

1 IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
 2 FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
 3 CIVIL TRIAL DIVISION
 4 CHRISTOS ANDRO : NOVEMBER TERM, 2002
 5 v. :
 6 WYETH f/k/a AMERICAN HOME :
 7 PRODUCTS CORP., WYETH-AYERST :
 8 PHARMACEUTICALS, INC. and :
 9 WYETH-AYERST LABORATORIES : NO. 0001083
 10 DIVISION OF AMERICAN HOME :
 11 PRODUCTS CORPORATION :
 12 RENEE BETZ : DECEMBER TERM, 2002
 13 v. :
 14 WYETH, INC., WYETH :
 15 PHARMACEUTICALS, INC. :
 16 WYETH-AYERST INTERNATIONAL, :
 17 INC. and WYETH PHARMACEUTICALS : NO. 003939
 18 DIVISION OF WYETH :
 19 MARNI BROOKE GANGEL : MAY TERM, 2002
 20 v. :
 21 AMERICAN HOME PRODUCTS, :
 22 WYETH LABORATORIES, INC., a :
 23 subsidiary of AMERICAN HOME :
 24 PRODUCTS CORP, WYETH-AYERST :
 25 LABORATORIES DIVISION OF :
 AMERICAN HOME PRODUCTS CORP. :
 and A.H. ROBINS CO., INC., a :
 subsidiary of AMERICAN HOME :
 PRODUCTS CORPORATION : NO. 001256

MOTIONS IN LIMINE - PM Session

Wednesday, June, 9, 2004

COURTROOM 246
 CITY HALL
 PHILADELPHIA, PENNSYLVANIA

BEFORE: THE HONORABLE MARK I. BERNSTEIN, J.,

APPEARANCES:

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ANDRO, et al. vs. WYETH, et al.

THE COURT: Okay.

MR. WEISS: Good afternoon, Your Honor.

THE COURT: Good afternoon. Are we ready to go, counsel?

MR. BLEAKLEY: We're ready.

MR. WEISS: We're certainly ready.

THE COURT: Good. Do we have our -- counsel for Wyeth, is evidence that the FDA approved Pondimin and Redux relevant to the question of whether Wyeth was negligent in failing to warn about the risks of the VHD?

MR. BLEAKLEY: Not really.

THE COURT: Then the example you gave on the form you submitted is inaccurate, right?

MR. BLEAKLEY: The example...

THE COURT: You say, "the evidence about the FDA that will be presented to you may be relevant to and you would consider it in connection with, for example, in determining whether Wyeth was negligent in failing to know or warn about the risks of VHD in association with the use of Pondimin and Redux."

MR. BLEAKLEY: Right.

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THE COURT: But the decision is not relevant to that, correct?

MR. BLEAKLEY: The decision to approve Pondimin and Redux for sale, approving an NDA, is not the same as the evidence that we're going to offer, if the Court permits us, about what the FDA did in connection with adverse event reports that were submitted, that's a different issue.

THE COURT: Okay. Fine.

MR. BLEAKLEY: So maybe I didn't make it clear.

THE COURT: No, I didn't understand the distinction when I asked the question. Okay. All right.

Is the question of whether the FDA acted negligently in their handling of the adverse incident reports concerning Redux and Pondimin have any relevance in this case?

MR. BLEAKLEY: Well, that's a hard question for me to answer because I don't think there is any such evidence that they were negligent in handling of ADEs.

I suppose the answer that I would

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have to give to the Court is if we are permitted to offer the evidence that we believe we are entitled to offer, and they can scrounge up some evidence that the FDA was negligent, that would bear on the issue of whether or not Wyeth should have known and should have warned.

THE COURT: So if there was any negligence on the part of the FDA that the plaintiff can demonstrate, that would be relevant in this case, in your opinion?

MR. BLEAKLEY: If we're allowed to offer the evidence?

THE COURT: No, it can't be if.

MR. BLEAKLEY: Well, if we weren't then neither would their evidence. But, yes, I'll answer your question yes.

THE COURT: The answer is yes because you think the evidence that you're going to offer about what the FDA did is relevant, then, therefore, demonstrating that what the FDA did was negligent is also relevant.

MR. BLEAKLEY: Absolutely.

THE COURT: And if they handled it wrongly, not negligently, but wrongly, that

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would be relevant?

MR. BLEAKLEY: If they can demonstrate the FDA acted negligently or wrongly, that would negate or at least affect the argument that we would be making based on what the FDA knew and did.

THE COURT: Or if they based their decisions on inaccurate information, that would be relevant?

MR. BLEAKLEY: Correct.

THE COURT: Or if Wyeth provided incomplete information, that would be relevant?

MR. BLEAKLEY: Correct, about valvular heart disease, putting PPH aside, correct.

THE COURT: No, no.

MR. BLEAKLEY: I'm just reminding the Court we have that issue, which is a separate one.

But absolutely, if the plaintiffs can demonstrate or if they think they can demonstrate or they can muster up some evidence that Wyeth mislead the FDA about valvular heart disease Adverse Event Reports, they would be

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entitled to put that in, absolutely.

THE COURT: And how about if they can demonstrate that the FDA would never have approved the drug if they had all the information; is that relevant?

MR. BLEAKLEY: If they had all the information about valvular heart disease?

THE COURT: No, all the information that we now have about the drug, is it relevant?

MR. BLEAKLEY: No.

THE COURT: So your position is that the FDA activity isolated to the disease that has not been settled is of relevance in this lawsuit, but the FDA activity concerning the diseases that Wyeth has paid millions and billions on is not relevant, correct?

MR. BLEAKLEY: Well, that's not how I would put it, but --

THE COURT: That's how I put it.

MR. BLEAKLEY: Well, I know that's how you put it, Your Honor, that's not how I would put it. Our position is --

THE COURT: Is that correct or

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incorrect?
MR. BLEAKLEY: I think it's incorrect.
THE COURT: All right. What's the correct way to put it?
MR. BLEAKLEY: The correct way to put it is that, in my view, in our view, is that it is the plaintiff's burden to demonstrate that Wyeth knew or should have known and if it did know or if it were negligent it would have warned about the risks of valvular heart disease.
Our defense is that we did what we should have done; that is, we reviewed the scientific literature, we reviewed the clinical studies that have been conducted, we conducted clinical studies when we got Redux approved -- Pondimin was before our time -- but when we got Redux approved; that we reviewed systematically and appropriately the adverse event reports that came in; and we also continued interacting with and had a dialogue with the Food and Drug Administration, who also, we argue, received all the same information we had; and that all

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of the scientific community, including Wyeth, the FDA, and scientists interested in the area did not see any signal of valvular heart disease before 1997. That's our position.
THE COURT: Did Wyeth in any way rely on the FDA to tell it what it should and should not warn? Or, alternatively, did Wyeth make an independent determination?
MR. BLEAKLEY: Well, the answer to that is -- there are a couple of answers to that.
In 1997, when the first evidence of a possible association between these drugs and valvular heart disease did come to Wyeth's attention, Wyeth had a dialogue with the Food and Drug Administration, changed the warning label for Redux and Pondimin to include a warning about valvular heart disease, and that warning was submitted to and agreed to, approved by the Food and Drug Administration. That's the answer to the question.
Prior to 1997, the FDA didn't require, there was no dialogue. Our position is the evidence demonstrates that no one had

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any reason to believe that there was an association with valvular heart disease before January 1997.
THE COURT: Did Wyeth rely on the FDA's determination or did Wyeth make its own determination?
MR. BLEAKLEY: Wyeth made its own determination based on all the evidence that was available, which included the fact that the people responsible for post marketing surveillance at the FDA, which reviewed all of the same stuff Wyeth did, came to the same conclusion.
THE COURT: Who's going to testify to that?
MR. BLEAKLEY: That would be --
THE COURT: Who's going to testify to the aspect that FDA's conclusion was a factor in Wyeth's determination as to no other warning was necessary?
MR. BLEAKLEY: Well, there are various people who can testify to pieces of it.
THE COURT: No, in this trial.
MR. BLEAKLEY: I mean in this trial.

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But the principal witness who can testify is Dr. Ginger Constantine. There are others.
THE COURT: Okay. At what point in time are we talking about when Wyeth relied on an FDA's determination? That was after the product was for sale, correct?
MR. BLEAKLEY: Well, it included the period after the product was for sale, but --
THE COURT: Did Wyeth rely on any FDA determination as to what warnings were scientifically necessary before approval by the FDA?
MR. BLEAKLEY: Well, with Pondimin, remember that Pondimin was approved for sale in 1973, long before Wyeth had anything to do with it, so I don't have any idea what the answer is.
I know that as a practical matter when Pondimin was originally approved by the FDA in 1973, there had to have been a warning label that was submitted along with the NDA application; and that the FDA must have approved whatever warning label was in existence in 1973.

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I know that the warning label was amended from time to time over the years because of evidence, various kinds of evidence that came out. And each time it was amended, it would have been approved by the FDA. But whether the FDA played a role in any of those changes, other than approving what was submitted, I don't know.

THE COURT: I don't know what you're talking about when you say the FDA played a role. Is that an official document that is promulgated in the federal registry or are you talking about conversations with scientific medical people who are employed by the FDA?

MR. BLEAKLEY: A combination of those things, Your Honor. The FDA can say hey, we see evidence in the scientific literature that there is a risk of this, and we want you to put that in the label, and if you don't, we're going to revoke the approval, that's one way it can happen.

THE COURT: Was there any official FDA action that Wyeth relied on?

MR. BLEAKLEY: At what point in time

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THE COURT: That's my next question.

MR. BLEAKLEY: In 1997 there was an official action and then --

THE COURT: When was it withdrawn, what month?

MR. BLEAKLEY: September 1997.

THE COURT: Okay. And in 1997 before it was withdrawn?

MR. BLEAKLEY: In July of 1997 Wyeth submitted revised labeling for both Redux and Pondimin that included a black box warning about valvular heart disease and PPH, and that was approved officially.

THE COURT: In deciding not -- was that the first time you gave a warning for valvular heart disease?

MR. BLEAKLEY: Yes.

THE COURT: In deciding not to give such a warning prior to that, was there any official FDA action that was relied upon?

MR. BLEAKLEY: I'm not sure what you mean by official, but I think the answer is --

THE COURT: I think official means published in the federal registry.

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MR. BLEAKLEY: I think the answer is no.

THE COURT: Isn't that what official means? Can the FDA act officially without publishing in the registry?

MR. BLEAKLEY: I could argue that the FDA acts officially in lots of ways other than being in the federal registry.

THE COURT: Well, that's what I mean.

MR. BLEAKLEY: But we'll take your definition, yes. I don't believe so. Oh, of course, the Redux label -- well, no.

MR. GROSSI: Your Honor, if I can address the Court.

THE COURT: Yes.

MR. GROSSI: In April and May of 1997, there were meetings with the FDA, and as a result of those meetings with the FDA, letters were sent to us about how they wanted the labeling issue with respect to valvular heart disease handled.

I can assure you that whatever the federal register says, people at the drug companies consider those to be official

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pronouncements of the FDA.

MR. BLEAKLEY: That's what I meant by official.

THE COURT: That's fine. That's fair.

Is the testimony going to be that Wyeth relied to any extent on these communications?

MR. BLEAKLEY: You bet.

THE COURT: Okay.

Okay. Have you seen plaintiff's statements?

MR. BLEAKLEY: Yes.

THE COURT: Do you agree with them?

MR. BLEAKLEY: No.

THE COURT: Well, you don't agree with two. That I can see is directly contradicted by what you said.

How about one, do you agree with that?

MR. BLEAKLEY: I think we probably do agree with that, don't we, number one, Mike?

MR. SCOTT: That's fine.

MR. BLEAKLEY: Yes, I think we agree

1 with number one.

2 THE COURT: And it is permissible for
3 plaintiff's experts to testify, if they're
4 qualified, to what a reasonable pharmaceutical
5 company would do under similar circumstances.

6 MR. BLEAKLEY: That's what they do,
7 yes.

8 THE COURT: Well, then how can the --
9 what's that drug in Europe, Aminorex, how can
10 the Aminorex epidemic be kept out of evidence?

11 MR. BLEAKLEY: Because it doesn't
12 have anything to do with valvular heart disease
13 and it doesn't have anything to do with
14 Pondimin and Redux.

15 THE COURT: Because chemically it
16 doesn't?

17 MR. BLEAKLEY: Well, among other
18 things. It also was in the 1950s, chemically
19 it's not the same, it tells you nothing that
20 has any relevance to valvular heart disease.
21 And it's so remote in time as to be -- with all
22 due respect, Judge, the purpose of offering all
23 this stuff is to show another epidemic.

24 THE COURT: And the purpose of
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1 developing all this stuff about the FDA is to
2 show if the government approved it, but I'm not
3 going into intent, I'm getting into relevancy.

4 If they can testify -- if an expert
5 can testify to the standard of care that a
6 pharmaceutical company -- it's not standard of
7 care -- to what a reasonable pharmaceutical
8 company would do, then a qualified expert who
9 thinks that that's something to take into
10 account can testify to why and be torn apart on
11 cross-examination, correct? It's a relevant
12 discussion.

13 MR. BLEAKLEY: Yes, except Aminorex
14 was about PPH, not valvular heart disease.

15 THE COURT: Okay. All right. So
16 it's a different medicine, but other than that
17 it's --

18 MR. BLEAKLEY: That's pretty much.

19 THE COURT: Other than that it's
20 relevant, the principle is relevant.

21 MR. BLEAKLEY: The principle that an
22 expert like Busch or Moye can come in and
23 testify that there was a drug that was very
24 similar to this one 30 years ago that caused
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1 valvular heart disease and you should have
2 known it, yes, I'd have a tough time arguing
3 that that wasn't relevant. But that isn't the
4 fact.

