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1 (The following was heard in open court at  
2 11:10 a.m.)

3 THE COURT: -- we've cut through some of it a  
4 little quicker than others, and already I'm going to  
5 change the order of some things. After we get through  
6 our status overview and some reports, I would like to  
7 briefly address and move up the GlaxoSmithKline motion  
8 if that is amenable, because given our conference this  
9 morning, it seems to me you wouldn't have to wait till  
10 the end of the day when it is scheduled for. And I  
11 think that if all counsel are ready to do that, we'll  
12 take you shortly.

13 The Court has a Judges' -- Board of Judges'  
14 meeting over the lunch hour, so I will not be able to  
15 work straight through. We intend to have our usual  
16 status conference that we're going to have now. I  
17 anticipate that will take about a half-hour, no more,  
18 and then we would take a brief recess and start the oral  
19 arguments that have been scheduled, whichever ones are  
20 still viable.

21 So without more explanation than that, let's  
22 start with a status overview, and I will turn to  
23 counsel, Dianne Nast. Thank you.

24 MS. NAST: Good morning, Your Honor.

25 THE COURT: Good morning.

1 MS. NAST: I am going to, in the interest of  
2 speeding along, I'm going to combine one and three which  
3 are both -- or 3A which are both status reports.

4 We're moving along well. We have taken 12  
5 depositions. There are more noticed that we're getting  
6 dates for, ten, maybe 12. We have provided the dates  
7 for plaintiff depositions in 32 -- for 32 deponents, and  
8 we are continuing to provide additional dates.

9 We have -- the defendants have taken four of  
10 our expert witnesses. That happened in the last two  
11 weeks. And we have dates for the defendants' experts,  
12 and they will be -- those depositions will be starting  
13 soon.

14 There are about 450 cases pending before the  
15 Court, give or take one or two or even three, and we  
16 have met frequently, often in person, sometimes by  
17 telephone with Mr. Chirls, and that's sort of a weekly,  
18 not always, like, we probably won't meet next week  
19 because it's Thanksgiving, but we are meeting with him  
20 quite regularly, and things are moving along.

21 THE COURT: Thank you.

22 MS. NAST: I'm going to ask Bryan -- you have  
23 his written report I think -- to give his state report.

24 THE COURT: Yes.

25 MR. AYLSTOCK: Good morning, Your Honor.

1 THE COURT: Good morning.

2 MR. AYLSTOCK: You have my report number  
3 eight, I believe, and in the interest of time, I won't  
4 run through everything but just highlight a couple of  
5 changes since that report was submitted, Your Honor.

6 We have worked on the numbers with Mr.  
7 Cheffo's firm and I think we're up to 510 plaintiff  
8 families in this MDL, give or take a few. As Your  
9 Honor's aware, you've recently granted remand in three  
10 cases, two California and one Illinois. I have made  
11 contact with counsel for each of those, and they have  
12 pledged coordination with this Court in discovery  
13 matters to the extent possible, and two of them are  
14 going back to San Francisco to the JCCP in California,  
15 one back to Cook County.

16 In the remaining Illinois case, the Wilson  
17 case, I believe a dismissal will be forthcoming, so on  
18 your next report, I would expect to see the Wilson case  
19 out and the newly remanded case in.

20 In Missouri, there has been some activity in  
21 that there have been some combo cases involving Zolofit  
22 in the coordinated Celexa/Lexapro litigation pending in  
23 Cole County in Missouri, and in New York, one of the  
24 cases was a generic version of Zolofit that had been  
25 dismissed.

1                   And in Pennsylvania, the case, the Zoloff  
2 case, the Robinson case that had been previously set for  
3 April of 2004, that trial's been moved to -- I'm sorry,  
4 2014 -- it's been moved to 2015.

5                   And then finally in West Virginia, six  
6 additional cases have been filed in West Virginia State  
7 Court. They're also coordinated before Judge Young in  
8 that jurisdiction, Your Honor.

9                   THE COURT: Thank you.

10                  MR. AYLSTOCK: That's my report.

11                  THE COURT: Thank you.

12                  And, Mr. Cheffo, can -- oh, I'm sorry --

13                  MS. NAST: Oh, I'm sorry. Did you have  
14 something --

15                  THE COURT: -- anything on these particular  
16 reports that you would like to add to?

17                  MR. CHEFFO: No, Your Honor. Thank you for  
18 asking. We do work pretty closely with Mr. Aylstock and  
19 his firm at coordinating, so I think it's -- for the  
20 most part a joint report on these -- on the status, and  
21 I think he's covered really good where we are in the  
22 litigation. Thank you, Your Honor.

23                  THE COURT: All right. Thank you.

24                  MS. NAST: Your Honor, jumping around just a  
25 little bit because item Roman number III and Roman

1 number IV, Mr. Robinson is going to speak to you, so I'm  
2 just going to go to 3B, which is the amended schedule.

3 We have filed a joint motion with Mr. Cheffo  
4 to adopt a schedule. It's pretty detailed. It goes  
5 right through giving the case to the jury in November, a  
6 year from now, and we did it with the idea of allowing  
7 25 hours per side at trial, not including picking the  
8 jury. And we have arranged it, we hope, so that it will  
9 -- the trial will be concluded and the verdict will be  
10 rendered before Thanksgiving.

11 Unless Your Honor has any questions about that  
12 schedule, we just have that motion before you. Mark,  
13 did you want to add anything?

14 THE COURT: Yes, I reviewed the motion that  
15 was presented as a joint agreed schedule, and it did  
16 seem to me that, although I admire the ambition, it is  
17 right on track. The last general causation experts of  
18 plaintiffs is scheduled right now for December 6, the  
19 deposition, and -- well, I guess -- why does that say --  
20 December 6, it says, "Pfizer will complete depositions  
21 of PSC's general causation experts."

22 And then the counter is January 6, so a month  
23 later, Pfizer's general causation experts will be  
24 deposed, at least that's the hope. And you get that  
25 done, you're setting everything up for the Daubert

1       hearings in April --

2               MS. NAST:  Yes.

3               THE COURT:  -- and all the briefing  
4       thereafter?

5               I think that these deadlines as they relate to  
6       the first trial, that says trial, but you do mean  
7       trials, plural, right?  I mean, you can't just have one  
8       trial because if it goes away, then we have no trial.

9               MS. NAST:  No.  We're going to have more than  
10       one trial -- one case ready for trial.  Mr. Chirls has  
11       that under consideration now --

12              THE COURT:  Okay.

13              MS. NAST:  -- because we have a little bit of  
14       a differing view about what it should be.

15              THE COURT:  Well, that can be worked out, but  
16       I just note --

17              MS. NAST:  But there will be more than one  
18       case, yes.

19              THE COURT:  -- that it says first trial, and I  
20       don't want one case that will go away.

21              MS. NAST:  And -- yes.

22              THE COURT:  And we have done it both ways  
23       before.

24              MS. NAST:  Well, we're asking you to set the  
25       whole month of November basically aside, so we -- we

1 certainly want to have a trial.

2 THE COURT: We certainly want one, too.

3 And I do look with some intellectual curiosity  
4 as to your paragraph three, each side having a total of  
5 25 hours to present its case including openings,  
6 closings and testimony. And although as a Judge, I  
7 rarely set time limits like that, I think in complex  
8 cases, especially like these, it is certainly  
9 appropriate, so --

10 MS. NAST: And it gives incentive to those of  
11 us who are loquacious to not be.

12 THE COURT: And if there isn't any other  
13 comment on this joint motion, is there is not --

14 MR. CHEFFO: No, Your Honor. And I would just  
15 add that I think we're actually ahead of schedule which  
16 is good on the experts, so I think -- we're supposed to  
17 have been completed by December 6 and we've completed  
18 those. And the January date, I think most of the  
19 depositions are scheduled prior to that date, so we  
20 should actually be done before that. But no other  
21 comments, Your Honor.

22 THE COURT: That's good news.

23 MS. NAST: The schedule does require the Court  
24 -- and we did this with some reluctance -- to rule on  
25 motions somewhat quickly, but if we were going to stick

1 with our November trial date, that was a necessity.

