IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

IN RE: PREMPRO PRODUCTS LIABILITY LITIGATION — MDL Docket No. 4:03CV01507 BRW — ALL CASES

Friday, July 20, 2012 - Little Rock, Arkansas - 9:05 a.m.

TRANSCRIPT OF STATUS CONFERENCE
BEFORE THE HONORABLE BILLY R. WILSON,
UNITED STATES DISTRICT JUDGE

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P R O C E E D I N G S

THE COURT: Good morning. Be seated, please.

Well, I see that Ms. Littlepage has made it here. The rumor was out yesterday that her plane was lost at sea.

MS. LITTLEPAGE: I was lost in Denver, Judge.

THE COURT: And I ironed my black suit last night, prepared to have a wake. Glad to see you made it.

All right. We're here this morning in In Re: Prempro, 4:03CV1507 BRW, a status conference. There is a generic motion, defendants' motion for judgment on the pleadings. This is bottomed on what's known as *Mensing*, M-e-n-s-i-n-g, case by the United States Supreme Court.

Does the plaintiff concede that this case controls insofar as a failure to warn involving the generic drug defendants?

MS. LITTLEPAGE: Judge, Ms. O'Leary from Mike Williams' office will be arguing for the plaintiffs, so she'll answer your question because I don't know the answer.

THE COURT: Would you mind coming around to the lectern? Keep in mind that your judge is "kindly deef."

MS. O'LEARY: Nice to see you again, Judge Wilson.

THE COURT: My pleasure.

MS. O'LEARY: In answer to your question, we concede *Mensing* controls only to the extent that the required warnings would be somehow different from or in addition to the FDA-approved labeling on the brand name drug.

THE COURT: I'm not sure -- I'm impressed with your answer, but I'm not sure I'm fully informed. Are you saying that the failure to warn against the generic drug defendants is still alive in some form?

MS. O'LEARY: Yes, it is, Your Honor.

THE COURT: In what cases is it still alive?

MS. O'LEARY: Well, there are a few different scenarios where it would still be alive. The first one would be where the generic manufacturer did not update the generic drug label so that it conformed in all respects to the brand name label. So, say, for example, you have a Provera label, and the generic Provera, the MPA label was just behind, it didn't reflect the accurate warnings, the warnings that should have been on the brand name label, and, likewise, if it was a generic estrogen, if it wasn't like the Premarin label.

THE COURT: All right. Didn't update. Do you have any of those cases?

MS. O'LEARY: I'm not sure because we haven't quite gotten through the post-*Mensing* discovery, which is another issue. After *Mensing* was decided, we didn't have the opportunity yet to question the manufacturers on when they made those updates to their label. So that's one aspect of failure to warn.

THE COURT: Are there any other examples?

MS. O'LEARY: Yes. Another example would be where the

generic manufacturers didn't send a "Dear Doctor" letter to notify the doctors of any changes that they had made to their package insert label that was in conformance with the FDA-approved one.

THE COURT: In other words, that means no "Dear Doctor" letter that would be updated?

MS. O'LEARY: That's right. And the "Dear Doctor" doesn't have to be different from the label or in addition to it, just that it accurately reflects what the updates were made in the label.

THE COURT: All right. Any other examples?

MS. O'LEARY: On failure to warn --

THE COURT: No, let's don't go to the failure to warn yet.

MS. O'LEARY: Yes, there are two other examples, Judge. One example would be where the generic manufacturer engaged in off-label promotion, which is a violation of FDA regulations, and that would be a situation where the FDA approved the drug for a certain indication and the generic companies were promoting it for something besides that.

THE COURT: All right. Do you have any of those cases?

MS. O'LEARY: Yes, we do. And, in fact, one example that we do know, based on the discovery we have so far, is what Barr did. Barr actually did fully promote for use of its MPA

for everyday use, not on a cyclic or sequential basis, but they were promoting it to be used every day with estrogen, and that was an off-label use.

THE COURT: All right. How about no "Dear Doctor" letters updated, have you got any of those cases?

MS. O'LEARY: Yes, we do. In fact, most of the companies didn't send "Dear Doctor" letters.

THE COURT: Most of the generic companies?

MS. O'LEARY: Yes, yes.

THE COURT: All right. You said you had another example.

MS. O'LEARY: The other example doesn't really have to do with failure-to-warn cases. It is a design defect case, and that would be --

THE COURT: Well, let's don't get into design defect. I'm going to get to that in minute. Do you have any other failure-to-warn examples?

MS. O'LEARY: Those are the examples I'm aware of, the ones that I described.

THE COURT: The three. All right.

Now, design defect, the companies are, as I understand it, the generic companies are required to use the same ingredients -- I'll call them "ingredients," that's about as scientific as I can get -- as the brand name. Is that correct? They're mandated by federal law?

MS. O'LEARY: Yes, they have to be equivalent to the one that's already on the market.

THE COURT: Then if they're required to do that, how could they be faulted for design defect?

MS. O'LEARY: It is not -- we're not arguing that they should have designed the molecule differently. What we're arguing is that from a consumer expectation test, which is the law in many states, and, in fact, has been the law in the state that the First Circuit issued its opinion on, the test isn't whether it could be made any differently, that might be one factor that some courts might consider, but that it's just unreasonably dangerous.

THE COURT: If they put a different ingredient in there or a different percentage, I could see that. Do you have any of those cases?

MS. O'LEARY: No, and that's not what we're arguing.

THE COURT: Okay then. Go ahead. I'm sorry.

MS. O'LEARY: What we're arguing is that under the consumer expectations test, design defect test, it's a separate inquiry from whether they failed to warn, because a design defect -- and this, of course --

THE COURT: How is it different from failure to warn?

MS. O'LEARY: It varies from state to state, Judge, and that's part of it. But, for example, in one state you just have to prove that this drug, as it is on the market, is just

unreasonably dangerous and defective, it's just more dangerous than a consumer would accept. And so that doesn't really depend on a duty of care or a duty to do anything in particular to warn. It's just a pure -- it's a pure strict liability analysis. And we know that some states have upheld that.

THE COURT: All right. Now, then, as I understand it, you contend design defect under the strict liability theory?

MS. O'LEARY: Well, some call it strict liability and some call it design defect. And, again, some states will split hairs --

THE COURT: What's the difference between unreasonably dangerous under strict liability and design defect in other states?

MS. O'LEARY: Well, let me use Arkansas as an example. Maybe that will help. Arkansas recognizes failure to warn as a defective design, it recognizes a manufacturing defect as a defective design, and then there's a just kind of design detective where it's unreasonably dangerous, it's just more dangerous than a consumer would expect. So it doesn't depend on an adequacy of warning or a change in the molecule. It's a different type.

THE COURT: Even though the federal law requires the generic company to put out the exact same drug, it can be unreasonably dangerous under state law despite that federal law?

MS. O'LEARY: Yes.

THE COURT: The federal law doesn't trump that?

MS. O'LEARY: No. I mean, the FDA isn't putting a gun to the company's head, saying, "You take this off the market" or "You keep selling it." It's really the manufacturer's decision, if they are going to put a drug on the market that's known to have a lot of risks, then when it gets sued, a jury may very well find this is unacceptable from a consumer standpoint and so we're going to hold the company liable. It doesn't have anything to do with the failure to warn or a change in the molecule, and that's not what we're arguing, that they should have designed the molecule differently. It's a very narrow area of strict liability, or pure design defect, if you will.

THE COURT: Thank you very much.

MS. O'LEARY: Thank you.

THE COURT: All right. Does the defense want to throw in the towel or does somebody want to make a presentation on the other side?

MR. PECK: Given those choices, Your Honor, I'd like to make a presentation on the other side.

THE COURT: All right. Come on. I'd love to hear you.

MR. PECK: Thank you, Your Honor. Jeff Peck. I represent Barr Laboratories, Barr Pharmaceuticals, Inc. and Duramed, now known as Teva Women's Health, but I'm sort of taking the lead for the generic defendants as a whole.

THE COURT: All right.

MR. PECK: I think maybe what I'll do, if I could, is start with the claims that the plaintiffs say that they have left somehow after *Mensing*, that they think survive *Mensing*.

The first one they said is a failure to update the label, three of them were under the failure-to-warn category, and then I'll go to design defect, unless you'd like me to handle it in a different order.

THE COURT: No, I'd rather you handle it just like you proposed.

