to qualify for admission." *Mihailovich v. Laatsch*, 359 F.3d 892, 918 (7th Cir.2004) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999)); *see also Bielskis v. Louisville Ladder, Inc.*, 663 F.3d 887, 893 (7th Cir.2011) ("It is the district courts' role to ensure that expert testimony is both relevant and reliable."). Whether to admit expert testimony rests within the discretion of the district court. *See Gen. Elec. Co. v.. Joiner*, 522 U.S. 136, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). Indeed, a district court has "wide latitude in performing its gatekeeping function and determining both how to measure the reliability of expert testimony and whether the testimony itself is reliable." *Bielskis*, 663 F.3d at 894.

Under Rule 702, "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed.R.Evid. 702; *see also Ortiz v. City of Chicago*, 656 F.3d 523, 526 (7th Cir.2011). The inquiry under Rule 702 is "flexible." *Bielskis*, 663 F.3d at 894.

District courts employ a three-part analysis before admitting expert testimony: (1) the expert must be qualified as an expert by knowledge, skill, experience, training, or education; (2) the expert's reasoning or methodology underlying his testimony must be scientifically reliable; and (3) the expert's testimony must assist the trier of fact in understanding the evidence or to determine a factual issue. *See Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir.2010). "The goal of *Daubert* is to assure that experts employ the same 'intellectual rigor' in their courtroom testimony as would be employed by an expert in the relevant field." *Jenkins v. Bartlett*, 487 F.3d 482, 489 (7th Cir.2007) (quoting *Kumho Tire Co.*, 526 U.S. at 152).

ANALYSIS

***3** In the present motion, Defendant seeks to exclude the expert testimony of Dr. Hollon and Dr. Fugh–Berman on the ground that such testimony is irrelevant and unreliable. To the extent the Court permits the experts to testify, Defendant alternatively seeks to preclude the experts from offering "narrative histories" of hormone therapy marketing practices; opinions on Defendant's

intent and/or motives; and opinions on the applicable standard of care. The Court addresses each of these issues below.

I. Relevance

The Court first considers the threshold issue of relevance. Rule 401 of the Federal Rules of Evidence provides that evidence is relevant if "it has any tendency to make a fact more or less probable than it would be without the evidence; and the fact is of consequence in determining the action." Fed.R.Evid. 401; *see also* Fed.R.Evid. 402 ("Irrelevant evidence is not admissible."); *Daubert,* 509 U.S. at 590–91 (observing that expert testimony must be relevant in order to "assist the trier of fact" under Rule 702).

In its motion, Defendant argues that neither Plaintiff nor her physicians relied on any of Defendant's marketing materials, and therefore evidence of Defendant's marketing materials and practices can have no bearing on Plaintiff's injuries, nor properly provide evidence relevant to the assessment of a punitive damages award.[2] (R. 116, Def.'s Mem. at 4–6.) Plaintiff responds that both she and her prescribing physicians relied on Defendant's marketing materials, and her experts "will limit their testimony in this trial to the marketing conduct of Wyeth that is relevant to this plaintiff's case." (*Id.* at 1; *see also id.* at 9 ("[T]hese doctors' testimony will be specifically tailored to the facts of this case.").)

The parties agree, at least implicitly, that the expert testimony is relevant to the extent that Plaintiff and/or her prescribing physicians relied on the marketing materials about which the experts would opine. (*See* R. 116, Def.'s Mem. at 6; R. 131, Pl.'s Resp. at 13, 17); *accord De Bouse v. Bayer AG,* 235 Ill.2d 544, 337 Ill.Dec. 186, 922 N.E.2d 309 (2009) ("If a consumer has neither seen nor heard [the marketing] statement, then she cannot have relied on the statement and, consequently, cannot prove proximate cause."). Reliance is a question of fact, and under the Federal Rules of Evidence, "[w]hen the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist." Fed.R.Evid. 104(b).