5 THE COURT: Okay. Good. What else
6 do you want to tell me?

7 MR. BLEAKLEY: Nothing else, other
8 than I submitted this because Your Honor
9 ordered me to submit it before lunch. We're
10 not actually proposing that the jury in voir
11 dire should be given these instructions because
12 I think it's pretty darn complicated, and I
13 don't think this is an appropriate time to do
14 it. I think the appropriate time to do that is
15 when the charge is given. But I understand
16 that you may do it anyway, I just want to make
17 sure that we weren't embracing it.

18 THE COURT: Well, over your
19 objection, if you object at the appropriate
20 time. But let me tell you something, I intend
21 to explain to the jury panel what the case is
22 about.

23 MR. BLEAKLEY: That I understand. I
24 would expect you to.
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1 THE COURT: Okay. And a lot of what
2 we're about to do is to help me figure out what
3 they should know.

4 MR. BLEAKLEY: Sure.

5 THE COURT: So it seems to me that
6 the remaining motions all go around FDA and
7 PPH.

8 MR. BLEAKLEY: Pretty much, even some
9 of the individual evidentiary motions are PPH
10 related.

11 THE COURT: Yes. If I rule on the
12 PPH or somehow how the FDA flows into this
13 case, everything else will sort of flow from
14 whatever principles I come up with.

15 MR. BLEAKLEY: I think most, I don't
16 know whether all.

17 THE COURT: Yes, check the list. But
18 is there any other discrete thing that is still
19 hanging out there?

20 MR. WEISS: Yes.

21 THE COURT: What?

22 MR. WEISS: If I may be permitted to
23 speak, Your Honor. The issue of settled claims
24 has not been resolved.
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1 THE COURT: Is that different from
2 PPH?

3 MR. WEISS: Yes. What's different is
4 that --

5 THE COURT: I'm losing you.

6 MR. WEISS: Okay. There is evidence
7 that Wyeth received a bunch of adverse event
8 reports of other disease processes, one of
9 which was hair loss, alopecia. And Wyeth,
10 without requesting the FDA, without a dialogue
11 with the FDA, changed its label to include a
12 warning or a precaution that one of the side
13 effects --

14 THE COURT: They're not saying any
15 more than that can't come into evidence. Isn't
16 that relevant to an evaluation of what a
17 reasonable pharmaceutical company would do
18 under similar circumstances?

19 MR. GROSSI: Your Honor, I believe
20 there is relevance. But if I may just say, the
21 problem is that -- take alopecia, we have no
22 problem with them talking about alopecia
23 because none of these plaintiffs claim to have
24 alopecia. The problem is that some of these
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1 plaintiffs do claim to have such other things
2 as neurotoxicity. And so, if they talk about
3 those claims, we run the danger that suddenly
4 we're, and formalisms aside, suddenly we're
5 litigating a case where Mr. Andro says he has
6 neurotoxicity, he has panic attacks, and the
7 jury hears that we had reports of these cases,
8 then it doesn't take them a long time to be
9 awarding damages or finding negligence, and
10 that's settled.

11 THE COURT: Is that your only problem
12 with that?

13 MR. GROSSI: It is, Your Honor,
14 because under the settlement agreement every
15 other claim for those types of things is
16 settled.

17 THE COURT: But that's your only
18 problem?

19 MR. GROSSI: That is my problem, yes,
20 Your Honor.

21 THE COURT: Okay. Then the motion in
22 limine is denied. And I will appropriately at
23 the appropriate time instruct the jury as
24 specifically as necessary as to what they may
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1 award damages for.

2 And if Wyeth asks, I will instruct
3 them specifically what they may not award
4 damages for, even though they may have heard
5 testimony about it that was relevant to other
6 issues.

7 MR. GROSSI: Your Honor, I think that
8 goes along with, if I may make one other
9 suggestion, if it is the plaintiff's intention
10 that, for example, Mr. Andro is not claiming
11 that his panic attacks have anything to do with
12 Redux, then I would like that, either by
13 stipulation or by instruction, to be explained
14 to the jury.

15 THE COURT: I would be happy to
16 discuss that with them later, all right?

17 MR. GROSSI: Okay.

18 THE COURT: But I don't care what
19 they agree to, if for whatever reason the
20 testimony about panic attacks is offered into
21 evidence and it has not been connected to the
22 valvular problem, which is the only claim,
23 you'll give me an instruction again, and I will
24 specifically tell the jury that they cannot
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1 award for that; or alternatively, you will make
2 a tactical decision not to specifically say
3 that to the jury, in which case the issue will
4 be waived.

5 MR. GROSSI: My point, Your Honor,
6 because I know these transcripts tend to be
7 used in other cases is it's Wyeth's position
8 that while I appreciate the stipulation, the
9 fact is as class members they are bound not to
10 make that claim in this type of litigation.

11 THE COURT: It doesn't matter what
12 they are claiming. I'm ruling on evidence.
13 I'm ruling that it's admissible for other
14 purposes.

15 Now, if your concern is that the jury
16 will confuse the mention with what they can
17 award damages for, I think that can be
18 straightened out -- I'm ruling that that can be
19 straightened out by appropriate instructions.
20 So at the appropriate time, you'll either
21 remember and give me the instructions that are
22 necessary, or you'll have waived the issue.

23 MR. GROSSI: Understood, Your Honor.
24 Thank you.
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THE COURT: Okay. So somebody on the plaintiff side, give me a little note about what I just ruled so I can write out the order, would you do that for me?
MR. MILLER: We will, Your Honor.
THE COURT: So that leaves us with PPH and FDA issues.
MR. WEISS: That's correct. Do you want a response to their FDA argument?
THE COURT: Let me think about it.
MR. WEISS: Okay.
THE COURT: I'd rather, if I may, hear argument on the PPH motion, which I don't think we argued at all.
MR. WEISS: Just tangentially. We have not addressed it straight up, that's correct.
THE COURT: This is defense motion to keep all mention effectively of PPH out of the case; is that right?
MR. ALEXANDER: Correct.
THE COURT: Who's going to argue for the defense?
MR. BLEAKLEY: If I may say just one

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more word about the FDA issue.
THE COURT: You may.
MR. BLEAKLEY: If Your Honor is seriously thinking about ruling on that issue before we start phase I, we really would appreciate the opportunity to submit a very short memorandum on that issue.
THE COURT: Anything that is submitted before I have ruled will be ready, particularly the charge.
MR. BLEAKLEY: That's really important. And I think we can articulate the reasons maybe better than I have here today, and we'll get something in to you the next couple of days.
THE COURT: The next couple of days? I was about to tell you there's some 20 hours between now and voir dire.
MR. BLEAKLEY: But none of this is going to come up in the first phase, the FDA issue.
THE COURT: I will rule on -- I will read whatever is presented to me before I make a ruling. That's why I point out that there's

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22 hours before we begin voir dire, but whatever, go ahead.
Like a test, you know, you got to study for the test, you calculate the number of hours and subtract the sleep, but somehow it's got to be calculated in.
MR. BLEAKLEY: Gotcha.
THE COURT: Okay. PPH.
MR. BLEAKLEY: PPH.
THE COURT: You see, this is a good opportunity. There are two schools of judicial thought on settlement. The one school of judicial thought is keep everything ambiguous, don't nail anything down, keep them guessing. I don't follow that.
The other school of judicial thought on settlement is step by step nail everything down, make it clearer and clearer and clearer and clearer, because there's enough uncertainty in what a jury will do for any case to settle. So I'm intending to nail and nail and nail.
MR. BLEAKLEY: We've gotten that impression.
THE COURT: Right, but now I've

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articulated why.
Continue.
So if people don't want nails, the time to avoid them is between now and the beginning of voir dire. After that, all bets are off. In fact, I don't even know if I'm going to start nailing within the next hour and a half, I hope appropriately and correctly.
Continue. PPH.
MR. BLEAKLEY: PPH, it is our position that there is no evidence about PPH, primary pulmonary hypertension, which should be heard by this jury.
THE COURT: I can't hear you.
MR. BLEAKLEY: It is our position that there is no evidence that is being proffered by the plaintiffs with respect to PPH that should be received in evidence in this case that is admissible, that is relevant. And to the extent that any of it is relevant, I'm certainly not suggesting that it is, for prejudicial value, the prejudicial harm that would be caused far outweighs the relevance and the potential for confusion by the jury.

The only part of this case that is complicated is the science and the diseases and the disease process. The jury is going to have difficulty comprehending all of these diseases with the evidence they're going to hear just about valvular heart disease and several different kinds of valvular regurgitation there are without cluttering up the record with a completely different disease.

None of these plaintiffs has primary pulmonary hypertension, none of them claims to have it, none of them is in danger of having it, no evidence will be presented that any of these three plaintiffs have or will have primary pulmonary hypertension as the result of taking Pondimin or Redux.

Valvular heart disease is a different disease, there is no dispute about that. We discussed that in the tail in our papers. They are different diseases. There is no claim that a failure to warn about PPH, and there will be no evidence that a failure to warn any of the three plaintiffs' prescribers about PPH affected their decisions to prescribe these

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drugs to these three plaintiffs.

And in this case in particular that is key. There are three prescribers. All have testified by deposition. All will either come live and testify or will be presented by deposition. Each of them has testified under oath that they knew about the risk of primary pulmonary hypertension and prescribed these drugs anyway.

With respect to Redux and Pondimin, by the time -- yes, Your Honor is frowning as if you don't understand what I'm saying.

THE COURT: No, no, I'm trying to drink it in, that's all.

MR. BLEAKLEY: Each of the three prescribers has testified that they knew about PPH when they prescribed these drugs to these three plaintiffs. So there can be no claim and there will be no evidence that a failure to warn about PPH caused these guys to prescribe the drugs and that they wouldn't have gotten valvular heart disease but for it.

Plaintiff's argument -- and it is just argument in their paper -- is that Wyeth's

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handling -- that's the word they use, handling, and I use that word because it's important -- handling of PPH, increases the probability that Wyeth failed properly to adequately warn about valvular heart disease. That's a very interesting statement, but there is no evidence to support that statement. That's just plaintiff's argument, it's just plaintiff's argument.

THE COURT: Okay.

MR. BLEAKLEY: They never said --

THE COURT: How can the jury evaluate what the FDA did if they're only given half a picture of what the FDA was doing?

MR. BLEAKLEY: Because the FDA knew about PPH, too. They knew the same thing that the scientific community knew.

Your Honor --

THE COURT: Well, I don't think plaintiff agrees with that. Just one minute. Do you agree with that statement?

MR. WEISS: No.

MR. NOLEN: No, Your Honor.

THE COURT: Let me ask them to

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articulate whether PPH is relevant and then come back to you.

Let me start by asking you to confirm what counsel just told me; that none of the -- that the prescribing physicians all knew the danger of PPH and nonetheless prescribed the medication. Do you as plaintiff agree with that?

MR. NOLEN: No, Your Honor, we disagree with that.

THE COURT: Okay. Let me ask them. It's your motion, but let me ask them to tell me what the relevance is and then I'll come back.

What is the relevance?

MR. NOLEN: Your Honor, it's relevant to the law, and that's where I have to begin on the argument for this, if you don't mind.

As the Third Circuit pointed out on Page 26 of their opinion, it says that similarly, the district court placed off limits any evidence that mentioned medical side effects other than VHD, valvular heart disease, itself.

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This evidence was not offered to support claims for these side effects, since plaintiffs did not suffer from them, rather, they were offered for other purposes, such as degree of duty to warn, evidence of the totality of the risk of injury may be admissible under state law to show the scope of the duty to warn even if the individual plaintiff has not sustained all of the injuries in question. And they cited a case that we had cited to them, Mr. Fleming and my firm, called Dartz versus Fibreboard, which was a Fifth Circuit case.

Now, that's the Third Circuit citing to that. And then they go on to say in effect, the district court trimmed evidence that was probative, but that it viewed as unnecessary and so inculpatory that it might inflame the jury to award damages that would punish Wyeth instead of simply compensating the plaintiffs. The district judge effectively adopted the role of the trial judge, balancing probative value against unfair prejudice. By doing that, he moved beyond mere enforcement of the damages

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ultimate warning goes to. And I think it says here -- yes. It says on -- continuing in Baldino, it says in addition -- this is going back to the Incalino (ph) case, a 1971 Supreme Court case. It says, in addition we held that where such drugs were available by prescription only, the warning required is not to be to the general public or to the patient but to the prescribing doctor.

THE COURT: Right. Okay. Go ahead.

MR. NOLEN: So there is a learned intermediary doctrine in the state of Pennsylvania.

Now, the issue then is how is it relevant. First of all, we would respectfully disagree with what has been told to the court about what was testified to. We believe that Ms. Betz' prescribing doctor, Corey Nyhus, testified that he would have liked to have known of such things as the death by cities and all of the evidence surrounding the pulmonary hypertension issue, because had he known of that, he wouldn't have prescribed the drug.

The same was true, Dr. Nyhus

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restriction and affected plaintiff's right to try her permissible liability case.

Now, if we go to the law of the state of Pennsylvania, specifically the Baldino case, which was a Pennsylvania Supreme Court case from 1984, the court said -- and I've got a poor copy -- it says, rather such a manufacturer is liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous.

And so what the court in Baldino holds is that the consumer, the patient, has a right to know all of the facts.

THE COURT: Well, it doesn't say consumer, does it?

MR. NOLEN: It says liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied.

THE COURT: That's on a prescription drug, that's not the doctor?

MR. NOLEN: Well, it does go on, Your Honor, to make clear that -- it actually does make clear that the physician is who the

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testified about valvular heart disease.

THE COURT: Where do they say that?

MR. FLEMING: We're getting it, Your Honor. We're going to go get it.

MR. NOLEN: We've sent somebody over to our office to go get it and bring back the testimony.