2 THE COURT: Well, we certainly will have a lot  
3 of time -- now, there's never enough time -- but we have  
4 a lot of time leading up to those motions now.

5 MS. NAST: Right, we do.

6 THE COURT: So given the other commitments  
7 that the Court has, and we appreciate a heads up.

8 MS. NAST: Okay.

9 THE COURT: Thank you.

10 MS. NAST: And Mr. Robinson will speak to  
11 those other two issues.

12 THE COURT: All right. If there is --

13 MR. ROBINSON: Actually, Your Honor, it seems  
14 to me that we've just covered the other two issues.  
15 I'll make a statement and then maybe Mr. Cheffo can talk  
16 about it.

17 THE COURT: Mr. Robinson, hold on a second.

18 MR. ROBINSON: Yes.

19 THE COURT: We have two attorneys that have  
20 phoned in, Adams and Etterman (ph), and there's some  
21 interference on the phone. So whatever it is, I don't  
22 know. That's one of the interferences. The other was a  
23 rattle. Now that -- now that we've identified it,  
24 whatever it is, I'll let you know if we hear it again.

25 Mr. Robinson, I'm sorry.

1 MR. ROBINSON: It might be someone who has  
2 something against me, Your Honor, so I'll --

3 THE COURT: It actually happened before you  
4 got up to the podium.

5 MR. ROBINSON: Well, thank you for coming to  
6 my aid.

7 Your Honor, I think, just to follow up, our  
8 goal is to start taking plaintiffs' depositions next  
9 month, and we understand that there's been an order now  
10 from Special Master Chirls giving more discovery and  
11 more documents and whatnot. And so plaintiffs have  
12 agreed that -- that plaintiffs will be deposed, but if  
13 there -- if the defense wants to re-depose them at a  
14 later date after we've picked the three and three --  
15 after we pick the three trial cases per side, they have  
16 the right to take their depositions again. So I think  
17 that's -- that's been very good. I think the parties  
18 have come together on that.

19 With regard to the schedule with expert  
20 depositions, we've been -- we've completed our four  
21 experts, Dr. Sadler, Dr. Levin, Dr. Berard and Dr.  
22 Cabrera (ph) were all completed as of last Thursday. So  
23 that now we're moving on tomorrow to start taking the  
24 defense Daubert experts' depositions.

25 One thing I would notice, Your Honor, though

1 we withdrew Dr. Fannelle, since Dr. Fannelle and Dr.  
2 Cabrera wrote their reports together, I would ask that  
3 the Court keep Dr. Cabrera's report, because Dr. Cabrera  
4 will testify at the hearing.

5 THE COURT: Yes, I noted that and I have done  
6 so.

7 MR. ROBINSON: Thank you, Your Honor.

8 So really that's all I have to report. I  
9 think we've worked out I think in chambers other things,  
10 so I think we're on schedule, Your Honor. Thank you.

11 THE COURT: Thank you.

12 I did discuss this. There are now pending  
13 four R&Rs from our Special Master, and three, four, five  
14 and six, and my question that I pose to the leadership  
15 was with the joint motion and its trial dates and  
16 protocol, does that eliminate the need to rule on or  
17 hear argument on R&R 3 to which one general objection  
18 had been filed and R&R 4, each of those being the trial  
19 pool selection protocol.

20 It's my understanding now that R&R 4 was  
21 submitted after R&R 3 had been continued to be discussed  
22 and negotiated. So I'm not certain if there is an  
23 objection to R&R 3 or 4 pending, and if there is, I  
24 don't know what that objection is, because it was a  
25 general one. So if there is an objection, I need

1 counsel to clarify that with Mr. Chirls and give me  
2 either a stipulation or just clarify what it is that the  
3 parties still cannot agree to. Okay?

4 Now, as to five and six, R&R Number 5 is  
5 regarding discovery by defendants concerning employment,  
6 substance abuse and medical records. That was filed by  
7 the Master on the 22nd of October. There have been no  
8 objections. This Court has reviewed that R&R, finds  
9 that the suggestions and recommendations of the Master  
10 are entirely reasonable and well-founded and unless  
11 there's a late objection, I'm going to adopt it. All  
12 right.

13 And as to six regarding defendants' detachment  
14 of documents from otherwise discoverable materials on  
15 the grounds of irrelevance or nonresponsiveness, while  
16 there's one or two more days left to pose objections, do  
17 we think they'll be any? Mr. Cheffo?

18 MR. CHEFFO: No, Your Honor.

19 THE COURT: Any from the plaintiff?

20 MR. ROBINSON: No, Your Honor.

21 MS. NAST: No, Your Honor.

22 THE COURT: Then that, too, striking a very  
23 reasonable middle ground is a recommendation that the  
24 Court can accept, and I thank the Master for his hard  
25 work. He certainly is working it seems to me almost

1 full-time on this, and I appreciate it. So we're going  
2 to adopt his recommendations to R&R 6 as well, just  
3 holding off on three and four until you clarify what I  
4 need to do there. All right.

5 I think that does it for the first page of the  
6 agenda, does it not?

7 MR. HEIM: Your Honor, the only thing that I  
8 wanted to mention to the Court this morning is, we have  
9 several times engaged in a colloquy with the Court about  
10 a Court-appointed expert. I think the way to move this  
11 along now that we have a Daubert hearing scheduled and  
12 now that Your Honor is reviewing expert reports is for  
13 us to simply file a motion in that regard, and we -- we  
14 will proceed to do that shortly.

15 THE COURT: And figure out where in the  
16 process you think that we can conduct some tutorials if  
17 we thought it was necessary. I will tell you this much.  
18 I am not all the way through and I have never professed  
19 to be a scientist or a medical doctor, but I haven't  
20 seen anything yet going a third through each side that I  
21 think I need a tutorial on. I don't say I'm in command  
22 of everything. I'd like to hear the oral arguments and  
23 have the hearing, but I'm not seeing the uniqueness to  
24 the science that I can't understand yet. I'll just let  
25 you know that.

1 MR. HEIM: Well, very well, Your Honor. But  
2 as I said, we will file a motion with some suggestions  
3 for Your Honor and I'm sure our friends, colleagues here  
4 will reply, and Your Honor can consider it.

5 THE COURT: Thank you, Mr. Heim. We will.

6 MS. NAST: Your Honor, we, of course, will  
7 wait for the motion and will respond to it. I just -- I  
8 want to say again. We've said it before. We have grave  
9 concerns about our ability, and I mean our collective  
10 ability, to find a totally neutral person to do the  
11 tutorial, so that's one of our major concerns, but we'll  
12 respond when appropriate.

13 THE COURT: All right. Okay. I think we have  
14 moved very quickly into argument, and yet I want to be  
15 sure that there isn't any other issue that I have  
16 neglected or run roughshod over. Okay.

17 I do wish to say that recently, that is,  
18 October 24th or thereabouts, we held our first status  
19 conference -- not our first, but we held a status  
20 conference forming the Effexor MDL, and we have already  
21 selected the leaders of Effexor. You will all be aware  
22 that Effexor was assigned to this Judge, in particular,  
23 because I was already assigned Zolofit and its  
24 similarities, similarities of attorneys let alone other  
25 similarities.

1           And yet, it is important to note that in  
2           formulating that leadership, the Court made it known  
3           that coordination not only with state cases but with  
4           this MDL was uppermost in our intentions. We think the  
5           MDL panel that assigned it to us expected that and we  
6           think it's natural to coordinate. That does not mean  
7           that it holds up the Zolofit itinerary and dates. It  
8           does not mean that it intervenes and causes any issues  
9           of delay, and that's not what anyone wants. That's not  
10          what the attorneys want either, I'm positive of that.

11           So we're going to expect that the coordination  
12          occurs, and, of course, since Dianne Nast is the  
13          specific coordinator to bridge these gaps between the  
14          two MDLs, and the leadership is Bryan Aylstock and Joe  
15          Zonies, I don't think there's going to be any problem  
16          with each MDL knowing what they need to know as far as  
17          plaintiffs are concerned, and, of course, the defendant  
18          is the same. So we're looking forward to seeing some  
19          coordinated matters in that. Mr. Zonies.