MR. PECK: Great.

The first point is the failure to update the label. Now, this, first of all, is a nonclaim, it's a claim that does not exist. What they are proposing is that they could come in and make a claim, try to make a claim based upon an allegation, and they don't have any facts for this -- I guess I should point out that our counsel used the example of if Barr did not update its MPA labeling, when they've said previously to the Court between '95 and 2007, Barr's label was the same as the Provera label. So factually they don't have that, and they really don't have any claims, and counsel was not able to identify any claims that fell into that category.

THE COURT: Counsel said that they didn't have enough updated discovery to know about this.

MR. PECK: Well, the ANDAs and the NDAs, which is

where you go make the comparison, you go look at the branded change, and then you go look at the ANDAs, those have been sitting in the depository for eight years, and they've certainly been there for the year-plus since the *Mensing* decision on June 23 of 2011. So that information has been available to them. It's not going to support what they're alleging, but it's been available to them.

But the other problem with this claim is that the duty to update labels that's --

THE COURT: Hold on just a minute. I need a cup. Excuse me. Oh, I need eyes. They were right there by me. Hang on just a minute. Ms. Beard put these clear cups up here to hide them from me.

All right. Go ahead.

MR. PECK: Thank you, Your Honor.

The duty to conform a generic label to a brand label is one that is found in the Federal Regulations. It's not a state law duty. There's not a state law duty that says a generic has to have the same label as the branded. That comes from the Federal Regulations.

THE COURT: Hold on just a minute. I'm going to read what you just said.

MR. PECK: Okay.

(Court reviews realtime screen.)

THE COURT: Okay. Go ahead.

MR. PECK: And as such, if what they are trying to claim is some violation of a federal regulation, an FDA regulation, they run smack-dab into the fact that that does not give rise to a private right of action under 21 U.S.C. 337(a) and the *Buckman* case decided by the Supreme Court. That claim's simply not available to them. And we've cited many, many cases to the Court, among the 73 that were in Exhibit 3 to our motion, that endorsed that proposition. It's a proposition that's been endorsed by this Court in the *Fullington* case.

So what they're trying to do then is not only pursue a claim that factually there's no basis for, but simply legally does not exist, and, therefore, they can't keep going on the basis of failure to update.

The second one they identified was that the generics didn't send out "Dear Doctor" letters.

THE COURT: Updated "Dear Doctor" letters, wasn't it?

MR. PECK: Right. I think the claim is, as I understand it -- it's a little bit of a floating target. But I think the claim that they're making is that when the labeling was updated by the NDA, that the generics should have sent "Dear Doctor" letters out saying, "Hey, the labeling has been updated," or something like that. A couple of problems with that. "Dear Doctor" letters are labeling. What *Mensing* says is that the labeling for a generic drug has to be the same as the branded. If a generic company sends out a "Dear Doctor" letter

and the branded company does not, the labeling for the generic drug is different than the branded. And it falls right into what the *Mensing* court said, which is that if a generic company were to send out a "Dear Doctor" letter when the branded doesn't, it implies a therapeutic difference between the two, it implies there's something different about the generic drug. And if we go back to what Hatch-Waxman was intended to accomplish here, it was intended to accomplish getting lower-cost drugs out to people, basically lower cost copies of drugs with a proven track record out to people to reduce healthcare costs. And the FDA takes a lot of pains to make sure that people in the prescribing community and the consumers feel comfortable that generic drugs are the same as and that people are not creating arguments that they're different so it doesn't frustrate the mission of Hatch-Waxman.

THE COURT: What about the case where the brand name sends out an updated "Dear Doctor" letter, but added something to it, and the generic company does not send out that same updated warning?

MR. PECK: Well, are you talking about -- just so I make sure that I understand the question, Your Honor. Are you talking about that the "Dear Doctor" letter would include something in it that was not in the labeling?

THE COURT: Was not in the original "Dear Doctor" letter.

MR. PECK: Okay. A couple of things about that. First of all, in my experience, and we've looked at this issue, when there are situations like that with the brands sending out a "Dear Doctor" letter, the generics don't send them out. The FDA doesn't ask generics to do that. That's not the way it works. In fact, there's not really even a procedure at the FDA. The FDA has an internal procedure called a "MAP" for sending out "Dear Doctor" letters for the branded drugs. They don't have anything like that for the generic drugs. So it's never really been an issue at all before in terms of differences between "Dear Doctor" letters, because the "Dear Doctor" letters are really something that is a joint venture between the brands and the FDA, and the generics aren't involved in that.

THE COURT: Let me ask you this. Suppose the brand sends out a second, an amended "Dear Doctor" letter and says we've discovered that this drug is more dangerous than we thought because of this, either the way it's prescribed or because of the ingredients, and the generic doesn't do anything, is the generic still not obligated to do anything?

MR. PECK: Correct. Until there would be a change in the labeling, in the package insert part of the labeling and the generics are told to do that, they would not. That kind of thing -- it would be a pretty extraordinary circumstance. But that kind of thing, that would be something that would come out after a dialogue between the FDA and the branded drug, and if

that were to happen, the FDA would have a game plan as to what's going to happen in terms of revising other labeling.

THE COURT: All right. What about the -- and I don't want to cut you off if you've got something else to say on that. What about the off-label promotion?

MR. PECK: Well, a couple of things about that. First of all, when they talk about off-label promotion -- I'm going to go back to the Barr example and what they're talking about. I know that's been submitted to the Court, but I want to go back over it so we go over what we're really talking about.

An off-label promotion is not, again, a claim. If, for instance, the argument is that you did something in talking about that drug that you shouldn't have said, that went beyond the labeling, we're now again into FDA enforcement. A violation of a federal regulation that you didn't promote it is really in a claim that you, again, violated FDA regulations, the duty comes from there, and that doesn't give rise to a private right of action. If what they're saying, which I think is really where they go to the next step, is that, well, what you did is you made these statements and then you didn't tell people to do something different in terms of the use or prescribing of the product that was in the FDA package insert. We're right back into the same territory. We're right back into the same position of them saying that they want the generics to say something different in the labeling than the branded companies

did, because the idea is, if you heard the claim, the claim as articulated by opposing counsel was, well, they made this statement, but then they didn't really tell people effectively not to use it continuously. Well, that's always been the complaint about the labeling in the first instance. It's just a circular argument getting back to the same thing, which is we want different labeling. But the generics can't change it. That's what *Mensing* says.

Now, the statement that's made that they continued to -- the print's small enough that I've gotten to a point where I've got to put these on to see it (indicating). Here is the statement. This is in a press release, a press release that was issued at the time that the approval for Barr's MPA product was given. Here's what was said. They said -- I'll skip. "Medroxyprogesterone, which has an estimated current annual sales of 160 million, is indicated for the treatment of abnormal uterine bleeding due to hormonal imbalance." That's one statement. I don't think there's any problem with that. That's the indication. Here's the one they take issue with. "This product is also often prescribed in combination with conjugated estrogens to treat postmenopausal symptoms." That's not a promotional statement. It's a statement to the investing community, who this is really directed to, about what doctors do. And while the plaintiff cited to Dr. Parisian's deposition, one of her depositions, she has acknowledged in a deposition in

the *Vance* case that that statement was accurate. There was nothing inaccurate about that statement. That was the standard of care at that time. It's not a promotional statement of any kind. It's simply telling the investment community this is how the drug is used. And that's part of the obligation you have to do, is tell the investment community, when you're a publicly traded company, how things are used, and that's what they did here. It's not off-label promotion. This is back in 1996.

THE COURT: Okay.

MR. PECK: But, in any event, it does not give rise to any kind of a legal claim because it is either trying to enforce an FDA regulation, which *Buckman*/21 U.S.C. 337(a) prohibits, or it's just a reconfigured failure-to-warn claim, you should have had different labeling. Either way, it's barred.

The last claim -- those are the three warning claims. I was going to move on to the design claim, if Your Honor didn't have any further questions on the failure to warn.

THE COURT: I don't. Move on, if you will, please.