THE COURT: Okay.

MR. NOLEN: So in just that respect alone we think it's very relevant.

Also, Ms. Betz of course has pulmonary hypertension, a condition that they claim they warned about in the early Pondimin label, which we contend they warned about inadequately and ambiguously because they cite four cases which we know is untrue. She is suffering from the condition of pulmonary hypertension. That has been diagnosed.

THE COURT: I hate to point out my stupidity, pulmonary hypertension, is that PPH?

MR. NOLEN: No, it's not, Your Honor. It's pulmonary hypertension secondary to valvular heart disease.

THE COURT: What's PPH?

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MR. NOLEN: PPH is primary pulmonary hypertension.

THE COURT: Okay. Continue. I'm with you now. She has pulmonary hypertension, which is different from PPH. Go ahead.

MR. NOLEN: It's different in severity.

THE COURT: Yes.

MR. NOLEN: And so she has at least a condition they claim to have warned about, although inadequately and inaccurately.

So we believe that it's directly relevant to the failure to warn, both from a legal standpoint, because how can any jury determine whether there is a failure to warn case if they don't hear all of the conditions that the defendant is supposed to warn about?

You asked a very salient question the other day, and I'm not sure that we answered it very well. I'm going to try again. You asked a question: Well, could the jury find on the first question did Wyeth adequately warn regarding Pondimin and Redux.

THE COURT: Regarding valvular heart

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number one about PPH only, could they find yes to number two?

MR. NOLEN: They could find no to number two.

THE COURT: Now answer my question. If they answered yes to number one because they thought Wyeth failed to properly warn only about PPH but had properly warned about valvular heart conditions, could they find yes to question two?

MR. NOLEN: Not if they followed your instruction in the law.

THE COURT: Correct. So there's absolutely no reason to allow them to misunderstand the question. One should say what the warnings are about.

Now, let's go to why they should be venerated about PPH.

MR. NOLEN: Well, again, Your Honor, it goes directly to the failure to warn issue.

THE COURT: Well, let me rephrase. To what issue that the jury has to decide is whether proper warnings for PPH were issued relevant? What issue that the jury has to

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problems.

MR. NOLEN: Well, if you keep going. But the question really should be, did Wyeth adequately warn regarding the risks associated with Pondimin and/or Redux. That, according to the Baldino case, that would be the question.

THE COURT: As to specific things?

MR. NOLEN: Well, I think the second question takes care of that.

THE COURT: What's the second question?

MR. NOLEN: Well, the next question would be was Wyeth's failure to warn a substantial cause of Renee Betz' valvular heart disease.

THE COURT: Well, maybe you inadequately answered it, but I'm going to give you another opportunity to inadequately answer it.

Can the jury find that the only failure to warn was about PPH?

MR. NOLEN: Well, the jury could easily find yes to number one.

THE COURT: If they found yes to

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decide concerning warning of valvular heart problems makes the question of proper or improper warnings about PPH relevant to it?

MR. NOLEN: Your Honor, I would respectfully have to say that I think it has to do with proper labeling of the drug, period, because that is the issue, that's the crux of the issue.

If you take this drug, for example, and you said well, does it have great efficacy, and a doctor says well, my patients have lost six to eight or ten pounds in a two-month or three-month period that I prescribe it, but they regained the weight once they stopped taking it. It's very conceivable that a physician looking at the Physicians Desk Reference or looking at the labeling would say I'm not going to prescribe this drug for six or eight or ten pound weight loss for a patient who's going to regain it if, if, there is a risk of a fatal disease, no matter what the likelihood is. But if I know there's a risk of a fatal disease, I'm just not going to prescribe this drug.

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We believe that Dr. Nyhus -- and I think we're going to have that testimony for you very shortly -- said that.
There is another issue, too, Your Honor, and that is, and of course I have to get back into science on this, but we talked about Aminorex, we talked about the issue that comes up with these serotonin re-uptake inhibitor type drugs, and what the science has shown us, Your Honor, is is that what these drugs do is they attack the 5HT2B receptor, which is part of the tissue inside both the heart and the lungs. And so the serotogenic effect on the tissue itself, whether it be PPH or whether it be valvular heart disease, is the same, because it's the same mechanism of action that is causing injury to the indial thallium (ph) inside the heart. And so that's how another way that it's directly relevant. You've got the same mechanism of action going on in both disease processes.

THE COURT: So the mechanism can be described in the valvular heart disease process without any reference to the same mechanism in

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PPH, right?
MR. NOLEN: Well, it's very well documented with regard to the PPH. In fact, it was documented at least in the scientific literature in the PPH context as actual causation before the valvular heart disease, which we also believe goes to the notice issue of putting Wyeth on notice that there was a potential for injury to heart valves as a result of the drug.

THE COURT: Okay. Anything further?

MR. MILLER: Your Honor, on behalf of Mr. Andro and his prescriber, his prescriber said that when he prescribed Redux -- this is on Page 58 of his deposition, his name is Dr. Tadley -- that he was not aware of the statistics of the reported cases of valvular heart disease or PPH deaths related to the use of Redux when he prescribed it.

He said on Page 86 that he expected them to tell him about these things, and also informed that he would have wanted to have this information before he prescribed; and that had he had it, particularly about valvular heart

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disease, but about all of it, he would not have prescribed it.

So I think it's the totality of the risks that this prescriber says he would have wanted to know about: The lack of efficacy, the primary pulmonary hypertension risk, the true risk, and the valvular heart disease risk. It was a totality; that he would not have prescribed it had he known about the totality. So I think that goes to not only the risk of the drug but to the proximate cause. Because had he had, Dr. Tadley had, the risks of pulmonary hypertension truly explained to him, he would not have prescribed this drug. So I just wanted to share that with the Court.

THE COURT: Okay. Which plaintiff has told me that they're calling the prescribing physician?

MR. MILLER: Mr. Andro is.

THE COURT: And Ms. Gangel?

MR. WEISS: Yes.

And I might, for the record, Your Honor, as class counsel, I abided by 2828, and I did not ask any questions to Dr. Kleinberg

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about the true risk of PPH.

THE COURT: Who's Kleinberg?

MR. WEISS: He's Ms. Gangel's treating physician. He's coming in live, and he's going to be seeing evidence that he didn't see before, and I wouldn't be surprised if his testimony is different on that issue.

THE COURT: Different from what?

MR. WEISS: Because --

THE COURT: Different from what?

MR. WEISS: He testified at deposition --

THE COURT: His testimony in court under oath is going to be different from his testimony at deposition under oath?

MR. WEISS: Absolutely, because he didn't have the evidence before him. He didn't know what the true risks were of PPH. He had no idea what the death count was, the number of surviving people.

THE COURT: Okay.

MR. FLEMING: We found the deposition.

MR. NOLEN: Would you like for me to

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hand it up or do you want to --

THE COURT: If it's short just read it for the record.

MR. NOLEN: All right. On Page 90 beginning at Line 9 of Dr. Corey Nyhus's deposition, who is the prescribing doctor, and who we designated testimony from in this case, it says you didn't have -- it starts in the middle, I'm afraid -- "you didn't have that warning in '95, '96 or '97, right?" And this is the warning regarding valvular heart disease.

"Answer: Correct.

"In addition to that we now have a black box warning to pulmonary hypertension, correct?

"Answer: Correct. All in all, we have three new issues in the 1998 labels. We have got not safe or effect, right? We have got not safe or effect, right? Right.

"We now have valvular heart disease warning; do we not?

"Answer: Yes.

"And we have a pulmonary hypertension

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"Would you have prescribed it then?

"Answer: No."

Now, he warned of the four cases label, which was the inadequate and incorrect, by their own admission, information that was contained in the Pondimin labeling from the years 1991 up until 1996. He gave that warning because it was available to him, but it was wrong, it was inaccurate, and it didn't warn of the severity of the disease.

We've had this brief discussion about the difference between pulmonary hypertension and primary pulmonary hypertension. Pulmonary hypertension, as defined by the national settlement, is something meaning on echocardiogram less than 60 millimeters of mercury, and they say everything below that is pulmonary hypertension.

Now, I think it's undisputed that you can actually have some effects of pulmonary hypertension on up, all the way up through to 60, but it becomes at least by the definition imposed by the national settlement becomes so-called primary pulmonary hypertension after

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warning?

"Answer: Yes.

"Question: So, in other words, you didn't, as Ms. Betz prescribing physician at that time, know about any of these things, did you?

"Answer: That's correct.

"Question: And you did not warn about any of these things, did you?

"Answer: None other than the pulmonary hypertension.

"Question: The four cases that we talked about, correct?

"Answer: Right.

"Based on everything that you know today, do you think that Redux and Pondimin should be on the market?

"Answer: No.

"Question: Why?

"Answer: Because of the findings that were reflected in the studies of 1997.

"Question: Based upon what you know now, would you prescribe it today?

"Answer: No.

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it reaches the 60 threshold. So you've got the beginning of a disease process in some patients who have pulmonary hypertension who may ultimately get to PPH.

THE COURT: Okay. Thank you. Now I'm back with you.

MR. BLEAKLEY: Valvular heart disease, pulmonary hypertension, primary pulmonary hypertension, we understand that the plaintiffs will in this case argue that pulmonary hypertension can be, is, whatever argument they want to make, secondary to valvular heart disease. We understand that the plaintiffs want to argue and will have their experts testify that an adverse event report which shows somebody taking Pondimin and getting pulmonary hypertension is a sign or a signal of valvular heart disease.

It is, with all due respect, bologna, but we understand the argument and we'll address it in the trial, and we're not suggesting that that evidence shouldn't be admitted. Their experts can get up there and testify about it, and we'll respond to it on

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cross-examination and with our experts. That is not what we are talking about here today. We are talking about primary pulmonary hypertension, which is very, very different. It kills, it's fatal, it's a horrible disease. All of the evidence about it is going to turn a jury off, it's going to make them sick to their stomachs, it's totally different.

And the claim with respect to primary pulmonary hypertension is different from the claim with respect to valvular heart disease, which I think will demonstrate why it is that if we go down this path, there will be hopeless confusion and we'll be trying a primary pulmonary hypertension case.

The claim with respect to valvular heart disease is that there was evidence in the adverse event reports in Wyeth's files that should have alerted, or did or both, Wyeth to the fact that there was an association between valvular heart disease and these drugs prior to January of 1997, which is when we say that happened, and we didn't see it or we saw it and ignored it. That's what that claim is about

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valvular heart disease.

The claim with respect to primary pulmonary hypertension is different, and it demonstrates the mischief that we'll get into if they can put their whole primary pulmonary hypertension case in here. There was a warning about primary pulmonary hypertension in the label. We don't deny that Wyeth knew that there was at least some association between primary pulmonary hypertension and Pondimin and Redux before 1995. It was in the label.

The argument that the plaintiffs make in a PPH case, in a real PPH case, is that that label was wrong, there were more cases than the four that were in the label, we ignored them, we mislead the Food and Drug Administration, we were negligent, it should have been a better warning, a different warning, sooner. It's different from the claim with respect to valvular heart disease, and what they want to do is they want to try that whole PPH case here.

Death by cities, they asked the doctor whether or not --

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THE COURT: Death by cities? Where?

MR. BLEAKLEY: This is one of the documents that they want to put in this case.

THE COURT: D-E-A-T-H, C-I-T-I-E-S?

MR. BLEAKLEY: Yes, death by cities.

A whole bunch of people died from primary pulmonary hypertension. That's what they want to put before the jury. That's one of the documents.

Aminorex, it's about PPH. There's all kinds of flow about this whole PPH issue out in individual pieces of evidence.

THE COURT: Well, there's a lot of range between no mention of PPH and no admission of death by cities.

MR. BLEAKLEY: There is.

THE COURT: There's many places that cites that.

MR. BLEAKLEY: My position is it's all irrelevant and all unduly prejudicial. Our position is none of it is relevant. They are different diseases, they are different processes.

Now, they got up here and told you

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that Dr. Nyhus said he would like to have known about the death by cities document. They got up here and told you that the four cases PPH label was the one that Dr. Nyhus had when he first prescribed Pondimin. What he didn't tell you is that Dr. Nyhus also prescribed Redux for that patient, for Ms. Betz, and prescribed Redux with a label that contained the most accurate up-to-date information in the world about the risks of primary pulmonary hypertension.

He didn't tell you that Dr. Nyhus prescribed Redux for Ms. Betz in 1997, when the Redux label contained the results of something called the International Primary Pulmonary Hypertension study, which was the state-of-the-art evidence about what the actual risk is.

THE COURT: Okay. Let me stop you because it seems to me, speaking in an advisory manner, without any intention to being held to this after I sleep on it, that the only relevance of PPH would be concerning FDA testimony, because I'm having a very difficult

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time understanding how the FDA can be hauled into the courtroom without presenting to the jury the whole picture of everything that had to do with the FDA. So unless there's something that you wish to add at this point, I'd like to move on.

MR. BLEAKLEY: Okay. I'd like to submit a paper on that, as I told you, but you already told me the constraints that we are under for submitting such paper.

THE COURT: You can do whatever you need to do. I'm sure you'll get it done. Okay. Then let's move to voir dire if we can.

MR. BLEAKLEY: Yes, sir.

THE COURT: Let's go to voir dire in this matter.

MR. FLEMING: Your Honor, if I might, I'd like to take a short break before we go to the voir dire. I've got my guy that's been working with Mr. Bleakley with regard to the questions you asked, he just walked outside, he's coming right back. If you just give us a minute.

MR. BLEAKLEY: I'm not sure, but I'm

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Honor, I didn't bring -- I don't have plaintiff's proposed charge with me. Could we take a few minutes, Your Honor, to get it?

THE COURT: I'll see counsel and everybody else in chambers at 3:25, Room 530. I'll see everyone at 3:25 in Room 530.

