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, June 24th, 2011 - Little Rock, Arkansas - 9:05 a.m.

**TRANSCRIPT OF STATUS CONFERENCE**
BEFORE THE HONORABLE BILL WILSON,
UNITED STATES DISTRICT JUDGE

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Proceedings reported by machine stenography and displayed in realtime; transcript prepared utilizing computer-aided transcription.

P R O C E E D I N G S

(Proceedings commencing in open court at 9:05 a.m.)

THE COURT: Good morning. Be seated, please. Mr. Heard, do you take this personally that nobody will sit by you? We're having a little hearing this morning in an MDL case. On the master rulings order, I'm working on one. Apparently the parties cannot agree on one. Is that a fair assessment?

MS. LITTLEPAGE: Yes.

THE COURT: I'm working on one. I'll send it out and let you try to persuade me it's not a good one. Again, be vigorous but brief, and not optimistic. Number 2 on my agenda is defendants' motion for summary judgment, no evidence of menopausal symptoms. It looks to me like that the defendant here is asking me to accept and apply Dr. Naftalis's theory and wants it applied in every case. How do I hold the plaintiff to that who did not retain Dr. Naftalis? Seems to me like that some way I need to have those plaintiffs that are still out there step forward and tell me who their expert is going to be to try to avoid the ruling that I made in the other case. That's my reaction. Who wants to go first in saying something? Mr. Heard, come forward.

MR. HEARD: Judge, keep me on the straight and narrow here. I don't want to address more than you want me to address on these motions. There were 27, I believe, we filed

in this first batch and to which the plaintiffs responded and to which we replied at the beginning of this week. Then there's a second batch that was filed later and to which oppositions are still coming in. I think with this first batch, we've defined the nature of the different kinds of oppositions they have filed to this motion. Before I get to some of the substance, go to your question. I would have put it a little differently than you did. We're not adopting Dr. Naftalis's methodology. Your Honor knows this is something we stubbornly --

THE COURT: I didn't mean to say you adopt it. What I said was you are asking me to accept it as the plaintiffs' position in all cases.

MR. HEARD: Well, that's correct. In other words, to say it's the only methodology that's been put forward in any bellwether trial and we're eight years down the road and if that's the methodology, then we've said it wouldn't get a plaintiff over the hump who said she didn't suffer menopausal symptoms. And this is against the background of knowing that it was to be expected, it seemed, that of the 10,000 or more plaintiffs who initially were in this proceeding, you would expect to have a substantial number who wouldn't have experienced symptoms since part of the plaintiffs' whole case from the beginning has been that Wyeth promoted these drugs for what they call off label uses, and Your Honor's heard them say

that we promoted it for its cardiovascular benefits and Alzheimer's benefits and all these other benefits.

So one would have thought that there would, in fact, be plaintiffs who took it for these other reasons and not because they had hot flashes or night sweats or vaginal atrophy. And when we look at the fact sheets that they filled out, it looks like on the fact sheets that there are maybe upwards of 7, 800, 900, 1,000 women who did not suffer hot flashes or night sweats or vaginal atrophy, and when they were asked what conditions that they had that this was prescribed for, they answered something other than these menopausal symptoms. So taking those verified answers and matching it with the only theory that the plaintiffs have put forward, we then moved for summary judgment. Your Honor's correct, it may be that some other plaintiff has a different theory or that they might have an expert who would come from a very different place, but that's why we've got the motion for summary judgment.

If they do have a different expert and they do have a different methodology that they want to advance, this motion simply says now's the time to tell us. And so this has given them the opportunity to do that. Now, of the 20 something oppositions that came in in response to this first batch, I believe it's correct that not one has invoked Rule 26(f). So no one has taken advantage of that provision in the rule that says if one requires further discovery, this should be put off.

They made arguments that sound like that, but nobody's invoked that rule. So we're not arguing with the principle that they can't come forward and say now we've got a different expert, we take issue with the plaintiffs' steering committee.

That's not our theory. But we're simply saying in response to this motion, now's the time to name the expert or identify the methodology. And if they do that, then maybe we all have to regroup and say what's the schedule for dealing with that. But in this first batch, no one identified a different expert by name. Several of them did complain that it was unfair that they should have to come forward and name an expert. Some of them said they thought there are other methodologies, but were not very specific about what methodology, if any, they were adopting. Several of them said, well, there's one possible methodology is simply to rely on the epidemiology, which they claim show that there's a doubling of the risk.

And if they could point to enough studies that shows there's a doubling of the risk, that alone would be sufficient to prove specific causation, that hormone therapy caused an individual woman's breast cancer. But they've pointed to that as a possibility without affirmatively claiming it as their methodology and without identifying any expert who says that they can, to a reasonable degree of medical certainty, say it caused breast cancer in this woman or that woman based on that

and nothing alone. So, as the record stands now, we would say nobody has adequately contested the motion for summary judgment. This is a vehicle for putting forward the expert or the theory, and they haven't done that.

Now, Your Honor, that's only one group of these oppositions. Let me just add this.

THE COURT: Hang on just a minute. My lawyer sent me a note here. Go ahead.

MR. HEARD: Let me regroup to this extent. In getting ready for this trip which included going to Montgomery for a hearing yesterday in one of the remand cases, there's one notebook I didn't pack which is the specific briefs in these 27 cases. But I know this much.

THE COURT: What judge were you before in Montgomery?

MR. HEARD: Judge Keith Watkins has a case that was going to go to trial in about a month, but the upshot of yesterday's hearing was to put it off. The interesting facet to us, I think, of filing this motion is, as I said, one would have thought that there would be a large number of women who took hormone therapy for some reason other than their hot flashes. In almost every case, though, the plaintiffs have responded to this motion for summary judgment by rushing to prove that they did, in fact, experience symptoms even if their fact sheet didn't say it.

THE COURT: You say symptoms, you're talking about hot flashes?

MR. HEARD: Hot flashes, night sweats, vaginal atrophy. Dr. Naftalis has given us a list of everything that she says is a symptom that's reflective of estrogen deficiency, such that a woman doesn't have enough natural estrogen in her body to fuel breast cancer. So we have a list that's longer than that, so I'm just using hot flashes, night sweats, and vaginal atrophy as a shorthand this morning.

So no one has said, well, I'm one of those women who took it for cardiovascular benefits. Everybody's raced to touch the base that I took it because I had symptoms. And so the opposition's fallen to these groups. A number of women came forward and said, well, despite what I did not say in my fact sheet, here are some medical records that I've now collected and they show that I experienced these symptoms. Where that's been true, we have withdrawn our motion for summary judgment, subject to thinking over the fact, should we be able to collect our costs of filing this motion because they filed fact sheets that they never supplemented.

THE COURT: Suppose someone, one of the plaintiffs, former plaintiffs are deceased and the state's now the plaintiff and the son of the plaintiff said, yeah, I was there with my mother and she complained of hot flashes regularly and night sweats and so forth, wouldn't that be admissible?

MR. HEARD: Your Honor's putting your finger on one of the cases. It's Farist and Cornwell, I forget which is the son and which is the --

THE COURT: The complaint of bodily symptoms, I believe, is the exception to the hearsay rule. I think his testimony would be admissible, wouldn't it?

MR. HEARD: There are two aspects as I remember it, Your Honor, about what the son says. He says, first, his mother told him she had symptoms. That seems to us to fall squarely within hearsay, and then he --

THE COURT: What about the complaints of bodily, that exception to the hearsay rule, why wouldn't it fall in that one where somebody complains of body -- I can't remember the exact language of the hearsay exception, but it's under the first batch of them.

MR. HEARD: Well, I don't recall it either, Your Honor, and if that's an exception, then it would seem to fall within it. His personal observation may fall within it. The question mark, I think, that is over that is that she provided the equivalent of sworn testimony in her fact sheet that she did not experience these symptoms.

THE COURT: Are you saying it's analogous to somebody saying something in a deposition and coming back to do an affidavit to try to patch it up?

MR. HEARD: That's our position.

THE COURT: Is there any law on that? I know there's law on depositions and a later affidavit, but what about a fact sheet and a later statement by someone?

MR. HEARD: Well, we've cited that information, those cases in our brief. And by those cases, I mean this, Your Honor. It doesn't have to be a deposition and then an affidavit. The initial statement can be a statement in a complaint, it can be interrogatory answers, it can initially be a declaration or affidavit. Whenever the plaintiff has given a sworn testimony before the motion and then comes in after the motion and contradicts it without adequate explanation, then it falls under this sham affidavit rule. So it should not matter here that it's a fact sheet because under the procedures we adopted, the fact sheet is the equivalent of interrogatories. It's better than interrogatories in this sense, and I think we come to this a little later.

These were worked out between the plaintiffs and the defendants and then went to Your Honor to get Your Honor's approval before these were sent out so we could avoid the whole issue of objections being filed by every single plaintiff to the fact sheet. We eliminate that whole problem of objections that these are ambiguous or unclear or unfair or unreasonable in scope by working it out in advance. Now, as Your Honor sees in a number of these oppositions, people try to use as an excuse that these are unclear, and they didn't know what was

being asked for. We think that's not only really nonsense on the face of these fact sheets, it's a very clear set of requests which have been answered by thousands of women in an appropriate and straightforward way.

But we're past that because of the way these were put in operation to begin with. And to go back to Your Honor's question, they are the equivalent of sworn testimony, and if the initial response is sworn and verified and here, coupled with a duty to supplement, which the woman herself signs, this duty to supplement isn't often the rule someplace, it's something that was part of the verification that the woman signed. I acknowledge that I have a duty to supplement these requests.

THE COURT: You don't contend then that the medical records reflect hot flashes or shams?

MR. HEARD: No. I mean, they clearly can come forward with those records and that's why we've withdrawn those motions. So Your Honor has put your finger on the one case in this group that is the most difficult because he says he personally observed it. And while we think that there is still an issue there about whether he can do what his mother could not have done, that is, contest after the fact her sworn testimony, that's a closer question. So there's the group of people who came forward with medical records, we've withdrawn the motion. There's a second group who came forward with

medical records and said in their response, see, here are the medical records, but when you look at them, the records don't show hot flashes or night sweats, and it's unclear why they gave us those medical records because they don't, on their face, support their claim.

The third group is some women who gave us a declaration or affidavit and said, well, I did experience symptoms. But the declaration is not accompanied by medical records. So that's the purest form of the sham affidavit. And I think there's nothing to argue to Your Honor about that. There's the fact sheet for what it is, there's the post motion declaration which contradicts it, and it seems to us to fit squarely within the rule that you can't create a material issue of fact in that way. And then, Your Honor, coupled with the case of the son, there are, I believe, two cases where the plaintiff identified medical records or said that she suffered osteoporosis or osteopenia, bone loss. And that's often identified as a symptom of menopause.

But when Dr. Naftalis was asked for her list of the symptoms that match up with estrogen deficiency, for purposes of her methodology, she acknowledged that osteoporosis does not fit in her list because she said it's not always reflective of estrogen deficiency, and that women who have osteoporosis have widely fluctuating estrogen levels. So this was a deposition, I believe, that Mr. Brown took. He asked her for the list,

they had a back and forth about this and it's based on her own testimony putting it outside her list that we say that these two plaintiffs, who have now listed that, fall outside her methodology. So those are the four categories.

I think the briefing provides our legal authority on the sham affidavit question. For those who say here are our medical records and we say they don't reflect these symptoms, the Court can make its own judgment about whether they do or they don't. And insofar as the plaintiffs want to say they want to prove a different methodology at this late stage in the litigation, then I suppose that simply is a question for the Court as how to schedule dealing with that. To jump ahead, we had said to the Court in response to your proposal about naming experts by January 2012 that we thought that was a good idea. And we had identified two other generic *Daubert* issues that we thought would benefit from having these experts named in a hearing.

