

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

 In Re: Levaquin Products)
 Liability Litigation,) File No. 08-md-1943
) (JRT/AJB)
)
) Minneapolis, Minnesota
) June 22, 2010
) 1:55 P.M.

BEFORE THE HONORABLE **JOHN R. TUNHEIM**
 UNITED STATES DISTRICT COURT JUDGE
(DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO PLAINTIFF
KARKOSKA AND
PLAINTIFFS' AMENDED AND CORRECTED MOTION TO COMPEL)

APPEARANCES

For the Plaintiff:

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WILLIAM LANHAM, ESQ. (VIA PHONE)
PAUL CORDELLA, ESQ. (VIA PHONE)

For the Defendant:

JOHN DAMES, ESQ.
TODD VINSON, ESQ.
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1:55 P.M.

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(In open court.)

THE COURT: You may be seated. Good afternoon, everyone. This is civil case number 08-1943, In Re: Levaquin Products Liability Litigation.

Counsel, would you note your appearances today? Let's start with the plaintiffs, please.

MR. GOLDSER: Good afternoon, Your Honor, Ron Goldser for the steering committee.

MR. SAUL: Good afternoon, Your Honor, Lewis Saul for plaintiffs as well.

MR. FITZGERALD: Good afternoon, Your Honor, Kevin Fitzgerald for plaintiffs.

MR. FRIEDBERG: Good afternoon, Your Honor, Joe Friedberg for the plaintiffs.

MR. CIALKOWSKI: Good afternoon, Your Honor, David Cialkowski for the plaintiffs.

MR. BECKER: Good afternoon, Your Honor, Tim Becker with the plaintiffs.

THE COURT: Okay. Very well. For the defense?

MR. DAMES: John Dames, Your Honor, for the defense.

MR. VINSON: Todd Vinson for the defendants.

MS. VAN STEENBURGH: Tracy Van Steenburgh for the defendants.

1 MR. DAMES: I just want to point out, Your Honor,
2 Todd is with my office. He has not been here before, but
3 he has done a lot of the written work up to date in the
4 case.

5 THE COURT: Welcome. It is nice to have you here
6 today. We have a new sound system, new electronics in the
7 courtroom. It may or may not work. Hopefully it will, it
8 will hold up. We have been having some difficulties of
9 late with it, so bear with us if we have any problems.
10 Okay. Let's see.

11 We've got the agenda here that has been proposed.
12 Anything to add or anything to change on the proposed
13 agenda?

14 MR. GOLDSER: I don't think so, Your Honor.
15 We're just waiting for your direction on when and how you
16 would like to handle the Karkoska summary judgment motion
17 and the motion to strike.

18 THE COURT: We'll start with that. Do we have
19 anyone on the telephone with us? Anybody on the phone?
20 Identify yourself for us, if you would.

21 MR. BROSS: This is William Bross with Heninger
22 Garrison Davis.

23 MR. CORDELLA: Good afternoon, Your Honor. Paul
24 Cordella from the Lanier Law Firm representing the
25 litigants in the New Jersey litigation.

1 MR. LANHAM: William Lanham at Johnson & Ward.

2 MR. JOHNSON: Charles Johnson here in Minnesota.

3 MR. WHIPPLE: Your Honor, Douglas Whipple,
4 Cleveland, Ohio.

5 MR. MILLER: Mike Miller, Fargo, North Dakota,
6 representing Bowles, Norman & Barnes, the cases filed in
7 Minnesota court before transfer.

8 THE COURT: Okay. Anyone else on the phone?

9 MS. MCCROIDAM: Pat McCroidam, a paralegal with
10 Lewis & Babcock. I'm not participating. I am just
11 listening in, and our client is the South Carolina
12 plaintiff George Small.

13 THE COURT: Okay. Very well. We are going to
14 proceed first -- oh, go ahead. Sorry.

15 MS. JOHNSON: Caia Johnson from Lockridge Grindal
16 Nauen.

17 THE COURT: Okay. We missed one. Who was right
18 before you?

19 MR. MCCAULEY: Matthew McCauley, Parker Waichman
20 Alonso, also from the New Jersey litigation.

21 THE COURT: Okay. Why don't you say your name
22 again? We just didn't quite get it.

23 MR. GOLDSER: It was Matt McCauley, Your Honor.
24 I think I know how to spell it.

25 THE COURT: Matt McCauley. Okay. Well, anybody

1 else on the phone that hasn't identified themselves? Okay.
2 We're going to proceed first with the summary judgment
3 motion in this case, and we've got a number of different
4 housekeeping matters to take up after that time. Anyone on
5 the phone wishes to speak, just let us know. Okay?

6 Okay. Let's proceed first with the motion, then.
7 Who is going to be doing the arguments?

8 MR. GOLDSER: Do you want to do the summary
9 judgment motion or the motion to strike, or do you want
10 them combined?

11 THE COURT: Combined.

12 MR. GOLDSER: Then I believe it will be
13 defendant's motion, and I believe that will be Mr. Dames.

14 THE COURT: Go ahead, Mr. Dames.

15 MR. DAMES: Thank you, Your Honor. I think I
16 probably logically should address in the initial instance
17 the allegation in the motion to strike that we had not
18 properly raised one of the grounds in the motion, that is
19 that there was an adequate warning as a matter of law, and
20 I want to just point out that I think there is a fairly
21 straightforward response to that.

22 On page 10 of the motion for summary judgment
23 that we filed initially, we point out that the undisputed
24 facts in this case invoke the learned intermediary doctrine
25 and refute the existence of proximate causation as a matter

1 of law on three related but independent grounds.

2 First, it is undisputed that defendants
3 specifically warned Dr. Butner, the prescribing physician,
4 of the risks of potential tendon rupture associated with
5 Levaquin, and it quotes the specific at the bottom of page
6 10 and the beginning of page 11, the brief quotes the
7 specific warning provided and then concludes, As such,
8 defendants sufficiently discharged their duty to warn
9 regarding the risks of the tendon injury.

10 And paragraph, footnote 2, it attaches or it
11 refers to the *In Re: Orthopedic Bone Screw Litigation*, and
12 it points out again, The defendants' warning should be
13 deemed adequate as a matter of law.

14 Now, plaintiffs recognize that specific ground
15 that we advanced in the motion because in their response on
16 page 12, plaintiffs' brief states: To meet their burden to
17 establish a learned intermediary defense, defendants must
18 demonstrate either that their warning to Dr. Butner was
19 adequate or that he was fully aware of the matters that
20 would constitute an adequate warning or that an adequate
21 warning would not have altered his treatment of plaintiff
22 sufficient to prevent plaintiff's injuries.

23 Defendants contend that Dr. Butner's undisputed
24 testimony conclusively establishes each of these grounds.
25 I think the issue had been adequately defined and

1 articulated. I'm not going to dispute that the focus of
2 much of our argument was on proximate causation. I think
3 the adequacy of the warning in this context is simply a
4 statement of the warning itself and the reference to the
5 fact that plaintiff suffered the very warning that was
6 advanced in the prescribing information.

7 Now, there is case law to establish that if you
8 reference the specific adverse event suffered by plaintiff
9 in the warning that that is sufficient as a matter of law
10 as an adequate warning, but let me back up and now restart.
11 I think plaintiffs' brief and our brief establishes the
12 three grounds we are advancing.

13 One, that the warning was adequate as a matter of
14 law. Number two, that Dr. Butner by his testimony clearly
15 demonstrated that he had independent knowledge of
16 essentially every aspect contained in the warning and
17 advanced by plaintiffs as an alternative warning based on
18 his own experience and research and training.

