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 June 24, 2015 10:14 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 10:14 a.m,)

THE COURT: Good morning.

ALL: Good morning, Your Honor.

THE COURT: Please be seated. This is a case management conference in the Tylenol MDL litigation and we have a rather full agenda today involving first, getting an update on the New Jersey litigation, and then talking about certain of the pending motions, both motions for summary judgment and motions in limine.

I know we have certain participants on the telephone and certain participants here. Melissa has given me a list. She has checked off everyone who is here and so I will dispense with the roll call. First of all, with respect to the New Jersey litigation, who wants to report on that?

MR. WEINKOWITZ: Your Honor, both sides have submitted letters and unless you have any questions about what is going on if you want a more detailed report, everything that we would report I think is in the letter.

THE COURT: Okay. Where are you in terms of a trial date with New Jersey?

MR. WEINKOWITZ: The trial date is set for September 16th.

THE COURT: So, it is still September 16th, okay. Ms. Jones?

MS. C. JONES: Your Honor, I just was standing up when you asked the question about the trial date, I think it is correct that both parties have submitted their responses.

I mean, we started out with five plaintiffs, we are now down to three and there are a series of parties in the course of doing discovery in those cases and there are a series of deadlines with respect to motions and hearings on those motions that are set before the trial.

I stood, because I am not sure that we have furnished those to Your Honor, and if that is important for any reason that you have that actual schedule we can certainly do that.

THE COURT: I don't think I need it at this point. Thank you. Okay. Anything else to discuss before we engage on the pending motions?

MR. MILLING: Nothing other than the fact, Your Honor, maybe we can just throw this on the table, I think as we get further into the motions one idea that we had was that at least a couple of the defense dispositive motions at the end have a section on preemption and we thought maybe we could just address

preemption maybe before we do the last two motions is the general proposition, because if the Court finds us preempted, then well then there is no reason to do the last two motions.

THE COURT: Right.

MR. MILLING: If that is agreeable to the defense, we just thought that might make sense as opposed to doing it twice.

THE COURT: The last two summary judgment motions?

MR. MILLING: Last two summary judgment motions.

THE COURT: All right.

MR. MILLING: I think there is a little bit of preemption in the fraud.

THE COURT: Yes.

MR. MILLING: I think Mr. Gainer is going to handle that, but failure to warn and the design defect both have a preemption component raised by the defense and it just might make sense to talk about preemption generally before discussing the motions or else we are going to do it twice.

THE COURT: That makes sense. Thank you. All right. With respect to the defendants' motion for summary judgment on the wrongful death time bar, who is

going to argue that?

MR. ABERNATHY: I will be arguing that, Your Honor, for the defendants.

THE COURT: I thought you might. Good morning.

MR. ABERNATHY: Good morning, Your Honor, David Abernathy for the defendants, Johnson & Johnson and McNeil, PPC, Incorporated. I guess maybe I am now a specialist in the Alabama Wrongful Death Act. I haven't anticipated being that, but here we are.

We have two motions addressed to this Act and it is, obviously, kind of an unusual law. The first motion is a dispositive motion based on the fact that the statute requires that a personal representative as defined in Alabama law be appointed and file suit within two years after the death.

And the motion actually presents kind of a simple issue of law because there isn't any dispute that the statutory requirements weren't met. Everybody agrees that the plaintiff wasn't appointed until well after the statutory period.

There isn't any dispute, I don't think, based on the papers that if the case was in an Alabama court it unquestionably would have to be dismissed. There is a whole string of cases on that in Alabama and the

plaintiffs really didn't take issue with that.

Their argument against summary judgment, and I will put to one side for a moment, Your Honor, a couple of waiver-related arguments that I will touch on at the end, but their substantive legal argument is that this issue is governed by a federal procedural rule, Rule 17, and that the plaintiff is entitled to substitute her present self as the personal representative for her former self who sued when she wasn't a personal representative.

The key issue here, Your Honor, there is no issue as to whether Rule 17 applies here, clearly it does, we are in federal court. The question is the scope of Rule 17 and whether Rule 17 can be used to override a substantive requirement of state law when that state law provides the rules of decision and we suggest that it cannot.

You have to focus here, I think, Your Honor, on the fact that this is a very unusual state law. This is not a law that gives a civil remedy to a particular plaintiff that is then subject to a general statute of limitations, which is a procedural defense that can be waived.

The Wrongful Death Act itself incorporates the requirement of suit by a duly appointed personal

representative within two years and the Alabama courts are very clear that this two year period is part of the substantive cause of action, it is not a statute of limitation.

The substantive cause of action is governed by state law, and while this Court, of course, determines what Rule 17 does and how it applies, the Court, any federal court, has to accept what the Alabama Supreme Court says as to the substantive law of Alabama when it comes to the substantive elements of a case governed by that state law.

Actually, when you look at the statute, Your Honor, it is a very unusual statute because it actually doesn't give any remedy for loss to a private plaintiff.

The statute, as you know from the prior briefing and some of the other briefing on the motion we are going to talk about next, doesn't allow any compensatory damages at all. You can't recover for any loss or damage to the decedent or her survivors.

It only acts as a vehicle by which the personal representative can impose punitive, exemplary damages on a defendant as punishment for causing a wrongful death in order to carry out the state's public policy.

THE COURT: Which is what?

MR. ABERNATHY: Which is to uphold --

THE COURT: Prevent homicide?

MR. ABERNATHY: -- the sanctity of human life and discourage homicide as the Alabama courts define it. And the court in several of the cases, and I am quoting from the Hattis (ph) case, which is on page ten of our brief.

THE COURT: Right.

MR. ABERNATHY: But, it is one of the many that address this, says "The personal representative does not act strictly in his capacity as administrator of the estate. He acts rather as an agent of legislative appointment for the effectuation of the legislative policy. The personal representative of the estate has been empowered to act as a quasi-public person to carry out the legislature's policy."

Well, it is a very unusual law, but that is Alabama law, it is what it is. The point is the Alabama legislature had the right to and did impose what it defined as a substantive requirement of that action that you have to be the personal representative duly appointed and suing in two years and that the legislature had the right to do that and Rule 17 is a procedural rule that cannot be used to override the

substantive requirements of state law.

Your Honor, we filed a motion for leave to file a reply in support of this motion yesterday, and in the proposed reply we talk about the cases raised by the plaintiff.

They have cited a number of cases for the argument that Rule 17 allows relation back in the situation. Again, I would argue that this really isn't a Rule 17 issue, because this isn't a situation where you had one person suing, but somebody else was the real party in interest and now we are bringing the real party in interest is. It is the same person, first of all and, in fact, under state law there was no real party in interest.

The only person who could be the real party in interest is a personal representative appointed within two years, and that person doesn't exist. Leaving that aside, if you just take the assumption that okay, the belatedly appointed plaintiff is now the real party in interest, if you look at the Rule 17 cases that are cited by the plaintiff, they are all cases that either involved a federal procedural limitation that was effectively overcome by the relation back under Rule 17, or a state procedural limitation, in most cases a statute of limitations,

none of those cases involved what the plaintiff wants you to do here which is to take what the Alabama courts have said is a substantive element of the cause of action and simply write it out of the statute by the application of a Rule 17. Our argument is simple. The Rules Enabling Act is clear, it does not allow the use of procedural rules to override state substantive law.

Very briefly, Your Honor, the plaintiff argued we waived this motion because we didn't bring it as a motion to dismiss. First of all, it is a substantive element of the claim, so summary judgment is the proper time to raise it.

Second, if we had brought a motion to dismiss it would have been denied because the original complaint alleged that the plaintiff was the personal representative, it is right in paragraph one.

It wasn't true. She wasn't the personal representative, but the pleadings said so, so obviously a motion to dismiss would have been denied and ultimately the issue is only germane now because you have now ruled on choice of law as the plaintiff requested, that this Act applies, so now we have to address it.

Finally, they also argue that this is hypothetical because we don't know what the state court

judge would have ruled on this issue if we had moved then.

I don't think you can oppose a motion after a removal by arguing that the state court judge might have ruled differently. Once the case is here it is here.

THE COURT: You mean the state court judge -- this was filed in Philadelphia County, right?

MR. ABERNATHY: It was filed in the Philadelphia Common Pleas. It was never presented to the state court judge.

THE COURT: Right.

MR. ABERNATHY: They have argued it is a hypothetical motion because we don't know what the state court judge would have ruled. Well, you never know what the state court judge would have ruled when you are in federal court after removal, but I don't think that is relevant.

The only other point I would like to make, Your Honor, is I think without arguing it explicitly there is an underlying theme in the plaintiffs' opposition that this is unfair, that it is going to deprive the plaintiff of an adjudication on the merits and that this technical issue shouldn't be raised in order to prevent her from her substantive claim being

brought.

I take the point you can make a perfectly respectable argument that the Alabama state law requirement is overly technical, is unreasonable, isn't necessary. All interesting arguments, but I don't think they belong here.

This is Alabama law as the Alabama Supreme Court applies it. They asked for Alabama law and they can't now argue I shouldn't be required to meet its requirements. And the plaintiffs certainly could have.

There is no reason she couldn't have been appointed within the statutory period. When she sued she sued and claimed she was the personal representative, so she and her counsel obviously knew the capacity they were supposed to sue in, but she didn't have that capacity.

They asked for the application of Alabama law, you ruled that it applies, but they can't now turn around and say I don't have to meet its substantive requirements, and for that reason, whether we think the rule is technical or not it is Alabama law, it has to be followed and summary judgment should be granted.

THE COURT: Thank you, Mr. Abernathy.

MR. GAINER: Good morning, Your Honor.

THE COURT: Good morning.

MR. GAINER: Gil Gainer on behalf of the plaintiff. Your Honor, the defense began its argument with two statements which are certainly true. This is a simple issue of law, and Federal Rule 17 applies.

That is the analysis as far as the analysis needs to be taken. Every Supreme Court case, every circuit court case that has faced this particular issue has allowed the relation back of the subsequent appointment of a personal representative to the commencement of the action.