In light of these several oppositions that say there is a different generic methodology for determining cause in a woman, it would seem to us that this belongs on that list insofar as they want to say that there are 44 epidemiological studies or some other group that show a doubling of the risk, and if that suffices, that would seem to be another one of these issues that has generic potential and is best resolved here before such cases are remanded.

THE COURT: Good morning, Ms. Littlepage.

MS. LITTLEPAGE: Good morning, Judge. How are you?

THE COURT: Terrible, thank you for asking.

MS. LITTLEPAGE: Judge, we've now entered our eighth year here, and it appears at least to the plaintiffs' side that we are dissolving a global generic MDL into case specific evaluations, and with each time Wyeth starts these trends, we're now -- you're now facing case specific motions for summary judgment dealing with individual facts of individual women's cases which is really not the role of an MDL judge. You should not be looking at whether a son's testimony about a mother would be admissible at a trial to get to a jury. Those are all issues that are ripe for a transferor court applying the law.

THE COURT: Why is that not a summary judgment issue?

MS. LITTLEPAGE: Well, as you know, Judge, we filed a global motion to strike these summary judgments on that basis, that they were asking this court to do case specific evaluations on cases that have been stayed for eight years when that evaluation should be done by the transferor court and this court should wrap up the generic issues and get us out to the transferor court. I know that's another motion that's coming in just a minute, but let me address some of the issues that Mr. Heard raised.

First of all, neither side is asking this court to order expert reports on the 7,000 cases that are left in this jurisdiction. Wyeth asked for that several years ago, the Court flat denied it, said it was not your role as an MDL judge, you were not going to do case specific expert reports up here because they would be stale by the time the women went back and had to deal with the trial setting, so that's not what either side is asking. Mr. Heard said that he was surprised that in the women they filed the cases in, the summary judgment motions in, that some women hadn't taken this drug only for heart or brain benefit, that all of the women were saying they were symptomatic.

That shouldn't surprise anybody, Judge, because our position has always been that this drug was prescribed when a woman walked into her doctor's office and said I have vasomotor symptoms, and the doctor said, well, I've got a drug that can help your hot flashes or your vaginal issues and you should stay on it for 10 years or 15 years or 20 years because there's this heart benefit and this brain benefit. And so that was the correlation is that although they had gone on the drug for symptoms and that would have been a good use of the drug for three to six months, they stayed on it for four years, eight years, ten years because of the alleged heart and brain benefit that we now know wasn't proven. So that shouldn't surprise anybody that the women in this litigation are going to be

almost exclusively, if not the vast majority, symptomatic women whose symptoms were so strong it drove them into the doctor's office asking for what were options and the doctor offered Wyeth's drug.

Mr. Heard says that we did not say that these motions were not ripe. We have said it in our global motion to strike and we have said it in, I believe, every individual response that was filed, is that we have very clearly claimed that it is inappropriate to file a case specific evaluation motion for summary judgment in a case that has been stayed for eight years, where no discovery has been done, no depositions, no depositions of the treaters, and in eight years, although the Court ordered us to give HIPAA medical authorizations to Wyeth when the case was filed, in eight years, Wyeth has yet to order even a single medical record on people that were stayed.

As soon as a PPO-9 case is chosen, they order medical records, but we had all these HIPAA authorizations that we were ordered to sign and they were never used. So summary judgments are now being evaluated in a case where absolutely nothing has been done. The only thing a woman did is she answered a fact sheet. And Mr. Heard says that the sham affidavit provision comes into place if she now explains that the question on the fact sheet was ambiguous or unclear to her and she is now explaining it in her declaration. But the *St. Joseph* case in the Eighth Circuit squarely says that in that context. And

that's a context where there was a deposition and then an affidavit after the deposition. That's the only context the Eighth Circuit has ever looked at the sham affidavit issue.

Never has the Eighth Circuit held that a written discovery response and then an affidavit explaining that response later on even falls under the sham affidavit issue. Never. But in *St. Joseph*, they dealt with the issue where someone was asked specifically at a deposition a question and then later submitted an affidavit that said something different. And they said if the person says I submitted the affidavit because I did not understand the question, the Court cannot strike the affidavit, it is not a sham affidavit, and the Court must consider the information that is put into the affidavit.

Well, nothing could be more on point here because the question asked in the fact sheet and, Judge, if you look back at the fact sheet, it's very interesting because there is a 54 page fact sheet, half, 25 pages of it are long lists of conditions that the plaintiff has to answer whether she or her family member has ever had. When it came to symptoms, the question that Wyeth based this motion for summary judgment on, the question that was in the fact sheet was for the plaintiff to identify symptoms at menopause experienced before starting hormone therapy. Not symptoms of menopause, not menopausal symptoms, not a list of vaginal issues or hot flashes or night

sweats, but the woman was asked symptoms at menopause. Many women didn't understand that question. Frankly many lawyers didn't understand that that question had any great significance.

It didn't come with a list of symptoms Wyeth asked the woman to identify if she did or didn't have. It didn't come with any explanation, it had a little tiny line next to it and it said "symptoms at menopause". Many women in their declarations have said, first of all, I didn't understand vaginal issues were a symptom of menopause. Not until my lawyer called and said did you have vaginal issues did I even realize that my vaginal dryness, the fact that I was having difficulty having sex with my husband was related to menopause, and they put that in their declaration. But many woman didn't even realize that question was asking them for menopausal symptoms so they left it blank or they said "not applicable". When, in fact, their medical records and they themselves say we were having hot flashes or their son says, I saw her having hot flashes. I heard her tell me she had night sweats.

So there is no precedent, absolutely no precedent that the sham affidavit rule would apply in this context where the women were not deposed, the women were not asked those questions, the women were not even asked a specific question, did you have hot flashes. Never asked that question. That does not appear in the fact sheet. Women were never asked do

you have night sweats, do you have vaginal issues. So let me address each issue. First of all, Mr. Heard says if a woman has medical records that shows symptoms, they'll withdraw the motion.

THE COURT: Talk a little slower, please.

MS. LITTLEPAGE: Sorry, Judge. Mr. Heard says if the women have medical records that support symptoms, they'll withdraw the motion. They actually haven't done that. They have refused to withdraw the motion even in women who have medical records. They've withdrawn some of the motions and they've not withdrawn some of the motions. I don't know what the criteria is, but we asked and sometimes they say yes and sometimes they say no, we want the Court to rule. The second category, women who have a declaration that identifies --

THE COURT: Do you have a record here where they show hot flashes and they refused to dismiss?

MS. LITTLEPAGE: Yes, Judge. I've got three lawyers here who would all like to talk to you on this issue about their individual cases.

THE COURT: I'd like to see one of them. Can you put one of the records up on the --

MR. LAMPKIN: I can. Your Honor, I'm James Lampkin from Montgomery, Alabama.

MS. LITTLEPAGE: You want to see it now, Judge?

THE COURT: I want to see it right now. Just put it

on the ouija board.

MR. LAMPKIN: Your Honor, this is in the Beaver case and this is a letter from Dr. Joel Godwin, who actually prescribed HRT to Mrs. Beaver. And if you look, "She is having hot flushes (sic) with some evidence of menopause. For that reason, I started her on Premarin daily and will give her Provera." They have not withdrawn the motion in that one.

THE COURT: Read that to me again. I can't see the -- somehow I'm not seeing it on the screen.

MR. LAMPKIN: Your Honor, it is right here.

THE COURT: Read that to me again.

MR. LAMPKIN: It says, "She is having hot flushes (sic) with some evidence of menopause. For that reason, I have started her on Premarin and will give her Provera." And I didn't read the milligrams. That's one. These are the first -- I had five, our firm had five filed in that first group. Baumberger, prescribing physician, menopausal syndrome continues on HRT with occasional spotting. And actually she had numerous ones. Let me find the one where -- this is where he put her on HRT and it's under A, menopausal syndrome with estrogen deficiency. That one has not been withdrawn.

THE COURT: That's good right now.

MR. LAMPKIN: Your Honor, if I may, I have four, like I said, I had five. Four of the five, in the reply, their medical records support it. One of them even has an FHS

result, which is the test that measures the level of estrogen as I understand it. In four of those five, they've not withdrawn this motion.

THE COURT: Mr. Heard, what about those records and what do you say to them?

MR. HEARD: I'm having to resort to this chart. Beaver is -- there was Basham and Beaver both represented by Mr. Lampkin in this first batch, and they're marked on my chart as ones in which we were withdrawing the motion. I think you'll find we certainly didn't reply in either one of these because the doctor, and according to my notes, they had -- I thought they had a declaration from the doctor, actually, so we weren't contesting these. Now, Baumberger is not even in this first batch of motions so it's quite true that over the last week or so, I have put off responding to any of those that weren't ripe for this hearing. So I've got a whole bunch to review when I go back home. Because they weren't on the agenda for today. This is the list of the ones to which we either withdrew or replied for today's hearing, and the reason why there's no reply in Basham and Beaver is because we weren't contesting those and we withdraw them.

MR. LAMPKIN: Your Honor, if I may, our response in Baumberger was filed on May 25th, 2011, which was the day before Your Honor had entered the deadline for us to respond to that first group. So Baumberger was in that first group.

MR. HEARD: It's not in the first group. I've told Mr. Morgan what the list of 27 cases were that were -- to which we would be responding by today, and that's not on the list. It's in a further group.

MS. LITTLEPAGE: Let me go through each category. The first obviously was women who had medical records, and there's obviously issues even with those. The second were with women who had filed a declaration, which under the *St. Joseph* case in the Eighth Circuit says, the Court must use extreme care striking sham affidavits and it's only if the question is so clear, that there is no ambiguity, that it is exactly on point and the person does not say that I did not understand the question or that it was ambiguous. Other than in that context, the woman's declaration absolutely raises a genuine issue of material fact.

The second thing, the third category that Mr. Heard raised was he's decided or Wyeth has decided that only if Dr. Naftalis listed that symptom in relationship to one of the cases she's already testified in will they accept it as an estrogen deficiency symptom despite medical literature, published medical literature, testimony from other experts which clearly identify that osteoporosis and prevention of osteoporosis is related to estrogen deficiency. That, as a woman, her brittle bones is related to her lack of estrogen in her body. It's virtually uncontested in the medical literature

and by all of our other experts, it's just Dr. Naftalis hasn't had an osteoporosis case yet, and so Wyeth has decided that because they're only going to relate to Dr. Naftalis, they're not going to consider the medical science, which is obviously completely inappropriate.

I guess our real concern, Judge, is that we are now on a path of dozens and dozens of cases where this court is having to deal with the type of case specific evaluation we just talked about. Does the medical records really say it, does it not. Those are evaluations that really should not be handled by an MDL court, they should be handled by a transferor court looking at the exact context of the case, when Dr. Naftalis has been deposed, when the plaintiff has been deposed, when discovery has actually happened, which is when summary judgment is most appropriate. But I want to give each lawyer an opportunity because each one of these lawyers flew up here, Judge, because they have women that are in this batch and they feel very strongly, and I'd like the Court to hear from them. I'll start with Mr. Lampkin and then Ms. Presby and then Mr. Orr.

THE COURT: Fine. Come around if you will, please.

MR. LAMPKIN: Your Honor, I have, like I said, five in this first group and I've addressed four of them. That's Basham, Baumberger, Beier, and Beaver, and all four of those we do have medical records to support their symptoms and they have

provided declarations. The fifth one is the Carroll case and Ms. Littlepage was just talking about osteoporosis and Dr. Naftalis. One thing I wanted to bring to the Court's attention, she listed osteoporosis on her fact sheet as the reason she was given this medication. Listed the doctors. Wyeth's had that information since that fact sheet was filled out. I don't have a declaration of any other symptoms on Ms. Carroll because she was given it for osteoporosis. I do want to show the Court, may I put this up on the ELMO?

