IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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IN RE:	:	MDL NO. 13-2436
TYLENOL (ACETAMINOPHEN) MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION	:	Philadelphia, Pennsylvania February 17, 2016 10:18 a.m.

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TRANSCRIPT OF CASE MANAGEMENT CONFERENCE
BEFORE THE HONORABLE LAWRENCE F. STENGEL
UNITED STATES DISTRICT JUDGE

- - -

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(The following was heard in open court at 10:18 a.m.)

THE COURT: Good morning.

ALL: Good morning, Your Honor.

THE COURT: Please be seated.

(Pause in proceedings.)

THE COURT: This is our monthly case management conference. Laura and Melissa have provided me with a list, all attorneys present in the courtroom and by telephone. Will you waive a roll call?

MS. C. JONES: Yes, Your Honor.

MS. A. JONES: Yes, Your Honor.

THE COURT: And we have an agenda that the parties have provided in advance of this conference. The first item is an update on the New Jersey litigation. And I understand Judge Johnson has scheduled trial in the New Jersey case, is that right, Mr. Berman?

MR. BERMAN: Good morning, Your Honor.

THE COURT: Good morning.

MR. BERMAN: Lawrence Berman for the plaintiffs. Yesterday the parties received a letter from Judge Johnson, which I believe was provided to you as well, and he did state in his letter that he proposed May 2 as a trial date.

Then the letter does provide that if that date is unacceptable, he asks the parties to advice him and that he would schedule a conference call to select a date that's convenient to everyone.

The parties have not convened a call with Judge Johnson as yet, but that date obviously seems to present some conflicts with the schedule that Your Honor was talking about with respect to the trial of the Terry Hayes case, which we had understood would be set for May 9th.

(Pause in proceedings.)

MR. BERMAN: The parties have provided Your Honor with otherwise copies of the schedule that Judge Johnson had entered for the ALFSD issue, which somewhat mirrors the schedule that Your Honor had entered a few days earlier than his schedule.

THE COURT: Right.

MR. BERMAN: Just to bring us back in time a bit, at the January 27th status conference with Your Honor you had entered an order for that issue providing for the defendants to produce their expert reports and the Daubert motions on January 29, which they did do.

Your order provided that the plaintiffs will have until March 18 to respond to the Daubert motions and file responsive reports, and if any Daubert motions

are filed by the plaintiffs, the defendants would have an opportunity to respond to them.

With respect to Judge Johnson, he adopted the January 29 date for the defendants to supply their expert reports, which they did do and you were notified of that.

He also adopted the March 18th date for plaintiffs to file their responsive expert reports. But rather than providing for the briefing on the Kemp motion, which is the New Jersey name for the Daubert motion, he then provided that after the exchange for the reports there would be a 45-day period for the parties to take deposition discovery of the various experts and then a seven-day period thereafter for any party to file a Kemp motion and then seven days thereafter for the responsive motions to -- or the responses to the motions to be filed.

Frankly, Your Honor, those dates play out beyond May 2, which I'm not sure if Judge Johnson may have focused on when he wrote his letter yesterday suggesting the May 2 date for his trial.

THE COURT: Okay.

MR. BERMAN: I believe the parties will discuss further his proposed date.

THE COURT: Okay.

MR. BERMAN: And if I may just add one other thing? He was aware I believe of the May 9 date that Your Honor had set when we spoke to him on the January 29 conference.

(Pause in proceedings.)

THE COURT: Anything from the defense perspective?

MS. A. JONES: No, Your Honor. Mr. Berman correctly reported I think the status of things. I think it is fair to say that both parties were surprised to get the letter yesterday.

I did talk with Mr. Tisi and I think we anticipate taking Judge Johnson up on his invitation for a call to discuss the appropriate dates. But, frankly, we thought it might be more appropriate to do that following this conference today, number one.

Number two, I suppose the one thing that I can -- I think I can say on behalf of both parties is that probably neither party desires to be in two places at the same time. Beyond that, I don't think there's anything else to add to that discussion right now.

THE COURT: We don't want you in two places at once. And following our conversation on the telephone last month about scheduling, it occurred to me that you were sort of caught between our proposed

schedule and Judge Johnson's interest in getting another case up for trial.

So I called him and he and I had a very productive and good conversation I'm going to say a week ago, it might have been two weeks ago, and we talked about -- okay, is it the Taylor case in New Jersey?

MR. BERMAN: Yes, that's --

THE COURT: Right. Okay.

MS. BERMAN: -- the name, Your Honor.

THE COURT: Okay. So he indicated to me the Taylor case was fully prepped and ready to go. In the state court system, I know this from having been a state court Judge, there are some I'll call them docket pressures that we don't have in the federal court. He's got an administrative judge who is asking him when these cases are going to be tried. He's got the State Supreme Court that tracks the age of cases. And we have a similar tracking system but with less, or at least less perceived consequences.

In his case, the Taylor case, is an older case than the Hayes case in terms of dates of filing. So we talked about what we could work out. I don't like to take the position that the federal court will speak and others will fall in line. I think we need to

work out these things in terms of what makes sense for both of us.

So, he and I talked about the potential scheduling. He expressed a strong preference because of some of those docket pressures, administrative pressures in his system, that he would like to get the Taylor case up and tried, and I told him I was fine with that.

So I'm going to back off of that May 9 date. I told him that and I wanted to review that with you today, and we can get the Taylor case scheduled. What I would like to do is schedule trial in our case then for September 19th, and that gives us plenty of time to take care of all of the issues that we have to resolve in this case.

So I think when you have two courts that have competing schedules I think that puts the attorneys in a tough spot, and my feeling is that that's when the judges should be talking about what they're willing to work out. So that's the compromise that we struck. He indicated that he has -- because the New Jersey cases are not grouped like the MDLs -- they have a program in New Jersey. It's also got an acronym, but --

MR. BERMAN: There is -- there is a mass tort type of docket in New Jersey.

THE COURT: What do they call it, MES? I forget what it's called, but there is a mass tort protocol. These cases are not in that. And so he's looking at a series of individual cases which have some age to them, all right.

So he was talking about getting Taylor tried and then teeing up the next one, and I said I'm fine with you going in May, but I expect to schedule something in August or September, and I looked at that date right after Labor Day.

I have to be in Washington that week and the following week, and my schedule opens up September 19th, and I would like to try the Hayes case that week. So that's where we are with scheduling and with New Jersey.

(Pause in proceedings.)

MR. GAINER: Your Honor --

THE COURT: Yes?

MR. GAINER: -- if I could be heard for just a moment?

THE COURT: Sure.

MR. GAINER: The schedule that Judge Johnson has set carries the case out to the middle of May at least.

THE COURT: Yes.

MR. GAINER: The case is not fully worked on. There is considerable discovery yet to be done. There are Kemp motions, there are response to Kemp motions, there is quite a bit of work yet to be done.

Mindful as the Court obvious is that state courts operate differently in terms of schedule, again shows the conscientiousness and consideration of this Court. That said, we have had two cases that have gone before the New Jersey court.

This case, the Hayes case, is fully prepared with the limited acute liver failure study group work to be done. We do believe, and I think Ms. Jones will recall when we were here last we felt the case could be completed in probably three weeks time.

Understanding that, if we begin the case on May 9th, conclude it in three weeks time, the delay for Taylor would be very minimal, the discovery necessary to have Taylor ready would be completed, and we would have had our bellwether trial.

So it's simply a request, Your Honor, on our behalf that we maintain our May 9th date inasmuch as, again, Judge Johnson's order carries the discovery yet to be done and the work up yet to be done in Taylor far beyond May 2nd. We would ask that the Court perhaps reconsider.

THE COURT: Well, I appreciate that. The term Judge Johnson used with me to describe the Taylor case is it's fully prepped. I have no idea whether it is or it isn't. I take him at his word. If it's not fully prepped, then that might be something you want to take up with him.

And if you want to talk with Judge Johnson about what has to be done to put the Taylor case in line for trial and he accepts that and defers that trial for a period of several months, I'm willing to reconsider our schedule.

But I talked with him. He seemed fully informed about the cases, he seemed fully -- I mean it was -- it was a collegial, great conversation. I look forward to the next time I talk to him, delightful guy, but he was adamant that the Taylor case is ready to go.

I'm familiar with the dynamic that sometimes judges think cases are ready to go and attorneys don't. I don't have any basis to question that other than professional courtesy, one judge to another, and if he tells me he's got a case that's packaged and ready to go, then I accept that.

If you can disabuse him of that notion and string that out a little bit longer and that opens up

May, I'm willing to -- I'm willing to look at May. But if I'm going to look at May, I'm going to have to look at May soon because I have a lot of work to do between now and May to do a responsible job with this case.

I've got a colleague in New Jersey who says he's got a case that all the work is done, it's a question of setting a date and getting the jury in the box and presenting the case, and we still have some things to do on this case, and September seemed to make some sense to me.

So if there's some -- if there's some difference, I'm not going to keep a May 9 date. I'll issue a scheduling order that puts us at September 19th. If the May 2nd date collapses and you want to move to accelerate that date, I'm willing to listen to that. Okay.

Deposition designations, I still have a bunch of binders in my chambers with -- did they go?

MS. MAZUR: They left, yes.

THE COURT: Oh, thank goodness. Okay. So they're gone. I stand corrected. And you're working on new designations --

MR. MILLIG: Yes, Your Honor.

THE COURT: -- right, Mr. Millig?

MR. MILLIG: In fact, we've had -- for the --

for the Hayes case, we've had two very productive meet and confers, first just with attorneys and paralegals who are involved in the deposition designations, and then Monday we had a conference call where we involved each sides vendor who actually puts the tapes together that are played for the jury.

And big picture, and this is what we'll be explaining to Judge Johnson as well, the initial case that was tried helps us, but it was just tried on one claim, a design defect claim. And so what we'll be doing, and the burden rests primarily on the plaintiff because we play all the tape at trial of the corporate witnesses, the vendors have worked out the easiest way for our side to have the transcripts but with the bold part -- with it bolded what was played in the Jackson case, limited design defect, and then for us to be able to adapt and edit that testimony, get it to the defense, get it back to us, and get it to Your Honor.

The only real question that we were coming today with was really one of timing. The defense initially had said we want them all done by a certain date, and we had said we prefer to roll the deposition designations out.

On reflection, as we talked about it, we agreed with the defense that it gets really confusing

with things going back and forth and you can't remember which ones you've done. And we agreed that we would -- if the Court would allow us, we would pick a date and we would get all our designations to the defense.

So it was really -- we were going to kind of, unfortunately, throw the ball back to Your Honor and say when do you want them. We were operating under May 9th and what we ultimately agreed to, Your Honor, is that if you pick the date -- if you were comfortable with a date in -- if you were comfortable getting the designations, the actual designations, and as we understand it from what you've said, without nonsense objections, with just the substantive, real objections by April, the defense would be willing to give us until the middle of March to get the whole case to them. They could turn it back around and put objections in in two weeks.

On the other hand, we agreed that if you wanted the depositions to come to you sooner, that we would roll them out, but that we agreed we would roll them out in groups. For example, we would do corporate science witness, corporate pharmacovigilance witnesses, corporate marketing witnesses. So we would stay -- we put together our own little plan.

The bottom line is it all was premised on a

May 9th trail date. It all -- your preference as to when you need it done and we're going to have to do the same thing for Judge Johnson because the Taylor case isn't just a design defect case, so coming back to it being fully prepped, we have to do all designations in Taylor, too.

THE COURT: Well, it seems to me that if we -- given that you have a May 2nd, 2016, trial date for Judge Johnson in Taylor, unless and until that changes, but I have to assume that that's going to happen, that is the trial date is going to happen -- having you prepare deposition designations to provide to me by the middle of April might be difficult, right?

MR. MILLIG: It would be extremely difficult. I think a lot of what we're doing today may -- I know that with the plaintiffs we're going to express to Judge Johnson our desire for a bellwether trial to take place in this litigation and see if he will move the trial date. And hopefully we can get back with you as soon as possible to recapture the date.

If we can't, then I think you're right, I think that we would just have to -- I'll have to make the same pitch to Judge Johnson and explain to him that we're not prepared for deposition designations in Taylor and to give us -- we'll need a full schedule for

that type. That's -- the report was -- we're really working together, but I guess the point is it's a little -- might be a little moot.

THE COURT: So today we're talking about a schedule that if you can convince Judge Johnson then is totally out the window and we would have to come up with a new schedule. Why not just go on May 2nd with Judge Johnson and go in September with me?

MR. MILLIG: Two -- well, first, Judge, the Taylor case involves different experts than the Hayes case or the Jackson case, which these experts have not even been notified that there is a trial coming up. Judge Johnson has allowed depositions to go far beyond May 2nd in the --

THE COURT: This is --

MR. MILLIG: -- Taylor case.

THE COURT: This is February 17th.

MR. MILLIG: No, the depositions of the acute liver failure study group go beyond the trial date right now. The case has to be prepared from scratch in terms of deposition designations.

And from the plaintiff's perspective, as an MDL, we greatly desire a bellwether trial in federal court that would guide this litigation. The individual cases in New Jersey are not -- just don't carry the

same weight, Your Honor, as a bellwether case to put the whole litigation behind it. Thank you.