(Whereupon a short recess was taken.)

(Whereupon the following proceedings commenced in the judge's chambers with the Court and all counsel being present:)

THE COURT: Let's go on the record. There's some confusion, at least in my mind, that became clear, on the question of what kind of specials are going to be on the board, if we ever get that far in the trial.

When I was discussing things with people privately, I got some confusion, so I want to clarify it.

Mr. Weiss, on behalf of your client, Gangel, are you presenting a claim for past medical expenses?

MR. WEISS: Yes.

THE COURT: Can you give me just a

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certainly happy to wait until he gets back.

MR. FLEMING: You asked the two of us to get together.

THE COURT: I did?

MR. FLEMING: Yes, I thought you did, and --

THE COURT: Can we move on to points for charge?

MR. BLEAKLEY: Your Honor, we did narrow it. There are about four as to a disagreement.

THE COURT: Okay. Well, let's wait. Let's go to points for charge.

Who's dealing with points for charge?

MR. FLEMING: Mr. Weiss for the plaintiffs.

THE COURT: Who's dealing with plaintiff's proposed points for charge on the defense?

MR. SCOTT: I am, Your Honor.

THE COURT: Mr. Scott, do you have any objection to the standard definition of negligence?

MR. SCOTT: Unfortunately, Your

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ballpark estimate of the magnitude of that claim, if not the exact figure?

MR. WEISS: I can't give you the exact figure, but I can give you a ballpark figure, it's probably less than \$6,000 past.

THE COURT: Okay. Past medical, under \$6,000.

MR. WEISS: I suspect that's right.

THE COURT: Are you making a claim for past lost earnings?

MR. WEISS: No.

THE COURT: Are you making a claim for future medical?

MR. WEISS: Yes.

THE COURT: Can you give me a ballpark as to that?

MR. WEISS: It's the cost of an echocardiogram every year or two for the rest of her life, and the cost of having her mitral valve replaced or repaired, as testified by Dr. Hargrove and another doctor.

THE COURT: Ballpark?

MR. WEISS: Under \$100,000 for surgery is fair.

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THE COURT: The total future medicals is on the order of 100,000?
MR. WEISS: Probably.
THE COURT: Okay. That's fine. And who's going to testify to that?
MR. WEISS: Dr. Silvestry or Dr. Hargrove or Dr. Mallory (ph), one of the three.
THE COURT: Okay. And who else, Negrete is done, Gangel.
Andro, do you have a claim for past medicals?
MR. MILLER: Yes.
THE COURT: A ballpark amount?
MR. MILLER: Under 3,000.
THE COURT: And do you have any claim for past or future earnings?
MR. MILLER: No.
THE COURT: And do you have a claim for future medicals?
MR. MILLER: Yes.
THE COURT: And give me a ballpark, tell me what it is and the ballpark.
MR. MILLER: Identical to Mr. Weiss's, under 100,000 or thereabouts for

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\$700,000, as he has testified in the past, and Coumadin therapy.
THE COURT: Okay. 6 or \$700,000?
MR. FLEMING: Yes, sir, over her lifetime.
MR. GROSSI: Your Honor, may I be heard?
THE COURT: Sure.
MR. GROSSI: Probably not surprising given the pattern here, we have a serious objection to Mr. Fleming's attempting to have Dr. Polikoff testify about anything concerning the cost of future medicals, because we looked at the expert report over lunch, and unless I'm missing something, he doesn't describe this at all.
THE COURT: Mr. Fleming, where in his report does he discuss this?
MR. FLEMING: Your Honor, may I take his report from you real quick?
THE COURT: Yes, you can.
MR. FLEMING: At his expert report, Dr. Polikoff says, at page 1, "valvular heart disease is a chronic progressive disease, in

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mitral valve surgery.
THE COURT: And who's going to testify that this mitral valve surgery is going to cost whatever?
MR. MILLER: Dr. DeVaughn.
THE COURT: Okay. And as to Betz, do you have a claim for past medical?
MR. FLEMING: Yes.
THE COURT: Ballpark amount?
MR. FLEMING: Two to 3,000.
THE COURT: Do you have any claim for past or future earnings?
MR. FLEMING: No.
THE COURT: Do you have a claim for future medical?
MR. FLEMING: Yes.
THE COURT: Who's going to testify to it?
MR. FLEMING: Dr. Polikoff is going to testify, as he has in the past, with regard to it. It includes echocardiograms, includes doctor's appointments, includes pre and postop conditions with regard to one or even two valve surgeries, and will add up to between 6 and

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that Mrs. Betz will require life-long evaluation and treatment of valvular heart disease. Her cardiovascular status and general health have been compromised, and the consequences of exposure..."
And then the last part of his report he says, "my opinions regarding phentermine toxicity, valvular heart disease, and pulmonary hypertension is well known with Wyeth and have been studied in over 30 prior depositions and five courtroom testimonies. I've attached a list of my prior testimony."
And in it he goes through one after another where he has testified with regard to the cost of care as a result of the chronic and progressive ailment of valvular heart disease. And he's prepared to testify based upon his prior testimony and consistent with that testimony as they've seen in a number of different trials and in a number of different depositions.
THE COURT: Did Dr. Polikoff make any evaluation of anything unique to Ms. Betz?
MR. FLEMING: I can't answer that in

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terms of what the differences is between Mrs. Betz and the other people involved in here. But, yes, I mean, she's got some unique things about her; that she has valve conditions that are common to all of these cases, and his testimony will be consistent with his previous testimony.

MR. GROSSI: Your Honor, if I may, in those other cases, prior to the Eichmiller case in Georgia, what Dr. Polikoff did was he made an individual evaluation of the plaintiff, and that obviously differed in terms of whether they had one surgery or two or complications or no complications.

And secondly, he typically relied on a life care plan by a woman named Laurie Hinton, who is associated -- who works at least in the same building with Mr. Fleming; and therefore, in every one of those other cases, he and Ms. Hinton together came up with wildly different numbers, and not always 6 or \$700,000. In fact, that's the most extreme case.

In the Eichmiller case, for example,

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there was initially a report that came up with something like 6 or 700,000, and by the time he got done with testimony on the stand it was 200.

My point being: There is not a word in the report about Ms. Betz where he talks about Ms. Betz as an individual or says that he's evaluated her in any specific way. So it's meaningless and I think improper to at the end simply say, well, you know what I said in general in 30 other different kinds of cases about 30 other different life care plans and then come in on the eve of trial and say that they're going to present, with all due respect, I think the fact that two people, including Mr. Weiss, who has the youngest plaintiff, says it will be \$100,000, to let Dr. Polikoff come up with 6 or 700 with no warning in his report about that and no specificity in his report, we believe would be improper.

MR. FLEMING: Your Honor, if I may respond, he does say that he has considered Mrs. Betz in his report, and he's reviewed records, and he has reviewed information with

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regard that is specific to Mrs. Betz. And he also, you know, supplies all these -- and these guys have taken this guy's deposition like 30 times.

THE COURT: Does he always testify that anybody who needs such an operation has a future life care need of 6 to \$700,000?

MR. FLEMING: I think his testimony has been pretty consistent that the life care plan that he proposes for a patient that gets valvular heart disease and has surgery is in excess of a half a million dollars, yes, sir.

THE COURT: Well, isn't Wyeth permitted to know whether he's going to testify to in excess of a half million or 700,000 before 20 hours before jury selection?

MR. FLEMING: Well, Your Honor, it is consistent, we believe, with his previous testimony.

THE COURT: No, I'm talking about Pennsylvania law. Under Pennsylvania law, is Wyeth entitled to know whether an expert witness will testify that the healthcare plan that he thinks is medically necessary for a

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plaintiff is going to cost 500,000 or 700,000 earlier? Is Wyeth entitled to know that earlier than 20 hours before jury selection under Pennsylvania law?

MR. FLEMING: Your Honor, I don't know the answer to that.

THE COURT: Well, when you research it, let me know.

You can file a motion in limine to preclude testimony on the basis of not being contained in the report; on the basis of qualifications; on the basis of it being inadequate notice under Pennsylvania law to say this is such a generic situation that we don't have to tell you what he's going to testify to because he's testified the same way in 30 other cases; on the basis of Frye; on the basis of anything else.

And plaintiff is precluded from making any mention of these future medical or life care needs to the jury until such time as that's ruled upon.

MR. FLEMING: Fine.

THE COURT: How long do you need?

1 Can you have that by Monday?
 2 MR. GROSSI: Yes, Your Honor.
 3 THE COURT: Okay. And how ever much
 4 time you need to answer.
 5 MR. FLEMING: Just till Wednesday.
 6 THE COURT: How ever much time
 7 because you're precluded from doing anything
 8 until I rule.
 9 MR. FLEMING: Understand. Thank you
 10 THE COURT: And you know what the
 11 motion is going to be anyway. Okay.
 12 So let's go to the voir dire, are we
 13 now set for voir dire?
 14 MR. BLEAKLEY: Yes, sir.
 15 THE COURT: Okay. Plaintiff's
 16 supplemental jury voir dire, any objection to
 17 1?
 18 MR. BLEAKLEY: I can shorten this by
 19 telling you which ones I do have objection to.
 20 MR. DOYLE: Fifteen and 16 is the
 21 ones he has objections to.
 22 THE COURT: Are there any withdrawn
 23 by plaintiff?
 24 MR. WEISS: No.
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1 THE COURT: Is there any objection to
 2 1?
 3 MR. BLEAKLEY: No.
 4 THE COURT: Two?
 5 MR. BLEAKLEY: No.
 6 THE COURT: Who's arguing on behalf
 7 of plaintiff for this?
 8 MR. DOYLE: I am, Jim Doyle.
 9 THE COURT: Of what possible
 10 relevance is whether someone knows anyone in
 11 the world who has heart disease?
 12 MR. DOYLE: Well, the first six or
 13 seven of these questions are Sol's.
 14 THE COURT: Well, you were the one
 15 that said -- if you want to withdraw it, you
 16 can withdraw it, otherwise tell me, go ahead.
 17 MR. WEISS: It should be anyone in
 18 your immediate family.
 19 THE COURT: I don't know what it
 20 should be.
 21 MR. WEISS: It should be anyone in
 22 the immediate family.
 23 THE COURT: Three will not be asked.
 24 Any objection to 4?
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1 MR. BLEAKLEY: No.
 2 THE COURT: Somebody tell me why 5
 3 should be asked.
 4 MR. DOYLE: Five is a misconception,
 5 Your Honor. Some people believe that just
 6 merely because you're overweight, that that
 7 causes valvular heart disease, and there's no
 8 science to support that. And it's important
 9 for us to know the people who have that
 10 preconceived notion going in. Valvular heart
 11 disease is caused by --
 12 THE COURT: No objection?
 13 MR. BLEAKLEY: No objection.
 14 THE COURT: Six.
 15 MR. BLEAKLEY: No objection.
 16 THE COURT: What relevance is 6?
 17 MR. DOYLE: Your Honor, there is a
 18 preconceived notion that people are extremely
 19 overweight because they're lazy and have a lack
 20 of willpower, and there's some people out
 21 there, no matter how hard they try or how hard
 22 they exercise or eat right, they can't lose
 23 weight.
 24 THE COURT: And how does whether
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1 somebody believes that or not have any
 2 implication for whether they can be a fair and
 3 objective juror who will decide the case only
 4 on the basis of the evidence presented and the
 5 law as given to them by the judge?
 6 MR. DOYLE: Because I believe that
 7 there are people out there who have a prejudice
 8 against people just because they're fat.
 9 THE COURT: Well, why don't we ask
 10 that?
 11 MR. DOYLE: Okay.
 12 THE COURT: Does anyone here believe
 13 that extremely overweight or obese people
 14 should not receive justice in court; is that
 15 what you mean to ask?
 16 MR. DOYLE: That would be fine.
 17 That's fine.
 18 MR. WEISS: May I be heard?
 19 THE COURT: Yes, sure.
 20 MR. WEISS: The reason for that, Your
 21 Honor, is there is a charge for contributory
 22 negligence, and the jury may --
 23 THE COURT: Well, hold on right
 24 there. Are you claiming contributory
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negligence?
MR. WEISS: Yes, they are.
MR. GROSSI: They are claiming, yes,
Your Honor. In fact, our theory is that --
THE COURT: What's the contributory
negligence?
MR. GROSSI: The contributory
negligence is precisely since she was not obese
and since she initiated getting the drug
therapy even knowing the risk, even after she
was warned of the valvular heart disease risk,
that at some point she bears some
responsibility for taking the drug. And also,
Your Honor, she double-dosed. She went to two
different physicians and got two doses
inappropriately.
MR. SCOTT: And she concealed
information.
THE COURT: Well, wait a minute. Did
your special jury verdict interrogatory say
anything about contributory negligence?
MR. GROSSI: Yes, just as to Gangel.
THE COURT: Oh, it did, I'm sorry.
MR. WEISS: Yes, it did. And there's

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also the jury instructions talk about
contributory negligence, so that's --
THE COURT: Six will be asked.
MR. WEISS: Thank you.
THE COURT: What relevance is 7?
Anybody still think 7 should be asked?
MR. DOYLE: Sol, that's yours, you
want that one?
MR. WEISS: No, we can strike 7. If
they didn't object, you can strike it.
THE COURT: Eight will not be given.
What relevance is 9, have we
supervised anyone at work?
MR. DOYLE: It tells us a little bit
about the type of person, whether, you know,
where they are in the chain, whether they
supervise people or whether they're someone who
takes orders or gives orders.
THE COURT: So it gives you more
information in order to exercise your
peremptory strikes?
MR. DOYLE: Correct.
THE COURT: It will not be asked.
Ten, ten is fine.