It really is as straightforward as that. In the brief, the reply brief that the defense referenced filed yesterday, in page six it says "The fact remains, regardless of where this case originated, it is here now, that is exactly right." It is in federal court as they removed it here, and Rule 17 applies, and I hate to repeat, but I think it is that straightforward.

Every Supreme Court decision, every circuit court decision that has been faced with the issue of whether or not to relate back the filing of the formal, I should say, appointment of the personal representative to the commencement of the action has done so.

Now, briefly, this began over 50 years ago, or half a century ago, in the Levinson versus Deupree

case, and contrary to what I think I heard, which was that this is only applicable or the cases that we have cited has only been applicable to Rules of Procedure and so forth, the Levinson versus Deupree case was based on state law. It was based on the law of Kentucky.

There was a one-year statute of limitations and similar to Alabama and Kentucky they require that an administrator be appointed and that that appointment take place prior to the expiration of the statute of limitations, and the lower courts did apply that.

However, the Supreme Court in Levinson declined to do that and specifically held that because it is in federal court and the federal rules apply that the relation back of the subsequent filing or subsequent appointment of the personal representative related back to the filing of the commencement of the action. So, that was the genesis of it.

In 1966 Congress enacted Federal Rule 17 and in the committee advisory notes it was stated that this was intended to codify, if you will, the holding in Levinson.

Subsequent to that, again, every circuit court opinion that has addressed this issue, including a circuit court opinion coming out of the State of

Alabama has applied the relation back rule.

And I should back up and say, because this is a principle that has endured since the Levinson case, the Supreme Court said that when a case is pending in Federal Court the rules or procedures may not be identic, but that has continued to be the case and even though Kentucky would not have allowed the relation back of the formal appointment of the personal representative it did, nevertheless, relate back.

In the case of Hess versus Eddy, this is a case originating out of Alabama and similarly the appointment of the personal representative came after the statute of limitations.

The Eleventh Circuit held despite the fact that under state law a different outcome would occur, this is in federal court and the Federal Rules of Civil Procedure apply, just as was stated moments ago, Federal Rule 17 applies in every case, circuit cases or Supreme Court case, applying Rule 17 to this particular issue has related it back.

And there are other circuits, we mention them in the brief, the Crowder (ph) case, there was the Wadsworth case. Some of these involved the enforcement of the federal claims, some involved state claims. It really makes no difference. Once it is in federal

court the Federal Rules of Civil Procedure govern and Rule 17 allows relation back.

Insofar as the issue of waiver, it was simply to say, and it was misstated, it should have been motion for summary judgment if that had been solved, and that would have been adjudicated. It was not.

The point is, and has been amply made, the case is here now and yes, the Supreme Court has said, and it was quoted in several different cases, but one case it was stated that the "If the rules of procedure work as they should in an honest and fair judicial system they not only permit, but nearly as possible guarantee that bonafide complaints be carried to an adjudication of the merits." And that was in the Hess case citing a Supreme Court case, which is also in our brief in footnote 19.

However, the State of Alabama or the State of Kentucky or other states may look at the relation back rule, it is procedural. After all, the real goal here is to identify the real party in interest, that they be joined to the case before the case goes to trial so the defendant knows that however this case comes out, trial, appeal, settlement, whatever, it is res judicata.

It is a procedural issue in its nature and so

it has been treated by the federal courts from 1955 or 1954 when the Levinson case was first issued by the Supreme Court coming forward, and as a result, the real party in interest was joined or ratified, if you will, in this case, a year and a half before this motion was filed.

Under Rule 17 if there is going to be an objection to whether or not someone is a real party in interest that party is allowed additional time or reasonable time it says under the rule, to ratify or join, substitute and so on.

Well, in fact, this had already taken place a year and a half before. Ms. Hayes was formally appointed as the representative of the estate of her sister.

So, subsequent to that the short form complaint was filed. At the time the short form complaint was filed in this Court she was, in fact, the duly appointed representative of the estate of her sister.

And consequently, under the Federal Rules and under all of the case law that, in fact, related back to the commencement of the action which was well before the statute of limitations expired. Any questions, Your Honor?

THE COURT: So, you would agree that were this to be decided under the Alabama courts, the section is a nullity and it would be dismissed, right?

MR. GAINER: Well, I think that nullity, and I don't mean to shave words, there is a difference between nullity or void ab initio and voidable. Even in the state of Alabama there are cases where the suit has been filed and subsequent to the suit being filed, even though the statute requires that the personal representative be duly appointed at the time of the filing of the suit, they have allowed relation back to the filing of the suit provided the appointment took place before the statute expired.

THE COURT: That's not our case here.

MR. GAINER: It is not. So, arguably, was it voidable under Alabama law? Yes. Had we remained in state court and a state court judge decided to apply Alabama law instead of New Jersey law, then it would have been adjudicated and it could have been adjudicated in their favor.

On the other hand, the Court may have done just exactly as Judge Johnson did, which is apply New Jersey law instead of Alabama law, and in that case New Jersey works just like Rule 17 in federal court.

Just like the rule works in Georgia, which is that the subsequent appointment relates back. It is simply a procedural matter and it is simply a question of making sure the real party in interest is joined before trial so that the defense knows that it is res judicata and that that case will not be brought again by someone else claiming to be the real party in interest.

So, yes, sir, that is correct, but once again, there is not a single Supreme Court case, there is not a single circuit court case that has not applied the relation back rule in the exact circumstances that we have here.

And beyond that, there was some discussion, for example, in the defense brief about the Erie Doctrine. And the Supreme Court made it very clear in Hanna versus Plumer, it is only when a federal rule doesn't apply or that it does not cover, I should say, the issue in the case. Only when there is a federal rule or a lack of a federal rule that covers the issue in question do we consider (inaudible).

Here, clearly, we have a rule that covers the issue, which is Rule 17. And just as was said in the opening for the defense this morning, Rule 17 applies. And in every case the Court has treated it as a rule

that provides for relation back of the subsequent appointment of a personal representative.

THE COURT: Thank you.

MR. GAINER: Yes.

THE COURT: Mr. Abernathy, in reviewing the papers I had some concerns about your position in light of the Levinson case and Mr. Gainer has quoted language from the Hess versus Eddy decision. How do you get around Levinson, and that was a wrongful death case, right, that was Alabama law?

MR. ABERNATHY: Well, let me talk about both of those cases, if I could. First of all, you may have just gotten the impression that there are cases in which the late appointment of a personal representative was allowed to relate back in an action under the Alabama Wrongful Death Act case, and that isn't so.

If you read all of the cases cited in the plaintiff's brief, none of them involve relation back for a late appointed representative under the actual law we are talking about, the Alabama Wrongful Death Act.

The plaintiffs' brief says that Eddy is a wrongful death case out of Alabama. It is a bit of a misnomer. It is not an Alabama Wrongful Death Act case. It is a case under Section 1983 of Title 42 in

which federal law supplied the rule of decision and the federal court borrowed the two-year period in the wrongful death act as a federal statute of limitation for the federal action and said this is a federal action in a federal court, so we are going to apply Rule 17 to (inaudible) relation back. No quarrel with that, but it has nothing to do with overriding the Wrongful Death Act substantive requirement.

Levinson actually did not turn on state law. It was a federal admiralty case that, again, borrowed Kentucky's statute of limitations for a federal case. That said, if you look at the case law you will certainly find cases where a statute of limitations, either state or federal, was not allowed to bar the action because Rule 17 allowed relation back.

But, again, this is not a statute of limitation, it is a substantive element of the claim, and no case holds that under the Alabama Wrongful Death Act you can apply Rule 17 to allow relation back and override that substantive requirement.

It isn't really an Erie issue per se. The critical issue here is the Rules Enabling Act is a very specific federal statute that applies here that says the rules cannot be allowed to enlarge or modify a substantive right. That means you can't override the

substantive requirements of state law with the Federal Rules of Civil Procedure.

And by the way, there are cases in which the late appointment of a personal representative was not allowed to relate back, Mauer (ph) and Conley are both cited on our original brief.

Those are similar state laws where the federal court said you can't allow it to relate back because the substantive requirement of state law required the personal representative to sue within a specific period of time.

So, yes, it is certainly true, we agree Rule 17 applies here but, again, what is Rule 17 allowed to do and what is it not allowed to do? It is not allowed to write a substantive requirement of state law out of existence.

THE COURT: Thank you.

MR. GAINER: Your Honor, may I respond quickly?

THE COURT: Sure, Mr. Gainer, sure.

MR. GAINER: Thank you. First of all, Your Honor, again, going back to the Levinson case, there seems to be some confusion there. This was, in fact, brought under the Wrongful Death Statute of Kentucky. This wasn't some borrowing.

This was, in fact, at a time where there was no recovery under federal law, even -- and the Court references that a maritime law does not allow for recovery for wrongful death. That is at page 650.

This was, in fact, brought under the state law of Kentucky because it happened in Campbell County, Kentucky. And just like Alabama they had a rule that required the personal representative bring the case, file the case, and that that representative be duly appointed at the time of filing.

Notwithstanding that the Supreme Court of the United States ruled otherwise and the Federal Rules were considered to apply and this was procedural and it fostered, if you will, the codification of its opinion into Rule 17 as we now know it in 1966.

In Hess there also seemed to be some confusion. That case did happen, that wrongful death did occur in the State of Alabama and the Eleventh Circuit said, most importantly the rule, and they are referring to the rule of relation back, most importantly the rule is to be applied even where the courts of the forum state have rejected the relation back doctrine. They could not have been clearer about that.

It matters not whether the basis of the

wrongful death action arises out of a product liability case, a medical malpractice claim, an automobile accident, a 1983 action. Those can be filed in state court just as they can in federal court.

Jones Act cases, which is a federal statute, can be filed in state court as well as state and federal. It matters not which of those it is, it is a question of whether or not the Alabama result, which would be not to allow relation back, applies in federal court, and it clearly does not. Every Supreme Court case, every circuit court case has said that, and this Eleventh Circuit case was specifically an Alabama death case.

Now, the two cases that the defense just mentioned, first of all, the Mauer case, these were both district court opinions, so let's be clear about that. These were not circuit court opinions, these were not Supreme Court decisions.

