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IN THE DISTRICT COURT OF THE UNITED STATES
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: LIPITOR 2:14-MN-2502

TRANSCRIPT OF STATUS CONFERENCE
THURSDAY, JANUARY 22, 2015
BEFORE THE HONORABLE RICHARD M. GERGEL,
UNITED STATES DISTRICT JUDGE

Court Reporter: Amy C. Diaz, RPR, CRR
P.O. Box 835
Charleston, SC 29402

Proceedings recorded by mechanical shorthand,
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A P P E A R A N C E S

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APPEARED FOR PLAINTIFFS:

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- Andrea Bierstein, Esquire
- Christian Marcum, Esquire
- Josh Mankoff, Esquire
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- Frank Cetosa, Esquire
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- Clint Fisher, Esquire
- Eric Johnson, Esquire
- John Restaino, Esquire

APPEARED FOR DEFENDANTS:

- Mark Cheffo, Esquire
- Michael Cole, Esquire
- Sheila Brodbeck, Esquire

1 THE COURT: Okay. Good morning. We are here -- is
2 our telephone -- Ms. Eunice, are we connected?

3 THE CLERK: Yes, sir.

4 THE COURT: Very good. We are in our January 2015
5 monthly status conference in the matter of the In Re: Lipitor
6 Multidistrict Litigation, 2:14-2502. We have a number of
7 matters to address here.

8 Is there anything anyone needs to raise with me
9 before we proceed to hearing on the motion for judgment on
10 the pleadings on the Texas cases? Anything anyone needs to
11 raise with me?

12 MR. HAHN: Nothing from the plaintiffs, Your Honor.

13 MR. CHEFFO: No, Your Honor.

14 THE COURT: Very well. I'll hear from the defendant
15 on the motion for the judgment on the pleadings.

16 MR. CHEFFO: Your Honor, may it please the Court?

17 I know as always Your Honor is well prepared and I'm
18 sure has gone through the papers, so to the extent that there
19 are specific questions and issues, I know Your Honor will
20 direct me to those.

21 So what I thought I would do is just to kind of give
22 an overview and highlight really our -- what I think are our
23 main points here from our perspective. I think there are
24 many things which are not in dispute which are helpful.

25 There is no dispute here that Texas law applies to

1 the plaintiffs. There is no dispute that the Texas statute
2 bars all claims unless one of five exceptions apply. And
3 there is also no dispute that the plaintiffs have only
4 indicated or put forward one of the statutory exceptions that
5 they believe saves their claims, at least at this stage, and
6 that's the fraud on the FDA exception, and that's a
7 similar --

8 THE COURT: Mr. Cheffo, let me ask you this: The
9 cause of action here in which the Texas plaintiffs assert is
10 a failure to warn cause of action?

11 MR. CHEFFO: Yes.

12 THE COURT: And then Texas has modified that common
13 law cause of action with an affirmative defense?

14 MR. CHEFFO: Well, I think generally that's right,
15 Your Honor. And I think, you know -- the only reason I
16 hesitate on that is how we kind of, you know, it seems at
17 least between the *Desiano* court and perhaps the *Garcia* and
18 *Lofton* courts and the progeny, is the concept of how one
19 looks at an affirmative defense.

20 So if you read the statute, it's pretty clear, it
21 says, you know, there is a rebuttable presumption.
22 Essentially you have no case because, you know, Michigan, a
23 number of states through tort reform determined that in
24 certain areas the legislature was going to make a considered
25 decision that they were going to put some parameters, and

1 frankly, to limit lawsuits. That's why we don't have, you
2 know, frankly many of these mass torts, you don't see many
3 Texas plaintiffs and you don't see many Michigan plaintiffs.

4 So what you have is essentially the statute that
5 says, you know, there is a rebuttable presumption that you
6 have no cause of action unless you can meet one of these five
7 criteria.

8 THE COURT: First of all, it had to be -- as I
9 understand it, it is that there is this affirmative defense
10 for the warnings or information that accompanied the product
11 in its distribution were approved by the United States Food &
12 Drug Administration. I mean, that is the defendant's
13 affirmative defense, that if you demonstrate that this was
14 submitted and approved by the FDA, and then there is an
15 exception to that affirmative defense.

16 MR. CHEFFO: Well, with that one, I actually -- I
17 don't think that that's how the *Lofton* courts or the *Garcia*
18 courts or the progeny necessarily looked at it.

19 So I'm not quibbling with the fact that there is
20 this framework that certain facts have to be pled. But
21 essentially you have to have -- you know, there is kind of
22 this rebuttable presumption that you have no claim against a
23 manufacturer of a pharmaceutical product unless you can meet
24 one of these exceptions.

25 THE COURT: It says the warnings or information that

1 accompanied the product in its distribution were those
2 approved by the U.S. Food & Drug Administration. Are there
3 any warnings that might not have been approved?