20           MR. ZONIES: And just on that -- a note on  
21          that, we will not left Zolofit slow down Effexor, Your  
22          Honor.

23           THE COURT: Thank you. That's expected as  
24          well. All right. Do we need to take a break or can I  
25          just move right into the motion by GlaxoSmithKline to

1 limit the scope of --

2 MS. NAST: I think everybody's prepared to  
3 move forward.

4 THE COURT: Good. Then why don't we have  
5 counsel come forward and argue that.

6 (Pause in proceedings.)

7 THE COURT: And we have on behalf of  
8 GlaxoSmithKline Mr. Bayman and Ms. Boyd.

9 MR. BAYMAN: Yes, Your Honor. Thank you.

10 THE COURT: And we welcome both of you to the  
11 courtroom.

12 MR. BAYMAN: Thank you, Your Honor. Good  
13 morning. Nice to be here.

14 THE COURT: Good morning.

15 MR. BAYMAN: Andrew Bayman on behalf of  
16 GlaxoSmithKline.

17 As Your Honor's aware, we had -- we had filed  
18 a motion with Your Honor to limit the scope of general  
19 causation issues or in the alternative to participate in  
20 expert discovery and Daubert proceedings, the reason  
21 being that GSK has been named as a co-defendant along  
22 with Pfizer in three cases that are pending in this MDL.

23 My understanding is one has been dismissed  
24 with prejudice, and Your Honor, I believe, has entered  
25 an order recently on that. There's another one in the

1 process of being dismissed and another case that is  
2 still pending in the Court.

3 As Your Honor may recall, you entered two  
4 pretrial orders, Pretrial Order Number 15 and Number 23  
5 establishing the schedule for exchange of general  
6 causation expert reports, expert discovery, Daubert  
7 motions, and those orders made clear that the experts  
8 were to address only general causation issues as they  
9 relate to Zoloft. And, in fact, in footnote four of  
10 Pretrial Order Number 23, Your Honor specifically noted  
11 that there were a few cases in which the mother used  
12 other drugs in addition to Zoloft and that this schedule  
13 does not apply to those products and that none of those  
14 cases would be selected for this initial discovery  
15 group.

16 Unfortunately, Your Honor, then when the  
17 expert reports came out, the plaintiffs' experts in  
18 rendering their opinions, gave opinions not only as to  
19 Zoloft but said the entire class of drugs including  
20 Paxil were teratogens, and this caused us some concern  
21 because obviously we have cases in other Courts and  
22 we're concerned that we're not participating in the  
23 Daubert proceedings in this Court, yet there was some  
24 danger that an order might be entered that would  
25 implicate Paxil in addition to Zoloft, and that was the

1 basis for our motion.

2 And, in fact, not only did the reports say  
3 that, the experts testified to that and said things like  
4 -- Dr. Levin said, "Zoloft and other drugs in this class  
5 can and do cause or substantially contribute to  
6 congenital birth defects."

7 So because of the nature of the opinions  
8 offered by the plaintiffs' expert, we filed our motion.  
9 And what we would ask, Your Honor, is that if we are not  
10 able to work out a resolution of the -- the one case  
11 that may be remaining, that Your Honor enter an order  
12 that indicates that the Daubert proceeding should be  
13 limited to Zoloft only and that any finding made by Your  
14 Honor as part of these Daubert proceedings, apply only  
15 to Zoloft because that is the drug at issue in this  
16 litigation. This is in re Zoloft, and that would be our  
17 position, Your Honor.

18 THE COURT: All right.

19 MR. BAYMAN: Thank you.

20 THE COURT: Is that position opposed by  
21 anyone?

22 MR. ROBINSON: No, Your Honor, not for the  
23 plaintiffs. I think that we -- we agree -- I mean,  
24 there's evidence of class effect and that sort of thing  
25 that's going to be presented at the hearing, but we're

1 focused solely on Zoloft and the birth defects that are  
2 generally caused by Zoloft. So I don't think there's a  
3 problem here. Thank you, Your Honor.

4 THE COURT: Thank you. And would the  
5 defendants like to speak to it at all?

6 MR. CHEFFO: No, Your Honor. I think Mr.  
7 Bayman accurately characterized what I think -- I'm  
8 sorry -- accurately characterized what our understanding  
9 was and how the Court would -- would proceed. I guess  
10 my only comment would be to the extent that the Court  
11 grants our Daubert motion, Mr. Bayman may come back with  
12 a different position. But for now I think where he is,  
13 we understand that to be fine, Your Honor.

14 THE COURT: You know, I can -- I can perceive  
15 GSK wanting to intervene in a specific case, but on the  
16 general platform it would be very problematic. And yet  
17 it seems to me that sweeping rulings are never wise, and  
18 sweeping all drugs in a particular class into one MDL's  
19 rulings would be highly unsupported and not acceptable  
20 on many levels. So I've never doubted the wisdom of GSK  
21 making this motion. I just don't know if it applies to  
22 any particular cases any longer or will be. I don't  
23 even know that it's moot.

24 But I think it should be clear, because this  
25 is a question that is capable of repetition, I think it

1 should be clear, and I will say so when I rule, that  
2 this is limited to the case before me which is Zoloft.  
3 It's even for another day as to whether it would apply  
4 to, say, Effexor, and I feel very confident in being  
5 able to talk about Effexor here because I have all the  
6 lawyers representing those clients here. So I'm not  
7 worried that I'm speaking out of turn. But I think it  
8 is a sensible solution, and please keep me apprised of  
9 any cases where you do wish to be at the table where you  
10 are still named as a defendant. Okay?

11 MR. BAYMAN: Thank you, Your Honor.

12 MS. BOYD: Thank you very much, Your Honor.

13 THE COURT: Thank you very much. You're  
14 welcome to remain as well, but -- and could I address,  
15 please, next the motion to withdraw as counsel of record  
16 -- is Mr. Hingle present? Did I not see -- no, I don't  
17 see his sign-in sheet but then everybody doesn't like to  
18 sign in for some reason. So I've learned not to go by  
19 that. Mr. Hingle? Anybody from his firm here? He may  
20 need a call, Mr. Corr.

21 MR. CORR: Yes, Your Honor.

22 THE COURT: Because this is fully briefed.  
23 It's on the agenda, and we don't know why he is not  
24 present. We expected him to be.

25 MR. CORR: I'll give him a call this

1           afternoon.

2                       THE COURT:   Okay.   And I'll wait to hear from  
3           you, but you can tell him that I'm not going to  
4           reschedule oral argument, and he will -- we will have a  
5           special hearing but it won't be oral argument.

6                       And I'm also certain that I should say this  
7           for the good of the parties and I mean both sides, that  
8           leaving plaintiffs without counsel at this stage of the  
9           litigation in Zolofit is untenable.   So unless there's a  
10          really good reason, I cannot let attorneys withdraw  
11          without substitution of competent counsel.

12                      We deal with pro se litigants every single day  
13          of every single week in our general docket, and it is a  
14          nightmare.   This is complicated science, and I don't  
15          know how they would ever be able to represent  
16          themselves, so someone should give Mr. Hingle a heads up  
17          that he's not terminated and he still is obligated until  
18          further ordered --

19                      MR. CORR:   I understand.

20                      THE COURT:   -- he's obligated to represent his  
21          clients.   Thank you.   Or those cases get dismissed with  
22          the approval and agreement, that is, a stipulation  
23          signed by his parties, his clients, because he's not  
24          able right now under the circumstances that have been  
25          created to dismiss them on his own.   All right?

1                   Now, that leaves the motions to dismiss under  
2 Michigan and Texas statutes. Who's here to argue --

3                   MS. NAST: That's Mr. Cheffo's motion. I just  
4 wanted to tell the Court that Arnold Levin will be  
5 arguing it for the plaintiffs.

6                   THE COURT: Very well. Thank you.

7                   MR. CHEFFO: With your permission, Your Honor,  
8 I've given a copy of these to Mr. Levin.

9                   These aren't so much slides as they are kind  
10 of guideposts, but I -- if I could actually hand up a  
11 copy for Your Honor.