The Mauer case involved someone who had not filed the claim for wrongful death until after the statute had expired. That's simply not applicable here. The claim was filed before the statute of limitations expired by some seven or eight months.

In Mauer, again, a district court case, the plaintiff did not even file the wrongful death claim

until after the statute expired. It is clearly distinguishable.

The other one is frankly something of an outlier. It goes against the precedent set by the Supreme Court, the precedent set by certain courts of appeal. There are some other things that could be distinguished but, again, what has already been stated is that the Rule of Federal Civil Procedure 17 applies in this case and that is the simple issue before the Court.

It is here, under the Federal Rules of Civil Procedure, it relates back. There is no harm, frankly, to the defendant. The real party in interest, which is the whole point of the rule, has been accomplished. This case, whether it goes to trial, appeal or settlement, will be res judicata. Enormous time and effort has gone into this case since its selection and so forth, and it is set for jury trial.

And we would ask the Court to do just as the Supreme Court has done, nothing out of line with what the Supreme Court has done or the circuit courts of appeal have done, but simply apply the rule as it has been since 1954, which is to allow the appointment of the personal representative to relate back and as was stated in several different cases, allow this case to

proceed to an adjudication on its merits. Thank you, sir.

THE COURT: Thank you. Let's move to the next motion which is the motion regarding the punitive damages claim, punitive damages statute and the challenge to the constitutionality of that statute.

MR. ABERNATHY: Good morning, Your Honor.

THE COURT: Welcome back.

MR. ABERNATHY: Once again, I am in for a penny, I am in for a pound. So, we are back to the Wrongful Death Act and focusing in this motion on its rather anomalous rule for damages, which as you know does not permit any compensatory damages, does not permit any consideration of the actual loss to the plaintiff or the decedent or the value of the life lost, but allows only punitive damages.

Now, it is an anomalous law. I think it is actually unique. It has certainly gotten a lot of criticism, but to be clear, criticism by both federal judges and a lot of judges of the Alabama Supreme Court in various descending opinions, but to be clear that's not what the motion is about.

However strange, unusual, illogical, unfair, pick any adjective you want, this rule may be, it is the law of Alabama and Your Honor has to accept that

for purposes of this motion.

The only issue presented here is whether or not this unique way of assessing punitive damages is constitutional. The plaintiffs suggest in their brief that Your Honor has already ruled on this. I think Your Honor will no doubt recall your own ruling on choice of law which you discussed some of this law, but said this ought to be in a dispositive motion, so here it is.

THE COURT: We talked about in the footnote as I recall.

MR. ABERNATHY: Right. And you haven't ruled on it, you've certainly identified the issue. You said if we wanted to present it to present it in this kind of a motion.

THE COURT: That's the last time I will do that.

MR. ABERNATHY: Well, we are all learning lessons here, I guess, but the plaintiff also points out quite correctly that this specific statute was upheld by the U.S. Supreme Court in the Louis Pittis Dry Goods case in 1927.

I would suggest to Your Honor that that decision doesn't really tell us anything useful about today's problem for two reasons. First of all, the

issue in that case was whether you can impose vicarious liability for punitive damages, that's not our issue.

Second, and more importantly it was decided in a different world before any of the contemporary due process jurisprudence on punitive damages was issued by the Supreme Court six or seven decades later.

Your Honor, I want to focus on what I think is the central problem here and that is the proportionality requirement of Gore. The Supreme Court's --

THE COURT: This really is a Gore BMW issue, is it not?

MR. ABERNATHY: It is a Gore Campbell proportionality between compensatory and punitive damages. That is the core of the issue here, and I don't think there is any quarrel with the fact that application of the three guideposts in Gore is mandatory. The Supreme Court has said that again and again and the Alabama Supreme Court said that in some of the cases in which it dealt with this issue including Cherokee Electric.

So, the question is what is this proportionality guidepost require or allow you to do. If you look at the Supreme Court cases they are very clear and consistent in focusing on the proportionality

between the harm as measured by compensatory damages and the amount of the punitive damages. And that is the focus in all of these cases.

In Haslip the Court talked about -- it is not a Wrongful Death Act case, but it was actually an Alabama case, and talked about the fact that the compensatory damages or the punitives were four times the compensatories and said that is close to the line on due process, although they upheld it.

In Gore the punitives were found excessive because they were more than 500 times compensatory damages. In Campbell the Court specifically said "The amount of the harm to the plaintiff and to the general damages recovered," that's what the punitives have to be proportional to. And in Gore they talked about the long pedigree of this rule that punitive damages have to be proportional to compensatory damages.

So, the Alabama courts have also wrestled with this issue and addressed it in a number of cases. And some of those decisions, including Cherokee Electric and Lance have candidly admitted we can't really apply this Gore factor.

Cherokee Electric says Alabama law allows no compensatory damages in a wrongful death case. This factor, therefore, does not apply here. Can't do it.

So, then you will see other Alabama court cases which obviously recognize the problem that poses, because if you can't apply the guideposts and they are mandatory as the Supreme Court says they are, then you have a due process problem.

So, you do see some Alabama decisions including Tillis Trucking and Beaudreaux (ph) that say well, we don't apply the proportionality factor formulaically, but we kind of do it. We can't compare compensatories to punitives like the Supreme Court decisions do, U.S. Supreme Court decisions, but we are going to in some inchoate, undefined way compare our sense of the harm to the plaintiff, to the punitives and decide whether it's proportional or not.

I would suggest to Your Honor that, you know, it's an interesting rhetorical device and the Alabama courts have been very clear, we are just not interested in revisiting this issue. Beaudreaux said that very specifically, we're not going to revisit Tillis Trucking and these earlier cases, but it doesn't really work. It doesn't work on a logical level, it doesn't work on a legal level.

In fact, if you look at the Alabama cases that say this, well, we are doing it, we are just not doing it formulaically, they don't explain what that

means.

They don't explain how a court forms some inchoate sense of what the harm is when there is no compensatory damages to measure it, and then somehow comes up with a concept or a plug number or something, they don't say, and do the comparison that you otherwise would do under Gore.

But, there is really a more difficult underlying problem here because according to the Alabama courts compensatory damages are not permitted in Wrongful Death Act cases because the Wrongful Death Act addresses the inherent value of human life which cannot be measured in dollars.

So, the Alabama courts are not only saying we don't allow compensatory damages, they are saying we don't allow compensatory damages because under our state law we regard the thing that is being addressed as inherently non-measurable in dollars.

Well, if you can't, not only won't, but can't measure it in dollars how can you possibly do the proportionality review that Gore and these other cases contemplate?

The plaintiffs do point in their brief to the fact that there are a lot of Alabama decisions that apply state court standards and reduce punitive awards,

and there are a number of reported cases where they apply these Green Oil factors, that's the Green Oil case is one of the cases, and they reduce the punitive award.

But, the fact that a punitive award can be, in some cases, reduced under state law doesn't mean that the process by which it is awarded complies with federal constitutional due process requirements and, in fact, in Gore the Alabama Supreme Court did reduce the punitive damages under state law and the Supreme Court still held that the award violated due process.

Your Honor, again, we can't and don't argue that you should refuse punitive damages under the Wrongful Death Act because it is an anomalous, strange, old rule that nobody has anymore. That is not the issue. The problem here is that it is a very old and different rule and constitutional due process has passed it by.

The rules have changed. The standards by which punitive damages are determined aren't the same anymore and for whatever reason Alabama's legislature and courts have chosen not to adjust their process to meet those requirements.

You have to accept Alabama law as it is for the purpose of determining Alabama law, but you can't

defer to the Alabama Supreme Court on whether the Alabama law is constitutional.

THE COURT: So, if I understand you, the Haslip case and I think that was two years after the Green Oil case talks about Alabama having, well, not a compensatory damages claim. There is this, I think they refer to it as a full panoply of review that includes the jury verdict, the post-verdict motions and appellate review which in the end guarantees that proportionality, I don't know if you call it a right, but that there is a proportionality analysis, albeit possibly played out over several steps in the litigation and not a formula for the jury to apply.

That's an early 1990s case. Then, you have Gore decided in when, 1996?

MR. ABERNATHY: Gore was 1996.

THE COURT: Right.

MR. ABERNATHY: And I think the critical factor here, Your Honor, is that --

THE COURT: So, your position is that Gore changed the jurisprudence here?

MR. ABERNATHY: Well, both Haslip and Gore and even more so Campbell in focusing even more explicitly on the comparison between compensatory and punitive damages, and the presumptive single digit rule

which Your Honor recognized later in the Morris case all changed the jurisprudence, but I think the critical factor on Haslip and Gore is that they are not Wrongful Death Act cases.

So, in Haslip and Gore you have different kinds of claims where you have compensatory damages and you can actually do an analysis as to whether the harm as determined by the jury in compensatory damages, is proportional to the punitive award.

If you have a Wrongful Death Act case and you have no compensatory damages and you're determining sort of a proxy for what compensatory damages would be, you're in effect making the decision that really would normally be in the jury's hands as a matter of jury trial except a Wrongful Death Act, unlike these other claims in Gore and Haslip don't allow it.

So, it is really, I would suggest, Your Honor, a problem that is unique to the unique rule of this Act. It doesn't act as a burden on the normal punitive damage rules in Alabama for other claims or the kind of punitive damage rules you have in any other state where you do have compensatory as well as punitive damages.

THE COURT: All right. Gore wasn't even a personal injury case. I think that was repairs to a

car.

MR. ABERNATHY: Gore was the guy who was upset because they touched up the paint on his BMW and sold it as new and he said he should have been told that there were repairs. So, it was a consumer fraud case. Haslip was an insurance fraud case.

But, these are all cases where you have compensatory damages. It is the absence of that, the fact that harm is never determined or compensated under the Wrongful Death Act, it is that unique rule that creates the problem here.

THE COURT: Thank you.

MR. MILLING: Your Honor, good morning.

THE COURT: Good morning.

MR. MILLING: Clay Milling on behalf of the plaintiff and I am thrilled to hear that you say this is the last time you're going to invite this, because that hopefully means it is the last time I am going to stand up and talk about due process.