4 MR. CHEFFO: Okay. And I'm sorry --

5 THE COURT: Do you see where I'm going on that?

6 MR. CHEFFO: I do, but there is no allegation --

7 THE COURT: I understand. I'm just saying generally
8 speaking, we are not talking about these specific cases, but
9 generically speaking where this statute might apply.

10 MR. CHEFFO: Absolutely. If I represented another
11 company that just decided to sell medicines with no labeling
12 or put on the market labeling --

13 THE COURT: This -- they wouldn't have the benefit
14 of this defense.

15 MR. CHEFFO: Absolutely, or if it was an off label
16 marketing case.

17 THE COURT: So there is this -- but what you are
18 telling me is that's not one of these cases because Pfizer
19 did submit and did obtain FDA approval regarding its
20 warnings, right?

21 MR. CHEFFO: That's correct, Your Honor.

22 THE COURT: Okay. And then the plaintiff comes
23 back, the Texas plaintiffs, and they say, yeah, but there was
24 either information withheld or misrepresented to the FDA.
25 That's their exception to the affirmative defense. I mean,

1 am I on -- I think that kind of makes sense, the underlying
2 statute here. And I know you are sensitive about this
3 because it's sort of the way the Second Circuit characterized
4 it. There is some difference between the way the Fifth and
5 Second Circuits characterized -- and I'm not trying to take
6 sides on that -- I'm just trying to make sense to me.

7 MR. CHEFFO: Sure.

8 THE COURT: But it does appear that we only get to
9 this issue regarding preemption when we -- not in the initial
10 cause of action, not in the affirmative defense, but in the
11 exemption from the affirmative defense. It's sort of several
12 layers down that we finally get to an issue which you assert
13 is actually preempted.

14 MR. CHEFFO: And I think -- so I think I would
15 generally agree with that. I think that, you know, the
16 hesitation, obviously, is that if you were to follow
17 essentially the *Desiano* rule -- and I would say that there
18 are pretty stark differences -- I think it's a matter between
19 *Desiano* and *Garcia* and *Lofton*.

20 And, you know, I would also highlight that *Lofton*
21 essentially had the benefit of *Desiano*. *Lofton* is the Fifth
22 Circuit and basically very clearly and strenuously disagreed
23 with *Desiano*.

24 So I think, though, that, unlike a typical
25 affirmative defense, you know, where it's someone files a

1 claim, then you have a statute of limitations, this, I
2 think -- you know, if you want to call it affirmative
3 defense, that's fine. But I think what the Courts have
4 looked at it is essentially as a kind of a composite package.
5 Because the reason is this, as Your Honor well knows, that if
6 we were to say, Well, this is not an issue for a motion to
7 dismiss, they just said that you withheld information from
8 the FDA. Is there a product liability case where that's not
9 a claim?

10 So essentially you would be saying, contrary to the
11 Fifth and the Sixth Circuit, that really you could never make
12 this motion until you go through discovery, and then this is
13 a summary judgment issue.

14 And I think, again, *Lofton*, *Garcia*, all the cases,
15 the DeVore case that we've cited in New York basically said
16 the same thing. They say, no, no, no, you can't have a
17 fishing expedition. So there is an element of how you look
18 at it.

19 I would also say this: I mean, a second element of
20 our -- of our motion, as you know, Your Honor -- it's really
21 two prongs -- is the pleadings. So it's not just that they
22 haven't pled it under Rule 9, which they haven't, but it's
23 also that they haven't pled that even --

24 THE COURT: Fraud is not a necessary element. I
25 mean, there is information withheld is one potential basis of

1 the executive. It doesn't require the defendant to commit
2 fraud, it could be negligent withholding. It just says --
3 the statute says withheld, information withheld.

4 MR. CHEFFO: But I think -- you know, the way it's
5 been interpreted, I think frankly, by all the Courts that
6 have looked at it, this is a fraud on the FDA.

7 THE COURT: You know, people have sort of jumped to
8 that. I have -- you know, I see everybody -- you know, we
9 all judges like to sit there and characterize or put
10 everything into categories. And it's a really catchy, little
11 term, fraud on the FDA. But the statute is broader than a
12 fraud on the FDA. It really -- it really is. When you read
13 the language, it says, "withheld from or misrepresented."
14 "Withheld from or" --

15 MR. CHEFFO: There is also -- but then there has to
16 be a proximate cause element.

17 THE COURT: But proximate cause doesn't go with the
18 mental state. I mean, you can have -- you could negligently
19 withhold something that proximately caused injury. That's
20 what we call negligence, right? I mean, that's a negligence
21 claim.

22 MR. CHEFFO: Again, I would suggest that I don't,
23 you know, believe that kind of, in my view at least, a fair
24 reading of this statute is anything other than a fraud.