THE COURT: Surely.

MR. LAMPKIN: This is one of Wyeth's documents regarding Prempro or E plus P and also it was a promotional piece for the doctors to prescribe this for osteoporosis, which Wyeth recognizes outside of this courtroom that osteoporosis is a symptom of menopause. But here, now, they're saying it's not, even though all the time before, they've taken the position that it's a symptom of menopause, they've marketed it for that. So I think that even at this stage, Your Honor, with the cases stayed to throw Ms. Carroll out of court when she has not had an opportunity to be deposed, she's not had an opportunity to produce these fact specific experts to testify in this matter, it's just, it's improper at this stage, it's not the time.

We're putting the cart before the horse in regard to Ms. Carroll. She ought to have an opportunity. And then if

she can't, doesn't have an expert to say that prescription for osteoporosis is evidence of estrogen deficiency that would support that, that's the time for Wyeth to move for summary judgment, not now. I think, like I said, I think we're just putting the cart before the horse in a number of these, and I'm not going to speak on behalf of everybody else, I can't. I've got more coming up in this second round where we do have declarations, and on the declaration issue, the fact sheet specifically says you're supposed to amend, and Ms. Littlepage talked about it. The declaration, it asked 53 -- it identifies 53 different conditions for the plaintiff to identify.

But under menopausal symptoms, it doesn't list night sweats. Do you have it, yes, no, unknown. Hot flashes, yes, no, unknown. Vaginal atrophy or vaginal dryness or vaginal irritation, yes, no or unknown. None of that's there. Now, if one of the plaintiffs had -- if you had that and she said no, I didn't have hot flashes and then comes back and says yes, I did, you may be in the situation with the sham affidavit. That's not what we have here.

Summary judgment was filed, the declarations and the fact sheets were amended and supplemented, and that's the stage we're at right now. And I just believe, Your Honor, that the law doesn't support summary judgment at this stage in the current state of the pleadings and the facts. I thank you for your time.

THE COURT: Thank you.

MS. PRESBY: Good morning. My name is Ellen Presby and I am here from Dallas. I represent 725 women who have suffered from breast cancer as a result of the defendant's product. And I'm here today to talk about ten cases that have been filed for motion for summary judgment. And of our 725 cases, 80 have been remanded, and we are very happy to be spending our resources on the remanded cases so that we can bring these cases to trial and have an outcome for these women. We are most upset about spending our resources on stayed cases that are being brought for summary judgment at an ill timed moment before the evidence is fully flushed out.

The ten cases that have been filed against our firm, I have no reason to believe that's all that will be filed because the defendants have only gotten to the Hs. We actually represent people in all letters of the alphabet. I feel certain that if there is not a stop put to this procedure, we will continue spending our resources on these cases from after the Hs all the way to Z. I want to give the Court a little bit of summary of the cases that have been filed.

Two of our women, Ms. Gentry and Mrs. Higginbotham, have summary judgments pending against them filed by Wyeth. Those two women, there are symptoms identified in the medical records prior to their initiation of hormone therapy, prior to the time that it was prescribed by their doctors. We have obtained

declarations from those clients explaining that they didn't understand that the symptoms identified in the medical records were symptoms of menopause and they didn't understand that they were being requested in the fact sheet. We have provided the declarations and the medical records to Mr. Heard with a request that the deposition -- that the motions be withdrawn, and we have heard no response from Mr. Heard.

An additional two, Ms. Halle, Ms. Hawthorne recalled symptoms of menopause at the time of their depositions. These are the only two women of the ten who have been designated for PPO-9 discovery and, therefore, the only two of the ten who have been permitted to continue one step further in the discovery process, during the time that they were prepared for their depositions and they had an opportunity to review medical records and consider in detail the histories leading up to the prescription of hormone therapy, they recalled menopausal symptoms and identified them in their depositions. Coincidentally, those menopausal symptoms actually fit within the very confined list that Mr. Heard is relying on now. Despite that, and despite that that has been identified to Mr. Heard, those motions have not been withdrawn. The next two plaintiffs are Mrs. Fallick and Ms. Hartley and those are people who have had hysterectomies --

THE COURT: You probably ought to spell the names for the court reporter, please, ma'am.

MS. PRESBY: Ms. Fallick is F-a-l-l-i-c-k, Ms. Hartley is H-a-r-t-l-e-y. Those are two women who have had their ovaries removed. That has a special effect on the menopausal symptoms, puts them in a separate category, but does not decrease for them the risk of breast cancer from the defendant's product. They should not be granted -- summary judgment should not be granted in their case either because they failed to identify menopausal symptoms in their fact sheet either, because it shouldn't be granted because it's all premature anyway, but it wouldn't be granted at the end of discovery for that either.

The next plaintiff, Ms. Dumenil, D-u-m-e-n-i-l, reported low density in her fact sheet, low bone density in her fact sheet. Low bone density is identified in the medical literature over and over and over as a symptom of low estrogen. It was also used, if I may go to the ELMO, as a symptom to convince the doctors to prescribe the product and convince plaintiffs to take the product. I am showing the Court Wyeth's own document, Bates number W-ADSBRO-01279, which is attached as an exhibit to one of our motions. I happen to have Ms. Cox's motion response here.

It says that bone loss occurs at an increased rate. The document is entitled "How do I know I'm going through menopause?" One of the symptoms listed is bone loss occurs at an increased rate, which can lead to osteopenia and/or

osteoporosis in women at risk. The other three women, the final three of the ten that we're here on today, Ms. Cox, whose motion response is on the ELMO now, Ms. Ferguson, and Ms. Frudally, F-r-u-d-a-l-l-y, reported irregular menses, irregular periods. They have not been deposed because it was only those two who were designated for PPO-9 discovery. Irregular menses is also a sign of menopause and estrogen deficiency, monthly periods become irregular and gradually stop.

In the case of surgical menopause, which is the hysterectomies, periods stop abruptly, and these are signs that these are symptoms for which the defendants marketed their product and for which they expected and hoped plaintiffs would take their product. These are not issues that have been directly addressed by all of the plaintiffs' experts. The plaintiffs, my plaintiffs in these ten motions have not identified experts yet. Their cases have not come to the point where they are being asked to identify experts. They have -- we have just not gotten to that point. I can tell you, I can tell the Court, I do not know whether we will be using Dr. Naftalis or Dr. Naftalis's methodology in the 650 cases that have not yet been remanded.

That is not a strategic decision that I, as attorney for the plaintiffs, am required to make at this time in cases that are stayed for discovery. At the time that the cases go to the

trial court and we get on a course, I will make decisions about what methodology and what expert we will be using. It is inconceivable to me that our firm and all of the plaintiffs' firms have been forced to spend their resources and, therefore, be distracted from the trial cases on issues that are so easily resolved by looking at medical records, deposition testimony, declarations, or medical literature to show that there is a fact issue in these cases that would make summary judgment at this juncture premature.

It is our fervent request that this court deny the motions for summary judgment recognizing that as the MDL court, case specific summary judgment motions based on experts that have -- whose time for designation has not come, whose testimony has not been given, who have not analyzed the facts that are specific to each particular case, be denied. It makes no sense, with all due respect, Your Honor, that we are arguing case specific summary judgment motions at this juncture in the litigation in stayed cases with no discovery except something akin to initial interrogatories. At the time that the case is remanded, the very first step in every case is to provide disclosures pursuant to federal rule 26. The parties have all agreed that those disclosures are updated interrogatory responses by the defendant as prescribed by the MDL, and updated fact sheets by the plaintiff, as prescribed by the MDL.

That's how we start each and every remanded case, with

updated information to allow us to proceed from case specific moment to the end of the case. Just like a real case. The defendants know the updated fact sheet will come at the time that the case is remanded. That has been the practice, that has been what we are doing. We have explained that to every judge who has a remanded case. All parties are in agreement that that's what's happening, and at that point, if the defendants feel that it is appropriate to file a motion for summary judgment, they can. They won't, because they know that at that point, discovery is just beginning.

Case specific discovery is just at its infancy at that point in the trial court. Instead, they will wait until the end of case specific discovery to determine whether they think it is worth it to file a motion for summary judgment on this issue, whether there is a triable issue of fact. And with the evidence that we have presented in these motions here in the MDL court that will be supplemented and increased in the trial court, they will know at that point that summary judgment on this issue is inappropriate. But, instead, what they're trying to do is back door summary judgment motions and file them in a place where no discovery is permitted so that the plaintiff cannot fully flush out the issues of fact and so that the defendant can somehow avoid going to trial on the case in which there is a legitimate issue to be tried.

I would fervently ask, again, Your Honor, that this court

deny the summary judgment motions and make the defendants go forward in case specific discovery in the trial court.

THE COURT: Thank you.

MR. ORR: Good morning, Your Honor. My name is Chip Orr. I'm with the Mulligan Law Firm. I'm here from Dallas. And I represent Jason Cornwell, whose mother, Diane Farist, passed away two months after she signed her plaintiff fact sheet. You've already posed some questions to Mr. Heard. I'd be happy to address those if Your Honor wishes. I also represent Dorothy Hudman. Her response to the motion for summary judgment is actually due today, but Mr. Heard has graciously agreed to allow me seven extra days to file that response.

I am here today because I don't want to talk about my responses to the motion for summary judgment, I have a motion pending that I would like for Your Honor to consider and decide in my favor. That is a motion to dismiss on behalf of all of the clients of my law firm against whom the summary judgments have been filed. Initially when we filed that motion, there were four. Two of those provided medical records that showed hot flashes and Wyeth has withdrawn those motions, so the motion is now moot as to those two. It remains extent, however, as to Mr. Cornwell and as to Ms. Hudman. I want to go back to first principles.

THE COURT: Wait a minute. You say you have a

motion. Tell me specifically what that motion is.

MR. ORR: It is document number 17 in cause number 4-6-787 and that's Cornwell v. Wyeth. That is a motion to dismiss the MSJs as to all of the Mulligan Law Firm plaintiffs against whom such a motion has been filed. The reason that we think this motion should be denied, or dismissed, as to all of our plaintiffs is going back to first principles. When I sat down to respond to the motion for summary judgment, I asked myself what is this motion based on. It appears to be based on specific causation testimony of an expert, Elizabeth Naftalis, about what you have to be able to show to prove that there's a causal relationship between your use of HT medication and your breast cancer.

But stepping back from the specific causation piece of it, the motion is actually predicated on a discovery request and a discovery response. Now, that can be an appropriate summary judgment motion, we concede that in our motion, and if I may use the ELMO for a minute, I'd like to show Your Honor what I'm talking about. Your Honor, that is the discovery question on which the motions for summary judgment are predicated. In full, that's it, right there. As Ms. Littlepage already explained to the Court, that question is at best unclear. Mr. Heard says but the plaintiff fact sheet was the product of negotiation between the plaintiffs' steering committee and defendants and it went through this rigorous

process and then Your Honor approved it. That's all immaterial.

We're talking about that question. It doesn't matter where that question came from, it doesn't matter who wrote the question, it doesn't matter who approved the question. The question is what it is. Now, a summary judgment that's predicated on an answer to that question might be appropriate, but in this instance, it's not. And I want to put something else up on the ELMO from the PFS to show you what I mean. Your Honor, I put that X on "no" next to arthritis. Here's a hypothetical. Let's imagine that Dr. Naftalis had testified and it had passed *Daubert* analysis that a woman could not prove specific causation unless she had said yes, I had arthritis.