Here, although the pre-trial record contains some evidence of reliance on marketing materials,[3] a ruling on the relevance of the proffered testimony to the negligence or punitive damages claims is premature. Plaintiff has agreed to "specifically tailor[ ]" the expert testimony "to the facts of this case." (R. 131, Pl.'s Resp. at 9); *see also Barton v. Wyeth Pharm., Inc.,* No. 694/695 EDA 2012, 2012 WL 112613 (Pa.Super.Ct. Jan. 3, 2012) (applying Illinois law) (finding no abuse of discretion in the trial court's admission of evidence of Wyeth's "extensive marketing activities," where a physician's information on the drug at issue was "rooted, at least indirectly, in Wyeth's active promotion of its product"). If Plaintiff seeks to offer expert testimony on Defendant's marketing practices, Plaintiff must *first* introduce evidence that is "sufficient to support a finding" that the testimony relates to the underlying facts of this case. *See* Fed.R.Evid. 104(b) & adv. comm. notes ("The order of proof here, as generally, is subject to the control of the judge."); *see also United States v. Boling,* 648 F.3d 474, 482 (7th Cir.2011) ("A trial judge has discretion to control the mode and order of witness interrogation and evidence presentation.") (citing Fed.R.Evid. 611(a)).

*4 Additionally, given the breadth of the expert reports at issue, the Court orders as follows:

- By May 31, 2012, Plaintiff shall file a detailed statement of the specific expert testimony and opinions that she intends to elicit at trial *in this case* from Dr. Hollon and/or Dr. Fugh–Berman. The statement must include supporting references to the expert reports and depositions.
- The parties shall meet and confer in good faith on the relevance of the proposed testimony on or before June 8, 2012.
- If the parties are unable to reach agreement, Defendant shall file objections to the relevance of the proposed testimony by June 12, 2012. Plaintiff may reply, if at all, by June 15, 2012.

II. Narrative Histories

Defendant next seeks to preclude the experts from offering "narrative histories" of Defendant's promotion of hormone therapy. (R. 116, Def.'s Mem. at 7.) In their respective reports, Dr. Hollon and Dr. Fugh–Berman offer lengthy narrative summaries about Defendant's promotion of hormone therapy products over approximately the last 60 years. (*See* Hollon Report at 8–88; Fugh–Berman Report at 5–31.) Defendant argues

that this type of narrative testimony, based on the experts' review of documents, does "not involve any application of 'scientific, technical or other specialized knowledge' " and "will not aid the jury and will impermissibly interfere with its role as trier of fact." (Def.'s Mem. at 14 (quoting Fed.R.Evid. 702).) The Court agrees.

Under the circumstances of this case, allowing an expert to provide summary testimony "based on nothing more than [the expert's] review of certain discovery materials could give the jury the impression that he did something more than simply review the materials, which the jury can do itself." *United States v. Vance,* No. 07–CR–351, 2011 WL 2633842, at *5 (N.D.Ill. July 5, 2011) (citing *United States v. Hall,* 93 F.3d 1337, 1343 (7th Cir.1996) ("Unless the expertise adds something, the expert at best is offering a gratuitous opinion, and at worst is exerting undue influence on the jury that would be subject to control under Rule 403.")). Even if the expert may have relied upon his or her expertise to "wade through the multitude of possibly relevant documents," the "vast majority" of the experts' proffered narratives amount to a summary and statement of the experts' "advocacy-based interpretation of documents in the record concerning" HT marketing practices. *In re Viagra Prods. Liab. Litig.,* 658 F.Supp.2d 950, 967 (D.Minn.2009); *see also In re Trasylol Prods. Liab. Litig,* 709 F.Supp.2d 1323, 1346 (S.D.Fla.2010) (finding that expert's testimony "will not assist trier of fact," where testimony "mostly consists of a factual narrative of [drug's] regulatory history and summaries of [pharmaceutical defendant's] internal documents"); *In re Prempro Prods. Liab. Litig.,* 554 F.Supp.2d 871, 886 (E.D.Ark.2008) ("If an expert does nothing more than read exhibits, is there really any point in her testifying as an expert?"). For these reasons, the experts may not offer factual narrative testimony that simply summarizes documents relating to Defendant's promotion of hormone therapy.

III. Reliability

*5 Defendant contends that the experts' testimony "should [ ] be excluded because it does not come close to the standard of reliability." (R. 116, Def.'s Mem. at 9.) As explained below, Defendant does not present any argument that warrants exclusion of the proffered expert testimony on the basis of reliability.