This is, in essence, although framed a little bit differently, an issue that the Court has been analyzing over the last few months in your ruling on Alabama law you've articulated in, I think it is, footnote 42 or 44, all of the relevant cases.

We certainly adopt your reasoning that this

law, and to the extent that it was not said explicitly, at least our implicit reading that it is constitutional.

The issue that the defendants are raising in this Court boils down to, you know, really we talked about proportionality, but the defendants in their brief have raised two of the Gore what they call guideposts, the reprehensibleness and then the proportionality.

As to the first one, the defense says that the wrongful death verdict can't be reviewed for reprehensible conduct because no reprehensible conduct is required, and to that we say how can that be the case because Alabama courts have been doing this long before Gore.

And we cite the Hammond case, we cite the Green Oil case. We cite cases in footnote 19 of our brief going back from 1991 to 2012, all of which have been reviewed and all of which found that without having this precise -- well, and before Gore, without having this precision the concept was that at the end of the day we want to make sure that the punitive damage award is consistent with the conduct and the harm, and that's really actually what Gore says. Gore does not say -- Gore says -- Gore mentions a monetary

figure, but it doesn't say you have to use a monetary figure. And since Gore --

THE COURT: But, it says there does have to be a rational relationship between the actual harm to the plaintiff and the punitive damages awarded against the defendant, right?

MR. MILLING: The harm to the plaintiff and the conduct and I think I would direct the Court --

THE COURT: But, here, in this instance, in the Alabama wrongful death world we can award or have to award punitive damages for negligent conduct, right, or for a product defect. It doesn't even have to be negligent.

MR. MILLING: We award damages -- the Alabama measure of what I like to call level one damages is damages based on the conduct of the defendant, yes.

THE COURT: But, there is no level two, right? There is just one level of damages and it is punitive?

MR. MILLING: There is just one -- there -- it is based on the conduct of the defendant which in traditional other state laws would certainly be considered the second level, which is punitive, that is correct.

THE COURT: But, that is not Alabama. If we

were in Pennsylvania it would be were you negligent and caused an accident? Yes, here is the compensatory damages.

MR. MILLING: No question.

THE COURT: Were you wildly negligent and reckless and so forth, well, then maybe there outrageous conduct and then there is a punitive award, but we don't have that here.

MR. MILLING: We don't have that here. But, what we do have is we have case law up through the Supreme Court with Gore and then being followed by the Alabama Supreme Court with Beaudreaux. We have the Haslip case, which was before Gore, but saying, as you pointed out, that we have looked at this Alabama Supreme Court, Alabama Wrongful Death law and the factors are -- there are a full panoply, as you said, of protections.

THE COURT: Well, they said. I wouldn't use such a big word.

MR. MILLING: Yes, I would have to look it up myself. But, I think the case that sort of highlights this is the Beaudreaux case, and the Beaudreaux case was $20 million medical malpractice wrongful death verdict reduced to $4 million.

And one of the big reasons that the Court

reduced it was because the Court found low level reprehensible conduct. And as the lawyer in my office likes to say when she listed these guideposts and she really did it, it's not that hard.

The court reduced it because in medical malpractice cases, as Your Honor is very much aware, very much decisions are made on the spur of the moment, there was no -- in that case there was no allegation of reprehensible conduct. The jury just gave an award that the Court realized when looking at the guideposts didn't make sense.

You can compare that to a case of an alleged cigarette manufacturer who has known theoretically that cigarettes are addictive and carcinogens and they don't disclose that and the conduct goes on for years and years, the result would be different.

But, the bottom line is the defense in this case as it relates to both reprehensibility and as it relates to proportionality wants to say look, we demand more precision, but the truth of the matter is that after Gore both the Alabama Supreme Court has gone on in both Beaudreaux and Tillis to say that the proportionality, we apply the proportionality, but we just don't do it mathematically, and it doesn't have to be done mathematically. It can be done by a totality

of the evidence type of situation.

The bottom line from the plaintiffs' perspective is that going back to 1927 when the Supreme Court first looked at this, following through with the Green Oil, the Hammond case, the Beaudreaux case, the Tillis Trucking case, the courts that have analyzed this have all determined and, again, most recently, very recently, the Alabama Supreme Court that this is a constitutional way to do it and that Gore doesn't say you have to do it with mathematical precision and we would ask that the Court deny the motion.

THE COURT: So, how did Beaudreaux apply Gore?

MR. MILLING: Beaudreaux applied Gore, but with a reduction of the $20 million.

THE COURT: $20 million to $4 million, right?

MR. MILLING: To $4 million.

THE COURT: Right.

MR. MILLING: In order because the Court found that in looking at the guideposts, $20 million for that conduct and that injury didn't make sense.

THE COURT: Okay. So, what was the multiplier or the factor or the -- how did they -- they just laid their hands on it and decided that $4 million was better than $20 million?

MR. MILLING: There was no multiplier, but what the Court said in Beaudreaux it says "Because Alabama's Wrongful Death Statute provides for only punitive damages, Alabama courts are unable to apply formulaically the pertinent Gore guideposts in examining the reasonableness of a punitive damages award by comparing it to the compensatory damages award.

"As Tillis trucking makes clear, however, a punitive damage awarded a wrongful death case may nonetheless be compared and evaluated, though perhaps not in a strictly mathematical sense, by means of a 'proportional evaluation of the award amount, the conduct of the defendant and the resulting harm from the conduct.' Thus, because of the award of punitive damages in a wrongful death case is subject to a proportionality review," which is in essence what Gore says.

THE COURT: A proportionality review by the appellate court.

MR. MILLING: Or by the trial court.

THE COURT: Okay.

MR. MILLING: Yes.

THE COURT: All right.

MR. MILLING: We are inclined not to revisit

Tillis Trucking, and that's 2012.

THE COURT: Okay. So, what do you do with the notion that Gore, as a matter of due process -- the due process rights of the defendant, requires that the jury have some compensatory damages, some evidentiary basis upon which they can multiply or base an award? of

It seems to me that Beaudreaux is saying okay, the due process is there, but it is coming later in the game. It is not a due process situation when the jury is deciding punitive damages. They are just looking at what happened and saying $20 million.

MR. MILLING: But, at the end of the day, respectfully, wouldn't it be the same? If we had a compensatory award and then a jury decided in this case to give -- let's say that we were dealing with different statutes and the jury gave a very significant punitive damages award that Your Honor found was excessive under the Gore guideposts, Your Honor would still be in a position to remit that just as the Alabama court can do it, and the only difference is one is doing it -- if Your Honor decided to do it on a strictly mathematical basis that would be one way to do it, but Gore does not require that.

And so Alabama just says we're not doing it on the strictly mathematical basis, we are doing it on

a proportionality based on the conduct, the injury and the totality of the evidence which, while it may be different, I think you could logically argue that formulaically is awfully stringent and from the plaintiffs' perspective as it comes to an award of punitive damages, and so you can see the argument on both sides.

The bottom line, though, is all of the courts up through the most recent Alabama courts that have looked at this have come down on the plaintiffs side.

THE COURT: So, what is the jury instruction to those eight people sitting in that box about what formula or standards they should use to award damages under this wrongful death?

MR. MILLING: I cannot answer that, but I know Mike looked at them. Mike, do you know the jury instruction, by chance, of the wrongful death? I don't want to answer it if I can't answer it.

THE COURT: Well, yes, I mean I'm just trying to think through this with you and my concern with this law is how to instruct the jury. I mean, I get questions back from jurors that say what formula should we use. Well, then the response is apply the law that I gave it to you and base your verdict on the evidence and good luck.

I mean, I totally understand, I mean I think I understand your point. I am just a little concerned about, you know, where does Gore require that due process be -- that due process be part of the equation?

MR. MILLING: And I guess the response is on both sides. From the defense, the defense would like due process to be formulaic and a multiplier, and the plaintiff might say due process from the plaintiffs' perspective, we are not so keen on the formulaic. We would rather have it be more based on the totality of what the jury heard.

And what the Alabama courts say, it said we are leaning towards the latter, that has been looked at by the Supreme Court a long time ago. It has been revisited. It has been stated that there is all kinds of protections and it has been then followed by the Alabama Supreme Court up until recently. Thank you.

THE COURT: And, Mr. Abernathy I think makes a good point that the earlier review of the Alabama punitive damages statute was what, in the 20s, 1927?

MR. MILLING: The earlier -- the first time it was reviewed by the Supreme Court was 1927, I believe.

THE COURT: The Supreme Court was calling

baseball a game, not a business back then, so things have changed.

MR. MILLING: I do have a cite to the Alabama pattern jury charge in our brief and it says the Alabama pattern jury charge instructions inform the jury they are to determine damages in accordance with the culpability of the defendant, i.e. how bad his or her conduct was. That's what the charge is. Alabama pattern jury instruction 11.28.

THE COURT: Right. Okay. Thank you.

MR. MILLING: Thank you, Your Honor,

MR. ABERNATHY: Your Honor, could I just make two points very quickly?

THE COURT: Sure.

MR. ABERNATHY: First of all, I meant to say this earlier and I am sure Your Honor is probably aware of it, but I did not want to fail to note that Federal Rule 5.1 comes into play here.

We did give a notice under Rule 5.1 to the Attorney General of Alabama and the court, as I read the rule, is required to allow the attorney general to be heard within the stated period of time before it declares that the statute is unconstitutional. So, I did not want to miss that point.

THE COURT: Have we heard from the attorney

general?

MR. ABERNATHY: I have not heard from the Attorney General and I honestly don't know. I mean, obviously this issue has been litigated in other cases and I frankly have no idea whether the Attorney General ever intervenes to address this issue. I just wanted to note the rule because it does come into play.

MR. MILLING: Your Honor, I have heard from the Attorney General. The Attorney General will intervene on an appellate level, it will not intervene at the district court level.

THE COURT: Have they told us that?

MR. MILLING: That's what I have been told.

COUNSEL: No, but they are, as far as I read the rule we have to certify first and then (inaudible) if 60 days has passed, and after 60 days (inaudible)

THE COURT: All right. Thank you.