MR. PECK: So the design claim, as Your Honor pointed out, they can't come in here and say you should have had a different molecule or done something different with it, so what they're trying to do is say you should have never marketed it, this thing should be off the market. Now, it's kind of an interesting claim when you think about it because if the product's not on the market, we're not doing a preemption

analysis, there's no need to do that if it's not being put on the market. We have to assume when we look at preemption that the product is on the market. And so we know that under the sameness, they can't attack the product on that basis. But there's another piece of this too. This exact argument, this idea of solving or pursuing a claim, I should say, based on the fact that you could have taken the product off the market was specifically addressed by the Supreme Court and by the Eighth Circuit and it was rejected in both instances. In fact, in the Supreme Court what happened is that the plaintiffs there went back, after the original decision, and said: Hey, we don't think you quite understood us. One of the things that could have been done here is that PLIVA could have taken its metoclopramide off the market until such time as it would have gotten the labels to where we think it should be, as plaintiffs. And the Supreme Court saw that supplemental briefing and denied the petition for rehearing. So the plaintiffs in *Mensing* went back to the Eighth Circuit and they said: Hey, you know what? We don't think the Supreme Court really heard us on this piece. We're concerned that people don't understand the argument we're making. And they made the same exact argument to the Eighth Circuit, that the way you can solve this --

THE COURT: I thought that only happened in this court, coming back to the same argument. You mean the Supreme Court and the Eighth Circuit have done the same thing?

MR. PECK: At least in this instance, yes.
THE COURT: All right.
MR. PECK: They confronted the same argument, plaintiffs in that case asked for supplemental briefing, and it was rejected there. It's an argument that they made in the Sixth Circuit in the *Smith* case. It's actually three cases, *Smith, Wilson, and Morris* that were dealt with together. And it was rejected there. And the reason is is because the court is telling people you don't solve this issue by taking the product off the market. That is not the solution. So this whole idea of saying that that's a claim that we should be able to come in and pursue has been rejected by the Supreme Court, the Eighth Circuit, the Sixth Circuit, and it's been rejected by a number of other courts who are cited among the 73 decisions we provided to the Court. One of the problems with it, of course, is that it directly interferes with the FDA's discretion. It's again another situation where they would be asking you to substitute your judgment for the judgment of the FDA. The FDA has said that this product is approved as safe and effective when it was an NDA product, Provera in the case of MPA, and that we're going to now allow those people that show they can make it the same-as, with the same-as labeling, to sell the product. And presumably what the argument is is that what should be done is that all the generics should be taken off the market so that people will pay more for Provera. That's contrary to

Hatch-Waxman.

So all of these are the reasons why these courts, including the Supreme Court, have rejected this argument. So what we now have is a situation, Your Honor, where all the claims that the plaintiffs have identified as surviving *Mensing* don't. They don't exist. They either don't exist or they're squarely preempted by *Mensing* or by *Buckman*/21 U.S.C. 337(a).

And I guess we didn't talk about it specifically, but there was -- there's been something about amending the complaints and that kind of thing. I know the plaintiffs said that maybe they'll get up and talk about it again. But at the end of the day, where are we going with those amendments? They told you what they think their claims are. They don't exist. They're not claims that they can pursue. And for that reason --

THE COURT: Isn't there a First Circuit case that says they exist?

MR. PECK: What the First Circuit case said, the *Bartlett* case -- and it is very clear that the *Bartlett* court, by its own admission, was operating at least contrary to the message from *Mensing*. We think it was directly contrary to *Mensing*. But the First Circuit has decided that it is going to ignore clear teachings from *Mensing*, including you don't solve things by withdrawing the product from the market. That's not permissible. The second thing that the *Bartlett* court was wrong on is the idea that the Hatch-Waxman preemption is somehow a

subset of *Levine*. It's not. The Supreme Court said very clearly in *Mensing*, Hatch-Waxman's its own baby, it's its own thing. It is very different from the preemption analysis that they talked about in *Levine* and that applies to branded products. It's its own thing, and you've got to analyze it under that. The First Circuit decided it wasn't going to do that.

THE COURT: All right. Thank you.

MR. PECK: Thank you, Your Honor.

THE COURT: Ms. O'Leary, do you want to do a brief rebuttal?

MS. O'LEARY: Yes, Your Honor, I would.

THE COURT: I assume you're Irish.

MS. O'LEARY: I'm not Italian, that's for sure.

I would like to address the preemption issue first. The defendants claim that what we're asking this Court to do is to enforce a federal rule, but that's not what the Supreme Court has held. We're not enforcing a private right of action. What we're finding is -- and just about every court in this country has held that FDA standards are minimum standards, and if you've failed to comply with even those minimal standards, then that's evidence that you are liable for the injury that you caused. So we're not out there acting on behalf of the FDA. The FDA is a very busy agency. It can't keep track of every time a company violates an FDA regulation. And, in fact, the preemption issue

that the Supreme Court in *Mensing* was concerned about was very similar to the one that the court in *Riegel* was concerned about, and the court in *Buckman* was, which is forcing a company to do something different from or in addition to what the FDA required it to do. But that's not what we're asking -- that's not what we're asking the Court to do. That's not the claim that we're making. We're arguing entirely consistent with FDA regulations, and, in fact, the Supreme Court has repeatedly held in at least three Supreme Court decisions that a state court action that's based on a violation of FDA regulations is perfectly fine because it's parallel to what the Federal Regulations require.

So this notion that this is a whole new breed of animal or it's utterly preempted is just not correct. It's not.

Also, I want to raise something else. It was argued, well, the plaintiffs are asking these generic companies to do something not required by the -- that the name brand companies didn't do. For example, if Provera didn't change its label, well, we didn't have to do that either. But that's not exactly true. In 2000, the FDA issued class labeling and directed all of the companies, including all the generic companies, to comply with the class labeling. It drafted it and said here's what's going to go in there, and that is what the FDA told these companies to do, every single one of them, sent the letter out saying here's the class labeling that needs to go into effect. Now, just because Pfizer didn't do it doesn't mean that Barr

shouldn't have done what the FDA told it to do as well. So that's something that is entirely parallel with FDA regulations, and that's what we're alleging, is that they didn't do what they were supposed to do at critical times when our clients were taking these drugs.

Another argument that the defendants have made repeatedly is that our three bases for failure to warn are completely off the reservation, that no court has held that, not even *Mensing*. And that's just not correct. If *Mensing* were so broad in its preemptive scope, we wouldn't have dozens of these cases circulating in the lower courts now trying to define what the scope of *Mensing* was. Some courts have held: Well, it definitely preempts all of these arguments or all of these warnings that are different from the brand name label. But other courts have held that that scope is not so broad. And these decisions are far from unanimous. Take California, for example. These are state court decisions interpreting state law and have held that the very same claims that we're proposing to make now are fine. Those are not preempted. And several courts have. It just raises the question of whether the Court should be making these broad decisions when the state courts are kind of in disarray about it. Some decisions go one way and some go the other. But it depends entirely on state law and how they interpret that.

So should we be just wholesale getting rid of 411 women's

claims and just throwing the baby out with the bath water? I think that's premature. At the very least, we should be entitled to go back, ask the questions that we missed when we took these depositions a few years ago. We've only had a short time since *Mensing* to digest it. But we should be able to go back, get the discovery that we want. We don't have any -- we have their ANDAs. Where are their documents, where are their internal documents discussing whether or not they're going to make those FDA class labeling changes? Why did they not send a "Dear Doctor" letter out? Those sorts of questions. And we should be able to do that, complete that discovery, and then once we're done, be able to amend our complaints. But I think that sending these cases back to the transferor courts, as we have done with all of our PPO-9 cases, Rule 16 provides an avenue to amend the complaints, and then Barr and the other defendants can move against them at that point, and then they can make their state law arguments, and the judges who are really familiar with how the courts define their own state statutes and their product liability laws are in a much better position to do that. But I think what would happen now is that we'd all have to amend our complaints, which I think is the proper thing to do, and then the Court would have to look at every single case on a case-by-case basis, depending upon which defendant it was, when the woman took the drug, what the doctor understood about the label, and what the state law has to say

about design defect, failure to warn, negligence. All those things. So it makes sense not to just dump everything out now and not to leave these 411 women without a remedy. We ought to be able to be given a chance to complete our discovery, there is no discovery cutoff in place yet, get that done, have the cases sent back and have them resolved on that basis.

THE COURT: Okay. All right. Just a minute. Time out just a minute.

(Court confers with law clerk.)

THE COURT: Have I heard you out on this issue?

MR. PECK: Go ahead. I'll listen. I had a couple of points, but it appears you --

THE COURT: Well, I asked a question, have I heard you out?