19 Third, the final ground is the one that we spent
20 a good bit of time on, and that is even assuming what
21 plaintiff was advancing is true, that there was an enhanced
22 risk with Levaquin over other fluoroquinolones, that
23 Dr. Butner would have prescribed Levaquin to this plaintiff
24 nonetheless. So there are three independently operating
25 reasons to grant this motion.

1 Now, because this is a motion that focuses
2 predominantly on Dr. Butner's own testimony, I think it is
3 worthwhile to hear his words because what is being disputed
4 here is that somehow Dr. Butner's testimony which clearly
5 said in response to plaintiffs' counsel's questions when
6 asked, if we had told you it was two times more risky for
7 tendon rupture or five times, I think it went as high as
8 ten times at one point, would you still have prescribed
9 Levaquin, and Dr. Butner clearly and unequivocally said he
10 would.

11 Now, I have spoken to the Court on prior
12 occasions about why we selected this case and what I
13 thought this case stood for, Dr. Butner's testimony stood
14 for. It may not be, and I don't mean to imply it will
15 necessarily be the perfect case or maybe not even the
16 strongest case at the end of the day, but it is a very good
17 example of what a prescribing physician does before he
18 prescribes a drug.

19 Dr. Butner clearly talked about the kind of steps
20 he did to research a drug before he used it, and he was
21 proud of it because he was a researcher. That was part of
22 what he did was, he enjoyed conducting his own research,
23 and he had a variety of things that he was looking into on
24 his own time, such as the vitamin D deficiency he pointed
25 out and other things that he said he consulted with the

1 defense department.

2 So he was someone who was accustomed to going off
3 and looking things up himself. Nonetheless, he says quite
4 clearly that he listened to the sales reps. He read the
5 package insert. He went off and did his own Internet
6 research. He would go off and do his own reading. He
7 discussed issues with colleagues. So he actually -- and of
8 course he would refer to his own experience with the
9 medication.

10 But having said all that, I think it's still
11 worthwhile to listen to his specific words and what
12 examples I think I want to bring to the Court's attention.

13 THE COURT: Do you understand this lepton wave
14 modeling?

15 MR. DAMES: You know, I wish I did, Your Honor,
16 and you can smile at me now, and I think I really don't
17 know it. I mean I -- he is a -- to be quite candid, it was
18 interesting confronting a gentleman with whom we could not
19 speak, and I think we have mentioned this again before, who
20 was very much an independent actor. It was quite clear
21 that this was a man who relied upon his own judgment and
22 was very proud of his own judgment.

23 I know that in plaintiffs' brief they talked
24 about his self-serving statements and how he dug in his
25 heels. I think that is, frankly, a mischaracterization.

1 This was a man who was proud of the work and the own
2 research he did so that he would defend his judgment, and
3 he would defend his own research abilities and his own
4 learning, and that was part of what came across in the
5 deposition.

6 Now, he said on page, and this is on page 33 of
7 his deposition, and he was trying to describe here what he
8 was confronted with when he saw this patient for the first
9 time and had to make an evaluation as to what to do. He
10 said in an answer to a question and the question is
11 convoluted. I will just go to the answer.

12 "He is on an antibiotic that is designed
13 predominantly for the urologic system because it is
14 concentrated in the urine and basically most effective in
15 the GU system. The sulfa product" -- this was not
16 Levaquin -- "is not very effective in our world in our time
17 for respiratory infection.

18 "I guess what I'm trying to do here is, I'm
19 trying to do an evaluation of this patient. Does he have a
20 pneumonia? Is he seriously sick, or is this more of a
21 bronchitis, albeit one that has significant threat? The
22 guy is post op. He already has some antibiotic on board.
23 He is not responding, so I'm trying to make a determination
24 about how can I best manage this gentleman. Is he someone
25 who is going to require IV antibiotics? Is this someone I

1 can use a more potent, broad spectrum antibiotic? What
2 class of antibiotic should I be using? I'm trying to make
3 those decisions. This is what that is all about."

4 And he adds on page 35, "This is a guy that I
5 need to have a higher index of suspicion for serious
6 illness as opposed to a 28-year-old, 34-year-old person who
7 hasn't had surgery."

8 So he is facing a guy with an infection who is
9 post op and more elderly person, a respiratory infection,
10 and he is trying to give him what is going to be the most
11 effective pharmaceutical for that respiratory inspection.

12 Now, what kind of information does he have? He
13 says, "So I do get this information. I tend to, in that
14 situation, ask a lot of questions trying to define what
15 this product is, what it's designed for. I do ask for
16 product information. It's always been my practice then
17 when I have a quiet moment later, usually in the evenings,
18 I will do my research for my own purposes to see what the
19 heck is this stuff."

20 And then he adds on page 39, "This has, this kind
21 of product, like Ciprofloxacin, works to disrupt an enzyme
22 that has to do with genetic function and production of the
23 way the gene causes certain proteins to be manufactured.
24 So I was, I would have researched that and said okay, how
25 does this work? Then what are the side effects? Who is

1 likely to have issues?

2 "You know, with all of the quinolones right from
3 the get-go, I was made very clear that these products were
4 not designed for someone who still had active growth going
5 on."

6 And there were, there have been questions, many
7 questions in depositions about the effect on cartilage in
8 juveniles versus tendons in adults, and you will hear
9 probably before we're done with this litigation challenges
10 to testimony trying to make a connection between evidence
11 derived from child studies in children to tendons in
12 adults.

13 Here is a physician who is even aware of that
14 issue in pediatrics. He understands. He says, It disrupts
15 cartilage growth or could. He then goes on to talk about
16 how he understands that it works with, how it works with
17 creatinine clearances because these things do have variable
18 effects depending on a person's kidney capacity.

19 So he specifically understands not only the
20 mechanism of action but some of the ways, some of the
21 cautions he needs to be aware of generically, children,
22 elderly, and he's aware of tendon effects, and he's aware
23 of, you know, effects with steroids. So this is a
24 well-informed man.

25 There are, he says, I'm -- he answers the

1 question on page 43. "I'm doing this thing to put myself
2 back into a mindset that I'm sure I was in when I saw this
3 patient, so I have got this gentleman who has in my opinion
4 at that point evidence of a respiratory infection. He has
5 history of prostate infection which maybe he is still
6 having issues with.

7 "He is on an antibiotic already that may be
8 irritating his stomach. That's a common side effect with
9 the sulfamethoxazoles. He feels uneasy. Well, he is sick.
10 Is he horribly sick? In my judgment, no, but is he sick?
11 Yes. Does his situation require attention? While he's a
12 little older, he has come through a procedure. He's still
13 in the post op period.

14 "He had a previous history of not smoking now,
15 but previously I had seen in the record that he had been a
16 heavy smoker, up to three packs per day, earlier in his
17 years. He probably has some compromised airway structures.
18 I had already reviewed the chart and seen the previous labs
19 and had seen that he had adequate creatinine clearances.
20 So he was not someone who had compromised renal state, so I
21 said, okay. How am I going to manage this?"

22 Well, the way he managed it is, he prescribed
23 Levaquin. So having described that he knew from the
24 labeling the specific review about tendon rupture, having
25 described his own discussions that he had with other

1 individuals and how he did his own research and then
2 looking at the patient and realizing the patient's risks
3 and his age and of his respiratory infection he ended up
4 prescribing the drug.

5 Now, when he was asked about what he would have
6 done if he had been told that the drug was not, was more
7 tendon toxic than other pharmaceuticals, and I need to --
8 other quinolones, I need to mention so we don't lose sight
9 of this fact.