25 So I think there is three elements. We have the

1 preemption issue, we have the element of whether the Rule 9
2 standard on fraud applies. But even -- even under -- you
3 know -- if it wasn't a fraud, you still have to have the
4 proximate cause, and that's not in their pleading. So you
5 would have to say as a result of X, Y and Z, here is how I
6 was harmed.

7 THE COURT: This is where, you know, where I'm
8 having kind of an issue here. I frankly think these motions
9 on the pleadings and stuff get overdone by lawyers, and that
10 sometimes you've just got to go through discovery. That's
11 not the biggest tragedy in this case, Mr. Cheffo, because
12 y'all are going through discovery no matter what here.

13 And I frankly think that the harder claim for the
14 plaintiff is surviving summary judgment on this because
15 they've got to come through with specific evidence to
16 support, should they survive this. This is the easy part, in
17 my view. The hard part is actually showing evidence that A
18 was withheld and B was a proximate cause of the injury.

19 And I find -- you won't believe the kinds of things
20 people plead in front of me to survive a motion to dismiss.
21 And then we get to summary judgment -- and I've warned them
22 many times, I say, Watch out now, you are way out there on
23 this. Do you really -- you are going to marshal evidence.

24 And so A, I've got to address this issue. But if
25 they should survive this, that is -- their problems are not

1 over yet on this claim because they've got to come forward
2 with evidence to support this.

3 MR. CHEFFO: They do, Your Honor.

4 And I know we are in somewhat of a unique situation
5 in the MDL, but really in this one, I think the Court has to
6 look at this as de novo. The plaintiffs had 13 or so
7 Michigan plaintiffs. There is really little difference. The
8 statute has actually fewer exceptions, but the exception that
9 they would have relied on is here. The plaintiffs dismissed
10 all of those cases with prejudice, okay, in the cases. So,
11 you know, you have to ask yourself why that is. And now -- I
12 don't think --

13 THE COURT: I can't -- I've got to deal with this
14 Texas thing straight up.

15 MR. CHEFFO: Understood.

16 THE COURT: But what I'm trying to say to you is
17 that the force of your argument might actually be stronger on
18 the merits than it may be in this argument. I just want
19 to -- you know, part of this issue is, when we are talking
20 about pleadings and the structure of it, it ends up mattering
21 as you get down into the analysis, because if it's merely an
22 exemption to an affirmative defense, you wouldn't plead it
23 because the other -- the defendant hasn't even pled the
24 affirmative defense yet.

25 So if you characterize it as an affirmative defense,

1 then you can't fault the pleading. But that may solve your
2 pleading problem but not your proof problem, which, you know,
3 you end up having a problem under the statute but not at the
4 early stage; at a later stage.

5 MR. CHEFFO: Here is the problem, I guess -- I'm
6 sorry.

7 THE COURT: Let me just say this: I'm less troubled
8 at what's -- I know you guys want to knock something out now,
9 and I'm less troubled when I've got this massive discovery
10 going on, and within a couple of months I'm going to be
11 dealing with all these motions, that it makes more sense to
12 me just conceptually to deal with it, is there any evidence
13 even to support this claim? And, you know, I -- I'm not
14 privy to what y'all are getting in discovery. I have no idea
15 of that. Proving that Pfizer withheld -- I mean, I would be
16 curious to see what that evidence would show. The --

17 MR. CHEFFO: Can I address that?

18 THE COURT: Yes.

19 MR. CHEFFO: There is a problem. And I understand,
20 you know, that, but it's not just a matter of Pfizer. We
21 are -- you know, at some point, you know, we all have to --
22 it's just not a matter of culling cases, but it's, you know,
23 it's figuring out -- this is a very considered motion on our
24 part. You know, there are, whatever there are, 80, 90 cases.
25 And it's not just a matter of the same discovery, there has

1 to be discovery arguably on those plaintiff cases, and then,
2 you know -- so it's not just the cost of the same discovery
3 on Pfizer, there still has to be that individual pleading,
4 you know, on the proximate cause element. Because let's
5 assume they say X, Y, Z was held, right? There still has to
6 be some consequence to the plaintiff. Would that not --

7 THE COURT: But if it's an exemption to the -- to an
8 affirmative defense, it doesn't come up -- deficiency in the
9 pleadings; it's a deficiency of proof at the summary judgment
10 stage. I mean --

11 MR. CHEFFO: I don't disagree with that.

12 THE COURT: I kind of -- I kind of think we are, um,
13 that -- I'm a little skeptical about the plaintiffs' claim
14 here, by the way, but I'm less skeptical at this stage, but
15 at a later stage. And part of this is I do think there is a
16 strong presumption against preemption, particularly implied
17 preemption, when state law welfare and safety laws are
18 involved, notwithstanding y'all's argument or reading of
19 that 2011 case, because it was silent. And some -- now we
20 are going to have an implication of an implication to say
21 something about a preemption.