MR. ABERNATHY: So, we may have to deal without anything from the attorney general. The only substantive point I wanted to address from Mr. Milling's argument, I take his point with respect to reprehensibility and we address this in our brief, but it is a little bit different than the issue of proportionality.

At least with respect to reprehensibility you

can argue that the jury is told to determine the amount of punitive damages based on reprehensibility, so there is at least some basis for the Court arguably to address that, although there needn't be any reprehensible conduct at all as it is commonly understood, because it could be awarded on mere negligence.

The bigger problem really is proportionality because the harm to the plaintiff or her decedent isn't relevant and can't be tried. It is not part of the case.

You can't award the damages -- you can't award punitive damages based on the harm to the plaintiff, and we cited a number of the Alabama courts that have said you can't come into the trial under the Wrongful Death Act and say oh, look what you did to the plaintiff or look how valuable her life is, or look what she lost, it is not relevant.

So, here, you know, the argument is you're going to make some determination of proportionality without compensatory damages, but there isn't even a record because it isn't tried. It is not relevant to the case.

So, from our point of view it is the proportionality which has to focus as we read Gore and

Campbell at least in part on the proportion between compensatory damages and punitives, that's the biggest problem.

THE COURT: Thank you.

MR. MILLING: And the final word, Your Honor, I will just do it from here if it is okay. First of all, in Gore, again, Gore said -- Gore did not state that compensatory damages are the only permissible measure of harm.

In fact, the Court emphasized that there is no mathematical bright line in Gore, but there must be a reasonable relationship between the harm and the punitive damages award. That's on page 582 of the decision.

Secondly, when Mike walked over he made a good point which is the issue is is there due process. There is due process in this case both at the trial court level and at the appellate court level.

The trial court, although the jury is the trier of fact, you are listening to the entire case and you are able to exercise your discretion as Alabama courts have to say I believe based on the proportionality, reprehensibility and the guideposts as they are not formulaically applied in Alabama that I think the award is appropriate or I think the award is

inappropriate and take responsibility as is the appellate court.

So, I think the issue is at the core constitutionally is there due process and there has been -- I don't think anyone has stood up and said or cited a case that has come down and said this statute is unconstitutional because it does not afford appropriate due process to either party as I have discussed.

THE COURT: Except as I understand -- I will go back and think about this, but as I understand due process in the Gore context it is what process does the jury follow, what is available to the jury in assessing those damages.

And the due process that you want me to find here, I think, is maybe due process at, you know, 5,000-feet, looking at the whole process, start to finish, was there due process to both sides.

And I think Gore seems to focus on what is available to the jury and what process does the jury follow in assessing that award of punitive damages.

THE COURT: And the due process here, as we have mentioned with the jury charge, would be the jury is to determine based on the totality of the evidence if it finds that there has been a wrong and, again,

let's not forget, we have to find there has been a wrong before we get to the issue of Alabama's measure of damages.

If they find there has been a wrong, that the plaintiff has succeeded on a claim, then they have to determine their damages based on the conduct. That is the standard. And then the issue becomes -- so that would be -- that has been analyzed and has been the standard, as we know, going back to before the 1920s.

Then the issue becomes should the Court disagree with that as the Supreme Court stated in 1991. There are a panoply of protections to making sure that at the end of the day, just like in the malpractice case, the award is appropriate if, in fact, the jury got it wrong just like the Court is free to do with the remitter.

THE COURT: All right.

MR. MILLING: Thank you.

THE COURT: Thank you. Okay. I believe Mr. Milling's suggestion for the next three motions involve the general discussion of preemption as sort of a way to approach those?

MR. MILLING: I just thought, or we thought and, of course, we can do it however, that we might want to have a discussion of preemption and get Your

Honor's feeling on preemption, get some of those issues out on the table, and if it appears Your Honor wants to then continue with argument then the question would be okay, let's talk about is there a material fact, genuine issue of material fact on failure to warn, is there a genuine issue of material fact on design defect. Does that make sense?

I just think it might categorize the argument, unless you disagree, Christy?

THE COURT: Ms. Jones?

MS. C. JONES: Oh, I am happy to do whatever the Court wishes us to do. I think frankly, Your Honor, that we are dealing with very different things. The first motion that I understand is on Your Honor's agenda deals with the issue of fraud and --

THE COURT: Fraud on the FDA, right?

MS. C. JONES: Well, it deals with fraud on the FDA or fraudulent concealment.

THE COURT: Right.

MS. C. JONES: And I think those are very different issues from those that are addressed in the subsequent issues. So, I am happy to do it any way you want to.

But, I personally think it will make more sense to the Court, and maybe that is only because

that's the way it does to me, to put it in the context of the arguments that we are going to be hearing rather than a broad discussion of preemption. But, if that is what Your Honor wishes to do, I am happy to do it.

THE COURT: My preference I think would be to go motion by motion. If there is some overlap with the preemption discussion, I am okay with that.

MR. MILLING: I think that's fine. In fact, what I was going to say was that we were actually going to suggest that the fraud issue go on its own and the preemption issue, the basic, express and applied preemption really applied to the latter two briefs as Ms. Jones stated appropriately. So, I agree with that.

THE COURT: Okay. Why don't we take a five minute break and then we will talk about the short form complaint and fraud issues.

(Recess 11:23 a.m. to 11:42 a.m.)

THE COURT: We'll hear argument on the next motion or two, break maybe around 12:15, take a lunch break, and then we will continue this afternoon. Ms. Jones, good morning.

MS. C. JONES: Good morning, Your Honor. Christy Jones, and I am standing up here because I think that the next one that is on the agenda in the

order that it was suggested is one of the short form complaint.

THE COURT: Short form complaint, yes, yes.

MS. C. JONES: To be sure, Your Honor, you may remember that several months ago we talked about the contents of the short form complaint and the extent to which certain claims made under that complaint were recognized under Alabama law or whether, in fact, the plaintiffs intended to proceed.

And I am sure the Court is delighted that the parties were able to stipulate the applicability of the vast majority of those claims.

THE COURT: Yes.

MS. C. JONES: The only issue that is currently before the Court are the claims that appear in paragraph IX and XI that relate to the issue of fraud and fraudulent concealment under Alabama law.

Let me first say for the Court I think it is clear from our papers there is no question that Alabama law recognizes that there may, in fact, be valid claims for fraud and fraudulent concealment.

However, the issue before the Court today is whether or not those counts are, in fact, product liability actions recognized by the State of Alabama, and I suggest to Your Honor that that is not the case.

THE COURT: Okay.

MR. C. JONES: The reason that that is important is that we are here to address specifically the issue of express preemption here. As the Court is aware, under the FDA Modernization Act of 1997 Congress passed legislation that includes an express preemption provision under 21, U.S.C., Section 379 and specifically that express preemption provision applies to any requirement that relates to an over-the-counter drug that is different from or in addition to or not identical to the requirements under the Federal Food Drug and Cosmetic Act of the FDCA.

That provision, Section 379, also includes a savings provision that specifically says that nothing in that express branch and Shelby construed to modify or affect product liability law.

And under Alabama law product liability law or product liability claims include those based upon negligence, negligent misrepresentation, the Alabama Extended Manufacturers Liability Doctrine, AEMLD, or breach of express or implied warranty and no other provision, and that is specifically set forth in Alabama Statute 65501, which defines the product liability under Alabama law.

In this particular case there are two issues

that the plaintiffs have raised. The first the plaintiff had raised the question of whether or not there is, in fact, a jury question.

I respectfully submit to Your Honor that the law is clear that the question of preemption is a question of law to be decided by the Court and I specifically point Your Honor's attention to the Dubois versus National Passenger Railroad decision out of the Third Circuit for that authority.

The plaintiff, however, claims that the fraud claims do fall under the savings claims and they do, as I understand their argument, for two reasons. One, because Alabama recognizes the fraud claims, and that is true, Alabama does recognize that, as I said earlier.

However, the plaintiffs ignore the plain language of the statute, 65501, that defines and circumscribes what falls within a product liability claim, and more important, the plaintiffs in this case rely upon the Wyeth versus Weeks decision for their proposition that Alabama recognizes a fraud claim.

I think it is important for the Court to understand several things. First, Weeks involved a prescription drug. It did not involve an over-the-counter drug. Therefore, it did not involve

either the express preemption provision of Section 379 nor the savings provision of 379 and did not address either of those.

Secondly, and perhaps most important, the Weeks court specifically held that that claim that was being adjudicated in Weeks was not a claim about a plaintiff ingesting a drug that was defective. In other words, it wasn't a claim involving product liability, but it involved only allegations that the manufacturer fraudulently misrepresented information. And the court held that those claims were not product liability claims under Alabama law, but distinct fraud claims.

So, what that decision specifically held was yes, it is true, as we have said, that Alabama recognizes the existence of claims for fraudulent and fraudulent concealment, however, those claims are not product liability claims under Alabama law as defined by the AEMLD or under statute and, therefore, for those reasons, it is our position that the express preemption provision of 21, U.S.C., Section 379 expressly preempts those claims and they cannot be asserted in this particular action.

There are some additional arguments that we made that related specifically to (inaudible) and fraud

over on the U.S. The plaintiffs did not respond to that. I frankly suggest to Your Honor that that is not really an issue that is necessary to be addressed in this case inasmuch as one, the plaintiffs didn't respond to it, but more importantly, it is very clear that the express provision, the express preemption provision preempts the claims for fraud in this case because they are not product liability claims under Alabama law.

THE COURT: All right. Thank you.

MS. C. JONES: Thank you.

MR. GAINER: Your Honor, as the defense has just stated accurately, this is confined to whether or not a fraud claim survives in this particular case involving an over-the-counter drug.

However, there were a couple things which I think the Court needs to understand clearly in making its decision about the survivability or that this claim includes fraud claims in a product liability setting.

Ms. Jones mentioned the Wyeth versus Weeks case and indicated that it was not a product liability case, but it was, in fact, a pharmaceutical product liability case, and the question certified to the Alabama Supreme Court and this is cited in our brief, Your Honor, but this was decided by the Alabama Supreme

Court just last year, in August of 2014.