10 This comparison, which plaintiffs' counsel have
11 made throughout the litigation that Levaquin is twice as
12 tendon toxic as Cipro and the evidence for that, to put it
13 in -- our position is that it's scanty at best and
14 unreliable, but nonetheless, the comparison between
15 Levaquin and Cipro is a false comparison.

16 Cipro is not used the same way as Levaquin.
17 Cipro is, in the words of their own expert Dr. Zizic, a
18 below-the-belt medication for below-the-belt infection, and
19 Levaquin is for above-the-belt infections. So it isn't as
20 if you are comparing apples and apples. You're really
21 comparing apples and oranges, and no expert in this
22 litigation will testify, nor have they yet, that Cipro and
23 Levaquin are used for, both of them can be used effectively
24 for respiratory infections. It is Levaquin that is used
25 for that purpose, and that is what this doctor also said.

1 Now, he goes on, and what Mr. Binstock, the
2 plaintiffs' lawyer at the deposition, asks him, Is it
3 possible that you would not have prescribed Mr. Karkoska
4 Levaquin if he had been on steroids, trying to determine
5 about the enhanced risk allegedly present if Levaquin and
6 steroids are used together.

7 Well, his answer there was, "We would have gone
8 the treatment course that would have been an in-hospital
9 type of treatment which might very well have involved IV
10 Levaquin, so I -- it was still risk versus benefit. I may
11 well have chosen actually to become more aggressive with
12 Levaquin, understanding the risk of tendons because of the
13 magnitude of what I would perceive it to be, his
14 respiratory risk. If you don't breathe, nothing else
15 matters."

16 And again, he points out an answer to another
17 question that he was very concerned about his respiratory
18 status and how he was post op and he had a potential
19 infection postoperatively, so he wanted to deal with the
20 infection, but he didn't end there. We go on to if, the
21 question here by Mr. Binstock is, "If there was information
22 available to Johnson & Johnson about tendon toxicity in
23 Levaquin being greater than with other fluoroquinolones,
24 should they have provided that to you?"

25 I objected, and he said, "And if they would have

1 provided that to you, could that have affected your
2 decision?"

3 He said, "Well, it could have an impact upon my
4 judgment the same as it could have the realization that he
5 had been on 40 milligrams of Prednisone a day or just had
6 intraarticular joint injection the previous week with
7 steroids. All would have entered into my considerations."

8 And he pointed out, "I would have gone with my
9 knowledge at this point. As best as I can ethically and
10 morally reconstruct this situation, I would have picked the
11 same medicine."

12 That's at page 123. I think that the answers to
13 his questions, to the questions posed to him showed a
14 consideration for the information that was being proposed
15 by plaintiffs' counsel and a careful thought process that
16 he went through before he responded that he still would
17 have used the same medication.

18 THE COURT: Do you think it's clear from, is it
19 Butner? Butner?

20 MR. DAMES: Butner.

21 THE COURT: Butner? That he, because I think he
22 gave some slightly different answers. Do you think he
23 really understood the extent of the toxicity problem for
24 tendons?

25 MR. DAMES: Personally, yes, I do, Your Honor. I

1 think what the distinction in the question and answer
2 session in which he was asked if he got the information
3 from us, I think the inconsistency which you're talking
4 about was an inconsistency between how he derived the
5 information, and he responded later, I was aware of the
6 risk.

7 Well, where were you aware of the risk from? How
8 did you become aware of it? And he said it was from
9 discussions or from meetings. He said, I really can't tell
10 you exactly how I learned of it, but I was aware of it,
11 yes. I think it was more a question, were you originally
12 aware of it from the company, and he didn't remember that
13 he was.

14 Frankly, based on the prescribing information, he
15 would not have been told there was a doubling of the risk
16 from the company but that he was aware of it based on his
17 other experiences. He was, at least I think in the same
18 question and answer dialogue there, he said he was. So
19 that, I mean, those were his statements about, I was aware
20 of the risk.

21 THE COURT: Mm-hmm.

22 MR. DAMES: But he does go on, and he was never
23 inconsistent, even arguably, and I don't think it's really
24 arguable on the former, but even if you take plaintiffs'
25 argument at their own word and their own belief, on

1 proximate causation, he was never inconsistent. He always
2 stated that you could tell me doubling, you could tell me
3 four times, you could tell me five times, and I still would
4 have used the medication.

5 THE COURT: He made a statement at one point in
6 time that he said it depended on how toxic it was, which
7 suggested to me that perhaps there was an outer limit of
8 toxicity that he wouldn't have accepted.

9 MR. DAMES: I think that's correct. He said, you
10 know, you would have to define, and it was in that same
11 exchange, a magnitude of risk that I can't foresee or
12 something, but if it was really a huge issue, and he didn't
13 define what was huge, but we know it was more than ten
14 times at least, that he would have perhaps altered -- I
15 don't know if he used the word "altered" his prescription,
16 but he would have considered that.

17 It would have become important to him. So the
18 outer limits of what he suggested might be important to him
19 were the inner limits, frankly, were those we have not
20 reached in any statistical claim in this case or
21 epidemiological claim in this case.

22 I think it is, it is interesting that, frankly,
23 the debate on proximate causation on part of plaintiffs'
24 brief is not whether or not he was specific or consistent
25 with his proximate causation testimony. It is that that

1 testimony should not be considered by the Court. I think
2 it's more on the order that, well, it was self-serving
3 testimony on Dr. Butner's case; therefore, the Court should
4 not consider it.

5 So I don't believe anyone in this courtroom today
6 feels that Dr. Butner was in any way inconsistent with what
7 he would have done and what he said he would have done, and
8 as to the admissibility and self-serving nature of the
9 testimony, I think we have cited to the cases that
10 establish that testimony is properly considered by the
11 Court in a prescribing physician context.

12 And, in fact, it's probably the best evidence of
13 what a prescribing physician would do to have the physician
14 himself testify as to what he would have considered and
15 what he would have done based on that. Frankly, Your
16 Honor, the clarity of his testimony is why, quite frankly,
17 on the proximate causation issue above all is why we
18 brought the motion.

19 And it, it does to some extent strike at the
20 heart of the learned intermediary defense because we take,
21 the whole purpose of the defense is to point to the
22 knowledge and skill and experience of a physician and
23 providing that physician with information that person can
24 properly interpret and apply to the clinical position the
25 patient presents at the time he makes the prescription.

1 And in this case, the deposition amply
2 demonstrates that Dr. Butner in fact did the right thing,
3 did the right thing throughout his treatment, Dr. Butner,
4 which leads me to the final point I would like to suggest
5 in this motion: There is no criticism of Dr. Butner's
6 prescription of Levaquin under the circumstances presented
7 to him. I don't --

8 First of all, he was amply informed by
9 Mr. Binstock when the deposition began that no one is going
10 to sue you. No one intends to sue you. No one is blaming
11 you. I'm paraphrasing that last, but he was reassured that
12 he was not going to be sued, and that's correct. It's
13 perfectly consistent with their approach.

14 No one is criticizing Dr. Butner's prescription
15 of Levaquin, so it raises the final issue on proximate
16 causation. If Dr. Butner did nothing wrong, if the
17 prescription for Levaquin was appropriate, then what can
18 the company be charged with doing? With influencing
19 Dr. Butner to do the correct thing? That doesn't seem
20 logical.

21 Dr. Butner applied his knowledge correctly.
22 Cipro would have been an incorrect drug based on his own
23 testimony, but even based upon Dr. Zizic's testimony in a
24 deposition, and we will have a chance to get into that with
25 other motions down the road, but no one is suggesting that

1 for a respiratory infection these two drugs are
2 interchangeable.

3 And I think the way he exercised his judgment
4 amply demonstrates that he followed the correct procedures
5 and did the right thing. Thank you.