22 The -- I think the law is, as recent as *Levine*
23 talked about, the strong -- that there is a presumption
24 against preemption. And, you know, since the Second Circuit
25 ruled, if this was such a big deal, Congress hasn't moved to

1 adopt an expressed preemption here.

2 MR. CHEFFO: No.

3 THE COURT: You know, I had a case some years ago, I
4 thought -- sort of thinking about this, involving a -- that a
5 group wanted me to find an implied cause of action under
6 Bivens for Jose Padilla, the famous one guy, American
7 citizen, detained without trial. And I sort of -- and I
8 said, something this important, Congress could adopt a 1983
9 action for someone in this situation but never has done it.

10 And I'm sort of reluctant on something this
11 important to start implying things that have such tremendous
12 consequence. Texas has an interest in its tort laws. It's a
13 sort of state interest. It's an important interest. I think
14 *Levine* recognizes that. And I don't think we ought to be
15 real quick to pull the trigger on preemption unless the
16 demonstrated federal interest here, you know, would justify
17 that because there are important interests on both sides.

18 So I come at it as a sort of, you know, being
19 respectful of the prerogatives of the individual states. I'm
20 constantly being asked to interfere with processes in our
21 state prisons and foster care system, all this stuff. I'm
22 very reluctant to do that because I think we've got to --
23 we've got to use the powers of the Federal Court very
24 sparingly and only when necessary.

25 So I found the Second Circuit sort of analysis of

1 the interests here when -- that when you've kind of got the
2 exemption to an affirmative defense, that doesn't raise it
3 strongly. It's there, but strongly the concerns -- policy
4 concerns that *Buckman* legitimately raised, which is inviting
5 causes of action simply solely on the basis that it -- that
6 it -- that someone had lied to the FDA creating a state cause
7 of action.

8 Certainly -- you know, I found Justice Rhenquist --
9 Chief Justice Rhenquist's statement about when he said, you
10 know, in sum, I know all these things -- you know, the states
11 just didn't have a judicial interest in this particular cause
12 of action is, you know, it's not a common law cause of
13 action.

14 And here we have a common law cause of action
15 modified, to some degree, by an affirmative defense and then
16 an exception to the affirmative defense.

17 I'm going to give it to you, I think it's a close
18 question --

19 MR. CHEFFO: Can I --

20 THE COURT: -- but I wanted to share with you.

21 MR. CHEFFO: And you have -- and that's why I'm
22 going to be very judicious in my comments because, again, I
23 think you do understand me.

24 Look, what I'm hearing Your Honor, you've -- you are
25 telling us that -- telling me -- you are telling me that you

1 are kind of relying on the *Desiano* view, at least how you
2 look at it. Because that is a fundamental question.

3 I would just highlight a few things. One is, you
4 know, you talked about should Congress act? I would look at
5 it a little differently. I would say, well, shouldn't Texas
6 act? Because the Fifth Circuit in Texas, where most of the
7 people, you know, who would be subject live, has determined
8 it's not an affirmative defense first. Basically, it's a
9 pleading issue, you don't get discovery.

10 And the Sixth Circuit, where the Michigan statute
11 is, has also said -- and those are the people -- probably
12 some of the Judges who are on those panels are from Michigan,
13 and Texas certainly in the Fifth Circuit, and they've looked
14 at it. Now, the only court who has looked at it differently
15 is the New York Second Circuit Court.

16 THE COURT: Among Circuit Courts.

17 MR. CHEFFO: Among Circuit Courts. But then again
18 in state and federal courts in Texas, they have looked at it
19 the way *Lofton* and *Garcia* have looked at it; not this
20 distinction.

21 So the only outliers -- and here is where I think
22 the plaintiffs -- you know, and again, excellent lawyers --
23 we actually agree with *Wyeth Levine*. This is fully
24 consistent with *Levine*.

25 And the reason is this: We didn't come in and make

1 a 50-state allegation saying any failure to warn claim. We
2 were very targeted because the specifics, right, the
3 specifics of this require on a fraud on the FDA -- frankly
4 every court has looked at this, state, federal. They call it
5 the fraud on the FDA exception. And that's why it's outside
6 of *Wyeth vs. Levine*, and that's why it's exactly *Buckman*.

7 And then as further support, you have basically the
8 *Mensing* case which again looked at this, and then you have
9 the *Bartlett* case.