A. Dr. Hollon

Defendant argues that Dr. Hollon failed to undertake an "objective investigation of the facts" (*Id.* at 10), and "failed to gather relevant data." (*Id.* at 12–14.) Defendant presents these challenges as two independent arguments.

1. Objective Investigation of the Facts

Defendant relies on Dr. Hollon's deposition testimony to argue that he "made no objective investigation of the facts." (R. 116, Def.'s Mem. at 10 (citing *id.,* Ex. 20, Hollon Dep. in the MDL Court ("Hollon Dep."), at 67–68 (Mar. 27, 2006)).) According to Defendant, Dr. Hollon's deposition testimony shows that he "bases his opinions on material hand-picked for him by Plaintiff's counsel," and then " 'randomly' " delves into this limited material and, finding nothing to disprove his views, offers them as expert opinions." (*Id.* (citing Hollon Dep. at 67–68).) Defendant, however, grossly mischaracterizes Dr. Hollon's deposition testimony by offering only limited testimony ripped from its context.

Contrary to Defendant's representation, Dr. Hollon never testified that he relied exclusively on the documents that Plaintiff's counsel provided to him. In fact, he explicitly testified that "not all of it was provided by counsel." (Hollon Dep. at 77.) Dr. Hollon testified that he additionally relied on his "knowledge" and "expertise" of marketing practices (*id.* at 33), and on materials that he "found ... independently" (*id.* at 46). He further testified that he gathered a "substantial portion" of the documents he reviewed "well prior to any specific work that I did related to this case." (*Id.* at 36; *see also id.* at 28 ("most of the medical literature that I used to write this report was obtained by my own independent efforts").)

To the extent Dr. Hollon relied on documents that counsel sent to him, the record contradicts Defendant's assertion that these documents were "limited." (*Id.* at 21, 27 ("millions of pages").). As Dr. Hollon testified: "There were boxes upon boxes upon boxes of documents sent, numbering thousands upon thousands upon thousands of pages...." (*Id.* at 21 (further noting that he received an initial and then subsequent set of documents, and also 240 gigabytes of information on a hard drive).) Despite the breadth of counsel's production, Dr. Hollon also requested additional materials, which he received. (*Id.* at 24, 69.)

Furthermore, contrary to Defendant's arguments, Dr. Hollon did not simply look to counsel's documents to

disprove his opinions. Once Dr. Hollon reached his tentative opinions, he "went back to look in the medical literature ... and in the popular literature, using" electronic databases, including LexisNexis, to test his opinions. (*Id.* at 67–68; *see also id.* at 33 (testifying that he relied on his own experience combined with a "comprehensive summary of the available literature on the general impact of promotion on prescribing practices of physicians, and the influence that direct to consumer marketing has on those prescribing practices in this country"); *id.* at 67 ("It's my responsibility, as a researcher and scientist, to try and triangulate and to review as much as I can to form an opinion so that my opinion is valid.").)

*6 For all of these reasons, the Court cannot say that Dr. Hollon failed to undertake an objective investigation of the facts such that his expert testimony lacks reliability. (*Id.* at 33 (testifying that he relied on his own experience combined with a "comprehensive summary of the available literature on the general impact of promotion on prescribing practices of physicians, and the influence that direct to consumer marketing has on those prescribing practices in this country").) Defendant's challenges go to the weight of Dr. Hollon's expert testimony, not its admissibility. *See Walsh v. Chez,* 583 F.3d 990, 995 (7th Cir.2009) (holding that the "district court erred in concluding that whatever flaws existed in the expert reports ... went to their admissibility, as opposed to their weight").

2. Gather Relevant Data

Defendant next argues that Dr. Hollon "failed to gather relevant data." (R. 116, Def.'s Mem. at 12.) Defendant's somewhat undeveloped argument focuses on certain specific opinions.

First, Defendant argues that, with respect to "Dr. Hollon's opinion that Wyeth repeatedly ignored the FDA's directives regarding HT advertisements":

> [Dr. Hollon] did not obtain all the facts about those ads, including when they ran, where they ran, or even whether they ran at all. He is not familiar with the correspondence file between Wyeth and the FDA, and instead bases his opinion on his 'sense' of what happened.