MR. BERMAN: Your Honor, one of the other issues, just so it's in your mind, if I may, is that the Jackson case was tried under New Jersey law, as I recall. The Lyles case was scheduled to be tried under Alabama law.

The new case, the Taylor case is an Oklahoma law case, and the parties really I don't think have addressed in any great, substantive detail the elements of Oklahoma law, which is why Mr. Millig is discussing the idea that the experts are different, some of the designations will be different, the causes of action will be different.

MS. A. JONES: Your Honor, if I may address the point of the deposition designations?

THE COURT: Sure.

MS. A. JONES: The parties -- plaintiffs submitted a proposed scheduling order to Your Honor, and defendants also submitted a proposed scheduling order.

In follow up of Mr. Millig's statements, we are in agreement with a process and ultimately we're looking to the Court to determine the dates by which you would like to receive the deposition designations.

So I would represent that the defendants' proposed scheduling order lays out the process without the detail that Mr. Millig went through and that it would be up to Your Honor to enter the dates in accordance with the trial date that you set. So that framework is there.

THE COURT: Okay.

MR. MILLIG: And all I would say, Your Honor, is that's -- I really haven't looked at the scheduling order. We -- the attorney that I dealt -- have been dealing with on the defense, we've just been going from scratch. But the bottom line is we're totally ready to make this happen in a very easy fashion with the vendors on board. We just need guidance on the timing. Thank you.

(Pause in proceedings.)

THE COURT: Okay. Okay, good. Let us take a look at that. I don't want to just throw dates out randomly here. I will say that when Judge Johnson and I talked he talked about strongly preferring to do a May trial date. I deferred to that. And if you can convince him otherwise, if he wants to go in September, I'm happy to re-adjust.

But, I don't want any suggestion that this discussion should be interpreted as my preference that

we go in May. I've spoken to him, I said I'm okay with your May 2nd date -- or your May -- I didn't even know it was the 2nd, May whatever date, and I'll around that.

So I would not want it reported to Judge Johnson that Judge Stengel is just fine with going in May and hopes you change your mind. It's not that at all. I'm fine with going in September and let him have his trial in May.

And if you need to get Oklahoma law briefed or some experts scheduled and you have to move it until the end of May or the beginning of June, that's a New Jersey issue, that's not an MDL in Philadelphia issue as far as I'm concerned. Okay.

All right. What about the requests for admissions? There's a mention in the agenda to a discussion of a defendant's letter dated February 11, 2016, concerning alleged deficiencies. I have a letter here dated February 11, 2016, but it's a federal state liaison status report. I don't think I have the February 11, 2016, letter about deficiencies in the request for admissions.

MS. A. JONES: No, Your Honor, you do not. So let me put it into context. There are --

THE COURT: Was that a letter between the

parties?

MS. A. JONES: That's correct.

THE COURT: Okay.

MS. A. JONES: This has been a dispute between the parties. The request for admissions were served in September regarding the Terry case and they were case-specific requests for admissions served by the defendants on the plaintiffs.

Since that time, we have gone back and forth in letters and discussions with respect to those requests for admissions and the deficiencies the defendants have pointed out with respect to plaintiffs' answers.

THE COURT: And we talked about request for admissions at the August 26th --

MS. A. JONES: That is a separate --

THE COURT: -- status conference?

MS. A. JONES: -- set of requests for admissions. Those --

THE COURT: Oh.

MS. A. JONES: -- are requests for admissions that the plaintiffs prepared and served on defendants --

THE COURT: Got it.

MS. A. JONES: -- that relate to general

discovery. And you are correct, those were discussed both at the November conference as well as the August conference.

THE COURT: Okay.

MS. A. JONES: Those are two separate sets of requests for admissions.

THE COURT: Okay. So where are we with the requests for admissions, which are supposed to streamline and help the litigation process and --

MS. A. JONES: With respect --

THE COURT: -- not create more opportunities for litigation.

MS. A. JONES: Yes, Your Honor. On the set that the defendants issued, the requests for admissions related specific to the Terry matter, I would suggest that the parties could continue to discuss the deficiencies and streamline it.

These are a set of requests for admissions targeted towards the medical records, statements within the medical records, as well as statements within insurance documents made by the plaintiffs that the defendants are attempting to streamline for authentication purposes --

THE COURT: Okay.

MS. A. JONES: -- so that discovery does not

have to be done. And I do believe that we can continue to meet and confer on this. And it doesn't -- it has not, as you pointed out, been presented to the Court officially in writing.

THE COURT: Okay.

MS. A. JONES: And I don't believe it needs to at this point.

THE COURT: Okay.

MS. A. JONES: Certainly timing was more of a concern prior to the coming into this conference, looking at May as opposed to September, but I think the parties can continue to work and we will present it to the Court at the appropriate time, if necessary.

THE COURT: All right. So a lot of this has to do with the authenticity of documents.

MS. A. JONES: Defendants set of requests for admissions --

THE COURT: Okay.

MS. A. JONES: -- to the plaintiffs have specifically to do with the authentication of medical records and other records specific to the plaintiff in this case.

(Pause in proceedings.)

THE COURT: Well, that shouldn't be a problem, should it?

MS. A. JONES: Well, we don't see it as a problem. The plaintiffs take issue with certain parts, but as I -- as I referenced, we can continue to discuss which points we exactly want them to admit.

THE COURT: Authenticity doesn't govern admissibility. It simply means you don't have to bring somebody here from wherever.

MS. A. JONES: Correct, or you don't have to go depose 20 different treaters to establish what's --

THE COURT: Right.

MS. A. JONES: -- in the medical records --

THE COURT: Right.

MS. A. JONES: -- if there are statements --

THE COURT: That they are med --

MS. A. JONES: -- made by the plaintiff.

THE COURT: The medical records are authentic, genuine medical records. Whether they're relevant is another story, and that's what --

MS. A. JONES: Correct.

THE COURT: -- we've been talking about.

MS. A. JONES: We assert in the deficient -- in the letters back and forth that their objections -- refusal to answer the requests for admissions based on relevancy are not proper and that, in fact, they need to submit sufficient responses.

(Pause in proceedings.)

THE COURT: Mr. Millig?

MR. MILLIG: Your Honor, may I briefly address the defendants' request to admit and then I would like to address our request for leave if I may?

THE COURT: Yes, okay.

MR. MILLIG: We fully agree with Ms. Jones and we will work with Ms. Jones, Mr. Gainer in particular, who is handling the request to admit. It was -- for the I guess the plaintiff there were 250 requests to admit with 400 sub-parts. It was more than authenticity. But regardless, we're not here to argue about it. We'll work with Ms. Jones on that issue.

The second -- I'm moving to a completely separate issue, is the plaintiff last year, Your Honor, in the summer once full discovery had been completed of our generic case against the defendants, I inadvertently without leave of Court served a request for admission, a set of requests for admissions on the generic aspects of the Tylenol litigation on the defense.

Initially, I think to their surprise, they forgot I was supposed to get leave of Court and they wrote me back and they said Clay, your requests are not that good, will you re-work them? So I re-worked them

and I served them and we came before Your Honor and you said Clay why are you doing them, and I said well, I'd like to have them done before the New Jersey litigation. You said I'm not going to do them for the New Jersey litigation, but I'll let you do them for this Court at some point. And I said I think the record will reflect well, at least they get a gold star for being honest. And at this --

THE COURT: I re-read that in prep --

MR. MILLIG: Huh?

THE COURT: I re-read that in preparation for today, yes.

MR. MILLIG: And that's a -- I don't know -- that is the first time I think I've gotten a gold star my wife would say. But the point is is that we have now completed discovery.

We have taken depositions, and the defense I'm sure will stand up, and as I -- and it's -- I think it's -- I don't think it's relevant, but I'll tell you how many documents they have produced. We have served requests to admit in the past on certain issues.

But as it relates to the generic case, these are our requests to admit. There are -- I've got -- they were served on the defense in August. They have had them. There are 132. There are less than were

served on the plaintiff, who was only in the hospital for three days, only half as much.

We would ask the Court strongly from the PSC, from the plaintiff's steering committee, that we be allowed to serve -- be granted leave to serve these requests to admit to get admissions, denials, or inability to answer as to generic issues in the case.

There's no -- like I said, they've had these -- the defense have had these since August, no prejudice. Even with a May trial date there's no prejudice because it only takes 30 days to do these.

We are engaging with the defendants right now in the acute liver failure study group and working that through no problem, and we don't see any harm to the defendants in answering the requests to admit now that we are at the end of the generic discovery, and it is designed to, as the Court knows, to limit the issues. And their requests to admit under the generic case are traditionally served at the close prior to trial.

So we would strongly ask the Court for leave. Thank you.

THE COURT: All right. So you haven't yet obtained leave of Court to serve this?

MR. MILLIG: No, this is do -- I sent an e-mail to Melissa saying I'm coming in to ask for leave

right now pursuant to -- so I'm asking pursuant to CMO 13, which was entered at the beginning of this litigation. We haven't served any written discovery.

THE COURT: And is this leave to serve requests for admissions you've already served?

MR. MILLIG: Well, it's leave -- I'll serve them again, but I -- this is -- I served them inadvertently in July. They inadvertently responded and said we don't like the way they're worded them. I re-worded them and served them again inadvertently without asking for leave.

THE COURT: And what are the subjects of those requests for admissions?

MR. MILLIG: The subjects are pharmacovigilance, admissions about deficiencies, admissions about -- admissions about certain knowledge issues. It's all admissions about marketing, admissions about the -- what the company knew or didn't know about the safety profile of its product. It's all premised upon the generic discovery we've taken, as is the course in most litigations you --

THE COURT: You've taken --

MR. MILLIG: You take --

THE COURT: -- some statements from depositions.

MR. MILLIG: You take depositions, but you get kind of a -- you're not sure if -- you think you know what the facts are so you -- that's the -- that's the vehicle that you use is the request to admit in order to nail it down. Thank you.

THE COURT: All right, thank you. Ms. Jones?

MS. A. JONES: Yes. As Mr. Millig presented, plaintiffs sent a request to the Court on Friday for a motion for leave to serve the requests for admissions. I was not -- we were not certain what the requests for admissions would be. It does sound like it is the same set of 142 requests for admissions that --

THE COURT: 132 now.

MS. A. JONES: Huh?

THE COURT: 132 now.

MS. A. JONES: 132.

MR. MILLIG: Hold on one second. Nope, I was told you didn't get the last page. It's 142.

THE COURT: Okay.

MS. A. JONES: So --

MR. MILLIG: But --

MS. A. JONES: -- if the -- if the Court -- and I have a copy here, but in November when we last discussed this same set of requests for admissions, Mr. Berman represented that he would go back and streamline

the requests for admissions, and Your Honor stated that you would extend the time for us to respond, but also to come to some agreement between the parties with streamlining these so that there were not 142.

If Your Honor will recall, our main objections substantively to those request for admissions were that they were cumulative, that what they did, in fact, was to cover deposition testimony that the plaintiffs had already taken. The plaintiffs have had three years of general discovery taken.

Certainly requests for admissions can be used to streamline or otherwise get admissions used for the purpose of trial. But in this instance, it is going back on discovery that's already been taken, which is cumulative.

The plaintiffs have served over 250 with sub-parts requests for admissions that relate to general discovery already. So substantively, we have already taken issue with these requests for admissions. However, I was not aware until today that it was the same set of 142 that he was requesting leave for officially on Friday.

THE COURT: Okay. Do you -- do you have the request for admissions? Can I take a look at them?

MR. MILLIG: Yes, Your Honor, I do.

THE COURT: I mean the purpose -- could you hand them up? Do I have them?

MR. MILLIG: I don't believe you do. This is just a letter that I wrote to Ms. Jones.

THE COURT: Okay.

MR. MILLIG: I don't think you do.

THE COURT: I mean the purpose for requests for admissions is to narrow the issues and simplify the proof at trial, right, so you can stand up at some point in trial and read certain admissions?

MR. MILLIG: Absolutely.

(Pause in proceedings.)

THE COURT: When you say these are cumulative, Ms. Jones --

MS. A. JONES: Yes.

THE COURT: -- do you mean they're cumulative of other discovery that's been taken?

MS. A. JONES: Cumulative of other discovery that's been taken, specifically the depositions. If you look at, for example, request for admission number 21, or 23, starting at 23 through 31, the request for admissions go back and cover ground that has already been covered within the depositions. They ask McNeil to make admissions based on the sworn testament -- testimony that's already been taken by these

plaintiffs.

THE COURT: All right.

MR. MILLIG: Your Honor, the purpose of a request to admit, as you know, is often times in a deposition or when a witness is lying you don't get the -- you don't get the full -- you don't get the actual answer. And I'm not suggesting that witnesses didn't answer it truthfully, but I am suggesting that the company should answer the request that the plaintiffs steering committee has put together and take a position, for example, whether acute -- whether acute liver failure can occur based on their infor -- what their research is at seven grams.