MR. PECK: I thought it was a declaratory statement saying "I've heard you out." I do have about four points, if that's okay?

THE COURT: Why don't you come around. I'll give Ms. O'Leary a chance to slap you around a little in sur-sur-surrebuttal, I guess.

MR. PECK: Where do I have to stand for that to happen?

THE COURT: All right.

MR. PECK: Your Honor, four points. First of all, the claim was made that there are parallel state law claims. That

is something that is a creature of express preemption. This is conflict preemption. It's broader. There's no such thing as parallel state claims. That whole thing -- and while we can go through an analysis of why this situation doesn't fit that, it's not even relevant. It's a different class of preemption in a more limited class of preemption.

There was a statement here that there are dozens of cases that have come out differently. That's simply not true. There are a few outlier cases. We discussed them in our briefs. But that simply is not true that there are dozens of cases. The vast, vast majority, and when I say "vast," I mean the overwhelming majority of the cases have gotten rid of these claims, and including the exact claims that the plaintiffs are trying to assert here. And it's interesting that among those 73 that we cited, and then there were four additional that we provided to the Court in our reply, there are a number of instances where the plaintiffs went back a couple of times and said, Wait a minute. We've got something else we would like to talk about. How about this? And the Court said no, they're gone. Their failure to warn, their design defect claims, they are gone, they are preempted by *Mensing*. And there are one or two cases, there's a sort of peculiar situation involving one defendant in the metoclopramide litigation, PLIVA, that did not make a label update in that circumstance where some courts, we think wrongly, have decided that perhaps there could be a claim.

The Supreme Court was aware of that at the time it decided *Mensing* and in its broad holding did not make any exclusion. But whatever that is and wherever that shakes out, it's not this case. The *Fisher* case that they cited to you as an exception, the *Couick* case, that's very much a specific situation as to PLIVA in the metoclopramide litigation. The cases that are on par with the cases before this Court, all of them, they're getting rid of these claims. And that's why -- and it brings me to that third point. That's why we don't have to worry about state law. We know what these claims are. They're failure-to-warn claims and design defect claims. People may put different tags on them, try to gussy them up a little differently. Right? But they're still failure-to-warn and design defect claims against generic drug companies that are preempted by *Mensing*.

The last point is is you several times asked counsel on the other side for specific cases, tell me which of the cases fit into this category, and you were never given that answer. You were given one sort of general thing, not a case, but talking about the Barr, you know, press release that we talked about. In addition to the fact that the claims are barred, they simply are not cases that they've identified that fall into these categories, and that's just an additional reason why the motion should be granted.

Thank you.

THE COURT: Two minutes.

MS. O'LEARY: I think I can do it in less.

Regarding the parallel state law claims and that this is a subspecies, a special species of preemption, it's not. The reason why those express preemption decisions such as *Riegel* said the things they did was that it was Congress's intent not to create a conflict between complying with state law and federal court. They explained it. It's almost identical. Just because Congress went ahead and said we're going to carve out this area of law is because we don't want state law to conflict with federal law. It is not a different situation. Courts have allowed cases to go forward based on violations of FDA regulations because they didn't comply with a standard, an identifiable standard.

Regarding the argument that the cases we rely on are outliers, I don't think they're outliers. Many of these decisions came from large groups of litigations like this. Pennsylvania, Judge Moss said it was completely inappropriate to decide all these different state laws in that particular forum, and she found that the allegations that were like ours would be allowed, she allowed us to amend the complaints. And so these cases weren't dismissed. There are many cases, even though they granted the defendants' motion, said: But we're allowing you the opportunity to amend because that's the right thing to do.

The fact that there are no differences in state law is

simply wrong. I mean, I can tick off Florida, Illinois, Pennsylvania, Vermont, California, North Carolina, South Carolina, all those cases where those courts held that failure-to-warn claims could go forward, those are all based on their own state laws. Trying to throw out entirely all of these cases just doesn't make any sense, not only because those differences in the way courts interpret state laws, but we have different facts. We have 17, maybe 20 different defendants here who want out on a wholesale basis. We need the opportunity to finish discovery against each of them. Each defendant might have done something differently. And maybe they might have sent "Dear Doctor" letters out, or maybe they might have all done the right thing, but we don't know yet. We need discovery and then we can amend our complaints and then the decision can be made on a case-by-case basis whether those complaints are sufficient. This is not a summary judgment motion. This is a motion to dismiss. We ought to be given the opportunity to do what we need to do to get our complaints amended and have another chance.

Thank you.

THE COURT: How about now, have I heard you out?

MR. PECK: I promise, one point. And I will come up to the podium.

THE COURT: I'm beginning to feel like a ping-pong ball.

MR. PECK: Sorry about that.

Your Honor, *Mensing* was on a motion to dismiss. *Demahy*, motion to dismiss. Fosamax, MDL, motion to dismiss. Pamidronate, MDL, motion to dismiss. Propoxyphene, MDL, motion to dismiss. All of those motions granted because the courts properly recognized there was a governing principle of preemption here that barred the failure-to-warn and design defect claims.

Thank you.

MS. O'LEARY: Those cases, master complaints. We don't have master complaints here. In fact, Barr objected to our having master complaints, so we have individual complaints here. They have to be dealt with on an individual basis. The Supreme Court did not deal with those issues precisely. It dealt with a very narrow issue. One-page decisions from the Eighth Circuit and the Sixth Circuit.

Thank you.

THE COURT: Have I heard you out?

MR. PECK: Your Honor, I don't want you to feel like a ping-pong ball anymore. We are finished. And thank you for your attention.

THE COURT: All right. Well, you know, I don't know when to tell lawyers to stop. Your arguments have been forceful. One of my absolute biggest pet peeves -- it wasn't a small peeve either -- it was being cut off by courts on oral

argument, particularly appellate courts, federal and state, when they didn't understand the facts, and I'd be trying to explain it to them, and I lost a goodly number of cases on appeal because appellate courts didn't understand the facts. And it's been nearly 19 years since I've had that experience, but I can hold a grudge pretty well. I can remember those cases I lost very well.

All right. Let's move to the issue of Wyeth's motion to enforce protective order. Let me say this. I agree basically with Wyeth's position, the defense's position that an end-run has been made, but the question is, what can I do about it? I've been struggling with that idea and I can't come up with -- maybe you have an idea that's not in the papers. I don't know. I think there needs to be federal legislation in the MDL area.

MR. GEYERMAN: Well, Your Honor, I don't have an idea that's not in the papers, but just to articulate why what is in the papers we think is a reasonable solution at this point.

On the motion to enforce a protective order, at the time that Your Honor entered the protective order quashing the 30(b)(6) notice in this proceeding, the Plaintiffs' Steering Committee had advised the Court that there was the possibility that the deposition would go forward in a state court. Nevertheless, the Court entered the protective order in this proceeding. And so the relief we're seeking is not -- we're not asking for Your Honor to commandeer the *Morgan* court in Los

Angeles, or any state court, into how it ought to deal with the *Morgan* deposition. But if your protective order is to have any significance in this proceeding at all, we think it's reasonable to say that any testimony that's elicited in that deposition can't be used in a federal proceeding, admitted into evidence, or can't be used in any way.

THE COURT: Suppose I rule that, what keeps a district judge and transferor judge from saying "I don't have to pay any attention to that"?

MR. GEYERMAN: First of all, if the case is still before -- if the proceeding is still in the MDL and then it gets remanded, we would argue that that's law of the case, of that case and, therefore, your ruling is binding. For cases that are already in transferor courts, we probably will have to have briefing in the transferor court about the significance of your ruling today or tomorrow or whenever it comes out. I think it will be persuasive to the transferor courts to see how you handle this issue, even if, as a matter of law, it might not be binding on a transferor court that already has the case back before it, I think it will send a message to the transferor court to say: Well, at least Judge Wilson entered this order because he believed that his protective order entered on April the 11th of this year ought to have meaning in federal proceedings.

THE COURT: Could the national Congress pass a law

that would -- my feeling is that the basic purpose of MDL is being undermined, and I know that's your feeling. But what could the national Congress do, if anything?

MR. GEYERMAN: I haven't given all that much thought to that, Your Honor. Obviously, we're in a federal -- we have our Federalism system, and so we have to deal with any inherent tension between federal and state court, which is why we limited the relief we're seeking here to admission of this deposition in federal cases.