(*Id.* at 13.) This argument, however, mischaracterizes the portions of the record upon which it relies. (*Id.* (citing Hollon Dep. at 232–33, 270–74, 280–81, 284–87).) In the cited deposition testimony, Dr. Hollon offered limited testimony about certain advertisements that might not even be relevant to this case. (*See* Hollon Dep. at 270–87. *Cf. id.* at 257–60 (testifying that he created a binder of relevant promotional materials).) Dr. Hollon is not a case-specific expert, and nothing in the cited testimony establishes that Dr. Hollon is unfamiliar with Defendant's HT advertising generally, or otherwise lacks a sufficient factual basis to opine on Defendant's marketing activities. This is particularly true in light of his experience, research, and review of relevant records. Moreover, to the extent Defendant suggests that Dr. Hollon lacks familiarity with "the correspondence file between Wyeth and the FDA," Defendant offers nothing to support such a sweeping statement. Defendant relies exclusively on Dr. Hollon's testimony relating to Defendant's promotion of HT for off-label use—an issue that is irrelevant to this case. (*Id.* at 232–33.)

Second, with regard to Dr. Hollon's opinion that Defendant "exert[ed] profound control over" the medical literature on HT, Defendant argues that the opinion is unreliable because Dr. Hollon "admits that he cannot quantify the extent to which Wyeth allegedly influenced the medical literature." (R. 116, Def.'s Mem. at 13–14.) In support of its argument, Defendant relies on Dr. Hollon's deposition testimony that Defendant's funding of articles "was a piece of the overall marketing plan that influenced providers and patients together.... It's reasonable to suppose that they continued to invest in it because it was effective." (*Id.*) When read in the proper context, however, this testimony does not support Defendant's argument. Dr. Hollon's testimony was in the context of discussing the existence of thousands of articles on HT and how Defendant used these articles as "a piece of the overall marketing plan that influenced providers and patients together." (Hollon Dep. at 324; *see also id.* at 152 (discussing the effect of "comprehensive promotional efforts of Wyeth" and "integrated marketing tactics," which took place "through all these different channels").)

*7 Finally, Defendant argues that Dr. Hollon's opinion on ghostwriting "hinges on a single article that he admits he did not read." (R. 116, Def.'s Mem. at 14 (citing Hollon Dep. at 321).) Defendant neither discusses the content or methodological value of this "single article," nor does Defendant discuss the relevant portions of Dr. Hollon's expert report in which he references numerous sources upon which he bases his opinion on ghostwriting. (Hollon Report at 62, 72–73, 77.) Moreover, as to the specific article to which Defendant refers, Dr. Hollon never testified that "he did not read" the article, but instead testified that he only had an abstract of the article with him "here." (Hollon Dep. at 321.)

3. Scientific Standards

Defendant next argues that Dr. Hollon failed to adhere to scientific standards. (R. 116, Def.'s Mem. at 13.) Defendant reasons that Dr. Hollon has previously opined in the *Journal of the American Medical Association ("JAMA")* that, as a general matter, the net public benefit of direct-to-consumer advertising is unclear. (*Id.* at 15.) By now "offering a contrary [opinion] in this litigation," Defendant asserts that "Dr. Hollon is applying different standards in the courtroom than those applied in his professional practice."[4] (*Id.*) The Court again disagrees. Dr. Hollon's *JAMA* article does not discuss Defendant or HT marketing practices, and therefore is not counter to his opinions in the present litigation. In any event, the existence of this prior publication goes to the weight, not the admissibility, of his expert testimony.

B. Dr. Fugh–Berman

Defendant's sole challenge to Dr. Fugh–Berman's methodology is this: she failed to make an objective investigation of the facts because she "published ... a paper ..., which is critical of the 'lawful' practice of 'ghostwriting.' " (R. 116, Def.'s Mem. at 10–11.) Defendant reasons that Dr. Fugh–Berman's publication "reveals that she is simply a mouthpiece for HT plaintiffs' counsel" because she relied heavily on "plaintiffs' counsel" for the content of her article. (*Id.* at 11.) Other than offer a defense of ghostwriting, Defendant does not advance any legal argument in support of excluding Dr. Fugh–Berman's testimony under any applicable legal authority. To the extent Defendant disagrees with Dr. Fugh–Berman's opinions as to ghostwriting, Defendant may, if otherwise appropriate, explore these issues with the witness on cross-examination.