There are hard issues in this case that it's -- that the company needs to take a position on, and that is very difficult with depositions. And what we do in litigation, as Your Honor is well-aware, is we take depositions, then we figure out what the case -- what the testimony is and what we believe the facts is and we ask the company to take a position on it. Once it's admitted, we don't have to prove it. And then if a witness gets up and doesn't admit it at the court -- or admits it at the court and the company refuses to admit it, we can read it to the jury. But cumulative I don't believe is a proper basis for denying requests to

admit. They are, in fact, cumulative.

THE COURT: Well, I agree with that. I mean I think it's a proper function of requests for admissions to summarize or highlight information that's given through deposition, and it -- and it prevents the need to read depositions in front of the jury. So I get that. I guess my concern is that there are -- I'm looking at some of these request for admissions and they appear to be some of them interpretations of testimony.

(Pause in proceedings.)

MR. MILLIG: To be quite honest with Your Honor, I have not looked at them carefully since August, but I will -- what I will tell you I'd be more than happy to do is to go back and read them, to make whatever adjustments we need, and then to serve them and let the defendant answer them. As we said, we're about ready to answer -- we've been told that we have 150 related to just Ms. Hayes that we have to answer right now again. There's no burden for the defense to say this is an improper request or for -- there's actually no burden for you to say Mr. Millig, go tweak a few of these and if the defense has an objection, let them object. But there's some questions in here -- within there that we -- well, many questions and

requests that we would like to get a definitive answer from the company. And it's our right, respectfully, under the rules and it's the way we get to the bottom of things.

THE COURT: Yes.

MS. A. JONES: Your Honor, I believe you've already instructed them to go back and streamline 142. That's what you instructed them to do in October based on what they learned from the trial in September.

THE COURT: All right. I mean there's a request here to admit that tylenol products have been sold in the United States for over 40 years as of 2002. Shouldn't be any problem.

MR. MILLIG: Shouldn't be any problem.

THE COURT: Right. There's a request that says, "McNeil admits based on the sworn testimony of Ed Nelson, M.D. former medical executive of McNeil, that if employees of McNeil, in the course of their pharmacovigilance duties identify either a new adverse event or a change in the frequency, character, or severity of a known adverse event with the company's Tylenol products, such a finding could lead to a change in the product's labeling." It seems to me there's some interpretation or spin involved in that one, right?

MR. MILLIG: It's probably word for word of the testimony.

MS. A. JONES: Well, certainly, Your Honor, we do admit that a deposition transcript stated what it states. However, that seems duplicative of deposition testimony itself and cumulative. And we would represent that that is not a direct quote. There may be parts of it which is quoted, but not exact word for word. But, Your Honor, we are willing to -- if the plaintiffs will review the requests for admissions in accordance with some instruction and guidance from the Court and then we can work with them on which ones are feasible to answer and which ones we believe we have valid objections to. In fact, coming in I was not certain that it was the same set of 142. I was under the impressions they may have streamlined them already based on your Court's guidance in November.

MR. MILLIG: And, Your Honor, we would -- we would agree with that as well. If you will simply grant us leave, we'll go back and look at them. We'll serve them just like regular discovery vehicles and let the defendants object or answer based on the rules.

THE COURT: What I don't want to create here is yet another tier of discovery litigation, okay? On the one hand, you're telling me you want a May 9 trial

date, and on the other hand, you're telling me we're going to litigate 142 requests for admissions.

MR. MILLIG: No, sir --

THE COURT: I've been with you all long enough to know that there will be some disputes about this and that we'll have another case management conference or I'll appoint a special master or something will happen that will drag this out to 2018 while we litigate the requests for admissions.

MR. MILLIG: I --

THE COURT: Why put this in?

MR. MILLIG: I don't intend to --

THE COURT: You have the depositions. You have the witnesses coming in.

MR. MILLIG: Well, Your Honor, if the defendants don't respond appropriately to a request to admit that's from the -- that is foreign testimony, I can read it after the testimony and I can make the point that McNeil refuses to admit basis facts to this jury. And it's a -- it is -- that's the tool that you use with that.

THE COURT: You know --

MR. MILLIG: And I -- and I guess I've --

THE COURT: How --

MR. MILLIG: -- I'm a little surprised that

we're -- we have three months, that generic discovery is done, and the PSC has not served any written discovery since the beginning of this MDL, and I'm -- we're simply asking to serve our requests to admit, which is really not even a discovery tool, it's a --

THE COURT: Well, I think --

MR. MILLIG: -- consolidation tool.

THE COURT: -- you're allowed to do that. I just don't want to buy another level of discovery litigation here.

MR. MILLIG: I don't either.

THE COURT: What I think you should do is go back over this and if these are direct quotes from depositions, then reference the deposition at the end of the request for admission to streamline that.

MR. MILLIG: I will do it.

THE COURT: And if they are direct quotes, then they can decide whether they want to admit to the truth of that or maybe they don't agree with what they're own witness said. Maybe there is four or five ways of explaining the same point that were covered through that 14 hour deposition, God forbid.

The other thing is, I mean you have to think three times about whether you want to spend much time in front of a jury castigating the other side about not

admitting to a certain fact in response to requests for admissions under the Federal Rules of Civil Procedure. That's not -- that's not winning friends and influencing people among those jurors.

MR. MILLIG: Totally get it. All the plaintiff and the PSC is asking for is for the option.

THE COURT: Okay. I think that's fair. They'll rework them, you can respond, and then -- and then --

MS. A. JONES: Thank you, Your Honor.

THE COURT: -- we'll see where we go. Okay. How much time do you want, Mr. Millig?

MR. MILLIG: I'll turn them around in seven days.

THE COURT: Okay. All right, so we'll give you leave to file the requests for admissions -- or serve the requests for admissions within seven days from today. And, Melissa, would you give this back to Mr. Millig for me? Thank you.

(Pause in proceedings.)

THE COURT: All right. Anything else on request for admissions?

MR. MILLIG: Nothing, Your Honor.

THE COURT: Okay. How about motion in limine seven, to exclude evidence of manufacturing, quality

control, production matters?

MR. HEWES: Good morning, Your Honor.

THE COURT: Good morning.

MR. HEWES: May it please the Court? Mike Hewes on behalf of McNeil. Your Honor, motion in limine seven is to exclude certain evidence regarding manufacturing, quality control, and production matters regarding some of McNeil's facilities, governmental investigation, Congressional testimony, consent decrees, and plea agreements, and FDA inspection reports and follow up from McNeil.

Overall, the broad argument here, Your Honor, is the things in evidence the plaintiffs seek -- we believe the plaintiffs will seek to set forth at trial not only post-date the August 2010 injury of Ms. Terry, but they're wholly unrelated to the issues of the case. Nearly every piece of evidence, every document, deals with a manufacturing defect issue, Your Honor. In this case plaintiffs have made no allegations of manufacturing defects. The only reason the plaintiffs would like to get this evidence in is to taint McNeil with impermissible character evidence.

Moreover, Your Honor, the documents and things that the plaintiffs seek to introduce are pure hearsay, and we believe the plaintiffs will try to take

the information therein to prove the truth of the matter, sir.

By way of background, Your Honor, beginning in 2008, McNeil was involved in several unrelated issues regarding the manufacturing of some of their over-the-counter products, mostly children's liquid products. None involved liver -- none involved liver injury. None of the allegations or none of the manufacturing problems that the plaintiffs seek to introduce dealt with extra strength Tylenol labeling or the adequacy of the extra strength Tylenol labeling. None are relevant to the issues in the case, and, again, the plaintiff has not asserted claims to a manufacturing defect, and the plaintiffs will be hard pressed to argue how a manufacturing defect investigation plea agreement or consent decree has anything to do with this case. And if I could --

THE COURT: Tell me about the 2015 plea agreement. That's what they want to put in, you want to keep out, right?

MR. HEWES: The 2015 plea agreement came after a long investigation with the FDA. It was centered solely on children's motrin and children's Tylenol. It had nothing to do with the extra strength Tylenol and it was an agreement to basically wrap up an

investigation.

There was a consent decree entered in 2011 that dealt with changes to the manufacturing process, certain medications that would agree to be destroyed. Again, that was in 2011 and post-dated the plaintiffs injury, and, again, it dealt with manufacturing defects. May I approach, Your Honor?

THE COURT: Yes.

(Pause in proceedings.)

THE COURT: Do we have an issue here?

MR. HEWES: I'm sorry, Your Honor. Plaintiffs counsel just told me they don't intend to fight me on a lot of this, so this is news to me based upon the objection I read.

THE COURT: Why don't we hear from plaintiff as to what you hope to put in?

MR. MILLIG: I think that would -- I didn't mean to interrupt you, Michael, but I thought we might be going down a path that --

MR. HEWES: I'm certainly okay with that, Your Honor.

MR. MILLIG: -- might simplify things.

MR. HEWES: Can I go ahead and give you this? These are a set of exhibits I will use in my argument.

THE COURT: Sure.

MR. HEWES: I think Your Honor drew the short straw because I'm arguing three motions, so --

THE COURT: Okay.

MR. HEWES: -- there are three sets of exhibits I will be referencing.

THE COURT: Okay. Thank you.

MR. MILLIG: I'm sorry, Michael.

MR. HEWES: If you're going to withdraw it, I certainly will -- we'll hang it up from there.

(Pause in proceedings.)

MR. MILLIG: Your Honor, Clay Millig. May it please the Court? The motion in limine number seven filed by the defense, let me begin by just simply stating it's very broad and it covers a large list of areas of evidence --

THE COURT: Yes.

MR. MILLIG: -- seeking to exclude number one, manufacturing; number two, quality control and production facilities; number three, government investigations; number four, regulatory matters; number five, including FDA form 8483; number six, testimony before Congress; number seven, consent decrees; number eight, plea agreements. Mr. Hewes began his argument by saying everything in this motion is related to manufacturing, and that's really where I want to -- I

want to disagree, and I want to just make sure the Court understands what is important to the plaintiffs that we really take issue with and what we would suggest to the Court the Court reserve until it hears the evidence at trial.

So I think I -- I don't mean to take Mr. Hewes and supplant his argument, but I do think this might be a more efficient way, respectfully.

THE COURT: Sure.

MR. MILLIG: So --

THE COURT: That's why I asked you to step up here.

MR. MILLIG: So the -- so there are three areas out of all of the areas in this motion that I would put into group one, evidence we feel strongly about for direct or cross. Recalls, form 483s and plans and Congressional testimony. Recalls, why should evidence of recalls be admitted at trial? One of the central claims and allegations that we make in this litigation, Your Honor, and that we've made in the Jackson litigation is that McNeil at all times should have done exactly what the 2009 advisory committee recommended in June of that year, which is remove extra strength Tylenol from the over-the-counter market, i.e. recall the product.

We say they should have done that. The central defense to the case is, for the McNeil that we heard in Jackson and we'll hear again here, is people overdose on this product. If you follow the labels, you're good. However, the Court has noted in the dispositive motions that taking more than directed is not a bar because McNeil knows and we have evidence that went up in Jackson that will be presented to this jury of survey after survey showing that McNeil is aware that people take too much of their products.

So the plaintiff's case is if you know that a certain percentage of people take one of your products and if we know that taking more -- if there's evidence that taking more can cause a serious, life-threatening problem, you need to take action. One of those actions was 2009 said recall the product.

THE COURT: So what was recalled?

MR. MILLIG: What was recalled is that in 2007 -- and, Your Honor, I wish I had copies, but if -- I'll just -- if I can read to Your Honor?

THE COURT: I'll take your word for it, but what --

MR. MILLIG: Yeah.

THE COURT: -- was recalled and when?

MR. MILLIG: In 2007, McNeil recalled Tylenol

infants cold drop, Tylenol cough and cold pediacare -- there are three -- and three -- three Tylenol products that were withdrawn. And in an e-mail -- then this is part of the testimony in this case -- from a woman named Colleen Goggin -- she is the number two person in the company, head of the consumer products worldwide, she writes in 2007, "We recognize that consumers place their trust in us to provide them with products to meet their healthcare needs. In recognition of this true, McNeil Consumer Healthcare has made the decision to voluntarily withdrawn Tylenol infant drops plus cold, Tylenol infant drops plus cold and cough, and pediacare infant drop products from the U.S. market."

It goes on to say, "And the reason why is as follows: Although most parents use cough and cold medicines appropriately and follow the dosing directions, an assessment of available data on the use of pediatric cough and cold medicine side has identified," and here's the important line, "rare instances of misuse leading to overdose."

So when McNeil became aware of rare instances of misuse leading to overdose in three lines of its products -- at the bottom it says, "As an organization we have a responsibility to meet the healthcare needs of consumers while ensure their safety. What McNeil

did in furtherance of this goal is to withdraw three of those lines from the product -- from -- withdraw those three lines from the shelves. And the contrast there for the jury is we know that 30 percent, 25 percent of people, take extra strength pain reliever over the recommended does. There's no dispute from McNeil that they're aware of this, that it's foreseeable. Yet the risk mitigation methods were completely different, and the issue the jury is going to have to decide is did McNeil do an appropriate job of assessing the risk profile of its drug and take appropriate action in terms of labeling, warning, and protecting consumers? And the 2007 recall is probative certainly on that point of --

THE COURT: Probative of --

MR. MILLIG: -- acetaminophen.

THE COURT: -- their ability to recall a product?