The question was, under Alabama law may a drug company be held liable for fraud or misrepresentation based on statements made in connection with the manufacturer distribution of a brand name drug by plaintiff claiming physical injury from a generic drug and distributed by a different company.

Clearly, this was, in fact, certainly a product liability case. What the Court did make some distinction was to say that the product liability law in Alabama is not limited to the Alabama Extended Manufacturers Liability Doctrine, the AEMLD.

In fact, in that decision at page 657 for the purposes of this certified question we will not treat the Weeks' claim as AEMLD claims governed by the principles of AEMLD.

So, the point of that is to say this is certainly a product liability case and the Court would specifically ask whether a drug company can be held liable in fraud in misrepresentation in connection with statements it makes in connection with the drug, and the answer to that was in the affirmative, yes it can.

And so going back once again to that section and the savings clause as it is referenced, Section

379(r)(E), going back to another Wyeth case, Wyeth versus Levine case, while that involved a prescription drug the Supreme Court specifically addressed at footnote eight that Congress did enact, while it excluded some things as it relates to over-the-counter drugs it expressly preserved state product liability claims, and I just want to briefly address it.

In 1997 Congress preempted certain state requirements concerning over-the-counter medications and cosmetics, but expressly preserved product liability actions.

Well, this again, arising in Alabama it is a question of what are those product liability actions. Well, yes, they include the AEMLD, but they also include fraud, negligent misrepresentation, negligent suppression, and it is specifically so stated in the Wyeth versus Weeks case. Again this is referenced in our brief, Your Honor, but I will revisit it for a minute.

We do not find the boundaries of the judicially created AEMLD so that it subsumes common law torts actions of negligence, wantonness and other claims which are actually provided by statute. We have recognized that fraudulent suppression is a claim

separate from an AEMLD case.

So, in the context of product liability law in Alabama, to make it as simple as I can, they do have a judicially created doctrine. It is sort of a hybrid of strict liability, that is the AEMLD.

But, they also have other claims that can be made against a manufacturer which include fraud and suppression of material facts, misrepresentations, and it has been so recognized as recently in the Supreme Court decision in Alabama.

There was some mention, I believe, about an issue that is covered later, Your Honor, in our MIL that I think is not on today's agenda, but had to do with, I believe, an allegation of fraud against the FDA.

We have not pled fraud against the FDA. The Buckman case doesn't apply, but that will be addressed later, perhaps in part in the comments that Mr. Milling will make later today or Mr. Tisi, and it is certainly covered more in depth, if you will, in one of the motions in limine that the Court will hear at the next case management conference. Thank you.

THE COURT: Thank you. Go ahead.

MS. C. JONES: Just briefly, Your Honor. I think we clearly read the Weeks case very differently.

The Weeks case very specifically affirmed that fraudulent suppression is a claim separate from AEMLD, and Mr. Gainer did not respond to the fact that the Statute 65-5-501 specifically defines product liability actions as including negligent misrepresentation claims under the AEMLD and no other.

So, I think that the question is what actually amounts to a product liability action is recognized by Alabama, and as I tried to make the distinction the distinction is not that Alabama doesn't recognize a fraudulent or fraudulent concealment claim, it does. But, those are very different claims and separate and apart from the product liability actions.

THE COURT: Which are typically defect or design cases.

MS. C. JONES: Exactly. And, therefore, they are specifically and expressly preempted under the statute.

MR. WEINKOWITZ: Your Honor, Mike Weinkowitz, just to clarify one thing. There is a fraud on the FDA Buckman motion in limine, it is motion in limine number two, that's what Mr. Gainer was talking about.

Our entire fraud on the FDA argument is set forth in that motion in limine and I footnoted that, so we have addressed that despite what counsel said.

THE COURT: Okay. Thank you.

MS. C. JONES: I am happy to argue that, Your Honor, if Your Honor wants to argue that in this context. I would suggest to you that our same argument applies in that first a fraud on the FDA claim also falls within those that are specifically preempted but, secondly, and more importantly, under the Buckman claim, that is, specifically preempted.

And if Your Honor wants to argue that in the context of the motion in limine I am happy to do that.

THE COURT: Let's talk about it at that time.

MS. C. JONES: Okay. Thank you, very much.

THE COURT: Thank you.

MR. GAINER: Your Honor?

THE COURT: Yes.

MR. GAINER: I want to address this and I certainly want to for the sake of completeness for the Court.

First of all, again, what matters here is what constitutes a product liability claim in Alabama, and the Supreme Court case here in Wyeth versus Weeks decided just last year made clear what those were. That is the law of the state, if you will.

It included fraudulent suppression and material misrepresentation, fraud, so forth. Those

all, in addition to what would be under the AEMLD allowed in a product liability case.

THE COURT: All right.

MR. GAINER: This particular holding, and I want to be certain that this is made clear, again, for the sake of completeness for the Court, this actually provided for innovator liability, which is not an issue here. Innovator liability meaning that the case was against a name brand manufacturer for harm caused by a generic drug. So, it was not the actual drug made by the name brand manufacturer. The legislature in Alabama had subsequently determined not to have innovator liability, but they did not disturb anything else in this decision.

And the principles stated by the Supreme Court in Alabama about what constitutes a product liability claim which includes fraud, it includes material misrepresentation of facts or suppression of material facts, wantonness, negligence, AEMLD, is all still the law of the state, and I just wanted to be sure I was complete with the Court on that.

THE COURT: Okay. Thank you.

MR. GAINER: Okay. Thank you.

THE COURT: We have a motion for summary judgment on the failure to warn claim. Ms. Jones are

you going to argue that?

MS. C. JONES: I am, Your Honor.

THE COURT: Okay. And I am mindful of your suggestion that we ought to quit about 12:15 and so you are in a position to see the clock better than I am, but I would be happy to stop at any time --

THE COURT: Take whatever time you need, all right?

MS. C. JONES: -- that is appropriate for Your Honor. Let me see if I can put this in context. The plaintiff, as you know, asserts a wrongful death claim in which he claims that a therapeutic dose of Tylenol led to her death, led to acute liver failure and to her death.

There are several issues that will be before the Court eventually. They are not before the Court here that include the issue of whether or not she, in fact, experienced acute liver failure or whether or not it, in fact, was due to another condition such as sepsis or an overdose of Tylenol. And for our purposes here, setting those aside and we are only dealing with the issues of failure to warn.

The plaintiff claims that McNeil failed to adequately warn of the risk of acute liver failure associated with the use of Tylenol. Specifically, the

plaintiffs have taken the position that the warning is inadequate, and at least one of the reasons that the plaintiffs have said that the warning is inadequate is because there is no warning to specific populations of patients that may take the drug that they may be more vulnerable such as those who are fasting or malnourished.

In this particular case it has been and it is the position of McNeil that the science and the medicine establishes that the therapeutic and recommended doses of Tylenol have not been shown to cause acute liver failure.

In order for the plaintiff to recover for failure to warn under the AEMLD, and with the Court's permission I am just going to refer to it as failure to warn from now on, the plaintiff must establish three facts.

One, that the labeling is inadequate. Two, that an adequate labeling would have been read and heeded and, three, that the inclusion of a different warning would have prevented the injury.

THE COURT: Are you okay?

MS. C. JONES: I am fine. I thought that the court reporter and technical people were having some problem with me, so I apologize.

THE COURT: Okay. Fine.

MS. C. JONES: Under the Gurly (ph) case that we have set forth for Your Honor in the brief, it is clear that the warning must be one that is reasonable under the circumstances, but it need not be the best possible warning.

That there is no duty to warn of every potential danger or indeed to explain the scientific rationale for each warning, but only a duty to warn of those dangers which the user would not be aware of, and here I suggest to Your Honor that we clearly warned of the potential of liver damage.

Let me see if I can go back and to put this into perspective, but I think -- because, I think it is important for the Court to be reminded about the chronology that is applicable here.

If Your Honor will remember as early as 1977 it was recognized that with excess doses of Tylenol you could have liver damage and, in fact, that was recognized by both the FDA and in studies with that acknowledgment and still Tylenol was considered to be safe and effective when used according to directions.

Extra Strength Tylenol, which is what we are here about today, was initially approved as a new drug in the early seventies and, therefore, was under one

set of new drug application and regulations where the FDA specifically found it to be safe and effective as labeled.

Subsequently, in 1988 a tentative final monograph was promulgated by the FDA, and you will remember that there are two separate regulatory procedures, pathways, by which a drug can be approved and regulated and that the analgesics and acetaminophens, other than those that were specifically approved as new drugs, ultimately are governed under the monograph process.

In 1988 when the tentative final monograph was published there was no organ specific warning required under the monograph. So, that there was no specific requirement for a warning of liver damage at that time.

In 1994 McNeil amended its labeling to include warnings relating to alcohol, which are not applicable in this case, but nonetheless that was initially done with the new drug application which was subsequently withdrawn.

In 2001 an overdose warning specifically was added about the severe complications that might arise as a result of overdose. In 2002 the FDA held an advisory committee meeting to consider acetaminophen

and at that time McNeil advised of its intent to modify the label to include a liver specific warning associated with overdose and the like.

In 2003 the FDA, in fact, approved that liver warning, and in 2004 McNeil incorporated that liver warning on its Tylenol packages. That was before the FDA promulgated anything under the tentative final monograph.

In 2006 the FDA issued a proposed rule that would include liver specific warnings associated with excessive use or overdose of Tylenol. In 2008 there was an FDA working group that made certain recommendations, and in 2009 the FDA promulgated a final rule under the monograph which, in fact, became the final rule with the full force and effect of a final monograph, even though it is only one rule.

And in that -- at that time with the benefit of all of the foregoing, the FDA promulgated what now appears in 21, U.S.C., Section 3286, which is the requirements for the contents of the label insofar as it relates to liver damage in the event of excessive use of acetaminophen, and that label, Your Honor, appears on page seven of our brief.

And I had some -- a list of forewarnings that Your Honor does not have the exhibits here, I brought

with me copies of the 2009 and 2010 labels --

THE COURT: Thank you.