IV. Intent and Motivation

Defendant seeks to preclude Dr. Hollon from testifying about Defendant's "internal motivations," arguing that such testimony would amount to improper speculation. (R. 116, Def.'s Mem. at 15–16 .) Plaintiff responds that "opinions as to Wyeth's ultimate motives and intent are certainly not the main thrust of Dr. Hollon's report or testimony. Where he does touch upon the subject, Dr. Hollon provides objective sources." (R. 131, Pl.'s Mem. at 22.)

*8 The Court agrees with Defendant. Nothing in Plaintiff's brief or the record suggests that Dr. Hollon has personal knowledge of the internal motivation for any of Defendant's actions, and furthermore, the jury is fully capable of considering the issue of intent based on the evidence presented at trial. *See DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 720 (7th Cir.1998) ("He could give an opinion as an engineer that reducing the padding saved a particular amount of money; he might testify as an engineer that GM's explanation for the decision was not sound (from which the jury might infer that money was the real reason); but he could not testify as an expert that GM had a particular motive."); *Johnson v. Wyeth LLC*, No. 10–C–2690, 2012 WL 1204081, at *3 (D.Ariz. Apr. 11, 2012) (precluding plaintiff's experts from offering "opinions concerning defendants' motive, intent, knowledge, or other state of mind"); *In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig.*, 09–md–2100, 2011 WL 6302287, at *12 (S.D.Ill.Dec. 16, 2011); *Loewen v. Wyeth, Inc.*, No. 03–J–2166, 2011 WL 6942870, at *4 n. 3 (N.D.Ala. Nov. 14, 2011) (precluding Dr. Hollon from offering any testimony that "constitutes his personal views as to the intent, motive, and state of mind of Wyeth"); *George v. Kraft Foods Global, Inc.*, 800 F.Supp.2d 928, 932–33 (N.D.Ill.2011) (excluding expert's state of mind opinion as speculative and unhelpful); *United States Gypsum Co. v. Lafarge N. Am., Inc.*, 670 F.Supp.2d 768, 775 (N.D.Ill.2009) (citing *Dahlin v. Evangelical Child and Family Agency*, No. 01 C 1182, 2002 WL 31834881, at *3 (N.D.Ill.Dec. 18, 2002) ("testimony that does little more than tell the jury what result to reach is unhelpful and thus inadmissible, and testimony regarding intent—essentially an inference from other facts—is even more likely to be unhelpful to the trier of fact") (internal citation omitted)); *Nat'l Jockey Club v. Ganassi*, No. 04–3741, 2009 WL 2177217, at *8 (N.D.Ill. July 21, 2009) ("intent of the

parties must be determined by the jury, and expert opinion testimony is not necessary on this point").

Accordingly, the Court grants Defendant's motion to preclude Dr. Hollon from offering opinion testimony as to Defendant's state of mind, including intent or motivation.

V. Standard of Care

Finally, Defendant seeks to preclude Dr. Hollon from offering testimony "regarding the standard of care for pharmaceutical marketing." (R. 116, Def.'s Mem. at 16.) Defendant reasons that Dr. Hollon's opinion on the applicable standard of care amounts to his own subjective "views on marketing ethics" without any objective foundation. (*Id.*) Once again, the Court disagrees. Dr. Hollon is a physician and expert in drug marketing, and he may reliably draw on his vast experience in this area, and his expert knowledge of federal and industry regulations, to opine on the standard of care. (*See* Hollon Report at 23; Hollon Dep. at 219–21, 237–38, 264–65); *accord Loewen,* 2011 WL 6942870, at *1 n .1 ("the court sees no reason why Dr. Hollon's testimony regarding the standard of care should be excluded" on the basis that it amounts to "personal opinions"); *In re Prempro Prods. Liab. Litig.*, No. 03–CV–1507, 2006 WL 5217764, at *5 (E.D.Ark. Sept. 13, 2006) (rejecting Wyeth's challenge to Dr. Hollon's proposed testimony on the standard of care, reasoning that "[c]learly, Dr. Hollon has a knowledge of pharmaceutical marketing that is beyond a juror's common understanding").

CONCLUSION

*9 For the reasons explained above, the Court grants in part, and denies in part, Defendant's motion.