12                   THE COURT: Thank you.

13                   MR. CHEFFO: So I'm -- what we've agreed to,  
14 Your Honor, just from a format perspective is, is I  
15 think I'll be addressing both Michigan and Texas, if  
16 that's okay with the Court, and then I think --

17                   THE COURT: That is.

18                   MR. CHEFFO: -- Mr. Levin -- I think we've  
19 agreed generally on 30 minutes. I'm not sure I'll even  
20 need that. I think what I would, since we're doing oral  
21 argument here, not to be too formalistic, but I would  
22 ask for five minutes of saving my time for rebuttal. I  
23 don't think -- if I -- if I run close to the 25 minutes,  
24 my folks will -- will tell me. I don't think I will,  
25 though, but I would like a chance to just respond.

1 I think, Your Honor, in looking at the docket  
2 of cases, the Michigan case for several reasons is -- is  
3 easier, to the extent there's a fewer number of cases,  
4 and I don't think the plaintiffs really disagree with  
5 that. I think there's less than ten cases by my count  
6 of Michigan cases, and very few of the firms have  
7 actually brought cases under -- with Michigan  
8 plaintiffs.

9 And just as a preview of where I'd like to --  
10 to discuss today, I think that both the Texas and  
11 Michigan statutes essentially provide a bar to the types  
12 of product liability pharmaceutical cases that -- before  
13 us. There's very little dispute here today that in both  
14 of the cases Michigan law applies, to the extent to  
15 Michigan or to Texas under the Choice of Law Analysis.

16 I don't think there's much disagreement about  
17 the -- what the statutes say. I think where the  
18 disagreement may come is with respect to the -- the  
19 albeit limited exceptions of both Michigan and Texas  
20 law. So under Michigan, the plaintiffs have raised one  
21 exception that deals with a fraud on the FDA, and under  
22 the Texas statute they've raised, too, both a kind of  
23 so-called off-label exception and a fraud on the FDA.

24 What I would submit, Your Honor, that in both  
25 of the cases, at least the cases before the Court, you

1 don't even really need to get to the preemption  
2 analysis. And the reason for that is -- is quite simple  
3 -- is that, Your Honor has procedures in place. We have  
4 PTOs. We have complaints being filed. And in neither  
5 of the cases, as I'll discuss in a bit more detail, can  
6 you look at the actual complaints, which is the only  
7 thing before the Court and determine -- make a  
8 determination that there's even a facial argument that  
9 they've satisfied the pleading requirements with respect  
10 to the statutory language.

11 You know, kind of layered on top of that, we  
12 certainly do have the preemption arguments, which I will  
13 talk about and which are -- I think both sides have  
14 covered in the briefs, but on page three of these  
15 slides, we've basically laid out in Michigan what the  
16 exceptions are, and if you look, as I have, very  
17 carefully, at the complaints, you don't see any  
18 allegations in the complaints that would satisfy the  
19 pleading requirements of either statute.

20 I would also add, in the plaintiffs'  
21 opposition brief, in Michigan, they admit that they have  
22 not specifically alleged that Pfizer intentionally  
23 withheld information or misrepresented information to  
24 the FDA with respect to Zoloft, and that is a core  
25 requirement of the statute itself. So pleading

1 requirements, I think that is enough for the Court to --  
2 to dismiss both of the complaints before the Court.

3 So let me come back now and start with  
4 Michigan. Certainly not dispositive, but I think  
5 instructive is the fact that, to the extent we are all  
6 coordinating, I think coordination works both ways, and  
7 as Your Honor knows, we've cited and -- and attached the  
8 decisions, Justice Carol Huff in the New York cases --  
9 they're coordinated -- has addressed both of these  
10 issues.

11 And with respect to Michigan and Texas, and in  
12 both situations, she -- and they were Zolof cases.  
13 They were the, to my knowledge, the first and only  
14 Zolof cases to address this issue. She determined that  
15 as a matter of law, the -- she granted the motions to  
16 dismiss.

17 So as I said, with the Michigan case, there's  
18 -- there's no dispute that Michigan law applies. All of  
19 the contacts, the points of contact, the birth, are in  
20 Michigan. There's also really no dispute about the  
21 choice of law.

22 In Section 2946(5) of the Michigan Judicature  
23 Act says, "In a product liability action against a  
24 manufacturer or seller, a product that is a drug, is not  
25 defective or unreasonably dangerous, and the

1 manufacturer or seller is not liable, if the drug was  
2 approved for safety and efficacy by the USFDA and the  
3 drug and its labeling were in compliance with the FDA's  
4 approval at the time the drug left the control of the  
5 manufacturer and seller."

6 And as the cases that we cited in our brief  
7 highlight that the Michigan cases, both state and  
8 Federal, that's been read very broadly in Michigan, and  
9 again, it's no surprise that we only have a very small  
10 number of plaintiffs' here, because I think if you were  
11 to poll virtually all the plaintiffs in the room, they  
12 would tell you that they believe the Michigan statute  
13 bars such claims.

14 There are three exceptions. One is the FDA's  
15 ordering medicine to be removed from the market or  
16 withdrawn. That's certainly not applicable, and the  
17 plaintiffs don't argue that. Skipping to number three,  
18 the manufacturer made an illegal payment to an FDA  
19 official or employee, you know, a bribe, to -- to get  
20 approval. That's certainly not applicable. Plaintiffs  
21 don't allege that.

22 What they -- what they do argue is -- is  
23 exception number two. And I don't think they quote the  
24 entire exception, but what it says is, "The manufacturer  
25 intentionally withheld information from the FDA," but it

1 goes on, "and the medicine would not have been approved  
2 if the information had been submitted."

3 So it's not just kind of "fraud" on the  
4 market. There has to be a causal connection to this  
5 fraud on the market that would have caused the -- the  
6 lack of approval, if you will, of Zoloft.

7 And, you know, counsel will correct me if I'm  
8 wrong on this, but my understanding is, their experts  
9 don't even go that far in this litigation in saying that  
10 -- that Zoloft never should have been approved on the  
11 market. So that's where I said earlier, Your Honor,  
12 with respect to Michigan, I think this would bar all the  
13 claims as a matter of law, but with that case before  
14 you, there's certainly not the level of allegation that  
15 would satisfy the standards.

16 Then I think where the complaint moves into --  
17 where the cases and the analysis moves into the  
18 preemption analysis is the Garcia case, the Sixth  
19 Circuit case has determined that the exception is  
20 further limited by the fact that Buckman draws some  
21 additional parameters about the applicability of that  
22 exception to be raised.

23 And what does that mean? Essentially what the  
24 Garcia, the Sixth Circuit Court determined that even for  
25 the exception to be applicable, it can't just be some

1 allegation that you failed to produce or you withheld  
2 information. It has to be a finding by the FDA that a  
3 manufacturer, essentially, committed fraud on it, so in  
4 order to be both in line with Buckman and the statute,  
5 there would have to be a finding by the FDA which again,  
6 certainly did not happen here and certainly is not  
7 alleged in their complaints.

8 And as I noted, I think particularly  
9 instructive, at the second page of their opposition,  
10 plaintiffs admit that, "They have not specifically  
11 alleged that Pfizer intentionally withheld information  
12 and/or misappropriated information to the FDA with  
13 respect to Zoloft."

14 So they haven't even, in our view, Your Honor,  
15 met the first prong of the second exception, much less  
16 the second prong, and certainly, haven't met it to the  
17 extent that the Garcia holding further limits the second  
18 prong.

19 And I -- and I think this has also been  
20 supported by the Lofton case, which is the Fifth Circuit  
21 case, so there's some synergies. Admittedly, there are  
22 some differences in terms of the exceptions, but I think  
23 holistically, there are -- there are some conceptual  
24 similarities between the Lofton, the Marsh and the  
25 Garcia cases dealing with the Michigan and Texas

1 statutes.