THE COURT: Okay. Let me hear from the plaintiff. As you might anticipate, I'm against your position pretty much, but I don't know if I can do anything about it.

MS. LITTLEPAGE: Judge, the facts of this particular situation -- I'm dealing first with the *Morgan* case and the blood clot deposition case, because I think that's a very different issue. We did not in any way intend --

THE COURT: Keep in mind you need to talk slower than you usually talk.

MS. LITTLEPAGE: Yes, sir. We did not intend or set out to have an end-run against any of this Court's orders. When I realized that the blood clot deposition that we had been promised by Wyeth, that we believed we had an agreement from Wyeth would occur, they had told us who was going to be deposed, we had asked for dates, they had agreed we could take the deposition after the generic cutoff, we thought we had an

agreement. When I realized that we had not efficiently or expediently followed up on that agreement and actually taken the deposition of Dr. Camardo, as Wyeth had offered us and told us that we could have, I issued a depo notice in the MDL, in Pennsylvania state court litigation, and in Mrs. Morgan's case, because Mrs. Morgan's case is set for trial, and she lost her leg to this drug from a blood clot injury. So we have no blood clot depositions, no blood clot evidence. We have a state court case that's set for trial, and we've got, obviously, MDL cases that this Court is now remanding back to transferor courts that deal with blood clots. I didn't do an end-run. I didn't go just to the state court. I issued the depo notice in all the jurisdictions. I believed we had an agreement with Wyeth that Wyeth would present this witness for deposition. Wyeth opposed that deposition notice and filed a motion to quash. And it was my fault, Judge. At the time, Mr. Williams, Mr. Mike Williams had been handling this case. He was going through some of the discussions with Wyeth when this occurred. He was under strict instructions that he was not allowed to help the PSC in any of its efforts anymore. And so my response to the motion to quash was not a good response. In that response, I did not have the documents that Mr. Williams had showing that Wyeth had agreed to give us this deposition, had agreed the generic cutoff would not apply to it, had agreed who it was going to be, and then had told us that person had left the company and they were looking

for a new person to put in place. So my response was bad. The Court granted Wyeth's motion to quash because my response was bad. But in your order you said: If you want me to reconsider, plaintiffs, tell me why you waited this long. I then responded to this Court and said: Judge, in the interim, this state court judge has ordered the deposition to go forward, so there's no reason to relitigate the issue in multiple jurisdictions because the depo's going to happen. Wyeth then has filed another motion to make sure that that state court deposition can never be used by any blood clot plaintiff in the MDL. And in my response to that second motion, I finally had gotten the document from Mr. Williams that showed Wyeth's agreement, showed that they had said they would give us this deposition, showed that they had agreed we could have it in the MDL, and it was the PSC's fault that we did not take it as expediently as we should have. I agree, we should have followed up on that quicker, we should have done more, but to be honest, Judge, we thought we had an agreement.

THE COURT: Let me ask you this. This is at issue. You said Mr. Williams was under agreement not to cooperate with you. Is that permissible? Is that type of agreement permissible?

MS. LITTLEPAGE: I think that parties can agree to stand down on various issues in recognition of a settlement. Now, Mr. Williams obviously can work on the generic issues. And

Ms. O'Leary is here from --

THE COURT: Suppose they just said, "We'll settle with you and your clients if you won't have anything else to do with the litigation against our company," is that permissible?

MS. LITTLEPAGE: I think the lawyer, on a personal level, can decide whether he has an agreement, whether it's in writing or a handshake. I think each lawyer can decide for themselves where they are on that issue.

THE COURT: All right.

MS. LITTLEPAGE: So, Judge, I think on the *Morgan* issue, which is a very, very critical issue, because we are now facing women coming back out of this court who do not have discovery. They do not have blood clot discovery. And all we're asking for is a single, one 30(b)(6) deposition of someone knowledgeable on these issues to answer our questions. We had an agreement with Wyeth they would do it. Wyeth had agreed it could be done after the generic cutoff. It wasn't done. It's now become an issue because these cases are coming back. They're being set in state court. They're coming back to federal courts. The deposition is going to occur in the *Morgan* case in California because that judge has ordered it. And there's no reason for it not to be able to similarly be applied to all the MDL cases. What Wyeth is asking for is for the MDL plaintiffs to be punished, but I don't know why we should be punished. We thought we had an agreement. And, yes, we didn't

follow up as quickly as we should have, but now that we are following up, we would like our agreement to stand and we'd like the deposition, and we'll take it in the *Morgan* case, but there's nothing under the federal rules that says it couldn't be used for the MDL plaintiffs, because they need it. So that's on the *Morgan* issue. I know there are some other issues we can talk about separately. But the *Morgan* issue, there's no end-run. We didn't try an end-run. We filed it in every single jurisdiction at the same time.

THE COURT: Let me ask you, was it not an obligation of the Plaintiffs' Steering Committee to seek discovery in this court before asking for a remand?

MS. LITTLEPAGE: Judge, actually, if you look back at the status conference transcripts, we told the court in September of 2009 that we were finished with generic discovery on the breast cancer injuries only, and we informed the Court that we had an agreement that there were some nonbreast cancer injury discovery that was ongoing, and then we focused, unfortunately, on the *Daubert* issues because that's what came up in the blood clot injuries and we never followed up with the deposition discovery. But the Court then started remanding blood clot cases, and that was obvious to the Court, we'd been asking the Court to remand and we certainly weren't going to object to the Court remanding. But I absolutely accept responsibility, we should have done this deposition earlier. We

thought we had an agreement, and it was not time sensitive, but it's really needed now. And it's a single deposition that's going to be taken anyway. All we want is it to apply to federal cases.

THE COURT: All right. I'm going to call you "Mr. Grant" because I get your last name mispronounced every time.

MR. GEYERMAN: It's "Geyerman," but I will answer to "Mr. Grant." That's fine.

I spoke with my colleague Mr. Urbanczyk yesterday before I came here because he was the individual who is on the e-mails that are attached to the plaintiffs' opposition brief about this agreement, and his recollection was consistent with the latest word on the issue as attached to the plaintiffs' motion, which is, he says: "Mike, I'm awash in alligators. I've asked Bill," Bill Murray from our firm, "to respond. I have a firm recollection we're going to mutually stand down in the discovery. I'm happy to renew the effort, but please don't jump me with something at the 11-20 hearing in this. We can work this all out in a reasonable time frame."

We did have an agreement that there could be some other injury discovery that occurred after the September 1, 2009 time frame, but we certainly believed it was going to occur within a reasonable time frame. And the 30(b)(6) deposition notice here was not issued for two and a half years. Now, the suggestion that Mr. Williams was under some prohibition from raising this

issue really doesn't conform with the timing. Mr. Williams exited this litigation the same month that the deposition notice was issued, at least as to Wyeth. So the suggestion that, you know, his obligations under a contract prohibited this issue to coming to a head is simply not true.

So the bottom line is, we're not disputing that there was a discussion in the fall of '09 that said some things can spill over, but the documentation is this should happen in a reasonable amount of time. We're now two and a half years out. Nothing was followed up on. And the individual who we told the PSC we would have designated as a 30(b)(6) witness is gone by now.

This is really a side issue. I think your ultimate point, which is this is very troubling to you, that you've entered an order and that subsequent developments in other jurisdictions are undermining the effectiveness of that order still rings true, irregardless of whatever e-mailed communication from November of '09 shows. So we would ask that you enter an order that says that this deposition can't be used in federal cases from here forward.

THE COURT: "Irregardless"?

MR. GREYERMAN: Irregardless of the agreement, that's right.

THE COURT: I love that word. Judge Waters -- the late Judge Waters would come unglued. Over in Scott County,

where I grew up, it was "ir-by-God-regardless." I don't want to repeat that. That would be blasphemous.

MR. GEYERMAN: Are we ready to move on to the next issue?

THE COURT: What is the next issue?

MR. GEYERMAN: Well, the next issue is related. It's the motion to show cause about seeking generic discovery in remand courts. So it's related, but it is distinct.