All Citations

Not Reported in F.Supp.2d, 2012 WL 1802066

Footnotes

1 Plaintiff represents that the experts would offer materially identical testimony, and that she designated both to ensure the availability of at least one of the experts for trial.

2 On the subject of negligence, see generally *Robinson v. McNeil Consumer Healthcare,* 615 F.3d 861, 871 (7th Cir.2010) (" 'proof of negligence in the air ... will not do' ") (quoting *Palsgraf v. Long Island R.R.,* 248 N.Y. 339, 162 N.E. 99, 99 (1928)) and *Pipp v. Johnson and Johnson,* No. 09–CV–5944, 2010 WL 2365303, at *1 (N.D. Ill. June 9, 2010) (citing *Smith v. Eli Lilly & Co.,* 137 Ill.2d 222, 233, 137 Ill.2d 222, 560 N.E.2d 32, 560 N.E .2d 324 (1990) ("In a negligence action th[e] causation-in-fact requirement entails a reasonable connection between the act or omission of the defendant and the damages which the plaintiff has suffered."). On the subject of punitive damages, see generally *Woodward v. Corr. Med. Servs. of Ill., Inc.,* 368 F.3d 917, 931 (7th Cir.2004) (stating, in the context of punitive damages, " '[a] defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business' ") (quoting *State Farm Mut. Auto. Ins. Co. v. Campbell,* 538 U.S. 408, 123 S.Ct. 1513, 155 L.Ed.2d 585 (2003)).

3 Defendant argues that Drs. Avila and Akkineni did not rely on Defendant's marketing practices, reasoning that the doctors testified as much. (*See* R. 116, Def.'s Mem. at 3–4 (citing, e.g ., Dr. Avila Dep. (7/20/11) at 21, 256–57; Dr. Akkineni Dep. at 115–16).) Defendant presents this testimony out of context. Although the doctors may have stated that they did not rely on marketing materials, the doctors gave that testimony in the context of explaining that the decision to prescribe Prempro to Plaintiff was an exercise of independent medical judgment. This context is significant because throughout their depositions, the doctors explained that marketing activities and information from drug companies underlie and inform, at least in part, the exercise of their medical judgment. (*See, e.g.,* Dr. Avila Dep. (8/10/11) at 210 (testifying that information from a "sales rep" would go into the decision-making process); Dr. Akkineni Dep. at 15 (decisions based in part on marketing information received from drug manufacturer), 117–18 (advised patients of risk based on review of the literature).) The doctors testified about many of these influences. (*See, e.g.* Dr. Avila Dep. (7/20/11) at 15 ("whatever is out and recommendations and medical literature that is given to us"), 16 (letters from drug companies), 16–17 (textbooks), 18 (Physicians Desk Reference ("PDR")), 19–20 (lectures), 22 (journals), 24 (booklets), 27 (advertisements), 27 (materials brought in by patients), 50 (office visit by sales representatives); Dr. Avila Dep. (8/10/11) at 210 (pamphlets); Dr. Akkineni Dep. at 15 (visits by sales representatives who provide product information), 17 (text books and educational information from medical associations), 20(PDR), 24 (studies), 49 (specific document from Wyeth sales team), 54 ("Dear Doctor" letters), 58 (office visits by sakes representatives), 61 (continuing medical education); *accord* R. 132, Ex. 22 (medical records: "reading material on estrogen replacement [ ] given to the patient").)

4 Defendant also contends that "in the five years since he was retained as an expert in the HT litigation, he has never subjected his opinions (and accordingly his methodology) regarding Wyeth's advertising to peer review." (R. 116, Def.'s Mem. at 15.) This argument, comprised of one conclusory sentence without elaboration or reference to any legal authority, is waived. *See Appert v. Morgan Stanley Dean Witter, Inc.*, 673 F.3d 609, 617 n. 1 (7th Cir.2012) (holding that "perfunctory and undeveloped arguments unsupported by pertinent authority are waived"). Even if Defendant had not waived this argument, the existence of peer review is one of myriad relevant factors under *Daubert*. Defendant makes no attempt to explain how this factor, viewed with others, warrants exclusion under *Daubert*. *See Daubert*, 509 U.S. 593–94 ("The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.").

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