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Eleven is fine.
Any objection to 12?
MR. BLEAKLEY: No.
THE COURT: What's the alternative,
just enough frivolous lawsuits, is that what
you mean?
MR. WEISS: No.
THE COURT: It will be given.
Thirteen, anybody think 13 should be
given?
MR. DOYLE: Yes.
THE COURT: Why?
MR. DOYLE: Well, there is a bias, at
least a perceived bias, to personal injury
trial lawyers, and we're trying to get a fair
jury, Your Honor, of people who don't have a
bias to the lawyers in the system that we have
here.
THE COURT: Okay. The question will
be asked as follows: Is there anyone on the
panel that has such a bad impression of
personal injury trial lawyers -- and it doesn't
even say plaintiffs. Do you mean plaintiff's
lawyers or just everybody in the courtroom?

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MR. BLEAKLEY: I think it should be
everybody in the courtroom.
THE COURT: Well, I'm trying to be
clear.
MR. DOYLE: Personal injury trial
lawyers, that's fine.
THE COURT: Including defense?
MR. DOYLE: Sure.
THE COURT: Well, then how can having
whether or not somebody has a bad impression of
plaintiff or defense lawyers in a personal
injury case have any bearing on whether they
can be a fair juror in this case? They can be
equally prejudice against both sides, couldn't
they?
MR. DOYLE: Well, then I'll step back
a second. I think it should be limited to
plaintiffs' lawyers.
THE COURT: Is there anyone on the
panel that has such a bad impression of
plaintiffs' personal injury trial lawyers that
you could not fairly evaluate a plaintiff's
presentation of evidence; is that what you mean
to ask?

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MR. DOYLE: Yes, sir.

THE COURT: Is that what you want?

MR. DOYLE: That would be fine.

THE COURT: That's what I'll ask. Fourteen, what's the -- which one do you object to?

MR. BLEAKLEY: Fifteen and 16.

THE COURT: Fifteen and 16. This doesn't involve products that are dangerous and hurt people, this involves manufacturers who failed to appropriately warn of the inherent dangers in their products, doesn't it?

MR. DOYLE: Is there anyone who believes that manufacturers who failed to warn?

THE COURT: Well, I'll rephrase it, but isn't that what we're talking about?

MR. DOYLE: Yes, sir.

THE COURT: Okay. If they fail to appropriately warn of the known dangers of their product, right?

MR. DOYLE: Yes.

THE COURT: That's what you're talking about, isn't it?

MR. DOYLE: Yes, sir.

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question that's asking if they can follow the law of negligence.

THE COURT: I don't care whether they believe in the negligence standard, it won't be given. The question is whether they can follow the judge's instructions, not whether they believe them.

Seventeen won't be given. They can favor the drug company all they want. They can say they favor the plaintiffs all they want, as long as they can decide the case on the basis of the evidence, so if you want to rephrase it somehow.

MR. BLEAKLEY: Can I suggest a rephrasing of it?

THE COURT: Yes.

MR. BLEAKLEY: It seems to me it would be appropriate that if somebody raises their hand, we said is there anyone here who was favoring any evidence of one side or the other.

THE COURT: No, I don't care --

MR. BLEAKLEY: But it would be an appropriate basis for further questions, why,

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THE COURT: Okay. Any objection to that as phrased?

MR. BLEAKLEY: No.

THE COURT: Okay.

MR. DOYLE: Let me make sure I have it.

THE COURT: What I have is is there anyone who believes that manufacturers of products should not be held accountable if they fail to appropriately warn of the known dangers of their products. Okay. We set?

MR. BLEAKLEY: Yes.

THE COURT: Fifteen.

MR. DOYLE: This is sort of similar to 14, and basically this is a question to see if they can follow the law, but this is the failure to warn.

THE COURT: Fifteen will not be given. You want to ask if they can follow the law, we'll ask them if they can follow the law as given by the judge.

Sixteen.

MR. BLEAKLEY: Same objection.

MR. DOYLE: That's the negligence

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who. By itself it wouldn't tell you anything that would justify a motion to strike for cause.

THE COURT: I'm not going to permit questions into why people favor drug companies or seriously and permanently injured plaintiffs who are going to need life care, I'm not going to allow questions about that. The question is whether they can hear the evidence, evaluate the evidence, and decide the case on the basis of the evidence presented in accordance with the law as given, not what their favorite television show is, or whether they like Wyeth or not, I'm not going to allow questions into that.

So if you want to recouch it in terms of what the law is, is there anyone who before hearing any evidence feels... I'll let you rephrase it, but it's going to have to be something about cannot follow the law.

MR. BLEAKLEY: Would this be after you describe the case to them?

THE COURT: Yes.

MR. BLEAKLEY: Okay. Then I have no

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further comment.

THE COURT: Seventeen will have to be rephrased.

Eighteen, we got 40 people in a room, how are they going to answer 18?

MR. DOYLE: I'll withdraw it.

THE COURT: Nineteen and 20 will not be given. If you want to come up with a generalized statement about whether they would be willing to follow -- able to follow the evidence wherever it leads and the law as given by the court, I'd be happy to ask that.

MR. DOYLE: No, I will attempt to do that on Question 17.

THE COURT: All right. Let's go to plaintiff's -- I mean Wyeth's. Which is first? I got two. Is it the same?

MR. SCOTT: One should be dated the 7th, Your Honor.

MR. BLEAKLEY: As you read these, these were prepared as if they might be part of a written questionnaire. I'm sure you can figure that out.

THE COURT: Okay. Well, one is

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something go on.

I think it's appropriate to know whether the juror took it or whether an immediate member of their family, and that's how we couch this question.

THE COURT: Well, I'll tell you how I'm going to couch it, I'm going to couch it in a way that leads me to thereafter ask is there anybody who on this panel as a result of knowing someone cannot be a fair juror, and then everybody will sit down and that will be the end of that question.

MR. BLEAKLEY: That's fine. The only thing I'm suggesting is that we believe it shouldn't be just limited to immediate family, it should be someone you know well.

THE COURT: Well, it doesn't say someone you know well, it says someone you know.

MR. DOYLE: Ours does, Your Honor.

THE COURT: Member of your family or anyone close, I don't get it. One will not be given.

Ten will be given.

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covered, 1 is covered. We asked.

MR. BLEAKLEY: More or less.

THE COURT: We asked precisely that question.

MR. BLEAKLEY: The way you rephrased it, I think Your Honor, is somebody in the immediate family.

THE COURT: Ten, have you or any member ever taken these three things. In fact, that asked about Phentermine. Ten on plaintiffs, not yours.

MR. BLEAKLEY: The only reason I -- this is broader because it's someone you know, and I suspect plaintiff's counsel will agree with me that what we find out is that people have heard about phen-fen, they've heard about phen-fen cases and they think they've heard about people they know who have been affected by phen-fen, and that can affect their ability to be fair, so it isn't just immediate family.

MR. DOYLE: Well, that's where we get into arguing about this, because this is where a true taint of the jury happens, when they say well, oh, Mrs. Jones down the block, she had

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If you want to rewrite 10 and give it to me tomorrow morning, we'll see whether I use your words or mine, but 1 will not be given.

Is 2 covered?

MR. BLEAKLEY: I don't think so. You mean by another question? I don't think so.

THE COURT: All right. Two will be given if it's not covered.

Oh, do you have any objections to these? Does plaintiff object to any of these?

MR. DOYLE: I have objections, but not to that, Your Honor.

THE COURT: Where's the first objection given?

MR. DOYLE: Number 12.

THE COURT: All right. We'll get to it.

Three, Number 3 will be given. Number 4 is covered, isn't it? Didn't I ask that?

MR. BLEAKLEY: I think it's covered.

THE COURT: Okay. Five.

MR. BLEAKLEY: However, the second part of 4 hasn't been given, Judge, I'm sorry,

1 the have you formed an opinion regarding
2 phen-fen, Pondimin... And there will be people
3 who have.

4 THE COURT: Four, oh.

5 MR. BLEAKLEY: The second part of 4,
6 that hasn't been covered.

7 THE COURT: All right. Some version
8 of that will be given.

9 MR. BLEAKLEY: Okay.

10 THE COURT: Five is covered, right?
11 Is it covered or I said I wouldn't give it.

12 MR. DOYLE: You said you wouldn't
13 give it.

14 THE COURT: Right.

15 MR. BLEAKLEY: If you're giving us a
16 chance to give it --

17 THE COURT: No. It's got the same
18 problems. If you want to couch it in such a
19 way as to be do you have such a fixed belief
20 concerning a manufacturer of drugs or someone
21 who claims that they've been injured as a
22 result of the manufacturer, that you cannot
23 appropriately listen to whatever, if you want
24 to couch it like that, I'll probably give it.
25

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1 MR. BLEAKLEY: Okay. We'll rewrite
2 that one.

3 THE COURT: Six will not be given.

4 MR. BLEAKLEY: Can I stop you on that
5 one?

6 THE COURT: Yes.

7 MR. BLEAKLEY: This is pretty
8 important, Judge. There are a lot of people
9 who believe that if a drug kills one person, it
10 should not be on the market, the manufacturer
11 should be held liable. It doesn't make any
12 difference whether it's a wonderful drug, it
13 doesn't make any difference, those are people
14 who, our research and common sense tells us,
15 cannot be fair, they cannot be fair.

16 Judge, it is the most important
17 single question that we always ask when we pick
18 these juries, and we always get some people --
19 now, there's some people who won't answer it
20 even though they may feel that way, but there
21 are some people who will admit that they
22 believe that a drug should be 100, 1,000
23 percent safe, and if it isn't, it shouldn't be
24 on the market.
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1 THE COURT: Well, then you can couch
2 it in a way that discusses their ability to be
3 a fair and impartial juror who decides this
4 case on the basis of the evidence presented.

5 MR. BLEAKLEY: Okay. We'll have
6 something first thing in the morning.

7 THE COURT: Am I clear?

8 MR. BLEAKLEY: Yes.

9 THE COURT: I'm not going to ask
10 whether they should be allowed to sell the
11 drugs, because they can have an absolute belief
12 that you should not be allowed to sell a drug
13 that kills one person and if they can follow
14 the law in this case, then it's got nothing to
15 do with it.

16 MR. BLEAKLEY: We'll rephrase it that
17 way.

18 THE COURT: Seven is fine, but I
19 think it's covered, so somehow seven may be
20 given without one of the earlier being given.

21 Eight, why is that -- why should I
22 ask them this?

23 MR. BLEAKLEY: I withdraw that.

24 THE COURT: Okay. Too general.
25

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1 We have a question 9 that asks if
2 they have been a party to a lawsuit, and that's
3 the way it would be given, not having to do
4 with suing a doctor or hospital. So you want
5 to know if they were plaintiffs -- a plaintiff
6 in 20 auto accident cases?

7 MR. BLEAKLEY: Yes, I would.

8 THE COURT: Well, that's relevant,
9 but this is not, so 9 will be changed but
10 given.

11 THE COURT: What's 10 got to do with
12 whether they can be fair?

13 MR. BLEAKLEY: Well, I seem to detect
14 in Your Honor's attitude that the questions
15 that are designed to provide information upon
16 which we can exercise our peremptories is not
17 appropriate.

18 THE COURT: It certainly is
19 appropriate, if it's permissible for another
20 purpose to determine whether they can be a fair
21 juror.

22 MR. BLEAKLEY: I am admitting
23 candidly to you that this is one of those
24 questions that I would use to exercise for a
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peremptory.
THE COURT: In order to learn something about a juror?
MR. BLEAKLEY: Right.
THE COURT: Will not be given. Anybody else want to argue anything about it? (No response.)
Okay. Eleven.
MR. BLEAKLEY: I'm perfectly prepared to modify this the way we have modified the others.
THE COURT: Fine. Let's see what you can do with it.
Twelve will not be given.
Thirteen, this isn't a recall case, so what can this -- except to learn something more about the jurors.
MR. BLEAKLEY: I admit it.
THE COURT: Okay. Good. Thirteen won't be given.
Fourteen won't be given.
MR. BLEAKLEY: Fifteen we withdraw.
MR. DOYLE: That concludes all the objections I had, Your Honor.

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THE COURT: Okay. Here, take a look at this.
Okay. I think what I'm going to do in voir dire is I will ask all the questions. We, or you -- I don't know how we're going to work this out -- are going to come up with a statement of what the case is about and what the defenses are, which I will read to the jury. I will ask all the questions and then we'll see where we go from there.
So what Jennifer is copying is actually from my criminal years, and it's a series of questions that -- because in the criminal courts in Philadelphia the judge does conduct the voir dire. So it's a series of general questions. If it asks about a police officer or something, I'm not going to -- I may couch it as would you believe somebody more just because of their status. But take a look at it and then we'll see if there's anything else we need to add to it.
MR. BLEAKLEY: Can I ask a couple questions?
THE COURT: Yes. Just give me a

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minute. I'll be back in a minute.
(Whereupon a discussion was held off the record.)
MR. BLEAKLEY: Your Honor, do you want us to provide you -- each side provide you with a brief statement of what we would prefer to tell the jury at the beginning? You don't want us to give you anything?
THE COURT: On voir dire, are we together? If you want by whoever on your teams to sit down and recouch these things in a way that conforms to what I'm saying you're entitled to, which is questions that determine whether anybody has such a predisposition in any reasonable way that would interfere with their ability to be a fair and impartial juror, then that would be helpful. If you don't come up with those types of questions, what I will do is take my standards, take these, do it as we go.
In which case, at the conclusion of the questions that I've asked, if you think something has been left out, you're going to have to put it on the record --

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MR. BLEAKLEY: I'm going to give you three revised.
THE COURT: -- or it will have been waived.
MR. BLEAKLEY: When you say you are going to do the voir dire, does that mean we aren't?
THE COURT: I haven't decided that yet. We'll see how it goes, we'll see how it goes.
You've given me the questions, so these are the questions that are going to be asked.
MR. WEISS: Your Honor --
THE COURT: So I don't know what additional questions will be needed.
Yes, sir.
MR. WEISS: I have a question, two questions. The first one is I think obvious. We're still going to get the three-page standard answers that they fill out before they come up?
THE COURT: Absolutely.
MR. WEISS: The second question is,

1 assuming that you do ask the questions and
2 people raise their hand and say yeah, are we
3 going to have a separate session with each of
4 those people so they don't pollute the panel?