MR. MILLIG: Probative of how this company responds and has the capability to respond when it becomes aware that people may be taking slightly more than directed. And they did it when they have rare instances of misuse. They totally withdrew products. But, as we'll see in the case, the extra strength Tylenol is the flagship and amounts for a significant

percentage of the profits, and nothing was done to extra strength Tylenol.

THE COURT: Okay. All right. So that's the -- that's the evidence of recall, right?

MR. MILLIG: That's the evidence of one of the recalls. The second recall I think -- I would -- I will say to you honestly is more for cross-examination. And the central theme of the defense in this case that played out in Jackson that will play out -- was played out through the depositions is that McNeil cooperates and works with the FDA as it makes decisions. These decisions come about over time, and we may -- we're always interacting with the FDA. I think Your Honor pointed to that in your orders on dispositive motions.

Yet in 2009, when McNeil found that its motrin product was out of compliance and did not -- and had some bacteria, as I understand just from looking at the memos, McNeil conducted a secret recall without the FDA's knowledge, sent people into the stores without the FDA's knowledge, and purchased this product off the stores with the potential intent to alleviate the problem. That was brought forth at a Congressional hearing. The FDA itself has commented on the lack of trustworthiness of the company in that -- in that -- in that issue.

That particular recall will not come in in our affirmative -- in our affirmative proof. I would suggest though that it should be -- that it -- that it may well be relevant depending on what is said on the stand for cross-examination. The -- and so that has to do with the recalls.

We are not interested in recalled product regarding bad manufacturing unless -- I say that, Your Honor, and I just can feel my colleague saying that's too overstated, Clay -- unless it's needed for cross, unless the suggestion is made -- a suggestion is made about the overall manner in which the company manufactures products, its safety. If they tout themselves up about safety and concern for the public, then I think we would approach the Court about bringing that out on cross.

THE COURT: Yes.

MR. MILLIG: The second issue that I think is important is what they call 483s. Mr. Hewes said everything is about manufacturing. There are -- there are 483s that are not about manufacturing. A 483 is a document, Your Honor, that is generated after the FDA inspects a pharmaceutical company facility, and a 483 is a finding -- is a significant regulatory def -- finding of regulatory deficiency. And the 483s that we

want to put into evidence and the issue that we want to put into evidence all relates to pharmacovigilance. As an example, there's a 483 from 1999 where the FDA found that -- it's a chronology. "In 1999, the FDA found in an 483 document that McNeil was able to make changes to adverse event reports."

As the Court knows, adverse events come into the company, the company is obligated to investigate those, then they send them on to the FDA. There was a 483 that indicated that McNeil could make changes to those 483s without any tracking of who got in the document, who made the changes. That concern -- the 483 was of such concern that McNeil hired is first director of pharmacovigilance, Kenneth Kwon (ph), whose deposition was played in Jackson and who will be played here presumably.

He discussed the 483. That is part of why he was hired, to shape up the pharmacovigilance department. In 2003, McNeil then went out and hired its own contractor, a contractor called Quintiles, to evaluate its pharmacovigilance department, in essence, its own internal audit of -- to see if there's an "483 problems." And that audit came back, Your Honor, and had multiple pharmaco regulatory critical problems, unacceptable concerns indicating that even as of 2003,

information was not getting to the FDA, the wrong people, and we're triaging these cases as they come in.

There's a 2010 483 that deals with -- in part with pharmacovigilance. There's a 2011 that says you don't -- you're not getting your serious adverse events to the FDA in a timely manner. The bottom line is again there are pharma -- 483s are not -- the way this motion in limine is written, it can be very broad. 483s were interested in have to do with deficiencies in pharmacovigilance. Pharmacovigilance, as the Court knows, the company has a duty not only of the regs, but under common law, to investigate its adverse events, to appropriately analyze them, to assess them, to determine whether or not there's an issue in terms of the safety profile of its company, and it can't find a problem with your drug if there's evidence that you're not doing the pharmacovigilance correctly.

In fact, in 2005, ultimately the pharmacovigilance duties were taken away from Mcneil and moved to Johnson and Johnson. So that's on 483, why we believe the 483s should come in.

THE COURT: Are those 483s concerned with extra strength Tylenol or other products?

MR. MILLIG: They are concerned generically with pharmacovigilance of all products I believe. I

don't -- I don't know if it's specific -- I'm sure it's not specific just to extra strength Tylenol, maybe related to Tylenol. And if it's it -- these are from the Fort Washington plant, which only does Tylenol and motrin. So it would be either Tylenol or generic -- or Tylenol and motrin, but it's --

THE COURT: Yes.

MR. MILLIG: -- they're directed to the pharmacovigilance department of McNeil, which is what we'll be discussing at trial.

THE COURT: Okay. And then what about --

MR. MILLIG: And then the third --

THE COURT: What about the Congressional testimony? What do you --

MR. MILLIG: Congressional testimony, Your Honor, I just want to make sure the Court is aware that Ms. Goggins has been deposed. We expect her to be here at trial. She testified -- just as an example, one of her primary -- one of the lines in her Congressional testimony was, "We take every adverse event seriously and we investigate every serious adverse event thoroughly." And there is abundant evidence to the contrary.

The Congressional testimony we have -- we do not currently have a plan in our case in chief to use

Congressional testimony related to the inner workings of the plant at Fort Washington and the manufacturing issues. But to the extent the Congressional testimony bears on pharmacovigilance, bears on the issues related to the -- that we're talking about in this case, it's certainly relevant, it's a sworn testimony, and we would certainly, respectfully, submit we should be able to use it on cross-examination.

So the three areas that I put into group -- into bucket one, which I hope simplifies things for the Court, are recalls related to acetaminophen primarily, and then motrin would be on cross, 483s that are related to pharmacovigilance, Congressional testimony of Ms. Goggins. The second list I will concede are not the focus: manufacturing, quality control, government investigations, consent decrees and plea agrees. We tried the Jackson case, we didn't talk about them. But I believe -- I may be wrong -- maybe was mistaken, I believe the ruling -- I don't -- I don't know if there's a full ruling. We -- but all we would ask the Court to do is hold those issues in advance and hold us to our word that we don't anticipate putting that in at this point in our direct case, but we certainly would want to have the ability to raise these issues with the Court if we thought that the testimony from the

corporate witnesses live opens the door and makes the use of these documents relevant depending on the defense.

THE COURT: So plea agreements that are not your focus, manufacturing defects --

MR. MILLIG: Yep, you know there's not a -- there's not a manufacturing defect claim.

THE COURT: Right.

MR. MILLIG: Manufacturing defect, quality control in the plant, not quality control from pharmacovigilance.

THE COURT: Right.

MR. MILLIG: Government investigations related to quality control in the plant, the consent decrees, which had to do with the plant, and the plea deal, which had to do with the plant. Again, all we would say is, Your Honor, is we would -- we would ask the Court reserve final ruling on those until the evidence roles out because we -- the defense -- there's a lot of suggestion of -- to the extent the defense tried -- you know, uses the good company defense, we want to stick to the issues, and if they open the door on a more broad front in terms of how they're presenting this company and the insinuations that might flow from that, we may, depending on how the evidence

comes out, seek leave of the Court to use some of this on cross during the course of the trial.

THE COURT: And that's something we could talk about at trial --

MR. MILLIG: Absolutely.

THE COURT: -- if the door is opened and --

MR. MILLIG: Absolutely. That's all I'm suggesting with the latter group. And I hope that's fair and I hope that makes things easier. Thank you.

MR. HEWES: May I respond, Your Honor?

THE COURT: Sure.

(Pause in proceedings.)

MR. HEWES: I must say that was quite the concession if indeed there was a concession in there, Your Honor. Plaintiffs would like nothing more than to get up before the jury and throw around words like "Congressional testimony" and "recall" and other issues that are wholly unrelated to the case so they can taint McNeil before the jury and suggest that McNeil is engaging in other behavior that is nefarious or that is somehow improper as they're assessing the facts of this case. And what Mr. Millig failed to do in response to your questions in his argument was to bring this back to this case.

I looked through plaintiffs' brief, Your

Honor, to see if, in fact, they reference extra strength Tylenol, which is the drug involved in this case, in their brief as it relates to any of these evidentiary issues we're putting forth. Page seven of their brief, "infants Tylenol," page eight of their brief, "children's motrin," page eight of their brief, "motrin," page ten of their brief, "motrin," page 15 of their brief, "over-the-counter drugs for infants and children." All of the things that Mr. Millig argued to you just now have nothing to do with Ms. Hayes ingestion of the drug at issue in this case, which is extra strength Tylenol.

We talked about bucket one. I'd like to go through those briefly and distinguish this case from the evidence that Mr. Millig would like to put on. Recalls. He talks about a recall of infants Tylenol and infants motrin, and the issues relating to the change in the dosing for infants Tylenol and infants motrin are wholly unrelated to this case. And if that evidence comes in, we'll spend a lot of time litigating that issue and bringing in witnesses to explain that issue. But in a nutshell, Your Honor, infants medications for infants under two years of age have no dosing instructions on them and the dosing is required to be obtained from the doctor, and there are sheets

given to the doctor and certain weight-related dosings that are done with that medication.

There is a citizens petition that was filed, and this was discussed over years and years with the FDA because some parents were mistaking infants Tylenol with children's Tylenol, which have different concentrations, which led to a change in the labeling and a change into how these medications are dosed.

THE COURT: Right.

MR. HEWES: Wholly unrelated to the issues in this case -- wholly unrelated, the secret recall that Mr. Millig references, we object to that terminology. They would love to tell the jury that McNeil is engaging in secret behavior. That recall involves the motrin product. Again, Mr. Millig glossed over the fact that the drug referenced in the secret recall -- which, again, we object to anything being characterized or categorized as a secret recall is improper. It is not the drug at issue in this case. We have serious 403 issues if they bring these in, not to mention the hearsay issues.

The 483s, Your Honor, if you could turn to the notebook I gave you. I'm glad -- I'm glad those were brought up because they were in my outline to discuss. And if you could look at tab one under motion

in limine seven, Your Honor, I've got the three 483s at issue tab and highlighted for both Your Honor and the plaintiffs to look at. And as you thumb through 483, dated October 2010 at the right-hand corner, you can go through the 15 or so pages, and I've highlighted every drug I could identify that is flagged in the 483. And briefly, they are Tylenol arthritis relief, cherry or grape-flavored children's products, Benedryl fast melts, St. Joseph's coded aspirin, Benedryl fast melts again, Sudafed, diphenhydramine (ph).

You can look through the whole document, Your Honor, and in the 483 that the plaintiffs are talking about, not only does it post-date the August 2010 ingestion, but there is no evidence that anything in the 483 is related to the allegations in this case and is related to the extra strength Tylenol ingested by the plaintiff. There is one section at the very beginning that talks about some of the manufacturing complaints, and I think Mr. Millig said those are off the table, but they're talking about faint smells that were associated with some of the products. Again, that is not at issue in this case. And so nothing in the 483 from 2010 has any nexus to this case whatsoever.

The second 483 is behind tab two, Your Honor. It's much shorter. It's two pages. It likewise post-

dates Ms. Hayes' ingestion. Ms. Hayes ingested the drugs at issue in this case in August 2010. The 483 behind tab two is from March 2011. It addresses reporting of certain adverse event reports. There is no suggestion and the plaintiffs will not make a suggestion that Ms. Hayes' adverse event report was somehow improperly reported, and there is no suggestion that any of the adverse event reports referenced in the March 2011 483 have any relation in this case whatsoever.

Finally, Your Honor, behind tab three is the other 483. This one is a bit of anomaly compared to the others because it does pre-date Ms. Hayes' ingestion. However, it pre-dates it by over a decade and it deals with the law department not timely turning in two reports to the FDA. I think they delayed a few months. There is no evidence whatsoever that these were related to liver damage, that these somehow affected the safety of the product, that these somehow affected the viability of the product or the label, and they are clearly not related to Ms. Hayes' case because the allegations of ingestion were in August 2010 and not in 1997.

The final drop in the bucket that Mr. Millig referenced was Congressional testimony. And, again,

that's a huge buzz -- huge buzz word and it will surely get the jury's attention. But the Congressional testimony by Ms. Goggins and others dealt with what Mr. Millig said wasn't at play in the litigation, which is manufacturing defects and McNeil's efforts to correct the manufacturing defects. Unrelated to its extra strength Tylenol product labeling or unrelated to the product at issue here are the issues before this Honor's -- before Your Honor's case.

The Congressional testimony occurred in 2011. It post-dates Ms. Hayes' ingestion. It has nothing to do -- nothing to do with extra strength Tylenol's ability or inability to cause acute liver failure or liver injury at or near therapeutic doses. It is a sideshow that the plaintiffs would like to throw out before the jury. It has severe 403 implications in terms of the -- in terms of the prejudicial impact weighed versus the probative value, and it should be allowed.

If we're going to try the case that we want to try, the plaintiffs should be allowed to put on evidence related to Ms. Hayes' ingestion and related to the product at issue in this case and related to the time frame and the injuries that she allegedly incurred. To allow this would significantly prolong

the case, Your Honor, because we would have to put on people to counterbalance anything and show that the evidence is wholly unrelated. And for that reason, we think it should not be allowed as a threshold issue in the case.