10 And what is interesting -- and I think -- and *Lofton*
11 took great pains, I think, and appropriately disagreed with
12 the Second Circuit on this presumption of -- and that's where
13 I think the Second Circuit --

14 THE COURT: I've got to tell you something, I
15 thought the Fifth Circuit argument is very interesting. I
16 mean, it's very well written. The part I really disagree
17 with them was on this presumption, and the inference from a
18 2011 Supreme Court case which didn't mention it, and then
19 there is a 2009 case and a whole line of other cases that
20 have reiterated that for years that it is a presumption --

21 MR. CHEFFO: But they did say there is only a
22 presumption -- to your point, and I completely get it, right?
23 You know, the argument no Federal Court, frankly no court
24 wants to interfere with the state or other processes. But I
25 think there is this presumption when we are talking about

1 issues that are, you know, that are typically within the
2 bailiwick or purview of a state, right? We don't want to
3 have -- we have a federal system. But where I think every --
4 the *Lofton* court, the *Garcia* courts and all the progeny have
5 gotten it exactly right, which is essentially what *Buckman*
6 which says it's never within the State's purview, certainly
7 of Texas, to regulate whether the FDA would have done
8 something differently, right, with information, whether they
9 would have required a label change. That is actually under
10 the FDCA Act which has no private right of cause of action.

11 So that's why this is so narrow and that's why it's
12 only as to these claims because it's not an interference --
13 it's not interference with the state law.

14 And in fact, the State legislature, I think this was
15 passed in the late nineties, early 2000, and every state
16 legislature in Texas says if a Texas citizen goes to the
17 Texas State Court or the Fifth Circuit, they have no claim.
18 Have they changed this to say, no, no, no, what we really
19 meant is something different? That's the way it was applied
20 to Texas. That's why you don't see these cases filed in mass
21 torts, Your Honor.

22 And, you know, it would be completely incongruous,
23 and frankly unfair, to not have a situation simply because
24 there is a procedural mechanism of an MDL that if Mr. Jones,
25 or in this case -- excuse me -- Mrs. Smith was to file her

1 case in Texas, she would have no claim. There would be no
2 question about discovery. She would be done. Whereas here,
3 you know, the analysis should be different.

4 THE COURT: I tell you something, Mr. Cheffo:
5 Texas -- I mean, I read this statute, maybe I'm over reading
6 it, as an effort to balance interests, okay? On one hand
7 they are concerned that a pharmaceutical company would go and
8 get FDA approval of a label and then be sued for a government
9 approved label by the federal agency charged with reviewing
10 such matters.

11 But then they are bothered, the legislature, you
12 know, hold it, I don't know if that agency was misled, was
13 not given the relevant material information. And that would
14 make that approval not worthy of State -- of the -- of the
15 state credit against its common law on failure to warn.

16 That balance reflected to me a sort of compromise
17 between an absolute ban and a ban modified and written by
18 this limitation. What you would have me do is undo that
19 balance, undo what Texas legislators have tried to balance.
20 And it frankly raises to me -- though I know there is much
21 authority to the contrary -- that if I bought your preemption
22 argument, I would be inclined to declare the whole thing
23 non-severable because it's all part of one scheme. And I
24 don't frankly think that's the answer, either.

25 But it does seem to me that you would have me go and

1 change the calculation, the balance of interests, the policy
2 judgment of the Texas legislature, and to create an absolute
3 bar that it didn't intend to adopt.

4 MR. CHEFFO: And if I meant to say that -- so here
5 is my response to that, Your Honor, because I don't think
6 that's right.

7 First, what most of these cases -- the practicality,
8 there is an exception here in off label marketing. So if you
9 look at, just generally, a lot of claims have off label
10 marketing. They are not balanced, right? This case doesn't
11 involve an off label marketing case.

12 The second issue here is even within this exception,
13 what the Courts have said, it's not writing out the exception
14 completely; it's basically saying if the FDA finds within its
15 purview that there has been -- and they do sometimes. They
16 issue warning letters. They can do -- you know, Your Honor
17 is aware they can have a host of issues. They could issue a
18 reprimand, a warning letter. They could take a medicine off
19 the market. They could bring charges through the DOJ, right?
20 So even within that, no one is suggesting that that complete
21 exception is gone.

22 Here is the concern is that if you really pull this
23 thread, what we are going to wind up then doing is having an
24 entire litigation now about what the FDA would have done if
25 they would have seen it.

1 And, you know -- and the plaintiffs are going to
2 come in and say, Well, if they had done this and then we call
3 FDA witnesses to have them get into the administrative
4 process. And that's why what *Buckman* said and what *Lofton*
5 say is that there is a certain element of discretion that's
6 very important for the FDA to have. And it's within the FDA
7 because it's a delicate balance of regulating pharmaceutical
8 companies.

9 THE COURT: Not what the FDA would have done, but
10 whether there was material information and that information
11 withheld was information proximately related to the injury
12 suffered by the plaintiff.

13 MR. CHEFFO: No, no. I think it has to be -- I
14 think more than that. I think it says that it has to lead to
15 some type of labeling change. So it has to be -- there is
16 two elements --

17 THE COURT: It says: "The defendant withheld from
18 or misrepresented to the FDA required information that was
19 material and relevant to the performance of the product and
20 was causally related to the claimant's injury."