That's not the case, but imagine with me for a moment that it were. That question clearly asks the plaintiff did you have arthritis, have you ever had arthritis. The plaintiffs had an opportunity to say yes, I did, no I didn't, or I don't know if I did. A symptom of arthritis would be pain in the joints. So let's say that we had an arthritis symptoms question. If a woman didn't write pain in the joints, even then maybe it's appropriate. You've already heard from other plaintiffs' counsel who said there's way more than just these four symptoms that Mr. Heard is now telling you are the only ones that count. I respectfully disagree with Mr. Heard for the reasons that the other counsel have explained.

But my purpose in showing this to you, Your Honor, is that these summary judgments are predicated on a fallacy. These plaintiffs have never been clearly asked did you suffer from hot flashes, night sweats, vaginal atrophy, vaginal dryness. They've never been asked that question. Whatever they put in response to that question is incidental. It cannot form the basis for summary judgment as a matter of law.

I think this whole thing, we've gotten way ahead of ourselves, we've gotten sidetracked by specific causation; Dr. Naftalis, what do the records show, what can we prove, sham affidavit. It's the wrong question to ask right from the outset. And our motion to dismiss asks the Court please dismiss all these motions because they're predicated on a fallacy. And that's the relief that I'm here to ask for today. Now, as for Mr. Cornwell, his affidavit is neither a sham, nor is it hearsay. To the extent it is hearsay, it falls within the exception.

THE COURT: Thank you.

MR. ORR: Thank you, Your Honor.

MS. LITTLEPAGE: Judge, I'm here on behalf of my clients, and I have several in this first batch and even more in the second batch. I want to just highlight two issues on behalf of my clients. First, one of my clients, Judith Bayer, B-a-y-e-r, is like Ms. Presby's client, a hysterectomy client. Wyeth has agreed to withdraw the motion as to hysterectomy

clients in some cases, but they have refused to withdraw the motion in my case even though Dr. Naftalis has clearly discussed the fact that when you take away a woman's ovaries, she has no ability to have endogenous hormones because her ovaries cannot leak anymore hormones, they're gone, surgically removed. So although they've recognized that Dr. Naftalis has testified to that, they've agreed to withdraw motions that other firms have with hysterectomized women, they have refused to withdraw their motion as to Judith Bayer.

THE COURT: Why do you think that? Have you talked to them about why?

MS. LITTLEPAGE: I assume that Mr. Heard is busy. I assume he has lots of things to do, but I wanted to point out that on the record.

THE COURT: Mr. Heard, if we come upon one that you think the motion ought to be withdrawn, stand up and let me know.

MR. HEARD: It's marked on my chart as withdrawn, so it may not have happened. I certainly didn't refuse it. I don't think -- I've been dealing with Mr. Aylstock, her colleague. I don't think Mr. Aylstock has received any communication from me refusing. It's marked on my chart as withdrawn.

MS. PRESBY: Excuse me, Your Honor, may I have the same courtesies from Mr. Heard then for Ms. Fallick and

Ms. Hartley?

THE COURT: No.

MS. PRESBY: Apparently.

THE COURT: You may.

MR. HEARD: It's our position that if they had a hysterectomy, we're going to withdraw it. None of Ms. Presby's plaintiffs that she referred to are on the agenda today. None of them are ripe for this hearing. We haven't filed replies in any of those cases.

MS. LITTLEPAGE: Judge, I have a number of clients who have filed declarations, don't have medical records. Either medical records were destroyed or they didn't record what the women had told the doctors but the clients have now signed declarations, and I just wanted to point out that under the *St. Joseph* case, the sham affidavit rule only applies if the declaration directly contradicts the woman's prior testimony.

THE COURT: You made that point earlier today.

MS. LITTLEPAGE: The women were never asked if they had hot flashes or night sweats. There's no direct contradiction, and the sham affidavit issue, I think, is an inappropriate issue at this point.

MR. HEARD: Your Honor, I'm far less interested in any one of these individual summary judgments than I am in determining whether this approach and the related question of

whether there is generic methodology that will work or ways that can move this litigation forward. I want to come back to that broader question, but let me just address Mr. Orr's motion, in effect, to strike all these motions for summary judgment. Because he's wrong in two respects, and one of them is quite important.

I'm not going to belabor this because the Court's going to read this and make its own judgment. In section 7C of the fact sheet, under this section about menopausal history, which follows the section, I think, about menstrual history, there is this question. It's a fill-in-the-blank. Symptoms at menopause experienced before starting hormone therapy. This particular plaintiff answered "irregular periods". This is where most women put in hot flashes and night sweats. We think this question is as clear as clear can be. So when the plaintiffs' counsel get up now and say it's unclear, we just find that hard to believe on its face. But Mr. Orr also said this is the only question on which our motion is based, and that's wrong.

Because the fact sheet in section 9 asked about the use of hormone therapy medications and, again, was a fill-in-the-blank and the last column after asking what drug it was, to describe it, to give the dates, to say who prescribed it, was to say, what was the condition for which the doctor prescribed hormone therapy. If it was Premarin, why did the

doctor prescribe it. If it was Prempro, why did the doctor prescribe it. You'll remember what Ms. Littlepage said when she got up. Most of these women experienced symptoms were so strong it drove them into the doctor's office to ask what the doctor could prescribe for them. Well, that's why thousands of women filled in that blank by putting hot flashes. That's why it was prescribed for them. Or night sweats. That's why it was prescribed for them.

This combination of questions clearly calls for the information. That's not to say that a woman can't come in with a declaration or affidavit and if she can provide a credible explanation for why she didn't understand the question, perhaps the Court would find it's not a sham at all. But it does require under the case authority that the plaintiff herself provide a credible explanation for this contradictory answer because we believe it's clearly contradictory if they now say they had the symptoms, when before, they left the blank blank. And remember, the plaintiffs, although, I must say reading every one of these motions, one gets the impression that counsel are now arguing that these plaintiffs answered the fact sheet all by themselves as if they were a pro se plaintiff on their own and without the guidance of counsel. But they did answer this with the guidance of counsel.

You'll remember the disputes that began this litigation over complaints by us that counsel had altered the answers that

plaintiffs provided and they said oh no, this is work product, we've been in communication with our clients, we've discussed them with them, we've gone back to them and make sure they understood it. So when the answer changed in the fact sheet, that reflected our communications with the client. So --

THE COURT: What about the broad position of the plaintiffs that the MDL judge shouldn't be deciding these summary judgment motions? Does the MDL manual indicate that the MDL judge can decide summary judgments when there are common issues in the case or does it have a provision on it?

MR. HEARD: The manual certainly provides that the Court can grant summary judgment. I'd be happy to cite that provision, but that gets to the heart of the --

THE COURT: I thought it did.

MR. HEARD: The heart of the question is, and what we're trying to drive at is that there is, at the core of this summary judgment, an issue about is there a generic methodology for determining specific causation. Your Honor has answered that Dr. Naftalis's generic methodology passes *Daubert* muster, and so these summary judgment motions were predicated on the fact that if that generic methodology works, then plaintiffs who have symptoms can get to a jury, but if plaintiffs don't have symptoms, then they will not get to the jury under Dr. Naftalis's methodology. So our objective here is not to have the Court embark on a course of resolving case -- the

application of --

THE COURT: Let me ask you a question, random thought ran through my mind. What if I designated all these cases which you filed for summary judgment, and what if I designated all of them for PPO-9 discovery?

MR. HEARD: I understand what Your Honor is driving at. That would be one way to do it, but the other way to do it is because these plaintiffs are now saying, you hear it loud and clear in these responses, there is not only one methodology, they're saying there is more than one generic methodology for deciding case specific causation. If that's true, that should be resolved now in the MDL as all generic questions should be resolved here. So if the argument is that they can go to a jury without Dr. Naftalis, but with an epidemiologist who says here are 44 studies or 64 studies or two studies that show a doubling of the risk, then we should test whether that generic methodology for determining specific causation passes *Daubert* muster. That's our fundamental position.

So I think that can be done without designating every one of these cases for PPO-9 discovery, but that's another way to do it, and that should be resolved because that's a generic question and that question is separate from the question of whether for any individual woman the expert, be it Dr. Naftalis or some epidemiologist, has then taken that generic methodology

and applied it in light of the facts of that case. Let me just -- that's the broad question. And that, I think, should move us. If that's the gist of their response, that there is a different methodology, then it's time to tee it up and test it. The reason why we have only referred to Dr. Naftalis is because she's the only expert that the plaintiffs have put forward to defend that methodology in this case.

So when Ms. Littlepage says, well, there's other literature and there are other experts some place else, that may be, but not in this proceeding. That's why Mr. Lampkin and Ms. Presby are asking the wrong question. The question is not what Wyeth or some journal article says is a symptom or is not a symptom. The question is, for purposes of Dr. Naftalis's methodology, when she says that a woman is estrogen deficient, and when she says that a symptom signals estrogen deficiency, which symptoms count for her methodology and which symptoms don't count. We've asked her to list the symptoms that count, and she's done that. And in our papers, we have cited to deposition and page where she does that. And she's the one who says that osteoporosis and osteopenia don't count for purposes of my methodology.

So, for Mr. Lampkin who said he had three cases by my chart, he said he has four cases, he has only three that are ripe today, two of them have been withdrawn and the other one involves the question of osteoporosis. Ms. Presby has ten

cases. We have yet to reply in those cases, they're not ripe for today. Mr. Orr puts his finger on the one case that Your Honor and I discussed, which is the son, that's a close question we think that's covered by the sham rule. And Ms. Littlepage, we have not refused any hysterectomy cases but we may not have yet executed, and the others of her cases are governed by the sham affidavit question.

And on that, simply put, our belief is that the question was clear, it appears in two places in the fact sheet, we believe the legal authority says that however you first swear an answer, that a later contradiction invokes the rule if you don't have a credible explanation, and the last point is, the credible explanation has to come from the plaintiff herself, not from her lawyer who claims that the fact sheet is unclear or ambiguous. She needs to explain that. And where the declaration doesn't do that where she's simply saying now I have symptoms, then we have a contradiction without an explanation.

THE COURT: All right. Let's go to the plaintiffs' motion to release of common benefit funds.

MS. LITTLEPAGE: Judge, will you indulge me just quickly?

THE COURT: Very, very quickly. We got to move on.

MS. LITTLEPAGE: Let me just address the generic methodology thing that Mr. Heard raised about whether we should

have a *Daubert* hearing on whether epidemiology is enough to get to a jury. There are some circuits that have held that. The Third Circuit has held it, the Fourth Circuit has held it. If women are in their circuit, then when they're transferred out, their transferor court will be very familiar with what that circuit has held. The problem with having a generic methodology hearing in front of you, Judge, is you would then have to go and apply the different circuit law to every case depending on which circuit it came from, and some of those circuits have different evaluations of when you apply epidemiology only to prove case specific causation.

For example, a circuit may say, the Court has to look at the studies the plaintiff is relying on that shows more than a doubling and decide if the plaintiff fits into that study, is that study clearly the type of woman this plaintiff is. And that would have to be an analysis each transferor judge would have to do based on the facts of his case and the law of his circuit. And new articles come out every day. In the last year, we've had a series of articles that tell us that if a woman is newly menopausal when she gets on the drug, her risk of getting breast cancer is much higher than if she's been menopausal for seven or eight years when she starts the drug.

THE COURT: Let's go to common benefit fund.

MR. ORR: Your Honor, may I have just two minutes to respond because Mr. Heard has raised an issue about which we

disagree for the first time, just two minutes?

THE COURT: Be brief. Please come around.

MR. ORR: What Mr. Heard has up on the ELMO, section 9, he says that that also is a place where women were asked about symptoms. I respectfully disagree. I'm going to substitute Ms. Farist's sworn fact sheet. This question actually asked for conditions, it doesn't ask for symptoms. The condition could be menopause, it could be, as Ms. Farist said, hormone therapy, which is just another way of saying she's hormone deficient. That is a condition.