There have been three motions to show cause that have been filed, and I see that on the agenda all three docket numbers are listed. At this moment, we think that only the third of those motions is live. The first is moot because -- or it was resolved because on May 8 of this year, the Court, in a letter order, addressed the first motion to show cause, and you noted that you have an unquiet mind to a considerable degree about generic discovery being sought in remand courts. Three weeks after you made that statement, lead counsel served Wyeth with a draft motion to compel in a transferor court, the Corso case in Connecticut, that raised several interrogatories and document requests that seek generic information.

THE COURT: Are you talking about the motion to enforce federal rules regarding supplementation of discovery?

MR. GEYERMAN: No, Your Honor. I think it's item 3 on the agenda.

THE COURT: Hang on just a minute. Oh, yeah. I

overlooked a page of my outline here.

MR. GEYERMAN: No problem. So three weeks after Your Honor said you had an unquiet mind about generic discovery being sought in the transferor courts, we get served with a draft motion to compel in a Connecticut case. And that draft motion to compel included interrogatories and document requests that address such subjects as the salaries paid to former Wyeth employees, the documentation supporting statements in the Prempro labeling, the amount of money that we spent advertising Premarin and Prempro, the amount of money we spent studying the product. With one exception, all of those topics were addressed in discovery requests, propounded in this court before the generic discovery deadline. And while it's really kind of beside the point for purposes of the instant motion, I don't want you to think we just ignored this. We responded to this discovery. We've produced the documentation supporting the Prempro label. We've produced how much we've spent on marketing and advertising. We produced IMS data. We produced the studies of Premarin and Prempro to evaluate the breast cancer risk. The few things that we didn't respond to was either because Your Honor had entered an order denying that very discovery to the Plaintiffs' Steering Committee, for example, some of the very private financial information on these Wyeth executives' compensation packages, or we objected, we took a position and said this is kind of a fishing expedition and you've really gone

outside the bounds of reasonable discovery. For example, we'll produce sales reps' custodial files, but we're not going to produce the sales rep managers' custodial files. And so we objected on that basis. All of that was done before the generic discovery deadline. And if the plaintiffs had a problem with the adequacy of our production or objections, they could have moved to compel certainly before the discovery deadline and certainly before now, 2012.

In their opposition to our motion to show cause, the third motion to show cause, importantly, the plaintiffs don't dispute that generic discovery is the province of this Court. You determine when it starts, you determine its scope, you determine its duration, and you referee disputes concerning generic discovery. So, therefore, the question is not are there some interrogatories and document requests that seek case-specific information before the Connecticut court. Rather, the question is, why are there some requests that clearly seek generic information that were propounded in the Connecticut court and that now find itself in a motion to compel in the Connecticut court that's fully briefed and awaiting a decision.

So knowing that it leaves Your Honor with an unquiet mind that this practice is happening, the generic discovery is being sought in transferor courts, and knowing that you're searching for a solution, what we think is a reasonable first step on this issue is to force lead counsel to articulate on the record why

documents supporting the statements in the Prempro label, why the amount of money spent advertising Premarin and Prempro, the amount of money spent testing Premarin and Prempro for breast cancer risk, why those document requests were pressed in the transferor court. If there is no good explanation for that, which we think probably will be the case, perhaps that will discourage counsel from continuing to serve these types of interrogatories and document requests in the transferor court. Maybe that's wishful thinking, but we'll give it a shot. And if for some reason, and we can't envision what it would be, they have a good explanation for why this is happening, then maybe we won't have to file a fourth motion to show cause. So this is the best we think we can do at the moment.

THE COURT: For the plaintiff? Talk more slowly.

MS. LITTLEPAGE: Yes, Judge.

Wyeth has now filed three motions to show cause. Two are moot because one was Ms. Presby, who settled all of her cases, including the case where the motion to show cause, the transferor motion to compel was filed. The second was against Mr. Millrood, who was another PSC member. He has also settled all of his cases and is gone from the litigation, so that mooted that issue because that was filed in one of his transferor courts.

The only remaining issue is against me, Judge, so I want to address that specifically, because when I got your order that

you had a disquiet mind, I was very cognizant of that, very, very cognizant of the Court's feelings and my obligation as lead counsel when I filed my motion to compel in the Corso case. So when I originally sent Wyeth my draft motion to compel, I had, I don't know, 50-something requests that I wanted to compel on. We had a three-and-a-half-week meet-and-confer process, and Wyeth raised with me a number of those requests that they felt were generic and would fall under this Court's disquiet-mind category. And I withdrew them. And I did not file a motion to compel in my transferor court for that discovery, although I would love it, and I think it would be great for my woman. I, as lead counsel, made the decision to abide by this Court's rulings and to not pursue a motion to compel on those issues. But I did file a motion to compel on specific issues that relate to my woman's case coming to trial this November in Connecticut. So I want to address just a couple of the ones that Wyeth raised today.

Salaries. In Connecticut, I'm close enough to be able to subpoena many of Wyeth's former employees to come live for trial. Those employees are now on consulting agreements with Wyeth. They've been on consulting agreements since 2009. They're listed by Wyeth in that case as experts for Wyeth. So I asked Wyeth to tell me how much they had paid those consulting experts under their consulting agreements so that when they come live at my trial under a subpoena, I have some ability to show

the jury absolutely admissible bias and credibility evidence as to how much these people have made being experts for Wyeth since they left their employment. This does not conflict with generic discovery in the MDL. It's specific to my case in Connecticut where these people will come live, at least some of them will, I hope, if I get my subpoenas served. And I'm entitled to show that they are still on Wyeth's payroll and how much they get paid per hour and how much they've been paid to come in and be Wyeth's expert. That's a specific issue narrowed to my case.

The second is, Wyeth says I don't have the right to ask for district manager files? Well, we saw some documents in the sales reps' files from my case in Connecticut that showed memos coming from the district manager, where the district manager was specifically telling Connecticut sales reps to promote this drug off-label and to minimize the breast cancer risk. That's a specific issue to Connecticut. And I'm absolutely entitled, on behalf of Mrs. Corso, to pursue that discovery. Now, if my Connecticut judge says I'm not, if the Connecticut judge says, "Look, we don't need to know what district managers do in the state of Connecticut," that's her prerogative, but it is not a generic issue. We have not sought full-scale production of every district manager file in the whole country. But because of stuff I saw in the Connecticut sales rep files, the district manager files are particularly important to Mrs. Corso's case and, therefore, I've moved to compel their production. And the

Connecticut judge will agree or disagree with my arguments, but it's for her to decide because it is a very specific issue to her case.

So I do resent Wyeth's motion to show cause as if I flippantly ignored this Court's orders. With great concentration, I considered what this Court wanted me to do when I actively prosecuted Mrs. Corso's case, and I took dozens of requests that I was going to move to compel on and I narrowed it down to specific issues that I know from history are important to me presenting Mrs. Corso's case and that I believe are specific to her case. And I don't believe there's any end-run, and I certainly don't believe that -- there's only two -- well, three, Mr. Cloar -- three PSC members left; Mr. Meadows, myself, and Mr. Cloar. Under Wyeth's assertion, any lawyer in this country can go out and actively prosecute their client's case in a transferor court, but I can't, and that I resent, because my client is entitled for me to bring all of my energy to her case. But I did take into account this Court's counsel when I filed my motion to compel and, therefore, I narrowed it.

THE COURT: Mr. Grant.

MR. GREYERMAN: I'll say again, the question is not were there some case-specific discovery requests that were served in the Corso case. The question is, why were there plainly generic discovery requests also served in the Corso case.

Ms. Littlepage served the draft motion to compel first. Myself and her associate engaged in three lengthy meet-and-confers, and she's correct that probably a dozen requests were removed from the motion to compel that ultimately was filed. But here is the motion to compel that was filed, and here are some of the requests that remain in the motion to compel. I'll put them on the screen here.

"Underlying Support for Representations in the Prempro Label." This was discovery that was taken in 2003 in the first set of document requests. At the very bottom of the screen, "Termination of relationship with Burson-Marsteller" or "Wyeth's contractual relationships with public relations firms," "Wyeth's communications with Dr. Steven Cummings." These have nothing to do with Ms. Corso's case in particular. These are plain vanilla, generic discovery. And notwithstanding what Ms. Littlepage just told you, there was no answer to the question, why is she asking for this discovery in Connecticut? That is the point of our motion. And it's not about the motion to compel itself. It's about serving the discovery in the first place, because sure it's an annoyance to us to have to defend a motion to compel, but we had to answer this discovery in the first instance. And as our brief points out, this same discovery has been served in at least 16 different remand cases. So why the Connecticut court is the first forum in which it's gotten to the point of a motion to compel, I'm not sure. It

might have something to do with the fact that the judge right now has under advisement how much punitive damages she ought to award based on the jury verdict in the *Fraser* trial, but I'm speculating.