6 THE COURT: Thank you, Mr. Dames.

7 Mr. Goldser?

8 MR. GOLDSER: Thank you, Your Honor. Good
9 afternoon again. I was in Chicago this weekend, Mr. Dames'
10 home town, and I had the pleasure of going to one of my
11 favorite places, the Chicago Art Institute, and I was
12 imagining and frankly hoping that I would run into
13 Mr. Dames there. I like John. He is a good guy. We get
14 along quite well outside of the courtroom.

15 But I was just imagining what it would be like if
16 I did in fact run into him at the Art Institute, and I told
17 him this right before we started today. I was just
18 picturing the two of us standing in front of the same
19 painting, and I would ask John, what do you see, and he
20 would say black, and I would say, you know, that's funny.
21 I see white, and I think that really characterizes what
22 we've got going here.

23 First off, on the adequacy of the warning as a
24 matter of law, the motion to strike, you know in footnote 2
25 of their opening brief, they say, The Court need not

1 directly address the issue of the adequacy of defendants'
2 warnings in order to dismiss plaintiffs' claims.

3 And then they go along in their reply brief on
4 page 6 to say, Plaintiff failed to raise any genuine issue
5 of material fact refuting the defendants' warning was
6 adequate as a matter of law. I go, well, wait a second.
7 You just told me I didn't have to respond to the adequacy
8 of the warning as a matter of law, and now you're telling
9 me, gotcha. Well, I call foul on that one.

10 What we did say, and Mr. Dames is correct, we did
11 say that the warning is inadequate. It's factually
12 inadequate, and if their theory is correct that a warning,
13 if given, that covers some vague notion of an injury, if
14 that warning is adequate as a matter of law, I think they
15 just turned the law on failure to warn just completely
16 upside down. We can pack up and go home. There would
17 never ever be an inadequate warning case.

18 In fact, what it really sounds like, and we said
19 this in our motion to strike and in our proposed surreply,
20 is that it really is an effort to raise preemption through
21 the back door. What they are saying is, we gave a warning,
22 therefore we win. That warning was approved by the FDA,
23 therefore we win.

24 Giving an FDA warning, therefore we win is the
25 same thing as not being able to raise anything other than

1 an FDA approved warning, which is in fact preemption. As
2 you know, *Wyeth versus Levine* said that's not the state of
3 the law. In fact, if you look at the facts in *Wyeth versus*
4 *Levine* what you see is precisely what we have here, an
5 inadequate warning case.

6 There was a warning of --

7 THE COURT: Do you have a view, Mr. Goldser, as
8 to what an adequate warning would have said?

9 MR. GOLDSER: In this case?

10 THE COURT: Yes.

11 MR. GOLDSER: Yes. As a matter of fact, very
12 clearly. Dr. Butner did say, and I want to get to this in
13 some detail in a little bit, that he was not aware of the
14 variation in tendon toxicity between and among the various
15 fluoroquinolones. What the proposed warning in Europe was
16 going to say was that Levaquin had a tendon toxicity twice
17 that of other fluoroquinolones.

18 Now, Mr. Dames raises Cipro, and I hear him
19 whispering Cipro to me right behind me. The studies that
20 were done, the early studies that were done, compared the
21 fluoroquinolones that were on the market at the time, and
22 they tended to include ofloxacin or Floxin -- you remember
23 that issue -- Levo where it was available, norfloxacin and
24 ciprofloxacin.

25 Now, to be sure as time has progressed, doctors

1 have increasingly used levofloxacin, Levaquin, above the
2 belt and ciprofloxacin below the belt, but that has not
3 historically been true. If you remember that event called
4 9/11, which I'm sure we all remember as clearly as we stand
5 here today, not long after 9/11 you will remember that
6 there was a huge anthrax scare.

7 Anthrax is a respiratory disease. Anthrax is
8 cured by antibiotics. What was the antibiotic they were
9 going to use and they ran out of to prevent anthrax,
10 respiratory problems from anthrax? It was Cipro.

11 So to say that Levaquin is exclusively a below --
12 above-the-belt drug and -- Levaquin is exclusively an
13 above-the-belt drug and Cipro is exclusively below-the-belt
14 drug is just not accurate. If it were accurate, they would
15 never have done those comparisons between Levo and Cipro to
16 begin with.

17 So you have the question of comparative tendon
18 toxicity. The warning that we think should have been given
19 was similar to that which the companies, both Johnson &
20 Johnson and Aventis, fought so strenuously in Europe and
21 succeeded because they ginned up the Ingenix study to make
22 sure that there was only a classwide warning and not a
23 warning that elevated Levaquin's tendon toxicity above the
24 rest.

25 We think that's the warning that should have been

1 given. Cheryl Blume's expert report, which has now been
2 submitted to you as part of the record for this motion,
3 says that, at least in part, that that's the warning that
4 should have been given.

5 And when you get to the question of what a doctor
6 should have known -- and I'm jumping around a little bit --
7 I read Judge Wilson and the *HRT* MDL litigation to say, To
8 break the causal link between plaintiff's injury and the
9 alleged failure to warn, plaintiff's physicians must have
10 had substantially the same knowledge as an adequate warning
11 from the manufacturer should have communicated, which begs
12 the question what was an adequate warning.

13 If the adequate warning was, Levaquin was more
14 tendon toxic than the other fluoroquinolones, if that was
15 the adequate warning, and we maintain it was, and we have
16 experts to say that that's what it should have been, then
17 the question becomes for the learned intermediary defense,
18 did Dr. Butner know the different comparative tendon
19 toxicity between and among the various fluoroquinolones.

20 That's the factual issue that exists in
21 Dr. Butner's testimony, but let me go back to the adequacy
22 of the warning issue because I'm jumping around a little
23 bit. This warning --

24 THE COURT: So just to make sure I'm clear here.
25 So your argument is that he really didn't know because he

1 wasn't adequately warned or told the difference in toxicity
2 among the various drugs and that is the reason or that's
3 your reason for opposing the argument at this stage?

4 MR. GOLDSER: Yes, in part.

5 THE COURT: In part.

6 MR. GOLDSER: In part. First, is the warning
7 adequate as a matter of law? If the warning were adequate
8 as a matter of law we wouldn't be here. There would be no
9 such cases.

10 THE COURT: Was he, was he given your proposed
11 warning, the one that was at issue in Europe and then asked
12 to opine on that?

13 MR. GOLDSER: I believe he was asked the
14 question, were you aware that that warning was being
15 proposed in Europe, and he said no. I can't cite you the
16 page of the deposition, but I'm pretty sure that's in the
17 deposition.

18 So back to the adequacy as a matter of law.
19 There are a couple of things I want to make sure you know.
20 First, if the FDA approval makes the warning adequate as a
21 matter of law, then the FDA's disapproval should make that
22 warning inadequate as a matter of law, and you will recall
23 there is a letter in 2008 in which the FDA finds that the
24 warning that existed was inadequate. That's Exhibit 2 to
25 our submission.

1 Johnson & Johnson over the years has changed
2 their label. Karkoska receives his prescription in the
3 fall of 2003. They changed it in 2004. If they believed
4 the warning was adequate, they wouldn't have changed it,
5 but they changed it.

6 Defendant cites the *Orthopedic Bone Screw* case as
7 the basis for this argument that a warning as given is
8 adequate as a matter of law, but in *Orthopedic Bone Screw*,
9 the plaintiffs did not challenge on a factual basis whether
10 the warning was adequate. We do that here, so that's
11 distinguishable.

12 And finally, as I mentioned, *Wyeth versus Levine*
13 prevents this argument as a disguised preemption law.
14 Remember. This defense of learned intermediary is just
15 that. It is a defense, and as such, the defendant bears
16 the burden of proof on the defense. The plaintiffs don't.