21 So that is -- it didn't -- you don't have to find
22 that the FDA would have made a different decision, it is that
23 they withheld information that was material and that withheld
24 information was material, that was the proximate cause -- a
25 proximate cause of the plaintiff's injuries.

1 I frankly don't think what the FDA would do or not
2 do would be relevant to that argument. I don't think we
3 would be trying the FDA, whether they would change or not.

4 MR. CHEFFO: Whether they thought it was material
5 or not, whether they knew it, whether they were aware of it.

6 THE COURT: I'm not going to limit what it --
7 forecast what that evidence would be in terms of the going to
8 the FDA if you sought that out. But I'm saying, I don't
9 think it's necessary for the plaintiffs' assertion of the
10 exemption, it would just need to show, Hey, this information
11 was really material to the diabetes issue and it was
12 withheld, and that information -- and that is relevant to
13 their injury of the development of diabetes. So I know that
14 argument has been asserted.

15 Let me ask you, you know, *Buckman* raised this issue
16 of the potential fear that the FDA would be flooded with --
17 the pharmaceutical companies would behave in a different way
18 knowing about this exposure.

19 Is there any evidence since 2007 that the FDA has
20 actually had such a problem?

21 MR. CHEFFO: I think that was one of --

22 THE COURT: I'm just asking, do you know of any
23 evidence?

24 MR. CHEFFO: No. As I sit here today, I'm not
25 aware of a factual record or study that that has happened.

1 THE COURT: Or, you know, in 2001, I don't know
2 exactly how the pharmaceutical companies submitted
3 information to the FDA. I don't know if it was already
4 submitting digital information by then. Let's assume it was.
5 It wouldn't have been for a long time before, but let's
6 assume it was. Haven't there been a lot of advances in data
7 management, word search of documents, the type of things that
8 would make the FDA's receipt of massive information far more
9 manageable today than it would have been in 2001? So that
10 the advances of technology might make that federal concern
11 actually less today than it would be -- it would have been in
12 2001, just --

13 MR. CHEFFO: I certainly wouldn't disagree with
14 that, Your Honor. The technology is advanced. I don't
15 really see it as kind of a technology issue.

16 You know, I think essentially what the concern here
17 is, is that from a public policy perspective and from a
18 regulatory perspective, the way the FDA operates and the
19 decisions it makes are not black and white. There often have
20 to be nuances because issues are nuanced. And I think what
21 the concern is then, and has been in many cases, is once
22 you -- look, under the -- if we follow this, Your Honor, and
23 we are essentially saying that you can never get a motion to
24 dismiss if we follow it. You have to go through some level
25 of discovery. And, you know -- and I won't repeat really

1 what I've said or what's in our papers. I think that's just
2 fundamentally --

3 THE COURT: Doesn't it seem in this case -- I hear
4 your argument. I only do it one case at a time. I'm sitting
5 here in this case where y'all have exchanged how many
6 millions of documents, all right? I mean, it's not like we
7 are avoiding that --

8 MR. CHEFFO: Exactly.

9 THE COURT: -- avoiding our rule. And I'm not
10 trying to blow off your concern because I think the defendant
11 has a point here. The question is is when should we address
12 it?

13 MR. CHEFFO: Okay.

14 THE COURT: And if you hear what I'm saying.

15 MR. CHEFFO: I do.

16 THE COURT: And I'm just frankly inclined to do it
17 several months from now than with this. And I think in the
18 end we are not then dealing with whether the Second Circuit
19 or Fifth Circuit are right, or is right, or we are dealing
20 with -- even if you assume the Second Circuit is right, is
21 there really evidence that would be available in the record
22 that would even support such an exemption to the affirmative
23 defense? So I don't think we are there yet.

24 MR. CHEFFO: So you would like us to defer on this.

25 THE COURT: Yeah. I'm really -- I just think we

1 overdo in the federal courts -- I just -- I think we overdo
2 these motions to dismiss, these motions on the pleadings, and
3 that I find myself a lot of times saying to parties, I hear
4 you, but let's have some record here. And I think I'm better
5 off making a decision on the record. Listen, every one of
6 these cases, it's a close call. Everybody -- you can read
7 the analysis both in the -- I mean, I think both the Second
8 Circuit and Fifth Circuit are really interestingly written.

9 MR. CHEFFO: They are.

10 THE COURT: I told you my one small disagreement
11 with the Fifth Circuit, this conclusion about -- this whole
12 thing about this implied abandonment of the presumption. I
13 really -- it would be an overturning of an entire body of
14 case law in thinking -- modern thinking about respect for the
15 prerogatives of the states that I don't frankly think among
16 the people you are pointing to to do it. I haven't seen them
17 actually going in that direction. I know there has been a
18 dissent in *Levine* that discussed it. It was interesting.
19 Y'all pointed it out, page 624 of the dissent, and footnote
20 14. I read it a couple of times. It was pretty interesting,
21 but it's a dissent.