THE COURT: Condition and symptoms would be different?

MR. ORR: They are different, Your Honor, and let me show you another piece of the fact sheet that explains why. This is the family medical history portion. And as you can see, it asked for the following conditions. I've circled cancer, that's a condition. I've circled diabetes, that's a condition. Arthritis, I mentioned earlier, that's a condition. The symptom of arthritis is pain in your joints. So when they wanted to ask for a symptom, they asked for a symptom. When they wanted to ask for a condition, they asked for a condition.

That said, I agree with Mr. Heard that section 9 is relevant, and the reason I agree is because it supports my view. Ms. Farist put hormone therapy. That's another way of saying I'm hormone deficient, I need more hormones, and that's

exactly the crux of the issue. But to me, this just goes back to the point of why these MSJs are premature and should be dismissed. I just wanted to make that point briefly. Thank you, Your Honor.

THE COURT: Thank you. Does anyone want to talk about the common benefit fund?

MS. LITTLEPAGE: I do, Judge.

THE COURT: Be brief.

MS. LITTLEPAGE: Yes, sir.

THE COURT: I got some kind of statement on that from a bank without any explanation, I thought I'd found the bird nest on the ground. Turned out y'all's money.

MS. LITTLEPAGE: Judge, let me talk to you a little bit about the way the accounting system has been set up for the MDL through some of your orders. There are two orders and then a procedure that's in place. The first is PPO-5, the second is PPO-6, and the third is the HT litigation fund. And they all have different purposes and different roles. And we have filed a motion and the reason I want to explain the accounting system to the Court is because Wyeth has raised some objections that I think show a lack of understanding of what this court has ordered the PSC to do.

The PPO-5 is an order that the Court put into place. We asked for it, Wyeth had no objections. They had no standing really to object, but they didn't have any objections. And it

says that it is a procedure that lawyers record their expenses and their time that's used to work on common benefit issues. PPO-6 is merely a mechanism for setting up a bank account that's run by a trustee, into which Wyeth puts the money. The HT litigation fund is an active checking account that is run by Mr. Cloar, our treasurer, from which the PSC pays bills. PPO-5 is not a procedure to have bills paid. That is for people who have expenses, individual law firms who have expenses, who have attorneys fee time, they record it, they submit it, and that's going to be decided by the Court at the end of the litigation.

But what PPO-5 said is in PPO-5, the Court differentiated between held expenses, expenses law firms would just keep on their books and asked to be reimbursed later, from expenses the PSC were required to pay month by month. For example, fees and costs associated with pretrial discovery such as deposition costs, expert witness fees, exhibit costs, that's the cost of paying to get the documents out of the depository. The Court ordered the PSC to pay those expenses as they were incurred. Obviously we can't wait to pay experts till the end of the litigation, or court reporters, or Wyeth wouldn't give us the documents unless we paid the costs the Court ordered.

So the Court ordered us, as the PSC, to gather up some money from all the firms, put it into an account and Mr. Cloar pays our bills every month on these specific issues from that account. We are now asking the Court to release money from the

PPO-6 trust account into the HT litigation fund so that we can pay these kind of expenses. Wyeth -- although we claim Wyeth has no standing at all to object to our motion, this is the plaintiffs' money, the Court has ordered it's the plaintiffs' money, it's just sitting in the PPO-6 trust account, but Wyeth's only objection was we haven't met the requirements of PPO-5. But PPO-5 has nothing to do with what we're asking. PPO-5 is an audit process that would occur to make sure that the law firms held expenses met the Court's requirements.

For example, the Court said if you're going to fly to a generic expert's deposition, you don't get to fly first class, we're only going to reimburse you for a coach seat. So there's an audit process at the end for an auditor to go back and make sure nobody's charging us for a first class seat. The Court, in your order, says you can have a hotel room that's up to $200 a night but we won't pay $600 a night. So, again, the audit process would make sure the expenses matched the Court's procedure. But that has nothing to do with the question we're asking the Court.

Wyeth continues to want, eight years in, generic *Daubert* hearings, they continue to ask this court to have generic issues, and we need to be able to pay for it. Mr. Cloar needs money in the HT litigation fund to pay for it, and there's a lot of money sitting in PPO-6 that we're just asking for access for for these specific issues.

THE COURT: Mr. Heard, tell me why you're not an officious intermeddler.

MR. HEARD: I am. I don't really want to speak to this. We've stated the objections that seem to us to leap off the page. I don't doubt for a minute that the steering committee has incurred substantial expenses for which they're entitled to draw on the common benefit fund, it's just that there are a whole set of accounting procedures that these two orders set forth and I don't quite know why the steering committee wants to fudge on those procedures, but they do, and nothing that they've said today, which is anything different than in their paper, seems to me other than a dodge around these procedures. And as I read the order, it provides that the lawyers who have been taxed, the plaintiffs' lawyers whose settlements and judgments have been taxed to create this fund at the end of the day could conceivably be entitled to some of it back for their clients, and that's why there are these accounting procedures in place.

And it's been obvious that not all the plaintiffs' counsel see eye to eye. Mr. Caldwell, in the steering committee, didn't see eye to eye and he's one of those lawyers who settled and been taxed. So the combination of what they don't seem to have done and the fact that they didn't even serve this motion on all the plaintiffs' counsel just seemed to raise a red flag. But we don't have standing.

MS. LITTLEPAGE: Judge, may I respond just quickly? Nothing that Wyeth raised in their briefing was any really legitimate objection. What they claim is what they claim here, is that there's no specific provision in the Court's order so far to allow the Court to release the money to Mr. Cloar. That's what we're asking the Court to do. This is your order, we're asking you now to enter an order applying it and saying I'm authorizing the release of PPO-6 money to the HT litigation fund. That's a procedure we're asking for. It's not that we're asking you to apply a former procedure, we're asking you to enter an order saying exactly that, that we can use the money to pay the PSC obligations.

THE COURT: Thank you. Let's take a break until 15 till by the clock on the wall. We're in recess. Be at ease.

(Recess at 10:27 a.m., until 10:47 a.m.)

THE COURT: Anybody want to comment on my proposal to name experts by January of 2012, any further comment?

MS. LITTLEPAGE: Yes, sir. For the plaintiffs, Judge, this would only make sense if it was tied to a full remand of all the cases in the MDL, and the reason is is that things change, and we know every month Wyeth puts new documents into the depository. Every month, there's new science and new medical articles being published on hormone therapy and E plus P. We had a generic discovery cutoff almost two years ago and we still have thousands of cases here that are not set for

remand that don't get to do any new discovery on the new documents that Wyeth has put into the depository or the new science because generic discovery was cut off.

For the women who came out of the MDL right after that cutoff, that's one thing, but we've got women here that are looking at a five or six or eight year track to get out of here and they've been cut off for two years already to do the same thing with experts. Which means that Wyeth puts a new document in, we've tied a regulatory expert into an opinion that's not based on the new documents because it's not tied to remand. So deadlines are great if the cases come out of here and go back at the same time. So a mass remand tied to a discovery deadline or a expert deadline would be fine. It immediately goes stale for women who continue to get stayed and stuck here and don't get to go out.

And whatever the Court did on this issue, we would ask for two considerations. First of all, it couldn't obviously impact case specific experts because each lawyer gets to choose their own experts for their own plaintiff. But second of all, in all -- it would have to have a provision that someone, an expert who had the same opinions as a previously designated expert could then be designated because if a previously designated expert dies or gets sick or gets promoted and doesn't have time anymore to testify or changes jobs and the new job doesn't allow time to come to court, you know, the

plaintiffs can't then get punished for that, so there would have to be a provision that if we had a designation of X number of opinions, that someone who adopted those opinions could be duplicated if one expert became too busy or wasn't available.

THE COURT: If somebody died, I ought to let you get another expert? It would be unreasonable if I denied that request?

MS. LITTLEPAGE: The point is to not have to come back to the Court every time one expert has some issue that makes them not available anymore, if another expert's adopting the same opinions. But we would ask that if the Court is going to set a deadline such as this, we've really struggled under the staleness of the generic discovery deadline because there are so many women still here that are now double stayed, they're stayed and generic discovery gets stayed, and they're still not out, but if we're going to do that for experts too, it must be tied to the full remand of the cases so that it makes sense.

THE COURT: Mr. Heard.

MR. HEARD: I thought there was one thing in there I agreed with. Your Honor, we embraced Your Honor's proposal and rightly or wrongly read between the lines that if you were thinking January '12 is a deadline for these experts, that you might have in mind, you know, further remands and substantial numbers in that time frame. So that's what we had in mind in

responding, and we thought it would be useful to use this deadline as a way to make sure that experts get designated and challenged, if a challenge is appropriate, on some key generic issues that keep popping up. We hear about them here and then we see them showing up in the remand cases.

And we listed those in our response. And I think one follow-up, one thing actually will come up, I think, later this morning is the design defect claim, which continues to pop up and whether oral micronized progesterone is a safer alternative. There is the question raised and discussed this morning about whether epidemiology alone, whether the studies are a generic methodology for determining specific causation, and we believe we'd have a *Daubert* hearing there about cherry picked evidence. And we mentioned one in our case about those women who developed their breast cancer well after they stopped using the drug, and the question of whether any expert generically can say that hormone therapy caused the drug if the cancer only shows up years after they stopped, since the risk declines once they stop. All of those are listed in our papers.

And there is one other issue which one of my co-defendant colleagues reminded me of this morning, which really doesn't involve a hearing, I think, at all, but it's something we need to resolve in this same line and that is that Mr. Walker, who's not here today, and I have had a conversation about this. I've

said we wanted to nail down the fact that women who have estrogen receptor negative, progestin receptor negative breast cancers, there's no way to show that hormone therapy caused that kind of cancer. Mr. Walker said, of course not, we're not going to pursue any of those cases. And when we inadvertently drew one as a bellwether plaintiff for this most recent set of *Daubert* hearings, he said that case is not going to be pursued.

And I said, well, we at least need to do something formal. If you're not going to pursue these kind of cases, we need to make a record of that. And we simply haven't resolved the mechanism to do that, but simply a representation on the plaintiffs' part won't do it. A stipulation doesn't really do it because some plaintiff who's not part of the steering committee could say that doesn't count for me. So we really need to put this somehow into the context of a *Daubert* order that there is no reliable science that would say they caused receptor negative cancer. So there are these series of issues. I think in hindsight, if we could have started this process sooner, it would have been better. We all thought the bellwether trials would lead us to a resolution in a way that they haven't, but these rulings on broad generic *Daubert* issues do seem to be having a helpful effect on settling cases because we've settled almost one third of the docket in the last six months and another 500 plus cases resolved this week.

And whether the defendants win these motions or the

plaintiffs win these motions, that defines an issue for a broad number of plaintiffs and I think speeds resolution and it's also the business of the MDL court. So we would hope Your Honor would, keeping this January '12 deadline in mind, put us on a fast schedule, and have us resolve these additional issues.

THE COURT: You say you've resolved a third of the MDL cases?

MR. HEARD: I say a third of the docket. It probably includes some cases that are outside the MDL docket, but it's a third overall.

THE COURT: Y'all are going to put me out of business if you keep that up. Thank you. Let's go to plaintiffs' motion to remand "wave four" cases. That's docket number 2723.