17 Remember also that this is a summary judgment
18 motion, and the defendant has the burden of showing that
19 there is no factual issue for a jury to decide, and the
20 Court asked Mr. Dames, do you really think that Dr. Butner
21 understood the difference between the various
22 fluoroquinolones. That in and of itself, whether he
23 understood that or didn't understand that, is a matter of
24 credibility and jury province. That's not a decision that
25 you make on a summary judgment motion.

1 So you have those burdens that you have to deal
2 with. Now, it's funny that you should have mentioned
3 earlier today the difficulties with technology. I tend to
4 be a Power Point guy and doing things in Power Point. I
5 chose not to do that, and I was going to do big,
6 old-fashioned poster boards, and Holly tells me that you
7 don't allow poster boards. So it's going to be even more
8 fundamental and basic than that. I have it on paper, so if
9 I might approach.

10 There are two additional responses that have to
11 be made to the defendant's motion. One is that Dr. Butner
12 was not in fact learned, and the second that regardless of
13 whether he was or he wasn't, that there is a fact issue on
14 whether or not he would have changed his treatment of the
15 plaintiff. Let's talk about whether he was learned.

16 Now, as you have already elicited, the warning
17 that we think should have been given was a comparative
18 tendon toxicity warning, and the factual issue that we
19 believe is raised is whether he knew that. He knew only of
20 tendon risks based on the package insert. That's bullet
21 point number one with the citation to the deposition.

22 He did not have any independent knowledge of
23 tendon toxicity outside of the package insert. I mean, he
24 knew all about vitamin D and the molecular structure and
25 all those things Mr. Dames said in his opening argument,

1 but you didn't hear anything about tendon toxicity in that
2 argument above and beyond what was in the package insert.

3 Dr. Butner recalled no conversations with the
4 defendants' sales reps discussing tendon issues, so he got
5 no further information from the defense other than what was
6 in the package insert. Did he know the tendon toxicity of
7 Levaquin, 2 times, 10 times, 20 times, 50 times? He said,
8 I need an answer. He needed to know that.

9 In fact, I can't remember if it was precisely
10 there or not, but somewhere else he said, you know, what I
11 really think I would change my mind on is if I saw rates of
12 tendon toxicity that were one standard deviation greater
13 than the other drug, and I don't have this formally in the
14 record now, but I could put it in if you would like and
15 make an offer of proof.

16 I checked with one of our biostatisticians, our
17 epidemiologist, and I said, so how many times greater a
18 relative risk do you need to have in order for there to be
19 one standard deviation, and he said somewhere between two
20 times and four times.

21 So if that's true, then a two- to four-time
22 greater relative risk is enough for this doctor to say,
23 well, gee, that's a boundary for me to start thinking about
24 changing, changing my position, but that is something that
25 the jury needs to be able to evaluate. That's a fact

1 question.

2 He never read any studies comparing the tendon
3 toxicity of ciprofloxacin with levofloxacin. He said that,
4 and he also said he was not aware of the distinction
5 between individual members of that class. I mean, there it
6 is straight up. You don't get to believe Mr. Dames on this
7 one, nice as Mr. Dames is.

8 What you have to find is whether there is any
9 evidence on plaintiffs' side of the ledger from which a
10 jury could find in plaintiffs' favor. On the question of
11 whether he is learned, you have that.

12 Now, would Dr. Butner have changed his treatment
13 of plaintiff? We've argued a couple of times already
14 through the status conferences that it's not whether
15 Dr. Butner would have changed his prescription but whether
16 he would have altered his treatment, and I think you might
17 find a specific reference to that in a case called *Johnson*
18 *versus Zimmer*, which is out of this court in 2004, and I
19 think Your Honor wrote that one.

20 If I can get my hands on that quotation, you
21 said, Where an adequate warning could not have prevented a
22 plaintiff's injuries, causation does not exist as a matter
23 of law. So the test is, could an adequate warning have
24 prevented a plaintiff's injuries?

25 To be sure, prescribing something different could

1 have prevented plaintiff's injuries, but there are other
2 ways, as we have argued on numerous times in prior status
3 conferences. So it's not just about changing
4 prescriptions. It's about would Dr. Butner have changed
5 his course of treatment, and so what he said was, if he had
6 been aware of a circumstance where Levaquin was having huge
7 issues, he would consider it.

8 If -- oh, here it is. If it was at least one
9 standard deviation greater, two to four times relative
10 risk, then maybe we have something to talk about. I
11 probably would have done several things differently. It
12 could have had an impact upon my judgment. All of that
13 would have entered into my consideration. I would have
14 been morally responsible to consider the factors.

15 Again is there evidence on plaintiffs' side of
16 the ledger from which a jury could conclude that Dr. Butner
17 would have done something different in his treatment of
18 plaintiff, and I submit to you that on this one simple
19 sheet of paper, the answer is yes. Mr. Dames' argument was
20 a fine closing argument at the close of trial to the jury,
21 but it's not a summary judgment argument.

22 You know, we're not done there. We could be done
23 there. If you find that based on those three arguments,
24 those three prongs, that the motion should be denied, we
25 can be done and I can sit down, but if you find that

1 defendant wins at that point in time, we have I think five
2 other arguments that are out there that you would then have
3 to consider.

4 Credibility by itself, Judge Wilson in the *HRT*
5 case said that credibility of the prescribing doctor all by
6 itself is a jury question, and he would not grant summary
7 judgment. Under the Minnesota Supreme Court case of
8 *Kallio*, you don't need any testimony of this kind at all.
9 We read the case to say that.

10 You have the heeding presumption issue, is there
11 a heeding presumption. In I think it's *Allgood* by Judge
12 Fallon, I can't remember which case it is, but one of the
13 decisions that we have cited says that implicit in the
14 learned intermediary doctrine is a heeding presumption.
15 Why? Because the learned intermediary doctrine is all
16 about, you've got to give the doctor notice, and just
17 merely giving the warning label presumes that the doctor
18 will read it, understand it and incorporate it into his
19 decision making process.

20 So whether *Tuttle* says in that case only or
21 *Kallio* says we have considered it, we think it's a
22 case-by-case phenomenon, and no court in this state has
23 addressed the question of whether the heeding presumption
24 is implicit in the learned intermediary doctrine, but other
25 courts have, and we think it is and for good reason.

1 But then if you decide that Minnesota law
2 wouldn't apply the heeding presumption, we think New Jersey
3 law should apply because then there is a conflict, and I
4 have told you about that. We have expert testimony to say
5 that there is a reasonable basis that a reasonable doctor
6 would have changed his prescribing habits and his treatment
7 habits.

8 And finally, if you find that the learned
9 intermediary doctrine bars all of that, we think that the
10 defendant knew that its warnings were going directly to
11 plaintiff for a variety of reasons. A, the package insert
12 has information to plaintiff section right in it, so they
13 knew that this information was going to plaintiff.

14 B, they were well aware of the whole patient
15 information leaflet process, including the fact that the
16 patient information leaflet is based substantially on their
17 package insert. So a duty once undertaken has to be
18 undertaken without negligence, Prosser, torts, you know,
19 law school year one, *Palsgraf versus Long Island Railroad*.
20 God, I didn't think I would ever cite that case. There is
21 a duty to the plaintiff directly.

22 So you have to jump through all of those hoops
23 to --

24 THE COURT: Is Dr. Butner unusual to the extent
25 that he apparently did some additional research on his own

1 and really looked into some of these issues? Are you
2 finding this is an unusual instance among the treating
3 physicians? It seems to me that it is, but maybe it's just
4 this particular person.