5 THE COURT: They will not be asked to
6 explain in front of the panel. That's the
7 thrust of your question.

8 MR. WEISS: That's right.

9 THE COURT: Yes, except perhaps for
10 hardship. I don't know what we'll do with
11 hardship.

12 MR. BLEAKLEY: You're going to decide
13 hardship, too, Your Honor?

14 THE COURT: I'm going to be there,
15 unfortunately.

16 MR. WEISS: When you're in the robing
17 room, wherever we're going to hold the little
18 questions of the individual jurors that waved
19 their hand and said yes, I think that's what
20 Mr. Bleakley is referring to, are we going to
21 ask supplemental questions or just Your Honor?

22 THE COURT: I don't know.

23 MR. WEISS: That was my --

24 THE COURT: I don't know. It depends
25

1 on how well behaved you are. And I don't mean
2 that in a technical sense because I know you
3 will be all well behaved.

4 I mean, if you all can ask the
5 questions in the correct way for the correct
6 reason and not try to drag things out in order
7 to find out little bits and pieces, then
8 probably I'll just say go ahead, any questions,
9 you'll ask two, any questions, you'll ask two,
10 and we'll move on. But if when I try that
11 you're going beyond what you need for the
12 proper purpose, the purpose that the law -- I'm
13 not saying that the other purpose is improper,
14 but the purpose that the law allows; namely, to
15 make sure that there's no juror who can't be
16 fair and impartial, if you're going to go into
17 getting to know you and is this the type of
18 person that I want that we're going to send
19 some jury consultant to, I'm not going to let
20 you do the questions.

21 And it may be with one person that
22 has one issue, maybe I'll just say ask whatever
23 you want, and somebody else who has 19 issues,
24 I'm going to ask them all because after the
25

1 sixth issue I'm going to know they're out of
2 here, so I can't answer the question except
3 that we will work together and get a fair and
4 impartial jury.

5 MR. SCOTT: Your Honor, will we have
6 an opportunity with each juror in an individual
7 session or only those who raise their hands?

8 THE COURT: Only those who raise
9 their hands. What's there to ask about
10 somebody who didn't have to respond to any
11 question?

12 I've asked all the questions that
13 generally you need to know and all the
14 questions that you have specifically asked to
15 know.

16 If somebody raises no question, there
17 will be no individual voir dire.

18 MR. SCOTT: Some judges do it
19 differently.

20 THE COURT: It's all right, I'm not
21 offended.

22 MR. BLEAKLEY: Are we going to have
23 eight jurors?

24 THE COURT: Eight, and we're going to
25

1 take two alternates.

2 MR. BLEAKLEY: We get four
3 peremptories?

4 THE COURT: You get four
5 peremptories.

6 MR. BLEAKLEY: How many will --

7 THE COURT: Four will be for the jury
8 unless there's a suggestion, something
9 different that's needed. Because really under
10 Pennsylvania law when you have a jury less than
11 12, a verdict is taken as long as there are six
12 jurors. So normally we don't select any
13 alternates, we select eight, plain and simple,
14 and take a jury as long as it goes down to six.
15 But because of the length of this, I'm going to
16 select two alternates.

17 MR. WEISS: So as I understand it,
18 Your Honor, there are the first 26 without
19 cause are what we have for strikes. Well, it's
20 18.

21 THE COURT: You worry about that in
22 your office.

23 Any other question about how we're
24 going to do it? So we're set on voir dire?
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MR. FLEMING: Not quite. Let me make sure I understand, you're going to have a general voir dire with everybody, anybody that raises their hands goes back in the robing room?

THE COURT: No, I didn't say that either. Anybody that raises their hand, you're going to make a note of what question they answered and then I'll decide which, if any of them, we need to talk to privately, individually.

Now, obviously there may be a lot that we do. When I say which, if any, I'm not trying to say I'm going to be Attila the Hun, but that's what I'm going to do.

MR. BLEAKLEY: I may be repeating myself, you don't want us to provide you a statement of the case?

THE COURT: We're about to get to that, if I could.

MR. BLEAKLEY: Oh, all right. Sorry.

MR. DOYLE: One quick question about your questions here.

Question No. 4 there says please

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THE COURT: I didn't see it then. Is this something new?

MR. WEISS: It's attached to the back.

MR. MILLER: Today's the 9th, if I'm not misspeaking, but I have a copy, Your Honor.

These are the special questions you asked to prepare.

THE COURT: Yes, but I haven't seen a new version. Well, let me see it.

MR. MILLER: Yes, Your Honor. I've made a marking on it, I apologize. If I could hand that to the Court.

THE COURT: Hold on. We're done with the can/does controversy?

MR. SCOTT: Apparently so, Your Honor, that's our proposal.

THE COURT: Okay. For the record, you're proposing to ask can it cause.

Moderate?

MR. GROSSI: Yes, Your Honor.

MR. WEISS: Yes.

THE COURT: Okay. Yes, sir.

MR. MILLER: I have three things I'd

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raise your number. We had brought you some big numbers to use. We talked to Jackie beforehand, Jackie said she didn't like to use those numbers.

THE COURT: Do you want me to overrule Jackie?

You talk to Jackie about things you have to talk to Jackie about.

MR. DOYLE: Okay.

THE COURT: All right. We set? With respect to Gangel, Mr. Weiss --

MR. WEISS: Yes, Your Honor.

THE COURT: -- since you're more familiar with Philadelphia practice. As I understand your claim -- oh, wait, hold on. Off the record.

(Whereupon a discussion was held off the record.)

MR. MILLER: Your Honor, I would like to on the record discuss Wyeth's proposed jury interrogatories on general causation as they relate to Mr. Andro. It's a short conversation. But I was submitted today, hand delivered to us --

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like to discuss quickly on that, Your Honor.

Number one, I don't believe it's appropriate for a general causation to single out Mr. Andro with a second question on 30 days use, because that is in fact case specific causation, it would seem to me.

The question on general causation is does phen-fen cause mitral regurgitation, that's the question. And then later, if I prevail on that issue, I have to prove case specifically can 30 days use, and Mr. Andro in this case, cause it.

But the way it's designed there, they're making me prove my case twice, and I think that's unfair. I have to prove to the jury that 30 days use -- I'm getting singled out, and I think that's unfair to Mr. Andro.

THE COURT: You'd be singled out if you tried it separately.

MR. MILLER: I understand, Your Honor, and I'd be willing to take that. If that's what has to happen, that's what has to happen. I think that would be more fair than being tried with two long-term users and having

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a separate question. I just think it's unfair the way it's being done.

If the Court does not incline to agree with me on that, I have two more specific ones that --

THE COURT: Well, then let's see whether I agree with you before you keep going, all right?

MR. MILLER: Yes, Your Honor.

THE COURT: I'm lost as to whether or not you wanted this trifurcated, I think you did; did you not?

MR. GROSSI: Actually, if I might, our proposal was, and this may get closer to what Mr. Miller wants, because I've been thinking about this issue a lot in the last 48 hours as well, we propose, and we think it would make sense, to have a medical case and then the liability case. And the medical case would solve the problem where these witnesses would on one time talk about do we do mitral and then do we do it in a shorter period as one month.

And by the way, at that point

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days, so it should say can 30 days use.

THE COURT: Okay. Do you have a problem with that?

MR. GROSSI: No, that's acceptable.

THE COURT: Okay. That's out. What else?

MR. MILLER: And the last one is, and the Court picked up on, it shouldn't say moderate mitral regurgitation. The general causation question is can this drug cause mitral regurgitation.

THE COURT: Well, does Wyeth concede that it can cause mitral regurgitation?

MR. GROSSI: Your Honor, there are studies that show that --

THE COURT: I don't want to know about the science, I don't want to know about the studies. I want to know as a position in this case on behalf of your client whether I can tell the jury Wyeth agrees that it can cause mitral regurgitation. The issue is whether it can cause moderate mitral regurgitation.

MR. GROSSI: Your Honor, if I may

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Mr. Miller would be allowed to put on, and I'd respond, with all the other things that are going on with a person's medical history based on the same people, and then at the end of that trial there would be a finding --

THE COURT: We're not trying damages and general causation together, given that I have ruled, I believe at defense request or some version of something that the defense requested, that we're doing general causation first and alone.

Is this the way we should do it in defense opinion, one and two?

MR. GROSSI: I think it has to be, Your Honor, because duration has to do with this.

THE COURT: Then plaintiff's request is denied.

What's next?

MR. MILLER: Next, Your Honor, as we are now going to do it that way, it shouldn't say 30 days or less in question No. 2 because there's no evidence of Mr. Andro or any plaintiff in this case taking it less than 30

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answer your question directly, we would contest that it causes mitral regurgitation, but we continue to believe very strongly that the only relevant question that should be put to the jury and that should be discussed with the experts is whether it causes moderate or greater perhaps mitral regurgitation, in terms of the rules by which we all have to play under the national settlement. That is all that they can sue for.

If the suggestion is that they are going to try to prove that they got mild mitral regurgitation, which by the way --

THE COURT: If it can cause mitral regurgitation, then it can cause severe mitral regurgitation.

MR. GROSSI: No, Your Honor, that's the scientific point that we will address. There are many things that might cause trace or mild regurgitation but would not cause moderate or severe. And since they can only sue for moderate or severe, the question in proof should be limited to that point.

THE COURT: Well, I don't get it,

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they can sue for moderate?

MR. GROSSI: Yes, but only moderate.

THE COURT: And they can sue for severe?

MR. GROSSI: Yes, Your Honor.

THE COURT: What can't they sue for?

MR. GROSSI: They couldn't sue for mild, or trace.

THE COURT: Okay. Do you concede that it can cause mild mitral regurgitation?

MR. GROSSI: Yes, Your Honor, I think there's probably proof of that.

THE COURT: I want to know whether you concede it, because when we start voir dire tomorrow, I'm going to say to the jury, ladies and gentlemen of the jury, on the first phase you're going to be asked whether Pondimin or Redux can cause moderate mitral regurgitation, and this is the question that you're going to be asked because Wyeth agrees that it can cause mild mitral regurgitation or trace mitral regurgitation, but they contend that it cannot cause moderate mitral regurgitation.

MR. GROSSI: As to that, Your Honor,

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took these products. They cannot prove that it causes moderate. And since that's the thing they have to prove, that's what I want to be able to have a clear question on.

THE COURT: Hold on, just let me understand this. You may be ahead of the game. Go ahead. Yes.

MR. MILLER: The question is whether phen-fen causes mitral regurgitation. If it causes mild mitral regurgitation which progresses, and it's a medical fact that once you have regurgitation, it begets further regurgitation, I mean, all of our plaintiff's witnesses certainly, and most of the textbooks agree with that, articles, we could cite them, but the point is this, does this drug cause mitral regurgitation.

It is true --

THE COURT: Okay. Hold on. I'm going to hold this under advisement until tomorrow, and you can show me tomorrow morning where your experts make this distinction. If your experts in their reports don't make this distinction, then plaintiff is certainly not on

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then I would respectfully say we don't agree, and more to the point, we think that asking that question and letting them proceed with that claim about anything less than moderate would violate the settlement agreement.

THE COURT: You're blending two different things. There's one thing about asking that question and another thing about allowing them to proceed with the claim, and that's two different phases. If it can cause mild mitral regurgitation, it must necessarily be able to cause moderate mitral regurgitation, no?

MR. GROSSI: With all due respect, no, that's a scientific issue. And that's where their witnesses will part company.

THE COURT: Part company with who? With each other?

MR. GROSSI: Based on what I reviewed -- part company with each other. And if they say it, they're going to have to part company with their prior testimony, because they can say -- point to studies showing mild regurgitation to a greater degree in people who

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notice as to what they're going to say.

Am I clear what I'm asking for?

MR. GROSSI: Yes, Your Honor.

THE COURT: Okay. What else?

MR. MILLER: No, Your Honor, that's everything from me.

THE COURT: Okay. As to Gangel, Mr. Weiss, it's my understanding that your claim is that the defendant failed to appropriately warn of what, sir?

MR. WEISS: The risks associated with ingesting Pondimin and Redux.

THE COURT: The risks of what?

MR. WEISS: Of contracting a serious side effects -- side effect.

THE COURT: You don't have a claim for serious side effects, you have a claim for a specific type of side effect.

MR. WEISS: That goes to the argument that we never completed today; is whether the jury can consider the PPH warning or not.

THE COURT: I don't need to rule on that in order to get a statement of what your claim is. Your claim is that the defendants

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failed to appropriately warn of the risks of contracting what? What did Gangel have that they failed to warn?

MR. WEISS: Well, if I say valvular heart disease, then you tell me anything about PPH is irrelevant.

THE COURT: I may very well do that whether you say valvular heart disease or not. But the only claim that you're presenting is a claim for the valvular heart disease that your client has because of defendant's failure to appropriately warn of it, right?

MR. WEISS: That's part of it, yes.

THE COURT: Okay. Is there any other claim that you're presenting besides the claim of failing to warn of the risk of valvular heart disease?

MR. WEISS: And the fact that she may -- she needs surgery to correct the condition caused by the damage to her mitral valve.

THE COURT: Okay. Now, with respect to the valvular heart disease, what kind of valvular heart disease does your client have?