22 MR. CHEFFO: I'm not surprised that you did, Your
23 Honor.

24 THE COURT: It's a dissent.

25 And so, you know, I'm -- I'm inclined -- Mr. Cheffo,

1 I've tried to give this a fair consideration -- that I'm
2 going to deny your motion at this point, but I don't want you
3 to take it as a final answer on this issue because I think
4 you need to address it at summary judgment, and you can
5 reargue these issues. But I'm really very interested to see
6 when the plaintiffs have the responsibility to actually put
7 up evidence of this, will that evidence, you know, survive
8 summary judgment.

9 MR. CHEFFO: Okay. Great. Thank you, Your Honor.

10 THE COURT: Thank you very much.

11 Now, I know able counsel has prepared herself for
12 this. Do you want to buy it back or --

13 MS. BIERSTEIN: Your Honor, in light of Your
14 Honor's ruling, I have nothing further to add.

15 THE COURT: I remember one time I was handling a
16 matter in front of an administrative agency on a school
17 board, and the superintendent was seeking to terminate the
18 niece of the most powerful man in town. And the
19 superintendent was from out of town and didn't appreciate
20 exactly what he was doing. And I prepared this hearing about
21 how wonderful this individual was and how inappropriate it
22 was. And I was ready to call my first witness and the school
23 board convened and they asked one of the board members to say
24 a prayer and looked to the Lord to give them guidance, and
25 then the superintendent said, Our first matter is this

1 termination. Hold on, we've got another matter. One guy
2 says, I move to fire the superintendent, and that second they
3 terminated him. And I'm like amazed, you know. And the --
4 this fellow who was the most powerful guy in town who had
5 retained me to represent his niece came up and said you did a
6 heck of a job.

7 So with that, we've got that issue. Let me move on.
8 And I'll be issuing a written order on the Texas 12(c)
9 motion.

10 Let's talk about this common fund order. And let me
11 hear from counsel on basically the nature of this proposed
12 order and the response we've received to it.

13 Mr. Hahn?

14 MR. HAHN: Thank you, Your Honor. To my knowledge,
15 there has been no response to the order. Everyone that I
16 have spoken to supports it. It's on the PSC and I have had
17 no objection from anyone else. The order, just so the Court
18 understands, will apply to all cases that come into your
19 Court, even if they are subsequently remanded.

20 THE COURT: Correct. My understanding -- it's
21 Docket Number 691 is the motion to adopt their -- that
22 regardless if I subsequently grant a motion to remand on any
23 case or on a pending motion or one later filed, all of them
24 would be subject to this order if I entered it, correct?

25 MR. HAHN: Yes, sir.

1 THE COURT: And I think that's clear from the order,
2 do you not --

3 MR. HAHN: I do, Your Honor.

4 THE COURT: I've reviewed it. I didn't have any
5 objections and I will enter an order adopting it --

6 MR. HAHN: Thank you, Judge.

7 THE COURT: -- as a management order. Okay?

8 Let me -- I had mentioned previously that there
9 were -- I had received multiple motions to withdraw as
10 counsel in cases. Just for the record, it's 319, 320, 323,
11 329 and 674. All those are, of course, docket numbers. And
12 I don't really want pro se plaintiffs in this litigation, in
13 this MDL.

14 And I have suggested -- and I think it's a
15 management issue, it's just -- and I have suggested that to
16 the extent there is not a voluntary willingness to dismiss
17 those cases, that the defendant move to dismiss them without
18 prejudice.

19 Mr. Cheffo, I would just suggest that you proceed
20 with that.

21 MR. CHEFFO: We will do that, Your Honor. Thank
22 you.

23 THE COURT: Very good.

24 Someone has filed a case on behalf of a male
25 plaintiff, *Timothy Alan Kula vs. Pfizer*, 2:14-4573. Is there

1 any dispute that that's beyond this MDL?

2 MR. HAHN: No, sir, Your Honor, from our
3 perspective. We are only discovering the case as to women
4 and diabetes.

5 THE COURT: Well, would you -- before I act, would
6 you figure out who filed that and see if it's necessary for
7 me to issue an order or whether there might be a voluntary
8 dismissal without prejudice?

9 MR. HAHN: Yes, sir, Your Honor. Would you
10 consider if they want to pursue that case remand it to their
11 state court?

12 THE COURT: I'm delighted to do that. I'm delighted
13 to do it any way, it's just an odd duck in the case. And it
14 might be, well, that we'll find out that it seems to have a
15 masculine name and it's a woman. We need to sort it out. If
16 you would do that and within 10 days get back with me, if you
17 would.

18 MR. HAHN: Yes, sir.

19 THE COURT: Now, Ms. Eunice, do we have our famous
20 wheel here?

21 THE CLERK: Yes, sir.

22 THE COURT: I see it over there.

23 In the olden days, folks, not as olden as we would
24 like to think for some of us, we drew juries not by computer,
25 random selection systems, but by a wheel. And sitting over

1 there on the table over there is our wheel, which is mostly
2 relegated to the museum here at the courthouse and not to
3 active use.