5 MR. GOLDSER: Dr. Butner has done more stuff to
6 look into it based on his issues of curiosity, which
7 happens to be the vitamin D issue. We certainly have not
8 seen anybody who has looked at the vitamin D question.
9 Doctors are really all over the map about the degree to
10 which they have studied this.

11 Some say I have never heard of this issue ever
12 before. Some have gone as far as what Dr. Butner has done,
13 but that's not with regard to the tendon issue. So yet the
14 treating, prescribing doctors do vary to a great extent. I
15 venture to say that for the most part, the doctors have
16 been pretty clear, clearer than Dr. Butner I will
17 acknowledge, that they would change their prescribing
18 habits.

19 And, of course, both Dr. Zhanel and Dr. Segreti,
20 defendants' experts, have told us that their prescribing
21 habits have changed. Their warning, their desire, their
22 need to counsel patients have changed and that that
23 practice has enhanced the more that they have known about
24 the problems with the drug over time.

25 The problem, of course, is that Johnson & Johnson

1 knew about these problems long, long ago. The medical
2 community did not know about it long, long ago. They
3 should have. The FDA should have. The FDA would have done
4 in 2003 what they finally did in 2008 if they had known in
5 2003 what they knew in 2008. Johnson & Johnson should have
6 told them. They hid it. I think you should deny the
7 motion.

8 THE COURT: Thank you, Mr. Goldser.

9 Mr. Dames?

10 MR. DAMES: Thank you, Your Honor. I must admit
11 to being a little disappointed that Ron didn't call when he
12 was in Chicago.

13 THE COURT: He wanted to see the black in the
14 pictures --

15 MR. DAMES: I would have taken him to see a
16 Picasso, so let's see what this is. In any event, here
17 is -- I looked at the sheet that Ron has handed out, and
18 the quote I gave the Court from Dr. Butner that when he
19 said, As best as I can ethically and morally reconstruct
20 this situation, I would have picked the same medicine, came
21 after the very next page to the statement that he would
22 consider -- sorry, Your Honor.

23 In any event, it came after his statement about
24 the things that he would consider information, and that's
25 fair. He would consider information, and then he

1 considered it, and he thought it through, and he responded
2 at the end to the question made by Mr. Binstock who said,
3 "It's just that all I'm asking is, if you would have been
4 provided additional information about the toxicity, tendon
5 toxicity of Levaquin, that you didn't have in 2003 that
6 made it worse than you thought it was, could it have
7 changed your prescribing Levaquin to this gentleman?
8 That's all I'm asking," and it was in response to that
9 summary question by Mr. Binstock that he said, "I would
10 have picked the same medicine."

11 Now, again, we didn't stop there. Mr. Binstock
12 didn't stop there. He's challenged a bit by Dr. Butner.
13 He's saying because if we're going to do an analysis saying
14 how much it would have affected me, give me some numbers,
15 which was fair. Tell me what range you're talking about
16 and maybe I can give you an answer.

17 He is asked first: "Doubling the risk would not
18 make a difference to you?"

19 "Not in this clinical situation.

20 "Okay.

21 "Answer: It probably would have had to have been
22 somewhere in the neighborhood of 10 to 20 times greater
23 risk. We're talking about an order of magnitude because I
24 deal with statistics. We're talking about order, you know,
25 standard deviations. So if I get into at least one

1 standard deviation difference, then maybe we have something
2 to talk about."

3 And it was then, "Were you aware," he asks him,
4 "about a reporting rate for tendon disorders higher for
5 Levaquin than any other anti infective," and that is where
6 Dr. Butner responded, "I was aware of that. I can't tell
7 you where I got the knowledge. It could have been talking
8 to people or meetings."

9 So it was a pretty lengthy dialogue, but the
10 consistent thread throughout this dialogue was, if you're
11 talking about a risk the order of magnitude well beyond
12 what plaintiffs' experts claim, I still would have used it.

13 THE COURT: Yeah. The problem is, and I have
14 read through much of the deposition, you know, at times
15 Dr. Butner seems so emphatic and so clear based on his own
16 research what he would have done, you know, as you have
17 properly argued.

18 And then, then he turns around and answers a
19 question in a way that makes it seem like, well, he's not
20 quite so sure of himself, and I don't know if this is the
21 nature of the questioning and the different questions and
22 just the vagaries of the deposition process, or sometimes
23 people get confused during a deposition. It's relatively
24 easily done, I think. Even learned doctors get confused.

25 I'm trying to figure out, you know, really where

1 he comes down here, and it's, it's difficult because he
2 does seem to be across the board a bit. Don't you think
3 there is some inconsistent answers there in some respect?
4 I know you think there is a consistency throughout, and
5 there surely is, but there are these inconsistent aspects.

6 MR. DAMES: Well, I mean, I think, here's where I
7 think that there is a lack of definition is the way I put
8 it, rather than an inconsistency, and the lack of
9 definition is, precisely what does he understand early on
10 at the time of the prescription about differentiation
11 between all of the fluoroquinolones, and that's because,
12 quite frankly, Your Honor, there isn't the medical evidence
13 about it.

14 For example, we hear a lot about the four
15 fluoroquinolones. Well, the evidence that has been cited
16 about doubling of the risk relates to Cipro, so that if you
17 start talking about Avelox, for example, there is no
18 evidence as to what the comparative rate is between Avelox
19 and Levaquin.

20 The citation is to Cipro, so I can understand the
21 lack of definition that comes across in Dr. Butner's
22 testimony. He's reflecting that the medical literature and
23 the medical science is not exactly precise, and it isn't.
24 What he does know and what comes across I think with the
25 definiteness that I think you also read in the deposition

1 was what he would have done because that was the position
2 he was defending, and that is based on his belief that
3 Levaquin was absolutely important for the respiratory
4 infection he believed he was faced with, and he was, and
5 the patient's medical condition.

6 So I do understand the distinction that the Court
7 is making, and I just hope that the Court doesn't carry the
8 distinction beyond what it deserves to be carried forward
9 to because I believe there is no inconsistency in
10 Dr. Butner's testimony, not a single one, about what he
11 would have done in the face of a reported greater risk in
12 this patient at the time, and there is no, there is no
13 deviation.

14 Quite frankly, Your Honor, when you're faced in a
15 deposition and someone is being asked repeatedly the same
16 question, will you have the precise, same answer every
17 time? He came about as close to someone doing that as I
18 have ever seen, particularly someone who has not been
19 coached before a deposition.

20 I mean, we all know that when you prepare a
21 deponent, you want to remind them, if you're asked the same
22 question, give the same answer, but both courtesy and
23 politeness sometimes cause trying to show an understanding
24 of the questioner, and he was as, frankly, as consistent as
25 I have seen on this issue, but thank you, Your Honor.

1 THE COURT: Thank you, Mr. Dames.

2 Do you have anything else, Mr. Goldser?

3 MR. GOLDSER: I have one brief comment.

4 THE COURT: Go ahead.

5 MR. GOLDSER: To add to the confusion of all of
6 this, Dr. Butner thought he was dealing in the deposition
7 with a patient who had pneumonia. He didn't remember
8 Mr. Karkoska at all, and so all the answers that he was
9 giving that Mr. Dames just described to you were based on a
10 patient with pneumonia.

11 Yes, of course, with pneumonia I would do this
12 and I would do that. The problem is that Mr. Karkoska had
13 bronchitis. Thank you.

14 THE COURT: Okay. Well, as to this motion, the
15 Court will take the motion under advisement and will
16 prepare and issue a written order just as soon as possible.
17 We have been in here for a shade over an hour. Let's take
18 a five-minute break, and then we will return to the agenda.
19 Okay?