THE COURT: They apparently want to feature Colleen Goggins' testimony about the company's policy of investigating every adverse event thoroughly, right?

MR. HEWES: Yes, Your Honor.

THE COURT: Did she say that?

MR. HEWES: I believe she did in her testimony, Your Honor, and they did depose her in the case. They asked her questions. The deposition was videotaped. They asked to play her videotape in the New Jersey litigation. It was not allowed because the -- Judge Johnson found that the information -- Colleen Goggins is not a McNeil employee. She's a Johnson and Johnson employee.

THE COURT: Yes.

MR. HEWES: Judge Johnson found that her testimony is cumulative and that the things that she sets forth in her testimony are more readily available for more relevant employees. They spent days and days and days and days deposing many McNeil employees. I was there for all of them. And we sat through hours

and hours and some depositions lasted multiple days. So they -- but they certainly want to get that in, and we make him cross that bridge down the road if Your Honor allows her video to be played. But that doesn't open up the doors to all discussions about what happened before Congress and why McNeil was before Congress, because that is extremely prejudicial to McNeil in a case involving extra strength Tylenol in a case that occurred years before the Congressional investigation.

THE COURT: Why was McNeil before Congress?

MR. HEWES: McNeil wasn't Congress. Johnson and Johnson was before Congress because there was an investigation into some plants where there were some findings of some metallic particles in some of the children's products. Some of the products that were on pallets were exposed to a chemical that created an unpleasant odor in the bottles for some of the products, and the plaintiffs were shut down --

THE COURT: Yes.

MR. HEWES: -- and totally re-tooled, and then they were just now being put online for the new products. And so the Congressional investigation had to do with the activities from a manufacturing standpoint that would allow some particles to get into

a bottle or to allow this unpleasant odor, things related to that.

THE COURT: All right. It has nothing to do with this case?

MR. HEWES: It has nothing to do with this case.

THE COURT: If in the course of that testimony she did make the statement that we investigate all adverse events thoroughly, and the plaintiff has evidence that, in fact, they don't, wouldn't that be relevant?

MR. HEWES: I think we need to look at it in --

THE COURT: On the issue of this term pharmacovigilance, right --

MR. HEWES: They asked that to Dr. Covener (ph) and they asked that to Dr. Temple and they asked that to Dr. Kwon, and similar testimony -- I can't say it's the -- I don't want to represent that it's the exact same testimony because I'm sure I'll get called out for not citing it directly, but the discussions regarding pharmaco -- the discussions regarding pharmacovigilance --

THE COURT: Yes.

MR. HEWES: -- and the discussions regarding

the scope and breadth of McNeil's adverse event reporting is explored in great detail with Dr. Covener, it's explored in great detail with Dr. Anthony Temple, it's explored in great detail with Dr. Kenneth Kwon, who used to be the director of pharmacovigilance for McNeil. Is it relevant in that context? It may be. I don't know that Colleen Goggins adds anything to it with her testimony, but subject matter perspective, it will certainly be before the jury. I have no doubt about it. It was before the jury in the Jackson case through Dr. Temple, through Dr. Kwon, and through Dr. Covener.

THE COURT: So what you're trying to keep out is the line of questioning that would include and so you lied to Congress, right?

MR. HEWES: I don't know that they would go so far as to say -- I don't -- and I could be wrong -- I don't --

THE COURT: Well, you said this in Congress and, in fact, that's not true?

MR. HEWES: I think they would play her videotape and say she said this in Congress and we will show here that this wasn't properly investigated, and they'll put on people to say that perhaps the adverse event reports weren't properly follow up on.

THE COURT: Yes.

MR. HEWES: But --

(Pause in proceedings.)

MR. HEWES: Ms. Jones always says it better than I could, Your Honor. It's the -- it's the adverse inference that could be drawn from referencing a Congressional testimony or lying to Congress.

(Pause in proceedings.)

THE COURT: Okay. All right, I think I --

MR. HEWES: Thank you, Your Honor.

THE COURT: Thank you very much. And you're fine with respect to this motion with that -- with Mr. Millig's list of those issues that they won't be covering unless there is a door open somehow, and then we can take a break and talk about it during trial?

MR. HEWES: We can certainly talk about it during trial, Your Honor. We don't intend to open the door to allow any of this type of testimony in and we would --

THE COURT: Right.

MR. HEWES: -- object for the same --

THE COURT: Doesn't sound like the plea deal or a consent decree or manufacturing quality control issues are going to be part of the plaintiff's case, nor should they be. Okay. Okay. Thank you.

(Pause in proceedings.)

MR. MILLIG: Your Honor?

THE COURT: Yes?

MR. MILLIG: Could I make a suggestion? And I think the defense will agree with it. If we're going to move to Dauberts, the way the Court has them organized, I think it would make more sense if we did Mr. Rationale (ph) and then did Ms. Jones. They are the -- they're the same issue. And then the other two are the treaters in the case.

THE COURT: Okay.

(Pause in proceedings.)

THE COURT: Okay. All right, let's take about a five minute recess and then we'll move into a discussion of those dauberts.

(Recess, 11:36 a.m. to 11:58 a.m.)

THE COURT: Please be seated.

(Pause in proceedings.)

THE COURT: Okay. We have daubert motions to argue regarding Gerald Rationale (ph), Gordon Sea (ph), Greg Smith, and Judith Jones. And, Mr. Millig, your proposal was to argue Rationale and Jones together?

MR. MILLIG: Rationale and then follow Judith Jones. They're the two reg -- both regulatory.

THE COURT: Okay. All right, I'm fine with

that. Are you fine with that, Melissa?

MS. MAZUR: That's fine.

THE COURT: Okay. Ms. Jones --

MS. C. JONES: They are both in the same --

THE COURT: -- I was wondering when we were going to hear from you this morning.

MS. C. JONES: You know, my troops have been sitting back there telling me to keep my mouth shut, I might set something up. So I hope --

THE COURT: I don't think that's -- I don't believe that.

MS. C. JONES: -- that I don't do that. I have --

THE COURT: It's binder day from the defense table.

MS. C. JONES: I'm here to address, Your Honor, only the motion in limine with respect to Rackono.

THE COURT: Okay.

MS. C. JONES: Or Rationale. I'm not -- I thought it was Rackono.

THE COURT: I --

MS. C. JONES: I noticed that --

THE COURT: I don't know.

MS. C. JONES: -- Mr. Millig pronounced it

Rationale, but --

MR. MILLIG: It is Rationale.

THE COURT: It is what?

MR. MILLIG: It is Rationale.

THE COURT: Rationale.

MR. MILLIG: Jerry Rationale.

MS. C. JONES: So in any event, what I want to remind the Court is that we are bringing this motion on -- for hearing on one very narrow, discrete opinion that has been offered by Mr. Rationale. I don't want to be misinterpreted as saying that there will not be other objections as to admissibility, but I think all o those can be taken up at the context of trial. So we're only talking for purpose of this motion to challenge Mr. Rationale's opinion that Tylenol or acetaminophen has not been generally recognized as safe and effective by the FDA.

We have set forth in the briefing our physician that it is not properly admissible, first, because it represents a legal opinion that's not properly admissible, and I'll suggest to Your Honor that it's not properly admissible even under Your Honor's opinion in the Wellbutrin litigation, which obviously recognizes that under certain circumstances, it's appropriate for an expert to outline, you know,

procedures and practices that may fall within certain guidelines. But what I really would like to talk about this morning primarily is the fact that the plaintiffs have not demonstrated the reliability of Mr. Rationale's opinion, and that's where I want to focus.

As Your Honor well knows, the Rule 702 sets forth the over-arching requirement, as set forth in the comments there, of reliability and an analysis of the sufficiency of the expert's basis cannot be divorced from the ultimate reliability of the expert's opinion. And I suggest to you that in this case the plaintiffs have not established the reliability of either the underlying methodology or the reliability of Mr. Rationale's opinion on the issue generally being recognized as safe and effective in large part because his conclusions are directly in conflict with those of the FDA, repeatedly acknowledge by the FDA, and the FDA is the very agency that regulates Tylenol and acetaminophen by statute.

That opinion that we're talking about specifically ignores the factual history as relates to acetaminophen and as relates to Tylenol, and in effect would rewrite the history of the last 40 years or so. The reason I say that is -- and the reason -- that's the reason, in fact, that we know that Mr. Rationale's

explanation that he simply read the regulations and came to that conclusion is an insufficient basis to rely upon that methodology.

What I'd like to do, Your Honor, is just to briefly kind of go through and remind Your Honor of the history that's applicable that I think makes this clear. As Your Honor will recall, in 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act, and under that act, in order to mark it -- legally mark it drugs in the U.S., there had to be a showing of safety.

THE COURT: Yes.

MS. C. JONES: And safety is the key issue. In 1951, you had the Durham-Humphrey amendment that was enacted, and that was the legislation that separate drugs into prescription versus over-the-counter categories. And the over-the-counter drugs, such as acetaminophen then were made available over the counter because the commission of the FDA in effect made a determination that the drug was safe and effective for use in self-medication, as directed on the proposed labeling.

In 1962, you had the Harris-Caphaupher (ph) amendments, and the importance of the Harris-Caphaupher amendments was that at -- for the first time, there was a separate requirement that efficacy, the fact that the

drugs worked, be established. And that -- those set of amendments grandfathered in, if you will, drugs marketed between 1938 and 1962, but they were still held as a requirement of establishing efficacy. And you'll remember that since 1955 I think, acetaminophen and Tylenol had been on the market and already approved at that stage.

Subsequent to that, in 1966, the drug efficacy study implementation, what's been called DESI, was implemented, and it was under that that the FDA took and they separated about 4,000 ingredients from the grandfathered drugs with thousands of therapeutic claims and required a review of the efficacy of those drugs.

In 1972, acetaminophen received its DESI classification -- bless you -- as effective. Now, remember it had already been held -- I mean required to be shown to be safe under the initial 1938 Food, Drug, and Cosmetic Act. It was categorized as a category one drug, which meant that, by definition, it included safety and efficacy.

In 1975, the FDA approved as safe and efficacious extra strength Tylenol. Now, that was under a new drug application, Your Honor, and at tab two we have -- then the book I've given you just has

the references to the various statements where the FDA has found it to be safe and effective.

Interestingly, in 19 -- when McNeil initially submitted the new drug application it submitted it with a request that it be a prescription drug, and the FDA said no, we'll approve it as an over-the-counter drug. But at that time it clearly had carried the definition of safety and efficacy.

THE COURT: Yes.

MS. C. JONES: In 1977, and this is in your notebook as tab three, the FDA established the monograph process for the internal analgesic antipyretic and antirheumatic products in which acetaminophen was classified. And if you look in your books, Your Honor, and I -- we have -- I've highlighted it for easy reference only because the federal register sites get a little bit verbose sometimes --

THE COURT: Yes.

MS. C. JONES: -- and difficult to find something. On page 35347, you'll see that acetaminophen was assigned to those drugs classified as category one, generally recognized as safe and effective and not misbranded. And that appears in both 35347 and on 35349, and on page 35412, the advisory review panel concluded acetaminophen is a safe and

effective over-the-counter analgesic when taken as -- in the recommended dose.

Subsequently, in 1988, the FDA issued the tentative final monograph for those products, and that's what you find under tab four is that actual final monograph. There the FDA adopted the advisory review panel's report, including its classification that acetaminophen was a category one analgesic generally recognized as safe and effective, and concluded that that panel's categorization of those drugs would remain unchanged.

In 1993 -- and this is tab five I believe -- 1993, the FDA specifically issued a final rule for categories two and three, those drugs that were not deemed to be generally recognized as safe and effective, and specifically, acetaminophen was not included in that regulation.

Now, after that and repeatedly, the FDA has specifically referenced the fact that its findings have been that acetaminophen is a safe and effective product when taken as directed and attached is -- tab six, for example, is the proposed final rule for organ-specific warnings where specifically they've said, and it's highlighted in your booklet at different pages, that the FDA recognizes acetaminophen and insets when

labeled appropriately and used as directed, as safe and directed over-the-counter products, should remain available over-the-counter products given their overall effectiveness and safety, continued to be generally recognized as safe and effective and so forth. And all of those statements were made in 2006.

In 2007, you had -- 2009, excuse me, you have under tab seven the proposed -- or the actual final rule for the organ-specific warnings that notes that they continue to consider acetaminophen to be safe and effective. And then you have attached as tab eight and tab nine the additional statements by the FDA which have recognized that acetaminophen is generally considered to be safe and effective.

I put all of that forward, Your Honor, in large part because it's clear that Mr. Rationale's opinion on this issue is diametrically in contrast with the factual history and the statements that have been repeatedly acknowledged by the FDA and have consistently resulted in the FDA allowing acetaminophen and Tylenol to remain on the market as an over-the-counter product. And for that reason, I suggest to Your Honor that Mr. Rationale's opinion that it has not been shown to be safe -- generally recognized and safe and effective simply because there is not a tentative

final monograph is inconsistent with the positions and history set forth by the FDA, and in and of itself, that demonstrates the unreliability of Mr. Rationale's opinion here.