4 But Ms. Eunice, we are ready to put it back into
5 service, are we not?

6 THE CLERK: Yes, sir.

7 THE COURT: We are going to draw our -- when we get
8 down to the selection of the bellwether cases, my
9 understanding is by the 30th of this month we will have -- we
10 will have eight cases identified by each side.

11 Is that correct, Mr. Hahn?

12 MR. HAHN: Yes, sir.

13 THE COURT: Okay. And we are, at 10 AM on the 30th,
14 for anyone who wishes to observe this, we will come into this
15 courtroom -- well, this or whatever courtroom is available to
16 us -- we will put the eight cases in the wheel. We will turn
17 it many times. If plaintiff and defense counsel wish to do a
18 few turns themselves, they will have the privilege of doing
19 so. And Ms. Ravenel, our long-standing clerk, will -- my
20 courtroom clerk will -- the courtroom deputy will reach in
21 there and pull the first one out and announce what that is.
22 She'll reach in and continue pulling until we -- the rule is
23 that if it's a plaintiffs' case, the second will be a defense
24 case and vice versa. So once we pull the first case, we will
25 announce it, determine whether it's a -- if it's a,

1 hypothetically a plaintiffs' case, then she will continue
2 pulling until she pulls the first defense case, and those
3 will be the two cases.

4 Now, does anyone have any objection to that system?
5 For the plaintiff?

6 MR. HAHN: No, Your Honor.

7 THE COURT: From the defense?

8 MR. CHEFFO: No, Your Honor.

9 THE COURT: Okay. Mr. Cheffo, you do not need to
10 come to Charleston for that if you don't wish to be here.
11 I'm sure Mr. Cole can handle that important responsibility.

12 MR. COLE: Thank you, Your Honor.

13 THE COURT: Very well. And I am open, as I have
14 invited counsel if they have other methods before the 30th
15 which to identify those final cases, that they consent to and
16 voluntarily submit to the Court, I'm open to removing chance
17 and allowing the parties to select those two, if that's what
18 they wish to do.

19 Okay. Are there other matters, first in the
20 courtroom, any matters that need to be brought to the
21 attention of the Court at this time?

22 MR. HAHN: Your Honor, as to the ADR issue, once
23 the defendants have answered, which I don't believe the time
24 has run yet, the plaintiffs are open and eager to have a meet
25 and confer in which you preside. And we believe that we will

1 be able to resolve the issues at that time.

2 THE COURT: You envision that to be in person, on
3 the telephone? How do you want to do that?

4 MR. HAHN: It's really up to Your Honor. We are
5 happy for you to do it by phone.

6 THE COURT: I'm really more concerned with y'all's
7 convenience than mine. I'm going to be here if you do the
8 meet and --

9 MR. HAHN: We'll meet in person. It may be in New
10 York and then get you by phone.

11 THE COURT: That would be fine. I'm willing to do
12 anything. As I said, I'm not intending to travel. And to
13 the extent that y'all want to avoid doing that in some way,
14 then that's fine. And if you are going to meet and confer,
15 you may want to try to meet and confer before you get me on
16 the telephone, and that it may not be necessary. And you are
17 at least -- it may be narrowed to where -- to the issues to
18 which I need to address. But I will -- I'm fully available,
19 I believe on the 27th is when the defendant is responding.

20 Do you intend to do a reply to that or --

21 MR. HAHN: No, sir, Your Honor.

22 THE COURT: So we are -- you set it up and let us
23 know. We'll work with you in proceeding and trying to
24 resolve this issue. And of course, if the meet and confer
25 doesn't resolve it, I'm going to -- I know how to say yes and

1 no on motions to compel, okay?

2 Any other issues? From the plaintiff?

3 MR. HAHN: No, sir.

4 THE COURT: From the defense?

5 MR. CHEFFO: No, Your Honor.

6 THE COURT: Okay. Very good. Counsel, I will -- do
7 we know when is our February meeting? Do we have that date
8 designated somewhere? I'm sure. Anyone have that handy
9 date? I normally say it for the record here. Well --

10 MR. HAHN: The 26th.

11 THE COURT: February 26th. Very good. Okay. So we
12 will next see you then, or I may hear from you earlier. And
13 of course, I remain available, and I remain available in the
14 interim on any matters that are of importance that need my
15 attention.

16 And let me just, because the oversight here as I sit
17 in the courtroom, is there anyone on the phone who wishes to
18 raise any matter with the Court? Let the record show there
19 has been no response. See you next month.

20 (Thereupon, the Court was in recess.)

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-titled matter.

Amy C. Diaz, RPR, CRR

January 23, 2015

S/ Amy Diaz