20 MR. GOLDSER: Thank you, Your Honor.

21 **(Recess taken.)**

22

23 **(In open court.)**

24 THE COURT: You may be seated, and, Mr. Goldser,
25 let's continue with the agenda.

1 MR. GOLDSER: Thank you, Your Honor. We will
2 move as quickly as we can. I don't think we have a lot of
3 consequential materials. Pending cases in the federal
4 courts and state court, Mr. Dames has that report.

5 MR. DAMES: Yes, Your Honor. There are 471
6 federal cases that have been served. Again, you know, the
7 caveat is, we don't necessarily know which ones have been
8 filed, but 471 served, and there are 383 state cases
9 overall in which we have been served, 366 of those in New
10 Jersey.

11 And the difference is made up by cases, about a
12 dozen cases in Madison and St. Claire County, Illinois, and
13 there is now a California case that was just filed last
14 week or early last week, San Mateo County, in which
15 actually we have a prescribing physician as a codefendant
16 in that case, so that is one wrinkle.

17 It's, I think, something in addition to a tendon
18 case. It's a very broadly drawn complaint, and it has some
19 tendon references, but I'm not sure if that's all it's
20 about.

21 THE COURT: I see. Okay.

22 MR. GOLDSER: The other state cases in New
23 Jersey, the trial date is still holding in January. I know
24 that Mr. Cordella or Mr. McCauley were on the phone with
25 us. I don't know if they would like to add anything about

1 the status of what is going on in New Jersey.

2 There is an upcoming status conference on June
3 30th. Paul? Matt? I don't know if you're still there, if
4 you have anything you want to add? I know a number of
5 people rang off after the argument was over.

6 THE COURT: Okay.

7 MR. GOLDSER: And in Madison County, I'm not
8 aware of any significant progress that has been made.

9 MR. DAMES: No.

10 MR. GOLDSER: No motions, no major discovery
11 disputes.

12 MR. DAMES: No. There is no motions, no major
13 discovery disputes.

14 MR. GOLDSER: Item number 4, the privilege log
15 motion, we have not heard anything from Magistrate Judge
16 Boylan yet. I know he has reached out to
17 Ms. Van Steenburgh on a couple of occasions with some
18 questions, or at least I think I have heard that, but maybe
19 not, looking at her face.

20 MS. VAN STEENBURGH: He did call about a missing
21 document and whether there was one document misplaced, but
22 that's all.

23 THE COURT: He has not ruled yet?

24 MR. GOLDSER: No, he has not ruled yet. You may
25 remember at a prior status conference the defendant wanted

1 to propose a pretrial order number eight dealing with
2 deficient plaintiff fact sheets. I was to get back to
3 them. My response was, their proposed order was acceptable
4 but shouldn't we do a mirror image for deficient defendant
5 fact sheets, and I have been sort of waiting for a response
6 on that one.

7 But as proposed initially, at least their order
8 was fine. Obviously, I would like to have it all combined
9 into one if we can. I would like to get a response from
10 them on that. Mr. Robinson was handling that.

11 THE COURT: Okay.

12 MR. DAMES: Yeah, Mr. Robinson was. I was trying
13 to figure out a rational way to make a distinction between
14 the defendant fact sheet and the plaintiff fact sheets in
15 terms of those deadlines, which is why I didn't respond to
16 Ron yet because I do think there is a possibility, but we
17 can put in some restrictions, obviously, on failure to
18 provide defendant fact sheets.

19 I don't think the entry of judgment, which would
20 be the counterpart to a dismissal, might be appropriate.

21 MR. GOLDSER: I was trying.

22 THE COURT: Good try. Okay. Well, let's see if
23 we can wrap that up.

24 MR. GOLDSER: Bellwether case status, discovery
25 is continuing on. I'm not sure if this is the most

1 organized agenda. We have farther down case-specific
2 discovery. Mr. Fitzgerald might report on the status of
3 depositions in the individual cases.

4 MR. FITZGERALD: Sure. The defendants have
5 identified 22 fact witnesses for plaintiffs. The
6 plaintiffs were listed on their fact witness lists. To
7 date we have removed one fact witness from our fact witness
8 list in the Christensen case. That deposition was
9 cancelled. We recently identified three additional fact
10 witnesses that we were going to remove from our fact
11 witness list that won't be going to trial, and those
12 depositions will not need to be scheduled.

13 THE COURT: So that's 18.

14 MR. FITZGERALD: Leaves us with 18. I am pleased
15 to report that we have already taken 5 depositions of the
16 18. Another 6 are currently scheduled, and that leaves us
17 with 7 remaining, which includes 3 spouses, 2 pediatricists,
18 a physician and a physical therapist.

19 MR. GOLDSER: We are making progress. I don't
20 know that there are any major disputes that the Court needs
21 to resolve in that context.

22 MR. FITZGERALD: No.

23 MR. GOLDSER: Discovery status item A, the report
24 to the Court on discovery review of other individual
25 litigation, that is sort of an ambiguous title. You may

1 remember the last time we were here we had a motion to
2 compel. There were 13 cases that we had identified. We
3 wanted defendant to produce materials in those cases.

4 You instructed defendant to reach out to them and
5 report back on what they had discovered. I have not heard
6 back on that report yet. I don't know if Mr. Dames has a
7 response on that at this point. Again, that's in
8 Mr. Robinson's purview.

9 MR. DAMES: Yes, it is in Mr. Robinson's purview.
10 I hate to dump on the poor man who is fishing right now.

11 THE COURT: I gave him permission so --

12 MR. DAMES: But I do know that we have followed
13 up on some of these things. We just need to communicate
14 with Ron about what we found and did not find. I'm not
15 aware of anything that is inconsistent with what I have
16 described to the Court, but I will confirm that with Ron.

17 THE COURT: Okay.

18 MR. GOLDSER: Paragraph 7B, items 1, 2, 3 and 5
19 Mr. Robinson told me before he left for his trip, those are
20 to be forthcoming shortly. The patent case documents, the
21 redacted financial documents, privilege log production, I'm
22 not sure if there is anything else that needs to be
23 produced other than what is before Judge Boylan, and the
24 Omnicare documents from the Omnicare litigation.

25 We still do have a motion that we need to bring

1 about rebates and kickbacks and that whole issue more
2 broadly than just Omnicare. That motion is in the process
3 of being drafted. That is not completed yet, but that's on
4 our radar screen. The deposition of Walter Pascale, that
5 is presenting a little bit of a problem. That was one of
6 the cases that we had raised of the 13 that the defense was
7 going to report back on.

8 I thought I remember your requiring that that
9 deposition itself be produced. Pascale is a former sales
10 rep. We had located the document that was under his
11 authorship. I'm still looking for that deposition. I'm
12 very interested in what Mr. Pascale has to say.

13 THE COURT: He's a former employee?

14 MR. GOLDSER: He's former employee, yes, but that
15 deposition is out there, and it should be within the
16 control of a Johnson & Johnson law firm of some kind. I
17 think we know who it is. I'm not sure that it is yours,
18 but I think it is in Chicago.

19 MR. DAMES: It's not mine.

20 MR. GOLDSER: I mean, that should be available,
21 that deposition, and I would really like to get my hands on
22 that one. I don't know where that one is at.

23 THE COURT: When was it taken?

24 MR. GOLDSER: Four or five years ago, I think.

25 MR. DAMES: It was a while back, and I think that

1 is another one of those that Sidley & Austin had.

2 MR. GOLDSER: Yes. Yes. It was Sidley & Austin.

3 MR. DAMES: The issue is where is it and trying
4 to track it down, and so I don't know the answer to that
5 yet, but I don't think they've gotten back to us yet.