2 And then the last thing I think I would say  
3 before I move to Texas is that the plaintiffs, even to  
4 the extent that they were pleading a fraud on the  
5 market, haven't done that under Rule 9 with any type of  
6 particularity. So with respect to Michigan, I would  
7 just highlight, I think, a practical consideration in  
8 addition to the, we think, very strong law from  
9 Michigan, from the Sixth Circuit, and that is this.  
10 While we understand that this Court is bound by the  
11 Third Circuit's rulings, I think both sides agree that  
12 the Third Circuit hasn't squarely addressed this  
13 particular issue.

14 So Your Honor is faced with the plaintiffs'  
15 argument saying, follow the Second Circuit in Desiano,  
16 and a few District Court cases that may have kind of  
17 followed that analysis, or to the extent we're arguing,  
18 follow the Fifth Circuit of which Texas is in, and --  
19 and the Sixth Circuit, of which Michigan is in. And I  
20 think as the Court considers the analysis, it's  
21 perfectly fair in -- in both the legal analysis, to also  
22 consider the practicalities.

23 If you were to follow the plaintiffs'  
24 perspective on this, assuming this wasn't a bellwether  
25 case that ultimately gets tried, MDL, under Lexecon, the

1 case gets sent back. Well, where is it going to get  
2 sent? It's not going to get sent to the Second Circuit,  
3 if it's a Michigan or Texas case, it's going to get sent  
4 back to the Fifth or Sixth Circuits. And I assume, the  
5 District Courts in those Circuits are not going to say,  
6 let me look to the Desiano case to determine what my own  
7 Appellate Court is thinking about these issues.

8 So while, again, I am not going to suggest to  
9 the Court that you are bound to follow it, I think, to  
10 the extent that there's no guidance from the Third  
11 Circuit, both the reasoning we have said and submitted  
12 is more cogent with respect to the Fifth and Sixth, but  
13 also the practicalities of -- of how the Court adopts  
14 those, I think, certainly weigh in favor of these cases  
15 that follow in the Fifth and Sixth.

16 And now, let me briefly turn to Texas unless  
17 Your Honor has some questions?

18 THE COURT: No, I'm fine.

19 MR. CHEFFO: Again, I think the analysis is  
20 somewhat similar. We would first say to Your Honor that  
21 if you look at the straight pleadings, they don't meet  
22 the two exceptions. Here you have a situation where the  
23 child was born on April 28th of 2010, alleged birth  
24 defects, as Your Honor knows. You have a situation  
25 based on some of the -- the fact sheet information that

1 the mother was prescribed Zoloft in 2004/2005, took it  
2 in 2007 as well. The child's born in 2010, but in 2008  
3 to 2013, there seems to be no dispute that the child was  
4 actually taking the medicine for an anxiety -- I'm sorry  
5 -- that the mother -- I'm sorry, Your Honor -- the  
6 mother was actually taking the medicine for an anxiety  
7 disorder.

8 And I think I go into that level of detail  
9 here just because to the extent that the plaintiffs have  
10 made kind of an off-label argument, which I'll -- I'll  
11 talk about in a minute, I think it's somewhat of a red  
12 herring in -- in this issue, because the child being  
13 born in 2010, and the issues of which, even they've  
14 alleged that there's off-label use or off-label  
15 prescriptions in 2007, which we disagree with.

16 But again to the extent the indication prior  
17 and the indication after, there appears to be no dispute  
18 about off-label. It seems to be somewhat of a  
19 distinction without a difference.

20 So what does the Texas statute say? It's --  
21 it's as broad in its scope and bar of product liability  
22 actions we submit, and I think the Fifth Circuit also  
23 agrees, but it does have two exceptions. And the first  
24 is a so-called off-label exception. And it requires  
25 that -- that the plaintiffs plead and -- and show, we

1 believe three prongs of that:

2 The defendant recommended, promoted or  
3 advertised the pharmaceutical product for an indication  
4 not approved by the USFDA; B, the product was used as  
5 recommended, promoted and advertised; and, C, the  
6 claimant's injury was causally related to the  
7 recommended, promoted or advertised use of the product.

8 So, again, under my first argument, you -- we  
9 believe you can't fairly look at the complaint and find  
10 those factors. You may have an off-hand, kind of  
11 boilerplate type reference to off-label, but certainly  
12 no allegation about causal relation that the doctor saw,  
13 that the doctor relied that why the medicine was taken.

14 In fact, the only evidence is what they  
15 submitted attached to their opposition brief, which we  
16 think, again, is kind of an improper way of proceeding,  
17 not just in the normal course, but the plaintiffs have  
18 had a long time to file these cases, a long time to  
19 amend.

20 The proper procedure is to not essentially  
21 amend your complaint via opposition to a motion to  
22 dismiss, as the plaintiffs have tried to do here, but  
23 even if you credit all of the information and arguments  
24 in the attachments in their opposition, they do not  
25 satisfy, and I don't think can satisfy the off-label

1           exception.  And --

2                   THE COURT:  Can't you see a scenario where the  
3           Court would issue a ruling, and if it were in your  
4           motion's favor, that the ruling be without prejudice due  
5           to the age of the children, in any event, as one  
6           consideration?

7                   MR. CHEFFO:  Your Honor, that's a -- that's a  
8           very fair question.

9                   THE COURT:  It's a pleading -- you -- because  
10          you are arguing a pleading issue here, a motion to  
11          dismiss based on pleading.

12                  MR. CHEFFO:  We -- we're arguing both, so I --  
13          I think I would say this.  To the extent that the Court  
14          just wanted to look at it from a pleading perspective --

15                  THE COURT:  Well, not only, but --

16                  MR. CHEFFO:  -- but -- but -- right.

17                  THE COURT:  -- in the first instance, I am.

18                  MR. CHEFFO:  Correct.  I think they haven't  
19          met that, and then, you know, probably to the extent  
20          that you were going to give leave to re-plead, as from a  
21          pleading perspective, I -- you know, we wouldn't  
22          encourage you, but certainly that would not be out of  
23          the ordinary of what, you know, a District Court Judge  
24          might do to the extent that they felt they haven't met  
25          it.

1           We would, actually, urge you also, to go the  
2 next step, right, which is to basically look at the law  
3 of Lofton and Garcia and Marsh and determine that in  
4 these types of cases -- because most of the cases that  
5 have dealt with this issue are on the pleadings, as a  
6 matter of law, without the discovery.

7           So to answer your first question directly,  
8 sure, to the extent that you -- you could dismiss it,  
9 and I think that would, at the very least, help frame  
10 some of the issues here, because to the extent that they  
11 believe that they have this claim, they could, in fact,  
12 try and meet the appropriate pleading standards.

13           THE COURT: Correct.

14           MR. CHEFFO: I would also argue, though, that,  
15 at least as to the off-label arguments, it's going to be  
16 -- it would depend I think on the facts of the case.  
17 Most of these cases -- these are not off-label cases. I  
18 mean, I think, frankly, to the extent -- the first time  
19 we heard -- or I heard, really, anything about off-label  
20 in this case, for the last year and a half was -- was  
21 when we made these motions, and then all of a sudden,  
22 you would think that this case was entirely an off-label  
23 case.

24           So, you know, that maybe getting into the  
25 specifics of -- of this case, but I also would say, to

1 the extent that the Court adopts the Garcia -- I'm sorry  
2 -- adopts, yes, the Garcia and Lofton and Marsh  
3 analysis, then I think it's easier to make a  
4 determination as a matter of law, particularly under the  
5 Buckman analysis.

6 So, in other words, if -- if you find, as  
7 those Courts have held, that just alleging that you  
8 didn't supply information or you somehow committed a  
9 fraud isn't enough, you have to have a finding by the  
10 FDA that fraud was committed. Then, I think, Your Honor  
11 would dismiss this case as a matter of law, because that  
12 just hasn't happened, and it doesn't -- you know,  
13 whether it's a child now or a child, you know, in ten  
14 years from now, those issues are somewhat fixed in time.

15 So on the -- on the off-label issue, you know,  
16 yes, but I do think to the extent that the Court was to  
17 -- to give a chance to re-plead, it should be just on  
18 that issue, but to -- and it should also be very clear  
19 from our perspective, Your Honor, that the exception  
20 under the fraud on the FDA, should be barred under  
21 Buckman, so it would only leave open the off-label issue  
22 to the extent that they can make those cases out.