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MR. WEISS: She has moderate mitral regurgitation. It's not an issue I don't believe in this case.

THE COURT: Moderate mitral regurgitation, right?

MR. WEISS: And I don't think the defense will contest that.

THE COURT: Of course they contest, they contest whether mitral regurgitation can be caused by --

MR. WEISS: No, they're not contesting that she had moderate mitral regurgitation.

THE COURT: Okay. And after you prove that, you're going to ask the jury to award what elements of damages?

MR. WEISS: Past, present, and future medical expenses.

THE COURT: Okay. We'll call it past and future, because she's not undergoing medical expenses in the courtroom, past and future medical expenses.

MR. WEISS: Okay.

THE COURT: Go ahead, what else?

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MR. WEISS: And damages that flow from having heart surgery.

THE COURT: Okay. Past and future medical expenses and all the pain and suffering.

MR. WEISS: Suffering associated with heart surgery.

THE COURT: Okay. That's it?

And with respect to Ms. Gangel, what defenses are you presenting?

MR. GROSSI: Your Honor --

THE COURT: First of all, you claim that what, that it can't cause this disease?

MR. GROSSI: No, Your Honor. I think the first point is that we claim that Ms. Gangel's moderate mitral regurgitation will not progress to the point where she will need surgery.

THE COURT: That can't be the first thing. The first thing has to do with general causation.

MR. GROSSI: We don't dispute the possibility with respect to Ms. Gangel.

THE COURT: You don't?

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MR. GROSSI: No.

MR. SCOTT: We do on moderate mitral right.

MR. BLEAKLEY: No.

MR. SCOTT: No?

MR. BLEAKLEY: See, here's the problem --

THE COURT: Does the jury -- I don't want your problem.

MR. BLEAKLEY: No, it's the problem. If we are --

THE COURT: Does the jury have to decide in phase I anything about Ms. Gangel?

MR. GROSSI: Yes, Your Honor, they have to decide whether we caused moderate mitral regurgitation, because that's what she has.

THE COURT: Okay. So the defense claims that Pondimin and Redux cannot, right, that's the word we decided on, cannot?

MR. GROSSI: Your Honor, could I say that our defense was it has not been shown to cause --

THE COURT: Okay.

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MR. GROSSI: -- to cause moderate mitral regurgitation, right.
THE COURT: It has not been shown, no, no.
That plaintiff's -- no, no.
Your claim is that Pondimin and Redux cannot cause mitral regurgitation, because if that's not your claim, let me know so I can tell the jury what you are claiming.
Are you claiming -- do you concede that it can cause mitral regurgitation of any sort? I think you've answered no repeatedly, but if that's being changed, that's fine with me, it trims down the case a lot.
MR. GROSSI: If I can be frank, Your Honor, the problem is simply that, to address Mr. Miller's point, which is relevant to Mr. Weiss's point, the studies show that if you take Redux certainly long term there may be a slightly higher numerical incidence of mild and trace mitral regurgitation. The same studies show that within a year of getting off the drugs it goes away, so we are now here seven years later, if these folks are claiming

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moderate mitral regurgitation, then it is our position that the scientific evidence does not show it.
THE COURT: The first phase which we have now done away with entirely is to ask them whether your drugs can cause mitral regurgitation, and the reason we have a first phase at all is because I was led to believe, correctly or incorrectly, I'm not saying you mislead me, that your position was that the drugs cannot cause mitral regurgitation. And rather than let that be blended in with liability and damages, I broke that out separately. If that's not your position, let me know and maybe we can do away with the entire first phase.
MR. GROSSI: If I can be clear, Your Honor, our position is that the drugs cannot cause mitral regurgitation in people who are seven years after they took the drugs, because while you may get a slight increase, it goes back down, that's the point. I thought we were -- I thought that the plaintiffs were clear, Mr. Miller, that they had to prove the

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moderate mitral today.
THE COURT: Okay. That's fine. Then I'll tell the jury this: Defendant concedes that these drugs can under certain circumstances cause mitral regurgitation, but as to plaintiff Gangel, that it did not; is that accurate?
MR. GROSSI: Yes, then we would be allowed to argue the different points; did not cause moderate mitral regurgitation.
THE COURT: Defendant concedes that these drugs can under certain circumstances cause mitral regurgitation, but that they did not in plaintiff Gangel's case.
MR. WEISS: In any plaintiff's case.
THE COURT: Excuse me, I'm not up to any plaintiff's case.
Is that accurate?
MR. GROSSI: I'm sorry, Your Honor.
MR. BLEAKLEY: No, it's in any case, Sol's right.
THE COURT: I'm not in any case. Excuse me, I appreciate the effort, but I'm in Gangel's case.

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Is this okay for me to tell the jury since it accurately reflects your position: Defendant concedes that these drugs can under certain circumstances cause mitral regurgitation but that they did not in plaintiff Gangel's case?
MR. GROSSI: That they did not cause the level that she currently has.
THE COURT: So you concede that it did cause something in plaintiff Gangel's case?
MR. GROSSI: No, I'll accept what you said.
THE COURT: Is that acceptable as your position?
MR. GROSSI: Yes, for Gangel.
THE COURT: For Gangel?
MR. GROSSI: Yes.
THE COURT: Do you have any other position as to Gangel as to why you should not be awarded 20 billion dollars, or whatever the jury does, but very large?
What's next?
MR. GROSSI: Well, can I also add that we would also dispute that she will go to

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surgery. I mean, if you're going to mention surgery as his claim, I mean --

THE COURT: Well, before we get to this, before we get to this, don't you disagree as to whether you were negligent?

MR. GROSSI: Yes. I thought that would be last, but, yes, Your Honor, we definitely disagree.

THE COURT: Okay. So defendant claims they appropriately warned of the risks they reasonably should have been aware of; is that fair?

MR. BLEAKLEY: Well, it's an accurate statement. A more specific statement in contrast to this case is the defendant claims that it was not negligent, we did not negligently fail to warn Mrs. Gangel's prescriber about the risks of valvular heart disease. That's the more specific. I mean, the statement you made is an accurate one, but--

THE COURT: Wait, hold on, say that again.

MR. BLEAKLEY: Defendant claims that

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it did not negligently fail to warn.

THE COURT: No, that's too many negatives. You can surely put it without double negatives.

MR. BLEAKLEY: Was not negligent in failing --

THE COURT: Claims they -- you got the double negative, were not negligent in failing.

MR. GROSSI: And we did ultimately warn, so I think -- how about affirmatively that it acted appropriately in providing labeling to the doctor?

THE COURT: Is that all right, that they appropriately warned --

MR. GROSSI: How about that they were not negligent in providing warning?

THE COURT: Fine. That they were not negligent in warning physicians, okay. So we've got on the one hand the drugs didn't cause it for Gangel. On the other hand, you weren't negligent, even if it did cause it, your warnings were appropriate.

What's next, you got contributory

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negligence?

MR. GROSSI: Yes, and I would like to address the issue of surgery damages.

THE COURT: We'll get to that, but how about --

MR. GROSSI: Wyeth further contends that Ms. Gangel inappropriately used the drugs.

THE COURT: Defendant claims that plaintiff was --

MR. BLEAKLEY: Plaintiff Gangel.

THE COURT: Yes, yes, was negligent in her use, usage, whatever I say, of the medications, right?

MR. GROSSI: Okay. Now, shall we say in the manner in which she used them so we're not suggesting that anybody's negligent just for using them, specific manner, special manner?

THE COURT: Something will happen about that.

What other defenses are you presenting as to Gangel?

MR. GROSSI: And damages finally.

THE COURT: Anything before damages

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MR. SCOTT: I think something about--

THE COURT: By the way, I'm going to get clear tonight, hopefully, what I'm going to say to the jury about each one of these cases.

If overnight you realize there's something that's not going to be good enough or not good, raise it with me again tomorrow morning, please.

Okay. Defendant claims that plaintiff was negligent in the manner she used the medications.

MR. GROSSI: And Mr. Scott reminded me of proximate cause.

MR. SCOTT: Defendant Wyeth contends that even if it had put a heart valve warning into the label sooner than it did, it would not have made any difference in the prescription of the drugs.

THE COURT: Defendant claims that even if plaintiff is correct as to warning, there were no injuries, any failure to warn caused Ms. Gangel, something close to that, right?

MR. SCOTT: Something like that.

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THE COURT: That's the concept?

MR. SCOTT: Yes.

THE COURT: Okay. And that includes your surgery issue?

MR. GROSSI: It would.

THE COURT: I can also put in defendant contests the extent of any injuries claimed; is that okay?

MR. GROSSI: Yes, Your Honor.

THE COURT: Defendant contests the extent of the injuries claimed by plaintiff; does that cover it?

MR. SCOTT: I think, Your Honor, if you say just injuries claimed, it's not clear that that includes a possibility of future injuries.

THE COURT: It's clear to me. All right. That's clear to me. I'm not going to get into that detail. I appreciate what you're saying. Now you want me to subpart particularly the future injuries. I'm not going to do that. I'll leave that to you.

What else?

MR. GROSSI: I think that's it, Your

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Honor.

THE COURT: So you've waived everything else that might be in the case?

MR. GROSSI: Well, I hope I'm not waiving everything for all purposes, but certainly they don't have to be instructed tomorrow on this.

THE COURT: Well, I want to know what you're claiming so I can make sure that we have jurors who don't find something offensive and can't be fair.

MR. GROSSI: Okay. General causation, specific causation, proximate cause, full prescriber, contributory negligence...

THE COURT: All right. I will allow you to revisit it tomorrow, if you come up with something. But my intention is to spell out to this panel what the cause is all about before they start answering the questions about whether they can be fair.

So next is Betz.

MR. WEISS: Do I have an opportunity to comment on what they just said?

THE COURT: Sure.

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MR. WEISS: There's an issue. The issue is their instructions to the jury say that there's no duty to warn the patient, the duty only goes to the intermediary.

I'm not sure that's right, and when they charge about contributory negligence, it's got to be spelled out, did she fail to hear what her doctor said, is that what they're claiming?

THE COURT: No, she failed to tell the one doctor that she was asking for a prescription from another doctor. We don't have to spell that out at all. This is ineffective assistance of patient.

MR. WEISS: I don't think that's a defense, but that's okay.

THE COURT: I don't know. But any other?

MR. WEISS: I certainly have my objection to that.

THE COURT: It's on the record. Anything else?

MR. WEISS: Yes.

THE COURT: Okay. Go ahead.

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MR. WEISS: I'm not clear, are we now no longer doing general causation first?

THE COURT: I don't know. I don't know. Just sit tight.

MR. WEISS: But I got doctors that --

THE COURT: I'm well aware of that. Betz.

MR. FLEMING: Yes, Your Honor.

THE COURT: Defendant failed to appropriately warn of the risks of contracting valvular heart disease, moderate mitral regurgitation; is that accurate?

MR. FLEMING: No.

THE COURT: What's your claim?

MR. FLEMING: Our claim is, first of all, we have a negligence claim for failure to timely withdraw both Pondimin and Redux from the market and in continuing to promote the drug or sell the drug after they knew or should have known of the dangers.

THE COURT: Okay. What else?

MR. FLEMING: The second thing is --

THE COURT: Defendant failed to remove the drug from the market timely. Go

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ahead. What else?

MR. FLEMING: And they continued to promote the drug after they knew or should have known the dangers.

THE COURT: Okay. What else?

MR. FLEMING: They also failed to adequately warn of the dangers of the drug with regard to PPH, PH, and VHD.

THE COURT: Okay. Do you have a claim for PPH, PH or VHD?

MR. FLEMING: We have claims for VHD and PH.

THE COURT: Okay. Go ahead.

MR. FLEMING: And that's the failure to warn claim, Your Honor.

THE COURT: Okay. Anything else?

MR. FLEMING: Yes. We have a claim for pulmonary hypertension for Mrs. Betz. We also have a claim for valvular heart disease, in the sense that she has moderate to severe mitral regurgitation and moderate aortic regurgitation, two valves. She also has pulmonary hypertension.

THE COURT: Okay. What valvular

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heart disease does she have?

MR. FLEMING: Your Honor, she has moderate to severe mitral regurgitation and moderate aortic regurgitation. She also has pulmonary hypertension.

THE COURT: Hold on. Okay. Do you have an expert that says that Wyeth should have warned of the risks of contracting valvular heart disease?

MR. FLEMING: Yes.

THE COURT: Who's that?

MR. FLEMING: It's Busch, Blum, Polikoff and Moye.

THE COURT: Okay. Now, what else did they fail to warn about?

MR. FLEMING: They failed to warn of primary pulmonary hypertension, PPH.

THE COURT: Does your client have primary pulmonary hypertension?

MR. FLEMING: No.

THE COURT: Then that will not be described to the jury. What else did they fail to warn about?

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MR. FLEMING: She had pulmonary hypertension.

THE COURT: Do you have an expert who says that they failed to warn about pulmonary hypertension?

MR. FLEMING: Yes.

THE COURT: Who's that?

MR. FLEMING: It's Busch, Blum, Moye and Polikoff.

THE COURT: Okay. Does Busch, Blum, Moye or Polikoff say that you failed to warn about pulmonary hypertension in their reports?

MR. GROSSI: I don't know, Your Honor. I know they talked about primary pulmonary hypertension. I don't know that they talked about the failure to warn, the alleged failure to warn.

THE COURT: Is there a claim against you by Ms. Betz for failure to warn about pulmonary hypertension?

MR. GROSSI: I don't believe it is, Your Honor. And if it is, it's illegal under the settlement.

THE COURT: Is that legal under the

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settlement?

MR. FLEMING: Sure, it's legal under the settlement. Basically what we're talking about is pulmonary hypertension, I'm not talking about primary pulmonary hypertension. And her claim is basically pulmonary hypertension.