I point out to Your Honor that if you look at the Inmate Paoli case from the Third Circuit that one of the things that the Third Circuit recognized was that it's not that the proponents have the obligation to demonstrate by preponderance of the evidence that the opinions are correct, but they must demonstrate that the opinions are reliable. And in this case I suggest to Your Honor that there's simply an insufficient basis upon which to include that the opinion of Mr. Rationale is reliable and, in fact, that it is so inconsistent with the positions taken by the FDA that it would be misleading to the jury. So I think --

THE COURT: Does the lack of reliability stem from the method at which he obtained his opinion or got to his opinion?

MS. C. JONES: Well, I think if when he was asked what the method was he stated I simply read the regulations.

THE COURT: Right.

MS. C. JONES: And I would suggest to Your

Honor that while that might be appropriate, one, that is demonstrated to be inadequate because -- or unreliable because there is no showing that he separately reviewed all of the other statements, pronouncements, and so forth by the FDA over time with historical accuracy. But more important, that then back you into the fact that Mr. Rationale is actually testifying as to a conclusion of law because what he's then doing is he's offering a legal conclusion as to what the regulations say.

It's an interpretation of those regulations, which even the plaintiffs suggested, at least when this issue was argued in New Jersey, was improper. And I put back in tab 12 the plaintiffs' brief at that point in time which suggested that that would, in fact, have been a legal conclusion that they were not recognizing. And I -- we have here under tab one Judge Johnson's opinion where he found that the -- that Tylenol had, in fact, been established to be generally recognized as safe and effective.

Now, in all fairness, Your Honor, I don't want to mislead the Court, it was not -- that finding was not made in the context of a daubert or kemp-type motion there. That was on another issue. But his finding is inconsistent with the opinion that is being

offered here by Mr. Rationale.

So I'd suggest to Your Honor that the other issue that I would call Your Honor's attention to is if you look at the comments to Rule 702, the advisory committee notes that there are occasions where not everybody is a -- not every expert is a "scientific-type" expert that necessarily the daubert-type criteria looking at methodology and so forth applied to. But nonetheless, the courts can look at that and consider whether or not, and should consider whether or not, the opinions are, in fact, reliable. And that's what I would suggest to you is that I think that we can say in this case methodology which simply incorporates by his own testimony a reading of the regulations is inadequate when he has not considered the promulgation of the final rules and all of the other statements that have been made over the period of the last 40 years, including the finding that extra strength Tylenol is safe and effective and should be marketed as an over-the-counter product. And separately, the fact that he ignores the findings, the reasons that I go back through, Your Honor, the historical development of the law, is that when you understand that beginning in 1938 there was a requirement of showing of safety, and then separately, beginning in 1962, there was a requirement

of showing of efficacy, which the FDA found acetaminophen had been when it categorized it as a category one drug as safe and effective, it's for those reasons that we believe that that opinion in and of itself is unreliable and should be excluded.

THE COURT: Okay.

MS. C. JONES: Thank you, Your Honor.

THE COURT: Thank you very much.

(Pause in proceedings.)

MR. MILLIG: Good afternoon, Your Honor.

THE COURT: Good afternoon, Mr. Millig.

MR. MILLIG: Let me see if I can just put some things out there for you to help us communicate, and I'll get right -- I'll get right to it. The issue in this case is really -- it's really -- we can call it a legal conclusion, we can call it a regulatory fact, we can call it anything. But this today, not Tylenol, but acetaminophen, does it have the regulatory status, not some writing that says it's generally safe and effective. But does it reg -- does it have the regulatory status of what is called generally recognized as safe and effective and not misbranded? And when -- and that's not for a product. And you don't have to have that to be sold or marketed, which keeps coming up.

Older products are either GRASE or they're proposed GRASE or they've been removed, as Ms. Jones showed you some have. And Ms. Jones wants to stand in front of you and say it's GRASE.

Acetaminophen as generally recognized as safe and effective, which means that anybody in this country can go to the federal register and go to the part where the final monographs are and look up how to manufacture acetaminophen and come up with the exact dosing and rules and regulations of acetaminophen.

It means that all the safety questions of acetaminophen have been answered, and it means that anybody can start manufacturing acetaminophen without even going to the FDA.

That's not the case with acetaminophen. There's no final monograph. But I'm going to do it -- I'm going to -- I'm going to take this one step further and I'm going to show you -- walk through Ms. Jones, but then I'll suggest to you where the answer is. Ms. Jones criticized Jerry Rationale for methodology, for looking at the statutes. I think she also -- what she omitted or maybe not unfairly, but nobody wants to stand up on the defense side and say Mr. Rationale is, in fact, the world expert on the monograph. He was the regulatory counsel for 30 years. He wrote the

documents that Ms. Jones is referring to.

He didn't just read the regulations, Your Honor. He has lived the entire monograph process. He is an author on the monograph. He has personally reviewed every document that McNeil has submitted as it relates to acetaminophen to the monograph division of the OT -- of the -- of the FDA.

I'm going to come back to it, but after we discuss GRASE I'm going to explain how important it is for somebody to explain the regulatory system to the jury who really understands it.

He is imminently qualified. The defense does not take issue with it. What Ms. Jones did is she read you from the regulations, and I'd like to briefly just walk you through them real quick if you have a moment. And if we go to tab two in the binder, tab two in the binder, Your Honor, is the approval letter for extra strength Tylenol when it was under the NDA regulatory system.

It has absolutely nothing to do with GRASE. Tylenol was -- under a total separate regulatory scheme, was deemed to be safe and effective with a specific set of instructions, which at the time says to take every three to four hours, not even the instructions that were in play in this case.

This NDA, you cannot file to it, use to file, you cannot put anything in this document -- in this docket because it has been withdrawn, as the Court is aware. If we go to tab three, this is the panel report. A bunch of scientists got together for five years, and if you go to the very first sentence of the whole document, which is on page 35346, it tells you right there it's a proposed rule. This is a proposal, and I want to keep coming back and have the Court and everybody in the courtroom focused on the word "proposed."

This is a proposal of scientists that acetaminophen should be category one. It's not the FDA saying it is category one and scientists are not allowed to say it's category one. Even we'll see Ms. Jones, Ms. Judith Jones -- there are three Jones in the courtroom, two lawyers and one expert. Ms. Judith Jones will tell you that only person -- the only (indiscernible) can determine whether a -- whether an ingredient such as acetaminophen is GRASE is the FDA, not doctors.

If we go to tab four, this is the document that Jerry Rationale write, the tentative final monograph, the pivotal document in the whole case. What is it? At the very top, it's a notice of proposed

rule-making. Summary, "The FDA is issuing a notice of proposed rule-making." This is what we might do in the future. On the right-hand side, second to last paragraph from the bottom under the bold word "Register" on the right column, "In order to confirm to terminology used in the OTC drug review regulations, the present document is designated as a tentative final monograph. It's legal status, however, is that of a proposed rule.

(Pause in proceedings.)

MR. MILLIG: One second, Your Honor.

(Pause in proceedings.)

MR. MILLIG: Within this document I believe -- actually, I'm virtually sure it's on the next page, but I can't put my finger on it. It also says -- I believe Your Honor quoted it in one of the motions. It says, "Final regulatory action will take place with the publishing of a final monograph in the future." This is a proposal.

If we go to -- and Mr. Rationale, again, you can't get -- it's really hard to get better than the person who drafted it. Tab five, Ms. Jones again using the same methodology she's criticizing Mr. Rationale for, looking at this -- looking at the regulations, she says, look, there's a list of -- there's a list of drug

ingredients that we say are category two and three, but acetaminophen is not included. That does not equate with we determined that this is category one and all safety questions have been answered. This is an irrelevant document. It doesn't make sense. Well, it does make -- it does make sense if you don't think it through, but this is saying we've determined as of this date, in the federal register, 1993, that these ingredients are going to not be -- are going to not be category one. We have still have not made a determine that acetaminophen is a category one.

If we go to tab six, Ms. Jones walked you through 2006. It's a proposed rule. The Food and Drug Administration was making a proposal in the federal register. Again, we haven't seen anything in the Code of Federal Regulations, where the final monographs are published. All we've seen is discussion by the FDA in an administrative format of proposals.

Tab seven, this is a final rule, but it's important. This is a final rule, and if --

(Pause in proceedings.)

MR. MILLIG: If you go back, Your Honor, if you look where is this -- this is a final rule. And I want to begin by showing you that it's not -- that it's not on point. If you look, this is going to -- this is

proposed to be published in 21 CFR Section 201. Do you see that, Your Honor?

THE COURT: Yes.

MR. MILLIG: Go back to the tentative final monograph, 1988, which is tab four. The monograph history of acetaminophen goes in 21 CFR Sections 310, 343, and 369. It does not go in this document. This is a -- 201 has to do with just a labeling rule, not a decision on whether an ingredient is GRASE. And so this is the document that says as it relates to labeling, you have to put this one sentence in about severe liver damage. But what's important about this document, Your Honor, is on the right-hand column where it begins about just below the -- where it says HIV. Do you see that, Your Honor?

THE COURT: Yes.

MR. MILLIG: Okay. It says, "The document states our final conclusions on the labeling of Section 201 and requires manufacturers to include this labeling on all anti-pyretic and anti-rheumatic drug products."

THE COURT: Which page are you on? I'm sorry. I --

MR. MILLIG: I'm on the first page of the document --

THE COURT: Right.

MR. MILLIG: -- third column.

THE COURT: The middle column --

MR. MILLIG: No, third column to the right.

THE COURT: Third column.

MR. MILLIG: I'm reading just two lines down behind where it says "HIV."

THE COURT: Yes, "This document states" -- go ahead.

MR. MILLIG: Okay. And if you go where it says "Dates" -- do you see in that paragraph it's all --

THE COURT: Yes.

MR. MILLIG: -- all bold, the word "Dates?"

THE COURT: Right.

MR. MILLIG: Here's the important part. "We, the FDA, are currently evaluating data and information regarding the remaining issues discussed in the proposed rule, some of which include the following." So let me stop right there. What is the FDA saying? They're saying we haven't gotten an answer to all the questions regarding acetaminophen to our satisfaction in order to create a final monograph. We are still not sure what the safe daily dose is, the safe daily dose for people with chronic liver disease, the safe daily dose for people who drink alcohol, package size

restriction, pediatric. It goes on to the -- to the next page.

There are open questions related to acetaminophen that the FDA has not addressed, including combinations with MAC or Methaniaide. They're still open and they're still ongoing. And that's why the status of acetaminophen as it relates to the regulatory determination of whether the product -- whether the ingredient -- that's what the term of art is -- is generally recognized as safe and effective, is that it's proposed. So what did I do? And if the Court's not convinced, I will ask the -- I would just encourage the Court to do what Mr. Rationale told me to do. He said e-mail the FDA and they'll tell you the answer. So I did. And you could just tape those to this if you want or not, but I e-mailed the FDA and they actually responded. I e-mailed them through their website.

If you read from the second page, it begins with my e-mail on the second page that says, "Hey, is acetaminophen GRASE?" And by golly, I got a response two months later that says, "Mr. Millig, your question below regarding whether or not acetaminophen is GRASE was forwarded to me in the regulatory department of the non-prescription drug products."

It talks about the tentative final monograph

for this, "In the tentative final monograph, FDA proposed that acetaminophen is generally recognized as safe and effective and not misbranded" -- that's exactly what Mr. Rationale said, "as an analgetic anaphylactic drug if it meets the conditions described in the TFN and the conditions in 330.1. Pending publication of a final monograph, FDA does not object to it being marketed as long as you follow the TFN."

So its proposed status -- but I wanted to be clear, so I wrote them back and I said in the e-mail, I said, "Thanks, Jade, for that answer. But the real question is simply given that there has yet to be a final monograph published in the CFR, is acetaminophen considered to be GRASE from a regulatory standpoint? I totally get that the drug can and is marketed pursuant to the tentative final monograph and final labeling rules, but does it carry the regulatory status of GRASE without a final monograph? Thanks. I really appreciate it."

"Hi, Clay. In response to your question, pending publication of a final monograph, the category one GRASE status of acetaminophen remains proposed." So it's almost -- it's not an -- it's not an opinion. This is what it is. And the suggestion by the -- that's been going on for years that because people say

it's safe and effective, well, it is generally safe and effective. But coming back to Dr. Rationale, Jerry Rationale, his methodology is the same as Ms. Jones used. And he's vital and super important in this case.

This was confusing to a jury and it was confusing to me until I met Mr. Rationale and really dug into this stuff. The jury is going to need somebody in this case, Your Honor, to articulate and help them understand the NDA system, the monograph system, and really the fact that it's okay to be proposed, that there are thousands of drugs out there like acetaminophen that are older drugs that don't have a final monograph. And you don't have to be -- have a final monograph to be sold. But when you don't have a final monograph the burden is on the company to make the changes. And we know that because in the monograph regulations itself -- and I believe Your Honor may have cited to these --

(Pause in proceedings.)

MR. MILLIG: Ms. Jones made the point about how acetaminophen has come up through the DESI system. And in the monograph regulations -- and we've brought these to the Court's attention before. 21 CFR Section 330.12, that is a regulation and it says, "Manufacturers and distributors should take notice that

the information on OTC drugs provided by the DESI review is valuable information as to the deficiencies in the data available to support indications for use. They," manufacturers, "are encouraged to perform studies to obtain adequate evidence of effectiveness for the review of OTC drugs," that's the monograph review, "which is already in progress.