23 THE COURT: All right.

24 MR. CHEFFO: And I think, Your Honor, you  
25 know, I've -- unless Your Honor has, you know,

1 additional questions, I think we've -- we've covered  
2 this in our brief. I think I've covered it with  
3 Michigan. The only thing I would say is I know Your  
4 Honor this morning, granted counsel's motion that they  
5 filed on Friday to submit a brief or a submission on the  
6 severability. I think we've largely --

7 THE COURT: I didn't -- I did not grant it,  
8 thinking that substantively it would make a difference,  
9 and I didn't expect that you would have an opportunity  
10 between then and now to respond to it, except this  
11 morning's opposition to actually approving it. I'll  
12 give you that chance.

13 MR. CHEFFO: All right. And I appreciate  
14 that, Your Honor. So to the extent that it becomes an  
15 issue, I think -- I do agree with Your Honor, I think  
16 you could certainly, you know, if -- if you were to rule  
17 in our favor, I think you could grant the motion, and  
18 then to the extent you had questions, we could certainly  
19 brief, you know, if it's not addressed, I think the  
20 cases that we've cited, I think the cases they cite  
21 determine that that these are severable. I think the  
22 laws of both of these states determine that they are  
23 severable, you know, as just one specific issue.

24 This -- the Buckman analysis would not,  
25 essentially, obliterate or take away all of the

1 exceptions, which I think is what the concern would be.  
2 So, for example, to the extent you can't just argue that  
3 there was fraud on the FDA, there is an exception to the  
4 -- to the extent that the FDA determines that fraud had  
5 been committed by -- committed upon it.

6 So I do think that these -- these are  
7 severable, and as you said, Your Honor, to the extent  
8 you had further questions, we could always submit a  
9 supplemental brief.

10 THE COURT: Thank you.

11 MR. CHEFFO: Thank you, Your Honor.

12 THE COURT: Mr. Levin?

13 MR. LEVIN: Yes. Good morning, Your Honor.

14 THE COURT: Good morning.

15 MR. LEVIN: Having heard that argument, I am  
16 very thankful I'm in the Third Circuit and not in the  
17 Fifth or the Sixth.

18 THE COURT: Where -- where they haven't ruled  
19 on it, you mean?

20 MR. LEVIN: They haven't ruled on it, but we  
21 have sufficient District Court opinions that -- that  
22 give me great confidence in my position, as well as the  
23 Second Circuit, which is only 90 miles away.

24 THE COURT: I love the Second Circuit.

25 MR. LEVIN: So --

1 THE COURT: I love New York, as they sing, but  
2 you know, that's not how I follow precedent.

3 MR. LEVIN: But the reasoning is very good.

4 THE COURT: Well, that's a different story.

5 MR. LEVIN: Your Honor, both these statutes do  
6 not have a pleading requirement for us to come forward  
7 and plead the fraud or misrepresentation. We filed  
8 traditional tort causes of action here, not a Buckman  
9 type action.

10 Buckman was our case. I know what we did in  
11 Buckman. Courts have said we concocted a theory in  
12 Buckman of fraud on the FDA, and we did, because we did  
13 not have a manufacturer in Buckman. We had an  
14 organization that submitted 510(k) clearance documents  
15 to the FDA. They were not the manufacturer, and we went  
16 on them on a per se theory that they violated the  
17 statute.

18 Chief Judge Bechtle did not agree with us.  
19 Third Circuit, Judge Stapleton, did agree with us. The  
20 Supreme Court agreed with Judge Bechtle, and the  
21 happiest person at the Supreme Court argument were two  
22 people, Judge Bechtle and his wife who were seated there  
23 and smiling when we left. That was Buckman.

24 That's not these Zolof cases. In fact, in  
25 Desiano, did go to the Supreme Court. That's our Second

1 Circuit case, 90 miles away. And in Desiano, there was  
2 a per curiam affirmation of that decision, which is the  
3 reasoning that we're asking you to adopt today in this  
4 Court.

5 It was four/four, per curiam, with the Chief  
6 Justice not partaking in it. We lost Buckman,  
7 eight/zip. The fact that it was four/four when Desiano  
8 went up shows that at least four of those jurists did  
9 not think that Buckman was prevailing. And Buckman  
10 doesn't prevail.

11 Now, certainly, was have a Fifth Circuit  
12 opinion and a Sixth Circuit opinion. The Fifth Circuit  
13 on a Texas law, Sixth Circuit on a Michigan law, but  
14 under Korean Air Lines, in an MDL, the law of the  
15 circuit where the MDL sits with regard to a Federal  
16 question. If this were a state question, Barrack vs.  
17 Van Dusen would apply, and this Court would be obligated  
18 to follow the law of another jurisdiction.

19 But it's not -- it's not Barrack. It's the  
20 Korean Air Lines case, with Justice Ginsburg, ruled when  
21 sitting on the D.C. Circuit. That case has been  
22 followed. I don't know of any case that hasn't followed  
23 it when you're dealing with a Federal question. And the  
24 defense in this case raises a Federal question on  
25 preemption, the applicability of Buckman.

1           Now, we have a Rule 12 motion here. There was  
2 no pleading requirement on the plaintiff to anticipate a  
3 Buckman defense or any defense until an affirmative  
4 defense was raised by the defendant.

5           We didn't know that they were going to raise  
6 the Michigan statute or the Texas statute. I guess, you  
7 know, if I -- if I had to put my right hand up, I might  
8 suggest they might raise it, being from -- being that it  
9 existed. But on the basis of the pleadings and being  
10 the master of our own complaint, we did not have to  
11 anticipate that defense until that defense was raised.

12           And when that defense is raised, it's no  
13 longer a Rule 12 motion. We don't have a pleading  
14 requirement under the statute. It becomes a motion for  
15 summary judgment, and now we have to produce the facts,  
16 and if this were a summary judgment motion, there would  
17 be a 56(f) affidavit that would be filed, and we could  
18 tee it up for a ruling at some time.

19           We're not completely through with discovery in  
20 this case. That would be the procedure. Now, the  
21 Supreme Court in Wyeth vs. Levine recognized the fact  
22 that Buckman wasn't a traditional tort case. It was, as  
23 I characterized my own pleadings, a concocted theory  
24 that the Supreme Court didn't buy eight -- eight/zip.

25           But we have cases in this jurisdiction --

1 Judge Buckwalter was faced with the very same issue in  
2 this case, involving the statute, and he followed  
3 Desiano's reasoning. If we go across the river to  
4 Camden, also in the Third Circuit, we have Judge Kugler  
5 following the reasoning of Desiano.

6 And if we go still further into Camden, we  
7 have Judge Simandle who I believe wrote a very  
8 definitive opinion, and it ends with the proposition  
9 that, "This is a summary judgment situation, and you  
10 cannot rule as a matter of law on a Rule 12 motion that  
11 the Michigan statute or the Texas statute in this case  
12 would prevail, and the plaintiffs would be out of  
13 Court."

14 It's very, very clear that we, being the  
15 masters of our own complaint have pled a traditional  
16 tort remedy. They have raised an affirmative defense.  
17 That's not a Rule 12 motion. That's a Rule 56 motion,  
18 and we should be -- this case should proceed, and we  
19 should be able to obtain discovery. And at the end of  
20 the day, maybe we win and maybe we lose. The same issue  
21 was before Judge Wolfson in the District Court of  
22 Camden, and she ruled against the plaintiffs, but it was  
23 on a summary judgment basis, Your Honor.

24 Mr. Zonies, if you have no questions for me,  
25 would like to --

1 THE COURT: I have --

2 MR. LEVIN: -- respond with regard to off-  
3 label use.

4 THE COURT: All right. I have a question,  
5 though, Mr. Levin, and that is, in terms of the  
6 discussion that I had with Mr. Cheffo, is your  
7 supplemental brief on severability an attempt to let the  
8 Court know that you would wish to amend your pleadings,  
9 because there's a procedure for that. It's called a  
10 motion to amend --

11 MR. LEVIN: Well, having --

12 THE COURT: -- which could be done at any time  
13 there is a pending motion to dismiss by the way.

14 MR. LEVIN: Well, I -- having -- the Court  
15 having addressed me on that issue, the answer would be  
16 yes. And I would say that I guess what we would have to  
17 do is amend the probata to conform to the allegata and  
18 give you -- give you that, yes. I raised that  
19 severability issue to preserve the issue, Your Honor.