6 MR. GOLDSER: Mr. Robinson did not have a
7 response on that particular item. On third-party
8 subpoenas, Aventis has produced documents. We have now
9 taken the deposition of Drew Levy, who is the one witness
10 that was allowed to us by the judge in New Jersey. It
11 became quite clear that Drew Levy was not the right guy,
12 that Dr. Wanju Dai, D-a-i, is the right person.

13 We are currently negotiating with Aventis counsel
14 to add that deposition to the list. There is a proposal on
15 the table on how to do that, so I think we will make some
16 progress on that in the near future.

17 THE COURT: Where is Mr. Dai?

18 MR. GOLDSER: I think -- Dr. Dai is a female, and
19 I believe she is in the United States and not in France,
20 but precisely where -- I'm not sure she is still working
21 for Aventis or not. Is she? She is in Pennsylvania? Is
22 she still working for Aventis?

23 MR. SAUL: I believe so.

24 MR. GOLDSER: Okay.

25 THE COURT: Well, you should be able to get that

1 tracked down then.

2 MR. GOLDSER: So we're working on that one. The
3 other ones that are listed, Excerpta Medica -- is Brian
4 McCormick still on the phone? No, he rang off as well. He
5 sent me a report on these. We have been in discussions
6 with Excerpta's attorneys regarding their involvement with
7 Levaquin. Not many documents or projects between the
8 companies.

9 So that doesn't seem to be a big one.
10 DesignWrite is a big one. We understand that they will be
11 producing boxes of documents for us beginning next week.
12 There are, I think I heard 50 to 100 boxes, and I expect
13 there will be depositions of DesignWrite people.

14 CommonHealth, we have a list of their projects
15 since 2005. We're asking for a list of Levaquin related
16 projects prior to 2005. They are in the process of
17 creating that. So we're still working with them on that
18 issue, and Falk Communications, the subpoena is out. We're
19 still waiting to hear from somebody on behalf of Falk.

20 That's the extent of the third-party discovery
21 that is going on in the MDL, and we are coordinating that
22 discovery with New Jersey. So I don't think there is
23 anything else in New Jersey on third-party discovery that
24 we're not involved in.

25 On experts, most experts have been taken. We

1 have a little follow-up with Dr. Zizic on case specific
2 testimony. Dr. Holmes, the defendants' case specific
3 expert, is scheduled for July 1st. Cheryl Blume,
4 plaintiffs' expert on warnings, is scheduled for July 9th.
5 Paul Waymack for defendant on warnings is scheduled for
6 July 23rd, and I think our request for Dr. Segreti's case
7 specific deposition has gotten lost in the shuffle. We
8 need to get him scheduled as well.

9 Some of those depositions may present some
10 difficulty with the *Daubert* deadline, which is July 30th.
11 Most of them are done, and to the extent that depositions
12 are done, we can make determinations about *Daubert* motions.
13 So for most of them the July 30th date will be fine, but
14 some of these coming up later, we may come to the Court and
15 ask for an extension on a couple of them with regard to
16 *Daubert*.

17 THE COURT: Do you have an anticipation yet on
18 the number of *Daubert* motions, or is it too early to tell?

19 MR. GOLDSER: I think it's too early to tell. We
20 haven't decided on our side.

21 MR. DAMES: It's too early.

22 THE COURT: Is the July 30th deadline a problem
23 for the defense, too, do you think?

24 MR. DAMES: I think we probably share some of
25 those concerns. It's going to be, we may need to approach

1 the Court for a brief extension.

2 THE COURT: Okay.

3 MR. GOLDSER: That may be as to some and not all.

4 THE COURT: Sure.

5 MR. DAMES: That's a good point.

6 MR. GOLDSER: And while there are a number of
7 other things listed under experts, I'm not sure that there
8 is anything else to add. On case-specific discovery,
9 Mr. Fitzgerald has told you about depositions of
10 plaintiffs' fact witnesses. Production of individual
11 plaintiff backup files, these are the backup files that
12 Johnson & Johnson has to support the MedWatch investigation
13 and evaluation.

14 I had a conversation with Mr. Robinson last week.
15 I believe they are coming. He told me that they had to be
16 redacted. I have a concern about that because if, you
17 know, I represent Joe Smith and I want Joe Smith's file,
18 why does Joe Smith's name get redacted? He is entitled to
19 his own information.

20 I'm told that HIPAA requires that, but that
21 regardless of that, they will identify which of the
22 redacted file is Joe Smith and which redacted file is Betty
23 Jones. So they are redacted, but they will tell us which
24 they are.

25 THE COURT: It sounds a little backwards.

1 MR. GOLDSER: It does instead, but that's a hoop
2 that they want to jump through. We'll see if that's
3 adequate. I mean, if it tells us who they are, I don't
4 need to have the name on it just so long as I know who it
5 is, but we'll see as soon as that is produced. Then
6 Mr. Dames' partner Mr. Essig asked that Phase II discovery
7 be added to the list. So that's their request, and I'll
8 let you speak to that.

9 MR. DAMES: Actually, it's just a concern that we
10 are going to be scheduling, and we would like to be able to
11 schedule obviously, the depositions in Phase II in the
12 Phase II cases and that we would be commencing with the
13 same hopefully orderly progression in Phase II that we had
14 in Phase I with prescribing physicians and plaintiffs.

15 THE COURT: Okay.

16 MR. GOLDSER: And we have always felt, at least
17 on an ongoing basis, that that is premature, especially as
18 we are preparing for a trial in November. Obviously we
19 will need to confront that at some point in time. We're
20 not ready to do that yet on our side.

21 THE COURT: Let's keep it on the agenda.

22 MR. GOLDSER: That concludes the agenda. That's
23 all I have.

24 Anybody else plaintiffs' side? I think that's
25 all for plaintiffs, Your Honor.

1 THE COURT: Mr. Dames, do you have anything?

2 MR. DAMES: No, Your Honor, I don't.

3 THE COURT: Okay. Anyone else? Okay. Very
4 well. Thanks for coming in today. I appreciate the
5 arguments on the summary judgment motion.

6 As the Court indicated earlier, that motion will
7 be taken under advisement, along with a motion to strike,
8 and should we set another time here?

9 MR. GOLDSER: Yes, please.

10 THE COURT: I know you have got a lot of
11 depositions coming up, so it may be a little difficult to
12 schedule.

13 MR. GOLDSER: I'm thinking the first week in
14 August. July will be busy.

15 THE COURT: That's a fairly good week for me. At
16 least Tuesday or Wednesday, the 3rd or 4th, looks pretty
17 good.

18 MR. GOLDSER: That's fine with me.

19 MR. DAMES: That's fine.

20 THE COURT: Tuesday the 3rd at 1:30, does that
21 time make sense?

22 MR. GOLDSER: Yes.

23 THE COURT: Ms. Van Steenburgh?

24 MS. VAN STEENBURGH: I won't be here, but I will
25 have someone from my office.

1 THE COURT: Okay. That's fine, and Mr. Robinson
2 is back by then?

3 MR. DAMES: Yes.

4 THE COURT: Okay. Well, let's set it for August
5 3rd at 1:30 in the afternoon. Very well. If we need to
6 gather before that, just let me know. The Court is in
7 recess. Thank you.

8 MR. DAMES: Thank you, Your Honor.

9 MR. GOLDSER: Thank you.

10 THE CLERK: All rise.

11 * * *

12 I, Kristine Mousseau, certify that the foregoing
13 is a correct transcript from the record of proceedings in
14 the above-entitled matter.

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18 Certified by: s/ Kristine Mousseau, CRR-RPR
19 Kristine Mousseau, CRR-RPR

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