MS. LITTLEPAGE: Judge, in November, you picked PPO-9 "wave four" cases and gave the parties six months to do discovery after which time the cases would be ripe for remand. Six months ran at the beginning of May and we're asking for the Court to remand PPO-9 "wave four" cases and at the same time either abandon the PPO-9 process and start releasing women straight into transferor court or at least select a new wave of PPO-9 cases so some more women can get active. We are seeing -- the parties have agreed and the Court has entered an amended order saying that if the depositions for PPO-9 are not

taken in that six months, they can be taken in the transferor court, and we're seeing certainly for the second wave of remands, many of the depositions were not taken here. Wyeth opted to not take those depositions and they're being taken in the transferor court. It does not delay anything in the transferor court because I've told this court we get no preference or precedential standing when we go back.

THE COURT: I've tried to address that and I haven't had much luck trying to get the transferor courts to give y'all some kind of priority, and thus far, I have not had any --

MS. LITTLEPAGE: We haven't either, Judge. A lot of it's just their dockets, but because we're getting no preference, we come back and get on a two-year docket just like if we filed the case yesterday. It does actually make sense for some of those depositions to be taken in the transferor court because then they're more current. The woman is currently talking about where she is in her medical treatment if her deposition is not a year old by the time she's transferred and the case is active.

The only objections that Wyeth has raised is Wyeth says that there are some cases that have been stayed and that they don't want those cases to go back, and they named three categories. The first are the short-term use cases because that appeal is being taken to the Eighth Circuit, and although as an aside, Wyeth says that your *Daubert* rulings help generate

settlements, short-term use cases can't get settled while the appeal is pending, so it actually can delay settlements on cases because lawyers can't evaluate those cases while the appeal is pending. But anyway, they've identified short-term use cases and HER2/neu-positive and PR-negative cases until the Court rules on those issues.

We would ask the Court to set a deadline for Wyeth to tell the Court which plaintiffs in PPO-9 "wave four" match their criteria, remand the rest, and if we don't agree with their list, we can come back to the Court and explain why we think some of the people on Wyeth's list should move over to the remand list, but at least we can get everybody else out of here. The six months has past and they're certainly entitled to remand. The second side is we're asking the Court to either remand cases without the PPO-9 process because it's really not being used. The cases are really going back with only one or two depositions taken and all the rest are occurring in the transferor court. But if the Court does want to continue the six-month waiting period, to please select more plaintiffs.

Now, Wyeth raises in their response that there were some lawyers who they felt weren't being particularly cooperative in getting depositions done. I can tell you, Judge, that of the hundreds of cases selected, they gave you two examples. There are dozens and dozens of lawyers who e-mail me every week saying I've tried to put my plaintiffs up, I've given Wyeth

date after date after date, they don't take them, and Mr. Clark flew all the way from Florida to talk to the Court about this issue because he's got some PPO-9 "wave four" cases and he's here to personally ask the Court to remand his cases, and I'd like the Court to give him just an opportunity to be heard.

MR. CLARK: May it please the Court, Your Honor. I'm Jim Clark from Tampa, Florida. My firm represents about 80 or 90 women in this litigation. One case was maintained in state court. One case was maintained in state court in Florida and was resolved by settlement. It was the *Esposito* case. We now have five cases that have been remanded and 12 that are currently activated. Of the five that are remanded, I just wanted to bring to the Court's attention that Wyeth unilaterally noticed at least eight or ten physicians, treaters and prescribers for deposition, and have now progressively canceled all of those depositions as we get within a few days or a week of their depositions. Of the activated cases, we wrote Wyeth and provided all kind of dates for our clients to be deposed. Of the dozen, only two have now been noticed and the six months runs in August. So that's our personal experience. I don't know about the others, but it's not the plaintiffs that are holding up the show. Thank you.

THE COURT: Thank you. Appreciate you coming all the way from Tampa.

MR. CLARK: Yes, sir. It's a pleasure to be here.

Thank you.

MR. HEARD: Well, Judge, the picture's a little more complicated. I don't know at the end of the day what even is the best approach. But what's complicated is this. We're not opting to delay discovery until the cases are remanded, we're trying to get these depositions taken in the window Your Honor has set forth, and these examples that we've given in our paper of plaintiffs who say what's the hurry about deposing my plaintiff and I'm not available anyway for the next three months are not typical, but they're not atypical.

We have plaintiffs' counsel who seem to have no sense of urgency about making their clients available for deposition. Then we have the case of Mr. Clark and others who make -- I'm sure he's prepared to put up his clients, but they make a show as soon as Your Honor puts them on the PPO-9 list of offering dates, but of course, we don't have a full collection of medical records at that time. We're not going to take the deposition of the plaintiff until the records are collected. Which means that these depositions tend to get bunched.

All of those on PPO-9 the first three months of the six-month period are very hard to get much accomplished because we're still scrambling to collect medical records with the updated authorizations at that time. So the process is not perfect. And all we note in our response is even the PPO-3 wave (sic) of discovery in terms of taking the plaintiffs is

not yet complete. It's far from complete in "wave four". But we understand the need to get some of these cases back. So I only provide those facts for Your Honor to take into consideration.

The one matter that I think is of great consequence is that cases not be remanded that are subject to one of the pending *Daubert* rulings. Ms. Littlepage addressed that in part and agreed in principle as to short-term use. We've talked before about the estrogen only cases and now the HER2/neu-positive and estrogen receptor negative which are pending. It would make no sense to remand such cases.

THE COURT: Has short-term use been argued?

MR. HEARD: It has not. The briefing's not complete yet. In fact, I'm not sure that the first brief has even been filed yet, but I'm not conscious of the schedule. It's very close, close to being due.

MR. CLOAR: July 12th is the plaintiffs' brief.

MR. HEARD: We've identified some other issues this morning that we think the Court should fit in to this period between today and January 2012 if that's a cutoff in Your Honor's mind. So it would make no sense to remand cases which if the Court said, *Daubert* motion granted, would make it impossible for a plaintiff of that kind then to prove an element of her case. For example, if the science behind oral micronized progesterone being a safer alternative were to prove

unreliable, those claims would be subject to summary judgment here. If a woman could not establish with reliable science that hormone therapy caused her breast cancer that occurred five years, let's say, after she stopped taking the drug because the risk declines to zero after three years, her case would be subject to summary judgment. So the point of doing these generic hearings would be to have the appropriate follow-through here.

Now, Your Honor, we could identify for the plaintiffs who those cases are and do our best to do that. But we reached an agreement with the plaintiffs several months ago about the process and it was presented to the Court in a joint motion, and the joint motion said that before any further cases would remand, the plaintiffs would take it upon themselves for any woman who said that she used hormone therapy for five years or less to certify in some fashion to us that, in fact, she used it for more than three years before that case could be remanded. And so the burden isn't on us by our agreement to provide that list. They agreed to do that for any list of plaintiffs that Your Honor created.

If you create the list, then they are to take that list and certify for any woman whose fact sheet said she used it for five years or less to go back and double check so that they can say, in fact, she used it for more than three years. There's a buffer in there. So one of the considerations, I guess I would

say, the discovery is not done, it's hard to get done in this six-month period. I just tell Your Honor that to take into account. I'm sure there are many plaintiffs' lawyers who are eager to push their cases to trial, but it's also true that when these cases are remanded, there are many plaintiffs' lawyers who appear not eager to press their cases to trial. Your Honor's familiar with Mr. Faries because he used to be Mr. Morris's colleague, and just in this past week, he asked us for a stipulation in eight of his remanded cases to continue all the deadlines in one case by 150 days, a second case by 150 days, and a third case by 60 days, and a fourth case by 90 days, and a sixth case by 90 days, and a seventh case by 150 days, and an eighth case by 210 days.

In another case in the Northern District of Illinois this week, the judge granted all our motions in limine because the plaintiffs had failed to file any response and did not show up for the hearing. So clearly not everybody's ready to jump in and push these cases to trial. So one thing that the Court might well consider is to really determine what lawyers want these cases remanded and which do not. Because some are clearly not ready and not willing to pursue.

THE COURT: How do I make that determination?

MR. HEARD: Maybe the plaintiffs' counsel need to say whether they're ready or not. Because when we get to the remand court, some are not ready.

THE COURT: You're talking about the steering committee plaintiffs' counsel?

MR. HEARD: I don't know what the process should be. It's easy for Ms. Littlepage to say she's ready and I'm sure she is, but clearly the proof in the pudding is many are not and it makes no sense to be remanding cases where discovery is incomplete when those lawyers are not ready to push the cases. Even on the schedule the Court gives them in the remand courts. The principal concern, however, is let's make good use of this period between July and January 2012 to deal with generic issues and we should not remand cases that could be subject to those orders.

MS. LITTLEPAGE: Judge, I do take offense to a defendant who stands up here when the Court has put a procedure in place that says you're going to choose women, there's going to be a six-month window, and at the end of the window, the women are going to get remanded, and defendant stands up and says, well, some plaintiffs' lawyers may not be excited about this process as others. It's the process we've used all along, it's the process the Court put in place. These cases are ready for remand. And if, when the case is remanded, some plaintiff's lawyer doesn't show up for a motion in limine hearing, that's at that plaintiff's lawyer's door.

But it's not this court's job to decide for plaintiffs' lawyers whether they're ready or not ready or happy or not

happy. You put a procedure in place that we've followed and we're asking the procedure to be followed again. Wyeth's response this time, and I think it's an interesting one because they've opposed remand every time, this time Wyeth's new opposition is we would like nobody to go on the list if we think we might, in the future, raise a generic challenge that we haven't raised yet but we're thinking about raising that we might raise that we might file. Judge, the six-month window has passed.

Those women should be remanded if they get the Court to agree that they should have a *Daubert* hearing on whether a design defect claim is or isn't reliable or valid, then the transferor court will look to this court for guidance on that issue, may or may not follow it because that's each federal judge's right to follow or not follow precedent that is established either by appellate courts or by you, but it's time for these women to get out. The other thing I want to point out is that Wyeth says that there's some process in the certification of these cases for short-term use. So I went and looked at the agreement between the parties.

The agreement is if Wyeth puts a woman's name on the list and says she's a less than three year ductal case and the plaintiffs don't agree, then we can bring medical records and we can come to the Court and say, Judge, this woman should get out. That's assuming Wyeth doesn't agree. But we can show it

to Wyeth and if Wyeth agrees, that woman gets remanded. If not, we bring it to the Court. But we don't have a process where every plaintiff's lawyer now has to step up to the plate and say I want my cases remanded. We have a procedure that you selected women and after six months, they're ripe for remand. The women that are selected should go to remand.

Wyeth says there are specific women that shouldn't be on that list. We'd ask the Court to set a deadline right now for Wyeth to identify those women and everybody else gets remanded and then we can focus on those women and bring any disagreements to the Court on those women, but at least the rest of the women should get out now. And that's all we ask, give Wyeth a date, let them tell us who they don't want to be on the list and everybody else on the list goes back just like we've done round after round.

The other thing I would say, Judge, is we do surveys from time to time about the status of the women in the litigation. We did one last week. There are now more than 600 women who have died while their case was pending. These women are getting older, so we ask the Court to abandon the PPO-9 process and just let the women out. But if not, please select more women.

THE COURT: I understand your position.

MS. LITTLEPAGE: Thank you, Judge.

MR. HEARD: Your Honor, I think, has this.

Ms. Johnson, I may need you to turn on the button. Judge, we're not asking the Court to hold on to cases that might speculatively be subject to a *Daubert* motion. We've been quite specific, I think, about the three or four *Daubert* motions we think you should put on the calendar. This is a quotation and it's in the filing document 2592. So that, simply, I'd ask the Court to look at. This is the plaintiffs' agreement about what they will do for women who are subject to the short-term use order, and it's they who will certify that the use involves use greater than three years. So the first step is theirs. This is the agreement to which I'm referring. 2592, paragraph 4. Thank you.

THE COURT: All right. Let's move on.