20 I don't think we get there, because I don't  
21 think Buckman prevails.

22 THE COURT: All right. Thank you.

23 Mr. Zonies?

24 MR. ZONIES: Good afternoon, Your Honor.

25 THE COURT: Good afternoon, already.

1 MR. ZONIES: Already. I'll be as brief as I  
2 can, practicing for the 25 or the 25-hour clock, that is  
3 in my future at some point.

4 Your Honor, I am actually counsel of record in  
5 the Stevens case for Tisha Stevens and her son, with my  
6 good friend, David Friend from the Hissey Kientz firm,  
7 and I've come today simply to address in a very pointed  
8 manner the Texas statute and the off-label portion of  
9 that statute.

10 The statute itself, as Mr. Levin stated, is  
11 very specific in that it says that the statute creates a  
12 rebuttable presumption. And I think most of us except  
13 me who was asleep through most of evidence class  
14 understand that that means evidence, facts, that this is  
15 a factual inquiry, that this is a -- this statute  
16 creates a presumption. Mr. Cheffo, by filing his  
17 motion, indeed created said presumption. It is now  
18 incumbent upon us for our clients to rebut that  
19 presumption with facts.

20 And it is true that in this case Mr. Cheffo  
21 and his client already know some of the pertinent facts  
22 about the off-label prescription and prescribing of the  
23 drug Zoloft, for example, the notice from the FDA that  
24 prescribing -- promoting for post-partum depression is  
25 an off-label promotion and getting warned for that.

1           They also know that in Ms. Stevens' case  
2 because of the fact sheet process that the Court put in  
3 place, that in her case she was indeed prescribed Zoloft  
4 for that off-label use, post-partum depression prior to  
5 the birth at issue.

6           Now, Mr. Cheffo correctly --

7           THE COURT: Okay. Back up. Post-partum  
8 depression, she was prescribed that prior to the birth?

9           MR. ZONIES: Correct.

10          THE COURT: Because they anticipated that she  
11 would have --

12          MR. ZONIES: It was after her first child.

13          THE COURT: Okay.

14          MR. ZONIES: And then she had post-partum  
15 depression and that's when she was prescribed the  
16 Zoloft.

17          THE COURT: But it's the next child --

18          MR. ZONIES: Correct.

19          THE COURT: -- that is the plaintiff here?

20          MR. ZONIES: Yes, Luke, correct.

21          And Mr. Cheffo correctly stood up and started  
22 to discuss those facts with Your Honor. 2004, date of  
23 birth is 2010. She's prescribed in '07. Those are all  
24 facts. This is a factual inquiry, and the proper motion  
25 in a little while from now under Rule 56 when the facts

1 are developed.

2 Ms. Stevens has to develop, according to Mr.  
3 Cheffo and perhaps the statute, that the physician saw  
4 ads about post-partum depression and that that off-label  
5 marketing meant something. That's something we  
6 anticipate doing during discovery. We also have to  
7 demonstrate that they promoted it off-label. We have  
8 that one FDA warning letter. There is indeed other  
9 evidence we intend to generate.

10 The problem, Your Honor, is, is we haven't  
11 even gotten the marketing 30(b)(6) deposition yet.  
12 That's the one we'd like to go forward with in December.  
13 It's difficult for us to create the facts to rebut this  
14 presumption absent discovery.

15 THE COURT: But is the off-label allegation  
16 clearly laid out in this particular complaint?

17 MR. ZONIES: The complaint does indeed discuss  
18 off-label -- the words off-label promotion are in the  
19 complaint, yes. Is there an allegation that the doctor  
20 saw the off-label promotion and therefore -- that is not  
21 in there. That's a discovery issue for us. I mean,  
22 Rule 11 also guides my -- how I plead a case. Some of  
23 us -- that is a rule I remember. So -- trust me.

24 So, you know, we're sort of caught a bit  
25 between a rock and a hard place. This -- as Your Honor

1 points out, this is a pleading that -- you know, I  
2 understand Twombly and Iqbal, but let's not go too far  
3 down the road on those issues. This is at the pleading  
4 stage.

5 All we would ask for is that this -- and it's  
6 typically common when -- when it requires facts outside  
7 of the pleadings or documents outside of the pleadings,  
8 that it gets morphed into a 56. We'd be happy to be  
9 here arguing this in a Rule 56 context shortly, in a  
10 month, two months, three, whatever it takes for us to  
11 develop the necessary evidence or for Mr. Cheffo to  
12 develop the absence thereof.

13 The cases primarily relied upon, there are two  
14 cases where it was in a pleadings context, but there's  
15 really no development of how that happened in those  
16 cases. Apparently they didn't have a great lawyer like  
17 me to argue there was an issue with this on a pleadings.  
18 But, for example, Ebel, McKay, these are cases where it  
19 says plaintiff has not offered any evidence to  
20 demonstrate off-label promotion. Plaintiffs have  
21 provided insufficient evidence to establish off-label  
22 promotion.

23 All we're asking for is an opportunity, Your  
24 Honor, to develop the necessary evidence. If it's not  
25 there, we'll be the first ones to stand up and take the

1 motion.

2 THE COURT: All right. I appreciate that.  
3 Did you actually file this complaint, Mr. Zonies?

4 MR. ZONIES: Actually, Hissey Kientz filed the  
5 complaint, Your Honor. I entered on it in the past week  
6 or so.

7 THE COURT: All right. When -- was this filed  
8 in the State Court, swept up into the -- removed to the  
9 Federal Court and then put into the MDL?

10 MR. ZONIES: If I may turn around for a  
11 moment, Your Honor? David?

12 MR. FRIEND: No, Your Honor. David Friend.  
13 It was filed directly into the Eastern District of  
14 Pennsylvania.

15 THE COURT: All right. Thank you. I wanted  
16 to know if the response, that is, the answer from Pfizer  
17 was a master answer or whether it was specific.

18 MR. ZONIES: Indeed it was the master answer,  
19 Your Honor, which -- which does not, by the way, contain  
20 this affirmative defense.

21 THE COURT: And we have -- we have seen those  
22 problems with master complaints and master answers, and  
23 we'd like that not to be a complication here.

24 MR. ZONIES: Correct.

25 THE COURT: So sometimes there are cases that

1           need specific pleadings from both sides.

2                       MR. ZONIES: And, again, Your Honor, every one  
3 of these cases will necessarily have involved with it  
4 some factual development to determine whether or not  
5 there was off-label marketing for -- for example, she  
6 was also prescribed Zoloft for generalized -- for  
7 anxiety. Generalized anxiety disorder was an off-label  
8 promotion activity we will demonstrate of Pfizer versus  
9 specific anxieties that were okay. So we need to  
10 develop those facts. And in every case -- it's just  
11 going to have to be a case-by-case analysis.

12                       And there aren't gazillions of Texas cases.  
13 And in a summary judgment context after depositions of  
14 the prescriber, we're going to need a deposition of the  
15 prescriber to go one way or the other on this, no matter  
16 what. So it's going to require discovery. We just ask  
17 for the discovery.

18                       THE COURT: Thank you.

19                       MR. ZONIES: Thank you.

20                       THE COURT: Mr. Cheffo.

21                       MR. CHEFFO: Thank you, Your Honor.

22                       We may have actually narrowed some of the  
23 issues. We can agree that the Second Circuit's in -- 90  
24 miles away. We could probably also agree that these  
25 people --

1 THE COURT: That's where you work, isn't it?

2 MR. CHEFFO: It is. It's very close to where  
3 I work and live.

4 We can also agree, though, that these people  
5 don't live in the Second Circuit. They actually live in  
6 that far off place in the Fifth and Sixth Circuit.