THE COURT: As a result of heart regurgitation, right?

MR. FLEMING: Right.

THE COURT: Okay. So that's only a symptom, what else?

MR. FLEMING: No, it's not a symptom, Your Honor, it's a serious problem for her, and it will worsen and so will her valves worsen with surgery.

THE COURT: Right. It will not be described to the jury at this time. It's no different than your claim that she needs a heart surgery.

Next, what else is your claim?

MR. FLEMING: May I object to that, Your Honor?

THE COURT: Yes, you just did.

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What's next?
Do you want me to describe that to the jury?
MR. BLEAKLEY: No.
MR. GROSSI: No.
THE COURT: What's next?
MR. FLEMING: Basically we believe that her pulmonary hypertension will worsen and her valves will worsen where she will have to have valve surgery.
THE COURT: Okay.
MR. FLEMING: She will have past and future medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and those are the elements of damages.
THE COURT: Okay. Is that it?
MR. FLEMING: Yes, all of it as I described it to Your Honor.
THE COURT: Okay. How about failed to remove the drug from the market timely? I've been dealing with this case for about a week, and this is the first I've heard of it as a claim, although it's been a veiled reference in many context.

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MR. GROSSI: Your Honor, I don't have this complaint in my mind, but I don't believe it's a claim in this sense. This is a straight failure to warn claim. It makes it clear that it's different, he has different claims.
THE COURT: Mr. Fleming, you show me your complaint tomorrow morning or it will not be given.
MR. FLEMING: Okay. I believe it is a short form complaint, Your Honor.
THE COURT: You believe it's in there?
MR. FLEMING: It's in the master? Okay. I'm corrected.
THE COURT: Okay. You'll show me a complaint or it will not be given as a description.
And what's the defense as to Betz? Is it different from any of the Gangel?
MR. GROSSI: No, Your Honor. I think -- well, in the sense that there would not be a misuse of the drug or contributory negligence claim as to Ms. Betz.
THE COURT: But other than that, is

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it different?
MR. GROSSI: No, I believe it would be the same elements.
MR. BLEAKLEY: Well, and specifically, we deny that Ms. Betz has moderate to severe mitral regurgitation.
THE COURT: So there is that other --
MR. BLEAKLEY: Yes, there is.
THE COURT: Defendant --
MR. BLEAKLEY: And denies the surgery, et cetera, et cetera.
THE COURT: But I'm not going to get into that. I've got the general extensive injuries.
MR. BLEAKLEY: We very definitely deny that she has moderate to severe mitral regurgitation.
THE COURT: Denies that plaintiff Betz has the injuries --
MR. BLEAKLEY: Both aortic and mitral.
THE COURT: I'm going to say the injuries claimed, because I'm saying what they are.

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MR. BLEAKLEY: That's fine.
THE COURT: Okay. Is that it for Betz, as far as you can tell right now?
MR. BLEAKLEY: I think so. We'll get one last shot to look at it?
THE COURT: Yes.
MR. BLEAKLEY: Okay.
THE COURT: And you know what else, this is preliminary stuff, so I may hold you to a waiver of what you haven't told me now for tomorrow morning is in the case, but if I don't throw everything into the jury voir dire, that's not critical as to the jurors.
MR. GROSSI: Your Honor, if I may just say, obviously if I'm incorrect and you rule that Mr. Fleming's shortfall complaint covers a separate failure to timely remove or a separate claim for overpromotion, we will certainly deny those as well.
THE COURT: Right, of course. Okay. Mr. Miller.
MR. MILLER: Yes, Your Honor.
THE COURT: Andro.
MR. MILLER: Your Honor, we are

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making a claim for failure to warn, failure to warn for three things: Lack of efficacy --
THE COURT: Wait, wait. Lack of efficacy?
MR. MILLER: The drug didn't work, Your Honor, lack of efficacy. We say they should have been warned --
THE COURT: Didn't we just have a motion in limine about whether or not Dr. Moye could testify to the comparison of efficacy on the one hand and risk on the other hand?
MR. MILLER: We did.
THE COURT: And did anyone say yo, Judge, he's got to be allowed to testify because we have a claim for lack of efficacy?
MR. MILLER: Well, I wasn't on the floor at that time, Your Honor, and I didn't want to get in trouble for jumping in.
THE COURT: You didn't want to get in trouble for jumping in and saying yo, Judge, I got a claim?
MR. MILLER: No, Your Honor, I did not. But I think that is very much part of the failure to warn claim.

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THE COURT: And what's your damages, your client is still fat?
MR. MILLER: No, Your Honor. I think under the Baldino case that it's the total inability to warn of all the risks and benefits of the drug, and I think that is a three prong--
THE COURT: The failure to warn of lack of efficacy, what's that case, Buchman?
MR. MILLER: I think not, Your Honor. That's the FDA defense case, if I remember.
THE COURT: Yes, that's right.
MR. MILLER: This has nothing to do with the FDA. This is just the drug didn't work, and they should have told our doctor we'd like you to prescribe a drug that didn't work because the drug didn't work, and I think that we're entitled to show that.
THE COURT: Okay. You're going to have to show me that in your complaint.
MR. MILLER: We will, Your Honor. We will have it in the morning.
THE COURT: Efficacy, what else?
MR. MILLER: Risk of valvular heart

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disease.
THE COURT: What kind did your client have?
MR. MILLER: Moderate mitral regurgitation.
THE COURT: Any other?
MR. MILLER: Well, Your Honor, specifically, yes. I mean, the symptoms of it, of moderate mitral regurgitation, which are shortness of breath.
THE COURT: Those are symptoms.
MR. MILLER: Yes. Well, then we don't need to talk about those.
THE COURT: No. Those are things -- once the jury concludes that they failed to warn about the risk of valvular heart disease, then you're going to recover for all the symptoms and progressions and medical expense, but those are damages.
MR. MILLER: Let me go back, if I can, and finish what I believe to be our failure to warn claim. Also warning about the accurate and true risk of primary pulmonary hypertension. We believe we are entitled under

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the Baldino case, we believe we are entitled --
THE COURT: Of course you don't. You don't have a claim for that. That's what the settlement is all about; is it not?
MR. GROSSI: Yes, Your Honor.
THE COURT: You don't have a claim for that.
MR. MILLER: We're not claiming that we have the injury primary pulmonary hypertension.
THE COURT: Well, I'm describing the claims.
Your presentation, if I understand it, is that evidence of that failure to warn is relevant to something in a claim in this case. That's not a claim, that's not what I'm going to tell the jury about.
MR. MILLER: All right.
THE COURT: What else?
MR. MILLER: Just negligently failed to warn of the totality of the risks associated with the use of Pondimin and Redux, and specifically Redux because that's what he took.
THE COURT: You're not going to get a

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judgment for the totality of the failure to warn, you'll only get a judgment if they failed to warn about valvular heart disease.

MR. MILLER: All right, Your Honor.

THE COURT: Any other claims?

MR. MILLER: Yes, Your Honor. I'm joining with Mr. Fleming on the failure to pull off the market and continue to promote the drug after they knew or should have known that the drug should not have been promoted.

THE COURT: Okay. What else?

MR. MILLER: That is it for our theories of negligence, Your Honor.

THE COURT: Okay. And defense as to Andro, anything different?

MR. GROSSI: Well, no. I know Your Honor just ruled, but they cannot have a claim for lack of efficacy; hence, there cannot be a failure to warn for lack of efficacy.

THE COURT: I haven't ruled because it's the first I've heard of it, so we'll deal with it tomorrow.

MR. GROSSI: I was going to say that it would also be a settled claim under the

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settlement agreement.

THE COURT: Well, since this is the first I've heard of this whole claim, how is that settled?

MR. GROSSI: Because the settlement agreement says that you can only sue Wyeth for valvular heart disease, period.

THE COURT: Okay. Is that what the settlement agreement says?

MR. MILLER: That's the only injury we're claiming. We're not claiming an injury of lack of efficacy, we're claiming liability for failure to warn about lack of efficacy. The settlement agreement says I can't sue for any other injury other than valvular heart disease.

THE COURT: Did your interrogatory ask about lack of efficacy?

MR. MILLER: Did my interrogatory ask about lack of efficacy?

THE COURT: Yes.

MR. MILLER: I didn't propound any interrogatories to plaintiff in discovery.

THE COURT: No, did the plaintiff's

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jury interrogatory ask anything about efficacy?

MR. MILLER: I don't believe.

THE COURT: Did it ask anything about pulled off the market?

MR. MILLER: No, Your Honor.

THE COURT: Forgetting everything else, why should I not say it's waived?

MR. MILLER: Because it's subsumed within that they were negligent, they were negligent for those reasons.

MR. WEISS: In the general charge we asked for they were negligent.

THE COURT: Yes, we know what that related to, we've talked about it for over a week.

MR. WEISS: Well, there was a second charge, Your Honor, about failure to warn, so there were two negligence charges that were submitted.

THE COURT: All right. I'll review it and revise it. But I'll just say for the record this is the first I've heard of these as claims.

What else, defenses?

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MR. BLEAKLEY: Same for Andro as it is for Betz.

THE COURT: Okay.

MR. SCOTT: With a one-month issue also.

THE COURT: Oh, this has the one month. Andro has the one-month issue; is that right?

MR. GROSSI: Yes.

MR. MILLER: Yes, Your Honor.

THE COURT: All right. That simplifies our first phase, doesn't it? You've conceded the first part of the first phase as to everybody.

MR. GROSSI: Your Honor, I was going to check tonight to see if the expert reports make the point that I'm trying to make, which is that while there is some evidence that these drugs may temporarily increase the risk of mild mitral, there is no proof that they lead to moderate mitral, and that's what these people say they have today.

THE COURT: Defendant concedes that these drugs can under certain circumstances

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cause mitral regurgitation, but they did not in plaintiff Gangel's case. That's the same in Betz' case. In Andro's case you claim that --
MR. BLEAKLEY: Actually, that subsumes the one-month issue, I think if you did it that way.
THE COURT: Well, yes, but there's an additional little thing in Andro, because in Andro you further claim that you can't for just the limited period that Andro had it.
MR. BLEAKLEY: Right.
THE COURT: Okay. But I don't see a whole phase just to determine that. I thought you were contesting that it couldn't cause it, but apparently you're not. You're conceding that, which is progress.
MR. WEISS: Your Honor, may I speak for a minute?
THE COURT: Yes.
MR. WEISS: I think there's confusion at least in my head and in my mind. The issue was general causation, and the defendants are contesting that generally Pondimin and Redux can cause moderate mitral regurgitation in any

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patient. That's still a general causation issue that hasn't been resolved.
THE COURT: You want this separated as to moderate mitral regurgitation?
MR. MILLER: No, Your Honor.
THE COURT: Well, I don't think it makes any sense for a jury to, generally causations, figure out between moderate and mild.
MR. WEISS: That wasn't the issue that we ever were going to try in this courtroom. I thought the issue was general causation on moderate mitral regurgitation. That was the first phase of this trial.
MR. DOYLE: I thought it was just mitral regurgitation.
MR. WEISS: I think we're playing with semantics. And I certainly was under the impression that that was an issue of general causation, not case specific causation.
Now, if I'm mistaken, I'm at a loss because we talked about who the witnesses are going to be, what they're going to testify to, and there was no one coming in to talk about

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specific causation of any plaintiff in phase one, and now you're saying that we have to do that.
MR. BLEAKLEY: No. He's just talking about the description of the case.
MR. WEISS: No, he's not.
THE COURT: No. I think you've withdrawn any reason to have a phase of the case concerning general causation, you've conceded it.
MR. MILLER: And it will shorten the trial, Judge. We can do general causation and case-specific causation damages at once, we can get this done all much quicker.
THE COURT: That's the way it seems to me, given what you've conceded.
MR. GROSSI: Your Honor, if I may, and if I conceded it, then I did it in error, but I'm not arguing now for the separate phase of the trial. That was something we were asked to comment about, and our comment was it made sense to do the entire medical case first.
THE COURT: Anything we need to discuss on the record before tomorrow morning?

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MR. WEISS: Yes, Your Honor.
THE COURT: What?
MR. WEISS: I like to know what we're trying because I release people from obligations based upon the fact that we weren't going to get this case specific causation for six days.
THE COURT: Well, you're not going to know anything this evening.
So anything else you need to put on the record?
MR. WEISS: Yes.
MR. FLEMING: One more thing.
THE COURT: Wait a minute, Mr. Weiss still has something else he wants to put on.
MR. WEISS: It's not just the general causation, it's liability and damages. Your Honor was very specific in your instructions to us the other day that Monday you were going to try general causation first, and that was going to take up till the 21st when Dr. Moyer would be back from vacation. And based upon that ruling, which was on the record, I acted accordingly, and now you're telling me I have

to try to retrace my steps that I might not be able to do.

THE COURT: I may require -- if you want to call in your witnesses twice for no reason as to Gangel, they say I can check yes, I may let you do that, but can you deal with that tomorrow, after we understand what we're talking about?

Yes, sir, Mr. Fleming.

MR. FLEMING: I just have a very short motion, and my oral motion to the Court is that based upon the concessions that Wyeth has just made with regard to this issue, that I would request the Court to go on and try liability and damages and go ahead and get this case on as of Monday morning.

MR. MILLER: I join in the motion.

THE COURT: Great. Anything else anybody wants to put on the record before we let our court reporter go and continue talking off the record?

(No response.)

THE COURT: Okay. Thank you.

(Hearing adjourned at 5 o'clock p.m.)

John J. Kurz, RPR, Official Court Reporter
(215) 683-8031

CERTIFICATION

I hereby certify that the proceedings and evidence are contained fully and accurately in the notes taken by me on the trial of the above cause, and that this copy is a correct transcript of the same.

John J. Kurz, RPR
Official Court Reporter

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