MS. LITTLEPAGE: Judge, please may I just show you 2592, because that's not what 2592 shows? And it's very important to the plaintiffs that this be right. This is document 2592. It was filed by Wyeth. It is the joint motion for stay referenced there. And the item number 5 says exactly what I just told the Court. Defendants agree to not oppose remand of any ductal cases on the basis that the fact sheet indicates short-term use if plaintiffs establish through records that the use was longer. If plaintiffs cannot resolve the disagreement, then we bring it to the Court. That was our agreement. If it was a less than three year case and a ductal case and Wyeth put it on the list and we didn't agree, we would

confer and, if not, bring it to you. Everybody else should go back.

THE COURT: All right.

MR. HEARD: It just doesn't say that, Your Honor, because she didn't read paragraph 4 just before it.

THE COURT: Beg pardon?

MR. HEARD: She just didn't read paragraph 4 before what she read.

THE COURT: I understand. I'm familiar with 4 and 5. What about Dr. Austin's preservation deposition, what do I need to resolve about this?

MR. HEARD: Well, maybe nothing. I was seeking clarification at the last hearing about two issues. One was whether the plaintiffs would agree that even after this preservation deposition was taken that any of his prior testimony could be designated in future trials. The plaintiffs were unwilling to agree to that. The second thing I was seeking assurance about was since his testimony is vast in scope, that we weren't going to be having to interrupt the deposition and bother Your Honor to make sure we had enough time scheduled. And Mr. Walker said they had set aside three days for his deposition. There's been some e-mail circulating that suggested maybe there was thought about cutting back on the time available for his deposition. If the plaintiff's standing by making him available for three days, there's no

issue.

MS. LITTLEPAGE: Judge, we have always told Wyeth that Dr. Austin's preservation deposition is going to span two days. We expect to take three to five hours and we expect to give Wyeth ten to 12 hours. So they'll have double the time of us. We're going to reserve some time for redirect and it will all be done in two days.

THE COURT: You're going to take how long, five hours?

MS. LITTLEPAGE: We expect three to five hours. I won't be doing it. Mr. Williams and Mr. Booth will be doing the direct, so that's what they tell me and we're going to give the rest of the day and a half to Wyeth. If at the end of that time Wyeth feels that they don't have enough time, then I'm sure we'll be back in front of you, but that's what's been scheduled right now. If Mr. Walker said something different, he was wrong, and we have always told Wyeth it will be next Thursday and Friday.

It's always been scheduled for next Thursday and Friday. We will go first and we're going to reserve some time Friday afternoon to do a redirect based on what they accomplish.

THE COURT: How about Mr. Walker, he hasn't pulled up lame again, has he?

MS. LITTLEPAGE: He is actually on vacation for the first time in eight years, Judge, and I fully support that.

THE COURT: I commend him. Mr. Heard, they're saying two days.

MR. HEARD: Can you switch on the ELMO again, Mary?

THE COURT: Let me ask you this. If they only take five hours, why wouldn't two days be plenty?

MR. HEARD: It may be, Your Honor, but if this is a preservation deposition, it's got to cover everything that Dr. Austin has testified to. And he's testified in short-term use, long-term use, ductal, lobular, tubular lobular. Every one of these different issues gets us into a different set of science. Now, as I said to you last month, this puts us in a bind because you want to do a cross-examination that's effective. At the same time, if this is a preservation deposition and he may not show up again, we've got to make sure we anticipate any general causation question, which is why I brought it up last month.

And Mr. Walker said, this is after I said it was -- let me see. Just point it out here. After I was pointing out the problem and said the plaintiffs have agreed to whatever length of time it takes, Mr. Walker got up and told the Court we've allotted three full days for this deposition of Dr. Austin. Ms. Littlepage is not telling the truth when she says they've always told us this. We raised it in court, got this understanding, and went away satisfied.

THE COURT: I'm not in a mood to resolve an issue

that might come up. Mark down when this deposition is and I'll be available for a conference call at the end of two days if you can reach me by conference call. Let's go to another issue. I understand that the parties can't agree on the scope of the upcoming *Daubert* hearing in the -- just a minute. I've been educated on this issue, but apparently not well enough. Point number 7.

MR. HEARD: Well, Your Honor, you issued an order, which was 2728, asking the steering committee to send out a notice.

THE COURT: Oh yeah.

MR. HEARD: It said if an individual plaintiff believes her case is an exception, she should come forward forthwith. We then objected to the notice that they sent because it didn't communicate that message. It seemed to us --

THE COURT: I'm getting my sea legs now.

MR. HEARD: It also didn't seem on the face of it to have been sent to all plaintiffs' counsel. So there was an exchange, and then Your Honor last Wednesday, I think, asked us to, since we didn't like it, to come up with an amended and substituted notice. We sent that to them last Thursday, a day early, and they presented objections to us on Wednesday morning. I was headed out the door to the airport at the time it came in so I accepted in part one of their proposed revisions. I didn't fully accept one the way they wanted to

reword a sentence and I sent that amended and substituted notice back to the Court.

They filed their objections. The larger question is this. Of course, ordinarily a plaintiff would designate their experts, we would look at their report in deposition, and we would say we think this part of the report or this opinion is subject to *Daubert* challenge. I mean, the challenger has to define the challenge based on the opinions that the expert renders. Here, a little bit unusually, but there's a lot of water under the bridge, the steering committee was very insistent that we tell them in advance before this whole process started exactly what our challenge was going to be on HER2 positive breast cancers. And I was irritated with Mr. Walker for asking and I made that clear and said I thought it was an odd request and had things backward, but at the end of the day, I wrote it up and sent it to him before the March hearing so he wouldn't have anything to complain about.

So we gave them a one-page statement that said this is what we intend to challenge. We intend to challenge the general causation opinion that hormone therapy causes HER2 positive cancer, and if you want to see a writeup of this, look at the brief we filed in the *Esposito* case. And I said we are also going to challenge that there is any generic methodology for determining what caused a woman's HER2-positive breast cancer. And if you want to see a summary of that, look at

these pages in our brief in the *Esposito* case. So, we think it's our prerogative to define the challenge. At their request, we did it in advance.

The parties then agreed with the Court's blessing that we would do this through the vehicle of naming individual women's cases so that we could view these scientific issues through the lens of particular women's cases. And we chose four who had HER2/neu-positive cancer and four who had receptor negative cancer, so we proceeded down the road of having individual women. Then we asked to depose their experts, and Dr. Naftalis was on that list of experts that they named for purposes of this *Daubert* hearing. And Your Honor may remember that they didn't want to give us depositions or didn't want to give us full day depositions, which Your Honor ordered that the witnesses be produced.

And Dr. Naftalis was then examined, deposed specifically on these HER2 receptor negative issues. The report they gave us for Dr. Naftalis was a case specific report. It was a report she had rendered in the case of an Alabama woman, the woman whose case we were in court on yesterday in Montgomery. So what they gave us was a case specific report for her. And then when she was deposed, not us, but Mr. Booth on behalf of the plaintiffs, asked her questions at her deposition and at pages 229 and 30 of her deposition, he asked her whether her method for doing specific causation was the same in these

HER2-positive cases as it has been in all her other cases, and she answered yes.

So they gave us a case specific report for her, they asked her whether her case specific methodology was the same, she said yes. We asked questions at pages I could recite for you about details of her case specific methodology. So from the get go, we defined it, we told them, we selected individual plaintiffs to be the vehicle for these challenges. They provided an individual report as a sort of stand-in report for how Dr. Naftalis does specific causation in cases even of receptor negative but even of HER2-positive and said it was the same methodology. They asked her questions at her own deposition to confirm that. And it's on that basis that this challenge -- and we've written it up and we've submitted our briefs.

We want to be able to challenge both the general causation question and the generic methodology question. It'll be for some other court to decide if this is a valid methodology even in HER2 cases, whether she applied it correctly to an individual woman. But the question of whether it's a valid generic methodology for HER2, which we believe is an independent cause of cancer, is another matter altogether. But, really, that's all apart from the question of notice, because Your Honor said I want to make sure that other plaintiffs who may take a different position in the steering

committee don't show up later and raise their hand and say, as Ms. Presby and Mr. Orr and Mr. Lampkin did this morning, I'm going to do something different and I haven't decided what it is and I'll tell you later.

And the notice that the plaintiffs offered simply didn't do that, so we've tried to word a notice that we think accomplishes what that court asked us to accomplish. If it's not right, I'm sure the Court will correct us.

THE COURT: Ms. Littlepage, what I want to get at is I want to get a notice out to the extent reasonably possible that we don't have a hearing like we had in Minnesota and then I later determine that this applies only to those particular individuals. I want it broader than that. I'm going to make it broader if I possibly can.

MS. LITTLEPAGE: Judge, we don't disagree with the Court on that. What we disagree with is a very narrow thing. Wyeth has asked the Court to put in that notice, and I don't know that we need another notice because what we've told all the plaintiffs' lawyers is we're having a generic *Daubert* hearing on the general causation issue of whether a plaintiff who is estrogen receptor positive but also has HER2/neu findings or PR-negative findings can show that E plus P promoted, caused, or aggravated her breast cancer. That is a generic issue that's being heard by this court.

What we object to is in Wyeth's notice, they ask the

Court to go on and say that also being challenged is case specific opinions in eight women's cases. That's not true. We have not presented a single case specific opinion in any of these eight women's cases because that is not our understanding of what the scope of this *Daubert* hearing is. Wyeth asked for women's names to be selected just so that the ruling would apply to a particular woman so that we could have a connection. And if something happened, there could be an appeal in a particular woman's case.

It would not just be an advisory opinion from the Court, it would be tied to a particular woman's case. Therefore, that woman's case could be appealed to the Eighth Circuit if necessary. That was the only reason particular women were identified. There was no belief, certainly from our side and I don't believe from Wyeth's side, I've seen their briefing, they're not actually -- what Mr. Heard just candidly said to the Court is right, they're not contesting whether any of the plaintiffs' case specific experts, whether it's Dr. Naftalis, Dr. Klimberg, Dr. Wertheimer, or any of the case specific experts have validly applied the methodology to Mrs. X, one of the named plaintiffs. That's not their challenge.

Their challenge is a generic challenge whether, in general, HER2/neu or PR-negative changes the approved methodology that the Eighth Circuit has already sort of blessed. So, our concern about the notice was they were

saying, Judge, the thing that's new that is going to require a second notice out to the MDL plaintiffs that we don't think was appropriately said in the first notice is that there's going to be a case specific evaluation of these eight cases. And last time I looked, you can't *Daubert*-challenge an opinion that hasn't been given. We didn't submit any case specific evaluations of these women. We didn't get their medical records looked at, we didn't have anybody go through the differential diagnosis for these women.

We handled the issue from a general causation basis, which is where we thought it was, and that's all we're saying is we think the first notice is valid and the only reason Wyeth articulated for the second notice was to add this case specific language which I don't believe has any relevance. It's not part of what the issue is that's coming up to this court and it misleads, frankly, the lawyers into believing that there is such an opinion out there that's being challenged when there isn't.

MR. HEARD: We may have more agreement than I thought trying to listen carefully to what she said. Here is the amended and substituted notice that we provided to the Court on Wednesday. Certainly our challenge, Your Honor, addresses the part that is underlined in red. In other words, there is a challenge to whether hormone therapy can cause HER2-positive cancer, that's a general causation challenge.

And there's certainly been a challenge made to whether there is a methodology for determining the cause of an individual plaintiff's HER2-positive or estrogen receptor negative case.

They did give us reports that said there is a methodology, and Dr. Naftalis did answer in her deposition on this issue there is a methodology, and it's my same methodology. So I take it that what the plaintiffs are objecting to is the last -- the tail of that sentence after the slash mark, which is, and that any such methodology was reliably applied in the test cases. And if that's our point of disagreement, it's a very minor one. Our motions do challenge by saying how could this methodology ever be applied to these four women, but the larger question on which the parties have engaged is, is there a methodology.