The bottom line, we've been facing these generic requests in at least 16 remand courts and there's no good reason for it. And we're not saying this is anything to do with Ms. Littlepage's position in particular by virtue of being lead counsel. We'd bring this same motion if a lawyer that's not on the Plaintiffs' Steering Committee had filed this as well. It might be a bit more egregious by virtue of her position, but we're not saying that these requests would be okay --

THE COURT: What about the two examples she gave, the consulting experts, how much you're paying them?

MR. GEYERMAN: Yeah. We don't think that her explanation fits the scope of what's asked for, Your Honor. Take a look at the interrogatory. They're asking for compensation packages back to 2007. That is when these witnesses were employees of the company. So if the argument they want to be able to make at trial is you're on a consulting relationship with Wyeth now, therefore, you have a financial incentive now to be testifying favorably about Premarin and Prempro, that has nothing to do with tell us what their total compensation package was back in 2007.

THE COURT: In other words, you concede she's entitled

to see how much they're being paid as a consulting expert?

MR. GEYERMAN: I think a footnote in our brief says we'll disclose that if they, in fact, testify at trial. We have no problem with that. I don't think that's really the basis behind why these discovery requests were propounded. Keep in mind, these discovery requests were propounded in the fall of last year, before, I believe, and I'm not certain on this, but before, I believe, there were any expert disclosures in the Corso case. So to suggest that our expert disclosures were the motivation behind this request is disproven by the chronology.

MS. LITTLEPAGE: Judge, just two quick points. I think it's clear Wyeth and I are never going to agree on the line that differentiates generic versus case specific. There are clearly things that are absolutely generic.

THE COURT: What I just saw there is different from just asking for their consulting fees.

MS. LITTLEPAGE: But remember, these discovery requests were drafted years ago when some of them were still employed and have now turned into consulting experts.

THE COURT: But why would you be entitled to anything other than the consulting fees, if they testify?

MS. LITTLEPAGE: Well, because some state law and, in fact, in many of the remanded cases and in many of the state court cases, we have been entitled to ask Wyeth employees who are on the stand testifying as experts how much they got paid as

an employee of Wyeth.

THE COURT: Before they became --

MS. LITTLEPAGE: Before they were paid under a consulting agreement, and then how much they've been paid under the consulting agreements. It's based on --

THE COURT: Under what theory is that produced, their former salaries? What does that show?

MS. LITTLEPAGE: Because when Wyeth started listing them as experts on their expert disclosures, how much an expert gets paid is part --

THE COURT: Well, I agree with that. I agree with that. But what about how much they got paid when they were employees, why is that relevant going to credibility?

MS. LITTLEPAGE: Well, because some judges have ruled it is and some judges have ruled it's not. And in my cases, Judge, sometimes judges have allowed me to ask what was their salary but not get into their stock options, some judges have allowed me to ask their salary and their stock options, some judges have allowed me to ask their salary and how many stock options they cashed in. It depends on the ruling of each individual judge based, of course, on whatever case law I can find in that state that supports the issue. But what's interesting, Judge, is that when we had our three weeks of meet-and-confer, Wyeth refused to give me any of this information. It took me filing the motion to compel for them to

put the footnote in that said they would give me the consulting agreement information if I got a good subpoena on the person and if they were going to come live. So the motion to compel process is working. I think clearly the absolutely generic issues are not part of my motion to compel because I didn't file them. What I did file are things that I believe are case specific. Wyeth has responded to my motion, telling the Connecticut judge that they're all generic and that I'm not entitled to any of them. And ultimately she'll rule, but I think that's her ruling --

THE COURT: When will she rule? Has she indicated?

MS. LITTLEPAGE: No, Judge.

THE COURT: When is it set for trial?

MS. LITTLEPAGE: It's set for trial in November.

THE COURT: All right.

MS. LITTLEPAGE: So I think at this point we're now at a point where I believe things are case specific and they believe it's generic, and it's not for this Court to make that decision, it's for the judge that has the case-specific case to decide if this is something she believes is relevant to her case or not.

THE COURT: Okay. It's your motion, isn't it?

MR. GEYERMAN: It is our motion. Nothing further from me.

THE COURT: All right. Let's move to -- I believe

we're ready for plaintiffs' motion to enforce federal rules requiring supplementation of discovery and motion for leave to serve additional discovery, Docket No. 3046.

MS. LITTLEPAGE: Yes, Judge. And here is my concern with Wyeth's position in this case. What Wyeth has said in its response is that the generic cutoff of 2009 eradicated its obligation under the federal rules to continue to supplement discovery responses.

THE COURT: Well, how are the materials that are later than that date, how are they relevant?

MS. LITTLEPAGE: Well, the particular documents that we're seeking is Wyeth's continued efforts to ghostwrite and impact the public literature, even after 2009. It's very important because we're seeing some prescribers show up in these transferor cases that are still buying sort of what we consider outdated science, but they're basing it on some newer articles that they're reading, some newer things that they're seeing. And the only way for us to rebut that testimony -- and as you know, the prescriber's testimony is crucial in a case -- is to show that Wyeth impacted or influenced the things they are relying on even today. And it's not that we didn't ask the requests. We did. It's not that we didn't ask the requests timely. We did. It's not that Wyeth didn't agree to give us the documents, because they did. Wyeth just has taken the position that 2009 stopped their federal rule obligation to

supplement. And they certainly have taken the opposite position as to the plaintiffs. They moved to dismiss a plaintiff's case if she doesn't supplement her HIPAA, if she doesn't supplement her medical records, if she doesn't supplement her fact sheet. They have taken a very strong position that we have an ongoing obligation to supplement the information that the plaintiff has. And this is a valid request that was filed timely, that Wyeth answered, and all we're asking for now is for them to follow the federal rules and supplement that answer on that specific issue. Again, we're not going back to try to supplement on every single thing. But on that issue, it has come up in a couple of cases, it is an important, crucial issue, and it's an issue that they don't contest we validly asked for, they just don't think they have any obligation to supplement it.

THE COURT: For the defense.

MR. GREYERMAN: So there's two issues that this motion raises. Number one, is Wyeth obliged to supplement its prior discovery responses, and, two, even if it is not, should plaintiffs be granted leave to get this additional discovery? I had thought, based on the plaintiffs' reply brief, that they were conceding that this was not a matter of supplementation under the federal rules because they don't even discuss our long body of case law that we cite that says for purposes of Rule 26 supplementation, there's a distinction to be made about documents that existed at the time that you make a production

and that you don't produce and documents that are created after the time that you make a production and then are created because of ongoing business relationships or business activities.

The rule on supplementing is geared to making sure that you have a complete and accurate production. And if you come to learn that your prior production was incomplete or inaccurate, you've got to cure that, but it doesn't mean that you have to continue to provide documents forever if you're a going concern, business.

I think, Your Honor, that the argument on supplementation really is a pretext here because it was not the argument that was advanced in the Northern District of Texas before Judge Furgeson when this discovery was first propounded. You'll recall that the Miller Weisbrod firm started by filing these interrogatories and document requests in front of Judge Furgeson and asking for expedited production. They said in a very odd, conspicuous disclaimer in the beginning of their document requests, which we block quote in our brief, this is not duplicative of generic discovery in the MDL. It's new discovery that's come to light since the MDL proceedings, therefore, give us the discovery. So they were saying this is new discovery and not a matter of supplementation. So I think the supplementation issue really goes away because of the case law. What we're talking about here is new discovery. Should they be entitled to evidence about alleged ghostwriting from September 1, 2009

onward? And I think the answer to that is no, and here's why. The argument that has been advanced in the briefs by the plaintiffs as to why this information is necessary today is to counteract the plaintiff's -- or excuse me -- the treating physician's -- the prescribing physician's testimony that they continue to prescribe hormone therapy today. And as Ms. Littlepage was saying in her argument, the plaintiffs are trying to suggest that Wyeth is polluting the medical literature using ghostwriting in 2009, '10, '11, and '12 and, therefore, they need this evidence. First of all, I don't think there is a good-faith basis to make that statement. We haven't seen any -- they talk about one prescriber who simply said: "I don't rely on the label. I rely on the medical literature." But there's no suggestion that Wyeth's been influencing that medical literature. But even if you wanted to say that ghostwriting evidence was necessary to allow plaintiffs to have this argument to rebut this testimony at trial, what they have is seven years' worth of evidence from July of 2002 through September of 2009, and in that seven-year period of time that evidence could be used to say, well, notwithstanding the change in the WHI label and the doctors' prescribing habits, they continue to prescribe the product, and we say that that disproves proximate causation.