"In the interim," meaning while your drug is proposed and not a final monograph, "it is in the public's interest that manufacturers and distributors of all OTC drugs, like acetaminophen, affect changes in their formulation and/or labeling to bring the products into conformity with current medical knowledge and experience." That's the policy the FDA is saying when you're in the system, you take action to make changes. And that's why we know, Your Honor, that when McNeil took the voluntary step to with -- to lower the dose the FDA wrote the letter that you've referenced that said hey, it's under the tentative final monograph. Manufacturers can do this and are free to do it at all times.

So is acetaminophen GRASE? No, it's proposed GRASE and that's just a fact. Is it -- did Judge Johnson rule the other way? Yes, but he's ruling it -- ruling on it based on whether or not it was -- for

the -- for a certain New Jersey statute that says if you're generally sold and safe, you don't get punitive damages incurred with you. He was -- that was his -- the lens of looking at this. But the answer is pretty clear. "Hi Clay. In response to your question, acetaminophen is proposed."

Mr. Rationale, I can't overstate it, is super knowledgeable on this and super kind and a good teacher, and this jury needs a good teach to explain to them this regulation and to help them understand this, and you've said on the Wellbutrin case and other courts that have said the same things, that complex regulatory statutes that are in play in a case need to be -- often times an expert is needed to explain them. And I would submit this is one of those times. It's hard to understand what an NDA is and why it's okay to be proposed because I don't think that -- that just doesn't come naturally. And the defense has not argued with any of the other opinions that Mr. Rationale intends to offer about the case. He'll explain the monograph system. He wrote it. He'll explain how it works. He lived it. And he was the chief counsel. And thank you for your time.

THE COURT: All right. Thank you, Mr. Millig?

MS. C. JONES: May I respond just briefly, Your Honor?

THE COURT: Sure.

MS. C. JONES: First, for the record, and I'm not sure this is appropriate, but I don't know any other way to do it having been handed an e-mail from counsel to somebody at the FDA. I move to strike that as being an inappropriate submission. I point out to the Court that it appears to be from Clay Millig to somebody named Walter Ellenberg (ph), and it says, "Hey, is acetaminophen GRASE or generally recognized as safe and effective," and I point out to Your Honor that there's no demonstration at all that this is an official response and, you know -- or anything other than hearsay, certainly not an FLI request.

Secondly, Your Honor, I would point out -- and I guess I ask Your Honor to consider whether or not it's logical to take the position that a drug that's been on the market since 1955, after separate findings of safety and efficacy, is not generally recognized as safe and effective, and specifically, to look at tab four on the proposed final monograph, Your Honor, on page 46248. In the right-hand column it says, "The agency's tentative adoption of the panel's report," and it says specifically -- I think I referenced it, but I

was in a hurry and didn't go through this -- that it says, "The agency has reviewed all of the claimed active ingredients submitted, as well as other data, and concurs with the panel's categorization of ingredients. In addition, the agency has reviewed three ingredients not reviewed by the panel for the convenience of the reader." And then it goes on to demonstrate that the agency concurs with the panel's classification of acetaminophen as category one, safe and effective.

Then, on the second -- if you turn the page and you look at the first full paragraph after the column, it says specifically, "After reviewing the available data and information, the agency has concluded that the panel's categorization of ingredients for safety and effectiveness as analgesic (indiscernible) will remain unchanged."

So I simply suggest to Your Honor again that it is misleading and inconsistent with the agency's history to suggest that acetaminophen is not generally recognized as safe and effective. Thank you, Your Honor.

THE COURT: Which might -- which might speak to the need to have the regulatory expert just explain what all this means, right?

MS. C. JONES: I --

THE COURT: I mean these are not necessarily inconsistent.

MS. C. JONES: Let me -- let me make myself perfectly clear. And we got Dr. Jones as a regulatory expert that is coming up, and we're not challenging -- there are -- there are certain limitations as to what a regulatory expert can testify to --

THE COURT: Yes.

MS. C. JONES: -- and it certainly is within a regulatory expert's ability to testify as to the appropriate procedures and so forth that are applicable under these circumstances, but a conclusion of law, number one, or number two, a separate suggestion that acetaminophen has not been recognized as generally safe and effective by the FDA, is an unreliable statement and misleading to the jury. You see, the -- I mean you got a product that's been on the market that the FDA has specifically said we're putting them in category one, it's safe and effective, it's been established pursuant to the Food, Drug, and Cosmetic Act as safe, under the Harris-Caphaupher amendments as effective, and repeatedly approved by the FDA under the NDA process as safe and effective and allowed to remain on the market.

So for a witness to come in here and testify that it has not been recognized as generally safe an effective I think is misleading to the jury.

THE COURT: All right. I think I get your point. All right, thank you.

MS. C. JONES: Thank you, Your Honor.

MR. MILLIG: Your Honor, may I have one minute to just clarify something?

THE COURT: I really need to move on --

MR. MILLIG: Okay.

THE COURT: -- or else were done, okay?

MR. MILLIG: I'm sorry.

THE COURT: I need to move on.

MR. MILLIG: Thank you.

THE COURT: So let's talk about Judith Jones, and then I have a sentencing at 2:00, so I'm going to have to break after this.

(Pause in proceedings.)

THE COURT: This is your motion to exclude Judith Jones, right?

MR. MILLIG: I'm just getting a few things together and I think I'll be good.

(Pause in proceedings.)

MS. C. JONES: Can I ask just a scheduling issue, Your Honor?

THE COURT: Sure.

MS. C. JONES: Does that mean -- is this going to be the last argument that we're going to have for the day?

THE COURT: I'm going to have to make it the last, yes.

MS. C. JONES: No, that's fine. I just am -- we had Mr. Cohen here and that's fine. That's not a problem.

(Pause in proceedings.)

THE COURT: What's Mr. Cohen arguing?

MR. MILLIG: Mr. Gainer is here as well and our preference, Your Honor, would be --

MS. C. JONES: No, no, that's fine.

MR. MILLIG: What's that? But he does as well.

MS. C. JONES: Oh, I'm --

MR. MILLIG: Yeah, Mr. Gainer is a plaintiff too for his witnesses. So both of the -- both of the lawyers for the other two would have planes.

MS. C. JONES: No, no, I have a plane to catch if we're not going to hear those. That's what I was addressing.

MR. MILLIG: Oh, okay.

MS. C. JONES: That's it.

MR. MILLIG: I --

MS. C. JONES: Go ahead.

MR. MILLIG: Okay. Your Honor, I wanted you to hear these arguments back to back so we can all talk about GRASE and regulatory only once. We are challenging Judith Jones in her entirety and certainly challenging multiple opinions that she offered at her deposition and had referenced in her report as conclusory, speculatory, replete with factual and legal errors, based on insufficient facts in the record, unreliability, based on a review of only a few samplings of documents, and an interpretation of FDA regulatory law that she even acknowledges is correct at times during the deposition.

Rule 702 says that evidence must be excluded if it's not based on sufficient facts or data, that it is not the product of reliable principles and method, or that it is not generally applied -- or that is not reliably applied -- the principles are not reliability applied to the facts. This courtroom is not a place for guesswork.

I want to take you through a few of Ms. Jones' opinions that she offered and help -- in order to help the Court understand why we seek her exclusion. And it may be worth even asking the defense if they

intend to call or if they withdrew her in the New Jersey litigation. My first is --

THE COURT: Will she be called?

MR. MILLIG: What's that?

MR. HEWES: We certainly don't plan to withdraw her at this point, Your Honor.

THE COURT: Okay.

MR. MILLIG: They -- Ms. Jones offered opinions related to the labeling and labeling changes of Tylenol. If you read her report, which I know Your Honor has, she repeatedly says that the FDA and not the manufacturers ultimately are responsible for the content of the label. She says it's very difficult for a company to change the label for OTC products under the monograph system. Paragraph four, 13, 14, and 15 in the report stand for those propositions.

On paragraph -- on page four of her report, paragraph 18, she says the final responsibility for labels and final decisions on label changes belongs to the FDA. I asked her if that opinion was consistent with the law of the land and I asked her if -- in her deposition I quoted in the brief, "Is that consistent with the law of The Supreme Court of the United States?" And her answer was, "It is not supported by the decision of that particular court at this time."

Your Honor cited the Wyeth decision and the motion to dismiss orders. The defense might try and argue that this is not a prescription case and it's an over-the-counter case, but as Your Honor knows from the letter from the FDA saying you can freely change under a tentative final monograph and people do it all the time. An regulatory expert who takes the stand in this case and it was to suggest -- it was just having a -- to any of us in here that the FDA is responsible, that it's hard to make changes, and the final decision belongs to the FDA in an over-the-counter product that mono -- that's regulated by a tentative final monograph. It's just wrong.

We cited, Your Honor, to the case of In Re Gadolinium where the Court was faced with the same conclusion, and based on that piece alone, excluded the witness' testimony. You can't just come in and testify contrary to The United States Supreme Court. And if you're saying that, it casts doubt on the integrity of your report, as well as the knowledge base upon which you're testifying.

Dr. Jones says changing the label of an OTC monograph product is difficult. She says McNeil cannot and would not make the changes without the FDA approval. She says there's a multi-step rule-making

process contained in the monograph regulations for changing a label. I asked her if she had seen the letter to Mr. Gainer where the FDA -- we are all familiar with where the FDA said manufacturers are free to change the label any time they want, taking into consideration the TFN. She was not provided the label by -- that letter by counsel. She was unaware of it. But then later in her deposition she flip-flopped and said she totally acknowledges that McNeil voluntarily lowered its dose, that they did it without any instruction to do so by the FDA, and that they could have done so since 1988 under the tentative final monograph.

She conceded in her deposition finally, after stating the facts that you can't make changes, that, in fact, there was a regulatory allowance to change the label without consultation with the FDA. So she's over here with her opinions, but then when confronted with the law she says I wasn't aware of the law and I wasn't aware of the facts from the case because I wasn't provided by counsel.

Number three, she makes a statement which is inappropriate for an expert and is the -- is in the province of the jury. She opines that the warnings for Tylenol were at all times appropriate. That's what the

jury is supposed to decide. If the Court looks, and I'm sure the Court has, 15 pages of Ms. Jones' report from page 26 to 41 entitled "Labeling" is nothing more than an overview of the history of Tylenol. It is 15 pages without one reference to any of McNeil's actions about the -- about Tylenol.

When she was -- Ms. Jones says the labeling was adequate, she did not review company documents in the -- in the case, she did not review depositions in the case, she did not review the clinical trial data, she did not review reports from outside experts like the -- her name's escaping me -- the FDA expert who came in and found a signal with acetaminophen at low dose. She was not giving any pharmacovigilance department testimony or documents.

Her file was this thin and she was going to make a statement that McNeil's warnings were all appropriate at all times? She -- every piece of evidence that virtually that this jury is going to be called upon to assess this very question, was McNeil's labeling appropriate, did McNeil -- was in appropriate in terms of risk assessment of the product and did it warn the consumers and take appropriate action, she wasn't provided by counsel. And it showed during here testimony.

She then went on to say not only are the labels fine, but without looking at documents, I'm going to tell you that acetaminophen is safe at four grams too. She hasn't been in -- practiced internal medicine or pharmacology for decades. She's not a hepatologist. She did not review any McNeil scientific data that would shed light on this and she did not review any of the depositions of the medical directors. Pharmacovigilance, she didn't review McNeil's animal studies, in vitro studies.

One of the key phrases Your Honor has come to hear in this case and the jury will come to hear is that when you are looking at a drug's risk profile we look at various -- multiple lines of evidence. What do we see when we look at clinical trials? What do we see when we look at animal studies? What do we see in the pop -- human population? Her answer was I didn't review them in detail. I reviewed some of them. That's on page 19 of our brief.

She says that McNeil at all times practiced appropriate pharmacovigilance. That's the jury's decision. But she even admitted in her deposition that she's speculating. She was not provided the deposition of Dr. Kenneth Kwon. He discussed multiple deficiencies. She was not provided with the report

from Quintiles that McNeil -- she never even heard of this document, one of the key documents in the case from Quintiles, McNeil's own company that audited pharmacovigilance and found critical deficiencies with it.

She goes on to say in her report -- and this is, again, I guess stepping back, her whole report is conclusory and just glossy and it's not filled with anything. She says she was particularly impressed with McNeil's review of medical literature. Particularly impressed this expert says. And I asked her during the deposition how she knows that the company carefully examined medical literature, as she stated in her report that she was particularly impressed. And her answer was well, I don't, I haven't provided a basis for that. She didn't read the -- all she did was she was given four or five annual reports that have summaries of some articles. And annual reports, Your Honor, again, are the NDA side of the FDA. They're not the monograph side. And she wasn't given all -- this drug has been ongoing for 30 years and this -- an expert is going to come in here and say great pharmacovigilance, I didn't look at the information, great review -- reporting of adverse events, it's really hard to change the label.