7 A few issues, really, what I heard a lot of  
8 essentially was an effort to bootstrap, you know, kind  
9 of Desiano. It was a little bit of, you know, heads, I  
10 win; tails, you lose, because they were saying well, if  
11 you follow Desiano, then of course it's an affirmative  
12 defense; and, therefore, here's all these pleading  
13 requirements. Well, let me address a few of them.

14 If you follow the Fifth and Sixth Circuit  
15 cases of which there are three Circuit Court cases, it's  
16 not an affirmative defense. Those were decided on the  
17 pleadings. The Devore case that we've cited, which is a  
18 First Department, albeit, from New York case, said  
19 essentially once -- you know, this was not a surprise --  
20 it may have been a surprise when we made the motion, but  
21 certainly once we made the motion, as you I think  
22 pointed out, Your Honor, there were a lot of different  
23 ways of dealing with this.

24 One was not to essentially argue the complaint  
25 today or file it, they could have amended their

1 complaint, and I think they had that obligation to do  
2 that once they did. And I think the Sixth Circuit is  
3 very clear in the Marsh case, in Michigan, and I think  
4 maybe it would help for a minute if we divorce Michigan  
5 and Texas, because I do think the Michigan case is  
6 easier. There's no question -- for the Court and  
7 probably from the analysis -- that the Marsh case says  
8 it's clear that unless you plead under Michigan law one  
9 of the exceptions, it's not an affirmative defense and  
10 you have no -- so they talk about it being in terms of a  
11 pleading requirement.

12 And I think there the only issue, right, for  
13 the only arguable exception is, was there a fraud on the  
14 FDA? And the question there, there's no allegations of,  
15 there's no exceptions for off-label, so I think as to  
16 those cases, we would submit following the Sixth Circuit  
17 precedent, that the Court can dismiss those six or seven  
18 cases, and we can make motions specific if the  
19 plaintiffs want us to in those cases. But at least the  
20 case before the Court, that could be a dismissal, you  
21 know, with prejudice on the law.

22 I think the Fifth Circuit, what I've heard,  
23 and while I disagree that, you know, essentially we  
24 should just let everything go to summary judgment,  
25 because this becomes somewhat of a moving target for a

1        few reasons.

2                    One is, in order to even get on the exception  
3 they've talked about, there has to be an allegation of -  
4 - of off-label, right. So what I would submit for the  
5 Texas is, you could treat the issue of fraud on the  
6 market just like you would under -- under the Fifth and  
7 Sixth Circuit cases. Say, you know, unless you have a  
8 finding by the FDA that there is fraud, that these cases  
9 should be dismissed, to the extent that the plaintiffs  
10 believe that they have an off-label claim and Your Honor  
11 is willing to adopt that, they can be, you know,  
12 dismissed with prejudice or without prejudice.

13                    And in the cases that they believe that they  
14 have met some type of off-label provisions, that could  
15 meet the statutes, not just that there was off-label  
16 conduct. Because still I haven't heard anything from --  
17 from Mr. Zonies today that would meet those three  
18 criteria. But then at least the Court would dismiss  
19 these cases, and to the extent there was off-label,  
20 rather than have all of these cases, the 20 or so cases  
21 where we just do discovery, wait for summary judgment,  
22 go through some discovery and trial pool cases, we would  
23 essentially limit the cases there with an understanding  
24 that the only exception -- and, again, this is to the  
25 extent the Court was going to entertain any of this,

1 they would have a chance to -- to re-plead with a  
2 direction that they have to meet the specific Texas  
3 requirements.

4 So -- and the final thing I'll say is, I think  
5 you heard Mr. Zonies, and I don't want to misquote if he  
6 said this differently, but the use of the product, even  
7 in that Texas case, was an on-label use. So during the  
8 2008 to 2013 period when the plaintiff mom was taking  
9 the medicine, it was on-label. So how this becomes,  
10 even under that case, an off-label situation, I'm not  
11 clear on.

12 So unless Your Honor has any further  
13 questions, you know, just to recap, we think the better,  
14 well-reasoned and more appropriate decisions are -- are  
15 the three from the Fifth and Sixth Circuit. We think  
16 that to the extent that the Hall case that they've cited  
17 which was an EDPA case relied on Desiano. I think a  
18 careful reading of that case, what the Court says is he  
19 believes that the Garcia case, the Sixth Circuit, was  
20 actually reversed by Marsh, and I think when you read  
21 Marsh, that's not correct. So query whether the Court  
22 would have come to the same conclusion if he had read  
23 the Marsh case the way we believe that the Court should  
24 be read -- the case should be read.

25 Michigan is, you know, an easy call in our

1 view, Your Honor, in terms of what the statutory scheme  
2 is, and Texas is as well. There is the complication of  
3 off-label, but that can be addressed by very specific  
4 pleading requirements to the extent the plaintiffs have  
5 them.

6 THE COURT: All right. Thank you, Mr. Cheffo.

7 MR. CHEFFO: Thank you, Your Honor.

8 THE COURT: And I do wish to ask that you  
9 respond to plaintiffs' supplemental brief. I think this  
10 would do well to get this aired out now, and let me  
11 figure out if this is more a pleading issue than a  
12 substantive law issue. But I have to deal with it  
13 separately.

14 MR. CHEFFO: Understood, Your Honor. We will.

15 THE COURT: So pleading is first and we'll see  
16 -- because we really don't want to have this decided,  
17 should we grant your motion just the way things are  
18 right now, if we granted your motion in each case, we  
19 could see this coming back again one way or another and  
20 maybe not being decided within the MDL. And I think  
21 that's worse. I think we need resolution of these kinds  
22 of issues. And I'd rather have it done here and in a  
23 holistic form.

24 So I think that's -- you have that opportunity  
25 to respond, and how long do you think you would need,

1 Mr. Cheffo?

2 MR. CHEFFO: I think we could -- we could file  
3 an opposition in a week.

4 THE COURT: Good. Thank you.

5 MR. CHEFFO: Thank you, Your Honor.

6 THE COURT: We'll take it under advisement  
7 then. Did you wish surrebuttal?

8 MR. ZONIES: Just Mr. Cheffo invited me to  
9 correct him. I rarely get that opportunity, Your Honor,  
10 so I wanted to. What I was discussing was the  
11 generalized anxiety for which she was also prescribed  
12 the Zoloft. GAD for a period of time was off-label. It  
13 may still be compared to social anxiety disorder, a  
14 specific disorder. And, again, the FDA had discussions  
15 with Pfizer about that off-label promotion for what was  
16 called GAD.

17 THE COURT: Okay.

18 MR. ZONIES: Again, facts, lots of facts, Rule  
19 56.

20 THE COURT: And expertise. Okay. Thank you.

21 I will take this under advisement. I think  
22 that completes our agenda, but is there anything else  
23 that we should be addressing?

24 MS. NAST: No, Your Honor.

25 THE COURT: All right. Then I would -- yes,

1 I'm trying to figure out when that is. I think we said  
2 it would not be December, right?

3 MS. NAST: Yes.

4 THE COURT: And the conference would be in  
5 January, but I don't have that date in front of me.

6 MS. NAST: And that would be the smaller  
7 group.

8 THE COURT: Smaller group, yes.

9 MS. NAST: Yes. Would you like us to submit  
10 some suggested dates?

11 THE COURT: Right.

12 MS. NAST: Okay. We'll do that.

13 THE COURT: We are certainly available. I  
14 don't mean that we're not scheduled every day, but  
15 schedules change, and I always -- I like to look forward  
16 to these on a Monday or Friday when I'm not in the  
17 middle of a trial.

18 MR. ZONIES: And we would like to, Your Honor,  
19 Bryan and I were discussing it with our PSC, also  
20 probably coordinate an Effexor around the same time, so  
21 we don't have multiple journeys in.

22 THE COURT: That would be a good idea, if you  
23 think that you're ready for that. So I'll let you all  
24 talk about that.

25 ALL: Thank you, Your Honor.

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THE COURT: Thank you very much. We're  
adjourned.

(Proceedings concluded at 12:22 p.m.)

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CERTIFICATION

I, Brad Anders, do hereby certify that the foregoing is a true and correct transcript from the electronic sound recordings of the proceedings in the above-captioned matter.

11/20/13  
Date

Brad Anders  
Brad Anders