So my point is that they have seven years' worth of evidence with which to make this argument. They don't have a good-faith basis to say that there's been any polluting of the

medical literature since September of 2009. And, really, this is just an attempt to create and make work that the generic discovery deadline was entered for a reason, and we don't think that it should be reopened on this issue.

THE COURT: Thank you.

Slowly.

MS. LITTLEPAGE: Yes, Judge.

We filed, in our motion, alternatives. Either this is a valid discovery request that Wyeth answered originally and doesn't want to supplement or we need the information. Either one. In their response, Wyeth admitted that we had asked for it originally, that they had given us the information, and that they did not believe they needed to supplement under the federal rules. So whichever way the Court wants to hold, whether it's asking Wyeth to supplement or allowing us this discovery, we've covered both bases in our motion so that we could be sure we could get it.

Again, one of the things that's relevant, for example, Judge, there are many states out there that the scope and the amount of punitive damages that you can receive under that state's law is impacted by whether there's evidence the corporate defendant reformed or didn't reform, in other words, stopped doing the willful misconduct or didn't stop doing it, and that impacts how the issue goes to the jury and how the judge actually enters a punitive damage verdict. So Wyeth's

continuing misconduct in terms of ghostwriting is very important for us because it impacts what the prescribers are telling us and it impacts state law in some of those cases. Wyeth says we don't have a good-faith basis for asking for this. Interestingly, Wyeth never filed a single affidavit attached to their response saying "We're not doing it anymore." If they weren't doing it, they would have told the Court: "We're not doing it anymore. Here's our precedence certifying we're not doing it anymore. There's nothing to discover." The reason we believe there's something to discover is we are seeing repeatedly people that we know are Wyeth's consultants, that are paid by Wyeth, that are Wyeth's spokespeople, showing up, publishing review articles, for example, trashing the Million Women study, a very important study for us, and the Court has seen it multiple times in these trials, the British study that shows a doubling of the risk after a very short exposure to E+P. We're seeing review articles being published by authors that we recognize as previous ghostwriters for Wyeth, authors that we recognize as paid consultants for Wyeth, and we need to be able to address the validity of that review article. Is it really an independent review or is it Wyeth ghostwriting?

So whether it's a supplementation or whether the Court says I'm granting you leave to do this discovery, it's discovery that we need, it's on a limited issue, and it's very important to the remanded cases.

THE COURT: All right. What about state court litigation?

Does anybody need a break? Even Mr. Cloar? All right. We'll go ahead.

MS. LITTLEPAGE: Judge, I'll go quickly then.

Let me go through all the different states. Pennsylvania, with Mr. Tobi Millrood settling his inventory of cases, that resolves about 90 percent of the Pennsylvania litigation. There is Mr. Meadows from Beasley Allen, the other remaining PSC member, has some remaining Pennsylvania state court cases. Six of them are set for trial in October. And I guess the Pennsylvania judge will now start setting only Mr. Meadows' cases because I think he's the only one left in Pennsylvania. In Nevada there were two sort of groups of cases, one in Reno and one in Las Vegas, that were consolidated in front of a single judge in each place. The judge in Reno, Nevada unexpectedly died over Christmas, and in February, the Nevada lawyer was able to resolve all of the Reno cases before a new judge got assigned that docket. So the Reno cases are gone, but the Las Vegas cases remain. And the next group of Las Vegas cases --

THE COURT: How many are there in Las Vegas?

MS. LITTLEPAGE: I think there's 80. And the next group of those Las Vegas cases, I think a grouping of four plaintiffs just got set for trial the beginning of next year.

In the federal litigation, there is, I think, a dozen cases set between now and the end of the year where the person is represented by either Mr. Meadows or myself. There's really not very many other lawyers left. I think we're now at about 75 to 80 percent of the litigation has been resolved through inventory settlements. But the two large inventories that remain are Mr. Meadows and myself, and there's obviously a smattering of people who have five, ten, 15, 20 cases.

THE COURT: What about the short-term case in the Eighth Circuit, what's the status of that?

MS. LITTLEPAGE: We haven't heard anything on it. We expect a ruling virtually any day.

THE COURT: When did you argue it?

MS. LITTLEPAGE: I think Mr. Walker argued it early this spring.

MR. CLOAR: January. End of January.

MS. LITTLEPAGE: January. Right at the beginning of the year.

THE COURT: By the way, for those of you that weren't convivial enough and congenial enough to join us at the reception last night, Mr. Booth is now the new Erik Walker.

MS. LITTLEPAGE: He is, and he whines about it every single day.

THE COURT: He did complain a little.

MS. LITTLEPAGE: Judge, obviously, we're seeing

tremendous movement in the litigation. Bristol-Myers has settled completely. That's one of the smaller defendants. They've resolved all of their claims. Solvay has resolved all of their claims and are gone completely. Aventis has resolved all of their claims and is gone completely. So we're seeing full defendants leaving, and then we're seeing Wyeth and Pfizer go through and settle their claims against lawyers that represent a mass inventory. So certainly in the last six or eight months we've seen a tremendous progress towards the end game in the litigation. I think we've still got some work to do, but we're definitely much further along than we were even at the end of last year.

THE COURT: All right. Thank you.

Does the defense have any statement on this?

MS. PRUITT: No, Your Honor.

THE COURT: Anything else we need to take up?

MS. LITTLEPAGE: No, Judge.

THE COURT: For the defense?

MR. GREYERMAN: No, Your Honor.

THE COURT: Good to see all of you, and even those who weren't gregarious enough to join us last evening, and I'll see some of you in August. We are in recess.

MS. LITTLEPAGE: I'm sorry, Judge.

THE COURT: We're not in recess.

MS. LITTLEPAGE: We're not in recess. Can I raise one

issue with the Court?

Mr. Booth and I will be trying the August case before Your Honor. One issue has come up. With the time limits that the Court has given us, we're going to try and present the bulk of the plaintiff's case-in-chief the first week of trial with maybe running into the first couple of days of the second week, depending on how long Wyeth's crosses are, obviously. One of our witnesses for that first week is Dr. Cheryl Blume. I know the Court has met her before. She is a former pharmaceutical executive. She has FDA meetings set that week that cannot be moved. And so I want to ask the Court --

THE COURT: If you can call her out of time?

MS. LITTLEPAGE: If I can call her out of time. If I can call her, I would not be able to finish her, she can go to her FDA meetings and we could bring her back. If we can do Saturday, that first Saturday, I can do her then. But some accommodation.

THE COURT: Any objection?

MS. PRUITT: Your Honor, I don't have any objection. This is the first I've heard of it. We should be able to meet and confer and work this out.

MS. LITTLEPAGE: I just wanted to ask the Court if the Court had any preference which one. But I'll try to work it out with the defendants so that we can get her maybe in pieces or maybe Friday and Saturday. Would the Court be willing to do

Saturday court that first week?

THE COURT: If necessary. But I don't want to do it unless it's necessary because there's a heck of a problem with the CSOs. I don't mind at all. As a matter of fact, I rather be in court because my wife wants me to work around the place on Saturdays. But I rather not go Saturdays because it upsets other branches of the court family. But we will, if necessary. You all see if you can work it out. If you can't, I'll resolve it. But calling her out of time would be all right.

MS. LITTLEPAGE: Thank you, Judge.

THE COURT: Anything else?

MS. LITTLEPAGE: No, sir. Sorry.

THE COURT: We're in recess. Be at ease.

(Whereupon, the hearing concluded at 10:43 a.m.)

C E R T I F I C A T E

I, Eugenie M. Power, Official Court Reporter, do hereby certify that the foregoing is a true and correct transcript of proceedings in the above-entitled case.

/s/ Eugenie M. Power, RMR, CRR, CCR Date: July 26, 2012
United States Court Reporter