MS. C. JONES: -- that are involved in this case and implemented. I brought those because I want to put this into context in that the plaintiff and the issues that -- the plaintiff we are dealing with here allegedly took Tylenol in August of 2010.

Now, I gave Your Honor both of those labels because the plaintiffs say on one hand that Ms. Hayes took Tylenol, Extra Strength Tylenol from a bottle purchased in 2009.

The testimony is also that in August, 2010, shortly before her death or her hospitalization, another bottle of Tylenol was purchased, neither of those bottles still exists.

Following the death of the decedent the testimony is that her sister disposed of all of the remaining medicine bottles that she was taking. That sister is now deceased and we do not have any evidence to speak of of showing exactly what product she actually took and exactly which label was on the product.

I gave Your Honor both of those labels and the 2010 is cited, and frankly we think that the 2010 is the standard that ought to govern in this case and

the final rule because we think, you know, frankly given the fact that it is the plaintiff's fault, if you will, that we no longer have the bottle that it makes sense that the 2010 label, which is the one that would have been applicable at the time would have been purchased in 2010 ought to be applicable.

THE COURT: Which one is 2010?

MS. C. JONES: Without looking at them I can't -- I can --

THE COURT: Do you know them, Melissa? Okay.

(Pause in proceedings.)

MS. C. JONES: The 2010 one is --

THE COURT: Okay.

MS. C. JONES: -- this one.

THE COURT: Thank you.

MS. C. JONES: And I will say to Your Honor that's 2010, that the significant difference of the 2010 versus 2009 label for our purposes is the word "severe."

THE COURT: Okay.

MS. C. JONES: And if you look at the 2010 label, and Your Honor, I apologize if I have been thinking appropriate, I would have had them blown up for easier reference, but if you look under warnings on the left-hand side, if you see the warning it says

"This product contains acetaminophen. Severe liver damage may occur" --

THE COURT: I see.

MS. C. JONES: -- if you take more than eight caplets in 24 hours, which is the maximum daily amount," do you see that?

THE COURT: I do.

MS. C. JONES: If you then compare it with the other document you will see that it refers to liver damage as opposed to severe liver damage. And for our purposes here that is the primary difference in the two labels.

THE COURT: Right.

MS. C. JONES: Now, the reason that I went through the chronology and think that it is important is the following. Beginning in 2004 and the 2009 label specifically says "Don't take more than recommended. Don't take more than eight tablets in 24 hours, don't take it for longer than ten days, acetaminophen may cause liver damage, stop using, consult a doctor if pain doesn't resolve within ten days and overdose taking more than recommended may cause liver damage."

That was in the 2009 label all before the promulgation of the final label in 2010. At the time of the 2010, excuse me, the 2009 final rule being

promulgated the FDA also considered whether or not there should be a mention of fasting or malnutrition mentioned in that label, and if you will remember, I went through the various history.

One of the things that the FDA had set out in 2006 is an issue to be determined or to study was whether or not there were certain groups who might be more vulnerable, including those who were malnourished.

In 2009 when the FDA promulgated the final label specifically the FDA said, and this is in Exhibit E to our brief, and it is in the 2009 federal register, Your Honor, that I have here, if you need another copy, a little bit more paper to add to what you already have.

THE COURT: Thank you.

MS. C. JONES: At that point on, I will tell you the page number, on 19397, Your Honor, of the Federal Register, it specifically said "We are not requiring any warning that malnourished consumers are at an increased risk of liver injury when using acetaminophen as directed," and goes on to say that "The data does not sufficiently demonstrate that acetaminophen when used according to label poses an increased risk of liver injury in those individuals relative to other individuals."

When the FDA promulgated the final rule in 2009 under the regulations that final rule must contain the language that is promulgated in that rule and that has since been codified, if you will at 21, CFR, Section 326.

Your Honor, I am mindful of the time, I am happy to go forward and I am also happy to stop, it's whatever Your Honor prefers.

THE COURT: How much longer do you have on this topic, do you think? I don't want to limit your presentation.

MS. C. JONES: I can, I mean if Your Honor will indulge me, ten or 15 minutes, I can probably go through the entire argument and just set it all out for Your Honor.

THE COURT: Let's do that, yes.

MS. C. JONES: If you want to. Okay.

THE COURT: Let's do that.

MS. C. JONES: So, having set that forth, I would like to go back and talk about specifically the requirements of the AEMLD, and I would like to start, first of all, with the proof that the language of the warning must be shown to be inadequate.

I think it is important for Your Honor to know the plaintiffs have suggested that 21, CFR,

Section 201.80 governs the responsibilities here of the defendant. That is incorrect.

The language there and the title of this is specifically "Specific requirements on content and format of labeling for human prescription drug and biological products, older drugs not described in 201.56."

And 201.56 is the section that sets out the requirements on content and format of labeling for human prescription drugs and biologicals, not the over-the-counter drugs, and that becomes important, Your Honor, for the following reasons.

That provision includes, the 201.80 includes a provision that the plaintiffs have relied upon under warnings that suggests that the manufacturer has a duty to revise a label and to include a warning as soon as there is reasonable evidence of an association with a serious hazard of a drug.

That does not apply to the manufacturer of an over-the-counter drug, and that is inconsistent with the promulgation of the final rule of the FDA, which specifically requires the use of the language on the warning or the use of the language as to the liver damage as promulgated in 2009. So, I think that is important.

So, if we go back to the adequacy then of the label, it is our view that the plaintiffs cannot demonstrate, first of all, that the labeling was inadequate to advise of the risk of liver damage because it, in fact, even in 2009 before the promulgation of the final rule McNeil had voluntarily incorporated language there that related specifically to liver damage.

And, secondly, the FDA promulgated specific language in 2009 that must be incorporated and was incorporated and even the plaintiff's expert, Mr. Rakanau (ph) specifically recognized and testified that once the final rule was promulgated by the FDA that exact language had to be used as it related to liver damage.

And, in fact, McNeil did that. That is important because in the plaintiff's brief on pages, I think it is page six and seven, they have a litany of things that they believe should have been included with respect to liver damage, none of which are included in the FDA's final rule, none of which are included there after the years and years of study and seeking comments and so forth.

So we would suggest, first of all, that the plaintiffs cannot prove by definition that the labeling

was inadequate. Secondly, the second point that plaintiffs must prove under the AEMLD is, in fact, that the plaintiff would have read and heeded a different label. They simply cannot prove that.

First of all, Ms. Hayes is deceased, and there is no evidence specifically as to what she did or did not read and, in fact, whether or not she followed the directions.

There is, it has been suggested, much supposition in the testimony of her sisters that we think she would have done this or we believe she trusted this, or we think she saw advertisements, but the reality of it is that none of that testimony gets beyond sheer speculation or indeed would be admissible, and it certainly ought to be excluded under Federal Rules of Evidence Rule 404 in terms of character evidence if that's what they would rely upon to get it in. It simply cannot supply them.

More important is what we do know is that she did in fact, according to her sisters, take Tylenol despite the fact that clearly liver warnings were on the package.

That two, despite the fact that the package says don't take it longer than ten days, she did. And despite the fact that the package in multiple places

says don't take more than recommended.

Now, the plaintiffs want to say here, and their allegations are that she took only a therapeutic does. But we have inconsistencies. On one hand, we have the fact that the plaintiffs say that no one specifically saw her take any pill or the number of pills that she took. On the other hand, we have documented evidence where the two sisters separately filed insurance claims saying that she took an overdose and if, in fact, she took an overdose, she clearly did not follow the directions.

So I would suggest to Your Honor that there is no way that the plaintiffs can establish that she would have read and heeded a different language, label.

Third, there's a requirement -- there's no basis to say that a different warning would have changed the outcome and, in fact, there's absolutely no evidence to suggest that the outcome would have been different or Ms. Hayes would not have died had there been a different label there. There's simply no expert testimony to that effect.

The plaintiffs try to fill that void again by saying well, first, her sister wouldn't have bought the Tylenol if there had been a different warning there.

But, Your Honor, with all respect, Ms. Hayes was a competent adult.

There's no indication -- this is not a parent/child relationship or anything like that, and what the sister might or might not have done with all due respect, doesn't supply the requisite degree of proof.

Secondly, anything as I've said, that it would suggest that she would have acted differently is pure speculation at this point, and there's nothing upon which you can base it off.

THE COURT: Was there a --

MS. JONES: I think --

THE COURT: Was there a --

MS. JONES: -- that --

THE COURT: -- deposition of the sister?

MS. JONES: I beg your pardon?

THE COURT: Was there a deposition of his sister?

MS. JONES: Yes.

THE COURT: Okay.

MS. JONES: Yes, Your Honor, there are depositions of the sisters, and I believe that the pertinent testimony is all attached as exhibits for Your Honor.

THE COURT: Right.

MS. C. JONES: We'll certainly be happy to supply those in the event that you need the entire transcript rather than the portions that have been talked about, Your Honor.

Now, we go back to -- I say finally, I think it is clear that it's very difficult for the plaintiff to meet the burden of the failure to warn. We have the other issue of, frankly, preemption, and I would suggest to Your Honor it's perhaps not necessary for Your Honor to get there because I don't think the plaintiffs can meet the burden of proof and can establish evidence that would present a question of fact for the Court.

But, there is at least the argument of conflict preemption, opined preemption, applicable here by virtue of the implementation of the final rule by the FDA because the final rule of the FDA, even as the plaintiffs' expert recognizes, mandates the use of certain language here that was, in fact, implemented before this Ms. Hayes death.

Even though we have, as we talked about in the last argument, the issue of a savings cause on the product liability issue, when you have a situation where you have a federal law, and compliance with a

state law would require, if you would, a party to violate a state law or a federal law then you, in fact, have conflict preemption.

Better said, conflict preemption occurs where it's impossible for a party to comply with both state and federal law, and following the implementation of the final rule in 2009.

McNeil was required to use the language with respect to liver damage promulgated by the FDA. And what the plaintiffs are suggesting here is that they ought to use different language from that prescribed, and with all due respect, I suggest, Your Honor, that under Maryland versus Louisiana, that is a clear case of conflict preemption that would preclude a successful pursuit of a failure to warn claim under the final rule.