They've said there is; we've said they're not, in the brief, and the notice ought to say that because I take it that's Your Honor's point. If somebody else has a different methodology, if they want to walk away from Dr. Naftalis and say we're not going down with her, we got a separate basis for sustaining our claim, Your Honor wants to know that.

THE COURT: All right. Let's move to depositions of Philander and Pickar, docket number 2743. It seems to me like this is a witness in a case that's no longer in the MDL.

MR. HEARD: That's true, Your Honor, and this is a problem we've dealt with before in slightly different ways.

Let me just give you a little background and it may work itself out before Judge Copenhaver. Mr. Williams was there at this hearing which I think was earlier this week, or was it June 17th? I've tried to get filled in on the facts over the last night or two. This is a trial remanded case that's going to trial. Mr. Williams indicated that he wanted to take, present the testimony of four witnesses, initially, by live video feed so they would be subpoenaed to appear at a location, you know, across the country or the other side of the globe and that would be fed in by live transmission in some way.

Judge Copenhaver, as I understand, said he wasn't going to do that, and Mr. Williams indicated he was filing a motion that morning to simply subpoena them to court, at which point our lawyers said, well, these witnesses have been deposed before and they're actually videoed depositions. To which, as I understand it, Mr. Williams said well, yes, that's true, but there's a new, there are new issues that have arisen in the case since they were deposed and these new issues about design defect, Mr. Williams' pet theory about micronized progesterone. And at the end of the day, the Court -- and Judge Copenhaver has what he calls a day book entry. It's not -- the conference is not on the record, but he's got somebody there who takes notes and then they're actually formally written down and you can get them.

So we have that here. And his day book entry reflects

that he discussed with counsel issues relating to the video depositions of former Wyeth and Upjohn employees. So Mr. Williams' answer to our protective order here as Judge Copenhaver ordered the depositions, that's his right, that's not Your Honor's business to fool with. So we filed a motion for protective order simultaneously with Judge Copenhaver to say you should stop the depositions because part of the law of the case is practice and procedure order number 2 which limits depositions to, one, these company witnesses get deposed once, you weren't told about that at the hearing, an oversight on the part of our counsel, and you also weren't aware that Mr. Williams was inaccurate when he told you that this was a new issue in the case, since obviously this design defect theory was part of the amended master complaint here.

Mr. Williams has sought discovery here. And when the Court established the September 2009 cutoff, there was plenty of time to come back to Your Honor and ask to redepose Mr. Pickar, Wyeth's former employee, or Dr. Philander, Upjohn's former employee, about these issues. It happens that Mr. Pickar has been deposed more than once already and there was a reason for that. He's been deposed actually four times in the MDL. And Dr. Philander once, but that was in roughly 2004, 5, 6. So Mr. Williams knew well before generic discovery closed that those depositions were old depositions, that his design defect theory had come up since they were deposed, and

he could have asked Your Honor to redepose them and made a case for doing that before the generic discovery cutoff.

Now, clearly if Judge Copenhaver says I'm not going to be governed by practice and procedure order number 2, he can do that and we're not asking Your Honor to trump Judge Copenhaver. We believe he has not ordered us these depositions yet and will not do so once he knows the full facts. But what troubles us is what Mr. Williams says in this court in his opposition to our motion. Plaintiffs do note that they intend to question these witnesses about a number of topics that have never been explored before, including new scientific developments and medical articles published since they were last deposed.

If that is a reason to redepose witnesses who were deposed in the MDL, it is an excuse that applies to every one of the company witnesses who have been deposed in the litigation. There have been 100. And Mr. Williams is, in fact, claiming the right to redepose, or at least this is the logic of this sentence, to redepose every one of the company witnesses again because he's doing it in a remand case.

THE COURT: What do you want me to do?

MR. HEARD: I want you to preclude the plaintiffs' steering committee and their counsel from renoticing depositions of company witnesses in violation of practice and procedure 2 simply because they're putting the caption of a remand case on it.

THE COURT: What if I entered such an order, how would that not be trumping the other judge?

MR. HEARD: Your Honor, perhaps the way that this needs to be resolved is if Judge Copenhaver believes there's some special basis for doing it in his case, the deposition will get taken for purposes of that case only. Otherwise, you know, ordinarily if the deposition is taken, it can be cited, designated in every other case, but that would just end run your whole practice and procedure order number 2.

THE COURT: I understand that. It's worrisome to me, but what can I do if the judge, the transferor judge wants to allow depositions? What can I do about it?

MR. HEARD: Well, in this one case, we can seek a limitation from Judge Copenhaver that the depositions should be used in that case and for that case only. But Your Honor certainly has jurisdiction over these counsel to do two things. One is if they want to redepose company witnesses on generic matters, which is exactly what this is, they need to come to Your Honor and seek leave to do that under practice and procedure order number 2. And Your Honor certainly has jurisdiction to tell them that if they have some special purpose for taking it in an individual remand case, that the deposition they take there can't be shopped around and used in every other case because that would simply circumvent the limitation Your Honor put, a twofold limitation.

The limitation proposed by practice and procedure order number 2 in the first place, one deposition videotaped with the understanding it was going to be used later on, and two, the limitation Your Honor placed by having a generic discovery cutoff. Because there's a way to solve this problem and not present a wholesale violation of those two orders, we believe.

THE COURT: Shouldn't Mr. Williams speak to this?

MS. LITTLEPAGE: He can, but I'm going to talk briefly before Mr. Williams.

THE COURT: It'll have to be briefly because we're going to quit at 12 for sure.

MS. LITTLEPAGE: Yes, sir. I'm going to be very brief. I just want to talk about PPO-2 and what it means, because that's what they're basing their complaint on. PPO-2 handles depositions taken in the MDL. That's it. This arose in the context of Mr. Williams asking his trial judge in a transferor court for live testimony at trial by video conferencing. The judge was ruling on whether Dr. Pickar would show up in his hometown in front of a videotape in front of the jury and just like if he was testifying live, give live testimony on all issues, any issue any lawyer wanted to ask him including current science or current issues.

The judge decided that instead of allowing Mr. Williams to video conference him into the trial, he asked Mr. Williams instead to go before the trial and do whatever he wanted to do

in front of the jury in a videotaped testimony that could then be played to the jury just like if it was live testimony at trial. PPO-2 has nothing to do with that. PPO-2 was generic discovery depositions to be taken in the MDL, not live testimony.

THE COURT: Let me hear Mr. Williams, if he wants to speak.

MR. WILLIAMS: Good morning, Judge. We issued four subpoenas to ex-employees of Wyeth for trial testimony in that case. We had a conference with the judge and he said I didn't want you to do it that way, here's what I want you to do, I want you to use video depositions instead. It wasn't my request for video depositions, it was the judge telling me the only way you're going to get this live testimony is to do it by video. And then he said, is there a way to limit it because, you know, they've been videoed before. And I told him yes, five years ago, we have a videotape of Dr. Pickar, but it hasn't been updated in five years. And he said, well, then give the defendant a list of what you want to ask him and if you can't agree, I'll handle it.

So that's where we are right now in that, plus he asked me to cut the list from four to two, which we agreed to do. But here's the problem. Dr. Pickar is a key witness. He's been subpoenaed to trial and has testified at trial in Philadelphia at least two times, maybe more. Dr. Philander,

who is a former Upjohn employee, lives in Las Vegas, he was subpoenaed to trial in the Nevada cases and testified at trial. We think the federal rules now allow live testimony by remote video so you can extend the subpoena range and we think every plaintiff should be entitled to have this live testimony.

Now, I see the problem of Dr. Pickar can't appear at 50 trials even if he only has to appear close to his home. What I think we should do, and this is something I've been -- we may have talked about this before, but in the Dalkon Shield MDL, which was similar in size and length to this, it was Judge Tyson, Wichita, Kansas had that MDL, and about six years into discovery, because of this same problem, he set up video trial preservation depositions in his courtroom with him on the bench presiding over the deposition and the witness in the witness stand, camera on the witness, camera on the lawyer, and it was wonderful. And we were able to use those depositions at multiple trials later on all over the country. And they were up to date and fresh.

Dr. Pickar hasn't been deposed for five years, Dr. Philander hasn't been deposed for four or five years. We all know lots more now than we ever did back then about what the issues are. The micronized progesterone issue didn't really arise until 2007. Dr. Pickar, I deposed him in 2006 and we didn't have the science then and we didn't have the theory, so we do need to update this. And I would suggest the Court

entertain literally having you preside over depositions in this courtroom or in your other courtroom of these key witnesses so we can use them in the hundreds and hundreds of trials that are getting scheduled.

THE COURT: I'll cogitate on that. Mr. Heard, you want to make a brief statement?

MR. HEARD: With two points. One is that Mr. Williams puts his finger on a interesting problem, but our view is he should have come to this court to iron that out and not sought these depositions, which circumvent the generic discovery deadline in that court. Because, to clarify one important distinction, when the judge, Judge Copenhaver, said no to live video feed, as other judges in this litigation have said no to live video feed, and was then told, well, these experts have already been deposed and on videotape and that videotaped deposition has been designated and used at trial before, what was Mr. Williams' response to the judge? Judge, there's a new issue that has just arisen in this design defect. But as he just told Your Honor, that arose in 2007, two years before the generic discovery cutoff, and he never came to this court and asked to redepose them and update those depositions before the cutoff.

Now we're faced with the problem of his wanting to update depositions by just noticing them in remand cases and then shopping it around. So the proposal he's put on the table for

the first time today that maybe Your Honor referee this process in a centralized fashion is an interesting one. We'd like to respond to it in writing. But that's where we should have started and that's where we should have started this process of dealing with it here and not in some random way based on misrepresentations to --

THE COURT: How long do you want to respond in writing to my presiding at depos?

MR. HEARD: Unless the plaintiffs want to flesh out their proposal more, if they just want to leave it the way it is, I'd like a week to respond to that.

THE COURT: What's a week from today at five p.m.?

THE COURTROOM DEPUTY: Friday, July 1st.

THE COURT: All right. How much time you want to respond to that, Mr. Williams?

MR. HEARD: Could I add this, Your Honor, before you set the schedule in place? One thing that would, I think, be pertinent to our response is whether they would be seeking to do this for two witnesses or ten or 20 or 50.

THE COURT: You got any idea?

MS. LITTLEPAGE: Less than ten.

THE COURT: All right. How much time do you want?

MS. LITTLEPAGE: A week.

THE COURT: Seven and one is eight. Five p.m. on the 8th. I'm going to enter orders on these issues we've

discussed this morning as soon as I can get to it. Is there anything else?

MS. LITTLEPAGE: No, sir.

THE COURT: All right. Y'all have a good -- yes, sir?

MR. WILLIAMS: Your Honor, I do have one thing I want to say about the state court litigation before I get accused by Wyeth of violating more orders. I have three cases set for trial in January in state court in Portland involving the safer alternative theory, and I have served discovery requests on Wyeth and Pfizer for documents that haven't been produced here because the discovery cutoff is gone. And so far, they haven't accused me of violating your generic cutoff order, but I believe my Oregon plaintiffs are entitled to discovery under the Oregon rules of whatever evidence is relevant to their case. And these are women who were diagnosed with breast cancer in 2009 and 2010, so a lot of evidence that's accumulated since your discovery cutoff is relevant to their case, and I just wanted you to know that's going on.

THE COURT: Are you trying to avoid a scolding or something? All right, we're in recess. Thank y'all for your time. Be at ease.

(Proceedings adjourned at 11:49 a.m.)

C E R T I F I C A T E

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

/s/ Karen Baker, RMR, CRR, CCR
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United States Court Reporter

Date: July 1, 2011