Then she comes on to say that it's GRASE and she says that -- on page 11 of her report she says that the doctors in the advisory panel determined it was GRASE. And she says that -- on page 11 of her report that they were required to determine a list of ingredients and to decide whether the ingredients were safe and effective and to place the ingredients into categories. And as we just saw when we looked at the 1977 report from the doctors, and as Mr. Rationale will tell the jury, that is not at all what the doctors did. They didn't decide anything. They didn't determine anything. They just gave their thoughts based on 1977 science to the FDA.

THE COURT: All right, let's wrap it up.

MR. MILLIG: Okay. She ultimately says -- when I asked her if it was GRASE her answer, Your Honor, is this. I think it's important. She said exactly what Ms. Jones said. Number one, there are lots of places where it says it. Number two, there is a document that says the -- it's not category two or three, or it's not included. And so finally she says it's GRASE by implication. Those are not appropriate opinions to be offered in a case of this sophistication and magnitude to this jury, and we would ask that Ms. Jones not be allowed to testify.

THE COURT: Thank you.

MR. HEWES: May I respond, Your Honor?

THE COURT: Go ahead, Mr. Hewes.

MR. HEWES: Briefly, Your Honor. Dr. Jones is imminently qualified to offer the opinions she sets forth in her report. In tab one of the Dr. Jones tab I lay out her CV, and I do not intend to go through it, but rest assured she's a former FDA division director. She spent -- she has spent 27 years working as a president of a research and regulatory company, she has authored or co-authored over 100 peer-reviewed journals on this topic.

I don't think Your Honor wants me to go through the regulations that were hashed through by Mr. Millig and my partner, Ms. Jones, so I won't do that unless Your Honor is inclined to hear them again.

But suffice it to say, if we go to the reliability aspect, which we argued as to Dr. Rationale -- excuse me, Mr. Rationale, the opinions cited by Dr. Jones are not only supported by the Code of Federal Regulations, but they are also supported by the FDA's pronouncements in the various federal registers.

The only one I would point to, Your Honor, which has been highlighted is to maybe shed a little bit further light on the question of whether the FDA

had proposed for acetaminophen as safe and effective or not. I think it's put to bed if you look at tab seven, which is the final rule, Your Honor, on page 19402.

Briefly, the final rule was enacted to mandate a labeling change to add the words "liver damage" or "severe liver damage" to the acetaminophen label, a move which McNeil had done five years prior with adding liver damage. On page 19402, left column, Your Honor, right in the middle, the FDA is talking and the FDA says -- and we're talking about the new warnings, "We find that there is sufficient incidence of liver injury associated with acetaminophen to warrant new labeling," And here's the -- here's the key language, "and that without the new labeling, acetaminophen products would no longer be considered generally recognized as safe and effective."

The FDA doesn't say the acetaminophen products without this labeling will no longer be proposed to be considered GRASE or GRASE or however you say it. It says we will not longer consider them GRASE if this new -- if these new labeling changes don't occur. This is in 2009 some several decades after the tentative final monograph was implemented. So her opinions are consistent with the regulations, they are consistent with the FDA's pronouncements.

The plaintiffs' beef with her opinions are better suited to cross-examination at trial, as discussed in the Reese v. Barley case, 2008 West Law 2653670 from Pennsylvania, which ultimately holds, "A plaintiff's disagreement with conclusions and opinions of experts is grounds for cross-examination, but is not a proper attack under daubert."

Now, the irony is not lost on me, Your Honor, that the plaintiff spends the majority of her argument suggesting that Dr. Jones relies on improper regulations or gets the regulations wrong. When on page 13 of plaintiffs' brief, which is the cornerstone of their argument that Dr. Jones' labeling opinions are incorrect, the plaintiffs say, and I quote, page 13 of their brief, "The regulation is found -- as to labeling is found at 21 CFR Section 201.80 in the Code of Federal Regulations is entitled 'Labeling Requirements of Over-the-Counter Products.'" Again, plaintiff quote, the regulations 201.80 in the Code of Federal Regulations and is titled "Labeling Requirements for Over-the-Counter Products."

If Your Honor would turn to tab 12 of the exhibit notebook I provided Your Honor under Dr. Judith Jones section, we see Section 201.80, and I would point out that 201.80 is entitled "Specific Requirements on

Content and Format of Labeling for Human Prescription Drugs and Biologics." That's tab 12, Your Honor.

THE COURT: Right.

MR. HEWES: So the plaintiffs say in their brief their cornerstone of their argument for labeling is a reg -- the applicable regulation is 201.80, "Labeling Requirements of Over-the-Counter Products," but when you read the actual regulation the regulations they site are regulations that are applicable to prescription products and biologics. They're incorrect in making their whole argument as to labeling as to Dr. Jones as for the foundation.

As to Wyeth v. Levine and The Supreme Court, Wyeth addressed an issue regarding labeling changes available to holders of NDAs, specifically the changes being affected option for manufacturers who hold a new drug application for a particular drug, as stated further in 21 CFR 314.70. As of 1998, McNeil was no longer a holder of an approved NDAR -- an approved application for acetaminophen -- or excuse me, for extra strength Tylenol. So Dr. Jones was correct when she said she did not exactly agree with the language set forth by Mr. Millig in her deposition because it's a different application to a different type drug.

Dr. Jones goes on to state and discuss

industry standard and industry practice where corporations such as McNeil do engage in a detailed back and forth with the FDA when making labeling changes for monograph drugs. And the FDA even provides some guidance. I've provided Your Honor with tab 13 to Dr. Jones motion, which is basically an FAQ, frequently asked questions, for over-the-counter drugs, and Section 15 -- or excuse me, line -- excuse me, number 15 or paragraph 15 discusses the process that the FDA suggests if a labeling change needs to be made. It includes -- it includes a new NDA for the drug or possibly issuing a citizen's petition.

The FDA makes it clear and it's consistent with the practice of the industry to go back and forth with the FDA and to not unilaterally in making labeling changes to products that are subject of a -- of a monograph.

Finally, in this case, Your Honor, we have a final rule, and in 2009, effective April 2010, the FDA mandated that certain portions of the acetaminophen labeling be changed to include a specific mandatory language. And although we don't have a final monograph here for the -- for the whole monograph, Your Honor, the final rule makes those portions of the label final as if it was a final monograph, and that element is

ignored as well as it relates to --

THE COURT: Wait a minute. Wait a minute. Tell me that again.

MR. HEWES: Sure. In 2009, the FDA said we are issuing a final rule for a certain section of the acetaminophen label, and the FDA mandated in 2009 that certain language be included in the label as it pertains to warning of severe liver damage associated with acetaminophen ingestion. In April 2009, the FDA said by April 2010, we are issuing -- this final rule will come into effect where we mandate that this section of the label include this language. That section of the label that the FDA mandates is a final monograph for all practical purposes for that -- for that section of the label.

So the FDA can piecemeal a tentative final monograph by passing or instituting final rules that make those portions final. Does that make sense, Your Honor?

THE COURT: No, it doesn't make any sense at all.

MR. HEWES: All right.

THE COURT: There either is a final monograph or there is a proposed monograph, right?

MR. HEWES: There's a tentative final

monograph and there's -- and there may later be a final monograph that encompasses A to Z.

THE COURT: Right.

MR. HEWES: In the interim --

THE COURT: But we don't have that yet --

MR. HEWES: We don't have it, but in --

THE COURT: -- for this medication?

MR. HEWES: We have parts of it. So in the interim the FDA can say --

THE COURT: Well, I mean you can have three tires and a steering wheel so you have parts of a car. Do you have a car? I mean we don't have a final monograph for acetaminophen, right?

MR. HEWES: We don't, but part of the labeling has been deemed final by the FDA by virtue of a final rule. And the final rule has the same application for that specific language as a final monograph would have.

THE COURT: And how do I know that?

MR. HEWES: In the final rule -- in tab seven of your book, Your Honor, is the final rule for acetaminophen from April 29th, 2009, and tab seven of the federal register lays out the FDA's action on that, as well as the mandatory implementation date of April 2010.

THE COURT: And your position is that makes it the same as a final monograph --

MR. HEWES: The language --

THE COURT: -- for that limited purpose?

MR. HEWES: Yes, Your Honor. The language enumerated in that April 2009 federal register is the final rule which becomes final for purposes of assessing the label.

(Pause in proceedings.)

MR. HEWES: And, Your Honor, that's the -- that's the federal register I read from earlier where the FDA said in order for this to continue to be recognized as safe and effective, we must do this label change.

THE COURT: All right.

(Pause in proceedings.)

THE COURT: Is there a difference in FDA parlance between generally regarded as safe and effective and the product being considered safe and effective? Is that GRASE status something different from just saying it's considered safe and effective?

MR. HEWES: Well, I think that the better answer -- the proper answer to that, Your Honor, would be go back to the regulations where the FDA laid out what is considered generally recognized as safe and

effective. And it is our position that subsequent to the category one assignment of acetaminophen to the generally recognized as safe and effective medication, every pronouncement -- every pronouncement by the FDA since then has been consistent with that finding. So up until 2014, 2015, 2016 in tabs I think it's eight, nine, ten, and 11, I give you some examples where the FDA puts up bulletins that continually say acetaminophen is generally recognized as safe and effective, acetaminophen is generally recognized as safe and effective. And Judge Johnson addressed this very issue in his order on GRASE and he kind of answered the question.

(Pause in proceedings.)

MR. HEWES: His language was much better than anything I could say, Your Honor, and he says, "While plaintiffs' arguments are creative, they urge the Court to make a ruling unsupported by the public record, especially in view of the FDA's mini action, vis a vie, extra strength Tylenol.

While the FDA may be an agency of limited resources, it has the power to remove a drug or strip it of its GRASE status if the situation is so warranted." And here's the important sentence, "The use of acetaminophen is so widespread in the

pharmaceutical industry both as a single ingredient and in combination with others, it is difficult to comprehend that the FDA would permit acetaminophen to remain an OTC drug were it not GRASE."

So from a position standpoint, the FDA has consistently, since it found acetaminophen to be GRASE to recognize it as GRASE in its pronouncements when it's taken according to the label. And I have that order if you would like to look at is, Your Honor.

THE COURT: Do we have that, Melissa?

MS. C. JONES: Your Honor, it's in --

THE COURT: We have it, yes.

MS. C. JONES: It's in tab one of that notebook I gave you earlier.

MR. HEWES: Specifically, the language is in page six and page seven, Your Honor.

(Pause in proceedings.)

THE COURT: Okay.

(Pause in proceedings.)

THE COURT: All right, thank you.

MR. HEWES: Thank you, Your Honor.

MR. MILLIG: Your Honor, may I please rebut for just briefly? I'm compelled to from that.

THE COURT: Very briefly.

MR. MILLIG: Yes, sir. You asked a question

is there a difference between just saying something is generally recognized as safe and effective and the regulatory pronouncement that the ingredient has been found from a regulatory standpoint to have this status? The answer is absolutely yes. As I said, if you go to the monograph section of the CFR, which is 21 CFR Section 343, you will see final monographs, and acetaminophen is not in there.

The reason it's not in there is because they still have unanswered questions that I brought to your attention in the 2009 proposed rule -- final rule. That final rule says we're still working on a lot of issues with acetaminophen. That's why -- that's why it's not -- that's why it's not final.

So it does not -- and it also, as I mentioned, remember that -- we all need to remember that once you're GRASE, you don't have to get FDA approval to sell your drug. Because there's still those unanswered safety questions that we went over, you have -- everybody has to get approval to become an acetaminophen manufacturer because they haven't decided what the maximum daily dose is officially even as of today, the safe maximum dose.

Judge Johnson got confused, just like our jury might. It was difficult when this was -- we

rushed, rushed, rushed to understand how could a drug like acetaminophen not be GRASE? It's sold everywhere, it's everywhere. That's why this jury needs to have an expert who can explain to them that there are thousands of drugs that remain in the proposed category -- maybe not thousands, but certainly hundreds. And there are drugs where all the safety answers haven't been -- haven't been addressed. That's what happened in New Jersey.

Third thing is it wasn't -- certainly is not a cornerstone, but as opposed to addressing our arguments on Ms. Jones, I think Mr. Hewes sort of tried to take a slap at us for citing to the section on when a company has an obligation to risk mitigation measures and if you read all of the regs, and we did at one time for Your Honor, you'll circle back around to that reg that has to do with prescription drugs. It's the same standard. When there's a reasonable association you have to take the -- take steps.

The big picture is Ms. Jones, unqualified, didn't have the information. Her opinions contradict The Supreme Court. They contradict -- they're conclusory.

Great pharmacovigilance, great FDA work, great, very hard labeling. And those are -- they're

not based on the facts, they're not based on the regs, they're not based on the regulatory history. We move for her exclusion. Thank you.

THE COURT: Thank you. All right, we're going to have to call it a day at that point. I have a sentencing this afternoon. We have to clear the courtroom and get ready for that. Okay, I think that's it. Thank you very much.

MS. C. JONES: Thank you, Your Honor.

MR. HEWES: Thank you, Your Honor.

(Proceedings adjourned, 1:11 p.m.)

* * *

CERTIFICATION

I, Michael Keating, 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.

2-22-16
Date

Michael Keating