I think that, just to be clear, although I would have to say honestly to the Court there is some question as to whether or not the bottle that Ms. Hayes had had the warning from 2010 versus the final warning label versus what had been voluntarily put on there before by McNeil, there's one very little difference between the two.

But, more important, under the circumstances here where we don't have the bottle and where the

bottle was, in fact, disposed of by the plaintiffs, I think we're entitled to the presumption that it's more likely to have been the bottle that would have been in effect in 2010 with the 2010 label which would, in fact, have been the label under the final rule.

So I guess to just quickly wrap it up, I would suggest to the Court that there's no showing that there is a genuine issue or that the plaintiffs can present a genuine issue in material fact as to the adequacy of the label as to whether or not the decedent would have read and heeded another label as to whether some other warning would, in fact, have prevented her injury, and that the plaintiffs cannot rely upon the testimony of the sisters on supposition to bootstrap an argument into suggesting that she would, in fact, have read and heeded that.

And, for those reasons, there's no genuine issue as to any material fact, and we believe that we are entitled to summary judgment as a matter of law.

THE COURT: Thank you, Ms. Jones. Why don't we take a break? It's 12:35. Can we be back at 1:45, and then we will resume with arguments at that time. Okay. Thank you.

ALL: Thank you, Your Honor.

(Luncheon recess, 12:36 p.m.)

AFTERNOON SESSION

1:52 p.m.

THE COURT: Please be seated. Mr. Tisi, good afternoon.

MR. TISI: Good afternoon, Judge.

THE COURT: Whenever you're ready.

MR. TISI: Sure. For the record, my name is Chris Tisi. I represent the plaintiffs in this case. I think I'm the only one in the room who has not had an opportunity to appear before you, so thank you very much, and your staff as well.

There are really three issues before the Court on the motion to dismiss for what we've called failure to warn, but it's really failure to warn and instruct on the proper use of the product.

The first is whether there is reasonable evidence from which a jury could conclude in this case that the 2009 Extra Strength Tylenol label, which really is the label at issue in this case for a reason that I will explain later, which says that an overdose of acetaminophen can cause liver damage, however, that is defined, adequately informed the plaintiff on the risk and how to mitigate the risk.

The second issue is is there evidence from which a jury can conclude that the appropriate warnings

and instructions would have changed the behavior of Ms. Hayes and whether or not that was a proximate cause of her liver failure and ultimate death.

And the third issue is whether or not plaintiffs' claims for warnings and instructions were impliedly preempted under federal law. Those are three really big questions, Judge, and I apologize ahead of time for the fact that I think we're going to have to go through some evidence and some of the regulations and all of that, and I apologize. It may take a little bit longer than I had hoped.

I think to make it easier for the Court and for the record, we've discussed over lunch that it may be easy for us to break this apart and discuss with you ahead of time two issues related to the regulatory scheme and where acetaminophen fits in the constellation of these regulations because I think it can be a little bit confusing, and I think picking and choosing different regulations might make it difficult to really understand the 40-year history of this drug.

So, what Mr. Milling and I have decided to do with your permission is to have Mr. Milling perhaps come up and talk about two issues, the first being the relationship between an OTC manufacturer of a drug and the Food and Drug Administration under the FDA

regulatory scheme.

And the second issue is the current and appropriate at the time and place that acetaminophen fit within that regulatory scheme and what, frankly, McNeil has done over time to change its label repeatedly and voluntarily in order to try and address certain issues and why we think that there was a failure to do so in this case.

So, with your permission, I would like to be able to maybe give some of my time to Mr. Milling, have him go through, and then maybe rejoin you after he is done.

THE COURT: That's fine.

MR. TISI: Thank you, sir.

THE COURT: Thank you.

MR. MILLING: Good afternoon, Your Honor.

THE COURT: Good afternoon, Mr. Milling.

MR. MILLING: And, again, Clayton Milling, for the record, for the plaintiffs. I was assigned preemption, but I think what I would -- what I really would like to be able to -- I think what the best use of my time today is for me to cover preemption, but cover it in with providing the Court an understanding of the regulatory systems that are at play, what McNeil has done and then, by inference, to show the Court that

they have not been -- there has not been any preemption in this case.

To begin with, I'll just say that every court that we could find in the country that has looked at a case involving OTC Tylenol and OTC Motrin, both manufactured by McNeil, has had this very motion filed against them on preemption, including two in the Eastern District of Pennsylvania from your colleagues, the Wolf versus McNeil case and the Brown versus Johnson and Johnson case, 2014. And every court that has looked at this motion has determined that there is no preemption.

That being said, the parties both agree in their briefs that there is no express preemption about the failure of warn, that the savings cost handles that. So the issue is applied preemption, and with implied preemption, as the Court knows, the issue is there an impossibility?

Is there some sort of impossibility for McNeil to, as some people say, worship both masters? Can they handle their state court responsibilities for their tort -- for tort claims while at the same time handle their federal responsibilities pursuant to the regulations and the answer, again, from every court that has looked at it is yes.

Let me start by just simply noting for the record, I think we've cited some cases, some Supreme Court cases. I do not have this in my outline, but since Mr. Tisi mentioned it, I will tell you that the United States Supreme Court and all courts have uniformly held that the manufacturer and not the FDA is ultimately responsible for its label.

When you buy Tylenol it does not say FDA on the label, it says McNeil on the label. And it is the obligation of McNeil to warn of risk that are known and knowable once it's -- as it is performing its pharmaco vigilance, as it's looking at the various lines of evidence, and if it determines that the risk profile of this drug has changed over time or a new risk has emerged.

Now, what I have done, and I have some documents and I'll hand them to Your Honor for a second, but I -- would it be okay if I move away from the microphone to draw? I was asked to do this by my colleagues.

THE COURT: Sure.

(Pause in proceedings.)

MR. MILLING: So at the top tell me -- maybe I'll turn it this way. At the top, Your Honor, is the FDA, and the FDA has many divisions within it. And the

two divisions that we're going to be talking about today are completely separate divisions.

One is called monograph. It's actually called the OTC, over-the-counter review. And the second is called NDA, new drug application. And those are two different regulatory pathways by which a drug can be legally marketed in the United States. In this case, McNeil has acetaminophen Tylenol products and has always had acetaminophen Tylenol products in both regulatory pathways.

There is a wall between these regulatory pathways of the FDA, and if McNeil, for example, learns of information and puts it in its annual report, that information goes to the NDA department. It doesn't go to the monographs department. So they're totally separate.

So what happened in this case? In this case, in 1975, McNeil filed documents with the FDA in the form of a new drug application, and the FDA reviewed McNeil's clinical documents, et cetera. It's not really important.

Initially, they had a couple of questions but eventually in 1979, the Extra Strength Tylenol was approved, and when a drug is approved for NDA it's approved as being safe and effective as labeled. And

NDA, Your Honor, is for an individual product, Extra Strength Tylenol with a specific label that the FDA has approved.

At the same time, backing up, going back to the fifties, there was a system called DESI, drug -- they were looking at old drugs, acetaminophen, old ingredients, aspirin, Bufferin, all this kind of stuff, and the government was trying to figure out what do we do with these drugs that have been on the market for so long and they're innocuous? They're in all of these products.

And they created a system that they believed at the time was going to be efficient called the monograph system. In the monograph system, this review would be a three-part process. And the three-part process would be that initially a panel of, they call them the legislation, qualified experts, would get together and have meetings to discuss what they thought was -- what they thought the safety profile of the drug was, what they thought appropriate warnings should be, what they thought appropriate doses should be, and they would then write up to the FDA a proposal. And that's -- I'll show -- we'll show -- I'll show you the language.

Then, after the proposal is written, there's

time for comment, there's time for new data. McNeil can always submit data as it's going along and edit. The whole premise is that the stake-holders will continually submit data so when we get to end game we have the most current information.

So in 1977, there was a panel report, acetaminophen, and that's terrible -- that's terrible, I'm sorry. The panel report was filed. It said in there -- the scientists said we believe that putting a warning, in fact, it's the identical warning that went on in 2009 that says severe liver damage may occur with overdose is obligatory based on data in 1977. Time passed. Eleven years passed.

1988, the government came in and issued a tentative final monograph, and the tentative final monograph is a lengthy document, I'm going to show it to Your Honor in just a bit, and it goes through lots of the comments that were made by various stake-holders and ultimately says -- at the end it has about three pages, it says "This is what we envision the monograph to look like," and it gives a proposed monograph, which is a cookbook.

But eventually -- what it is is it's going to be a document in the code of federal regulations that says if anybody, Milling Company, Stengel Company,

wants to sell acetaminophen, you don't have to get FDA approval once there's a final monograph because all the parameters of how you do the dose, the warnings, the duration of use, everything has been solved and is finished. As of today, as the Court is familiar, we're still operating under a tentative final monograph.

Now, in 1998, Extra Strength Tylenol -- McNeil wrote a letter to the FDA and said we want to withdraw our NDA and we want to proceed under the tentative final monograph.

There is no more NDA for acetaminophen, but NDA has a number, and when you file a document which is kind of -- it took me a while to understand, to an NDA you write -- just like you write a case number, the NDA number, blah, blah, blah, and it goes into that file. You cannot file a document to the Extra Strength Tylenol NDA because it doesn't exist anymore.

What does exist in NDA though is Extended Release Tylenol. So the signa, the longer duration Tylenol was never contemplated on the market, so we have now extra strength and extended release and all of the other Tylenol products but, again, McNeil has an NDA and it has a monograph. Make sense?

McNeil files all of its adverse event reports, all of its annual reports, to this NDA because

that's required. It does not file it to the monograph. Everything that McNeil files to the monograph, incidentally, is public.

Everything McNeil files to the NDA is completely private. So one of the things that the jury is going to be hearing about over the course of the trial is well, if the N -- when the -- when the regulators make certain rules what information had McNeil provided to the monograph, and the jury will be learning about that.

So, recognizing that we have an NDA and a monograph, we go back to when Extra Strength Tylenol was an NDA. The question for preemption and the question for warnings at the core is can McNeil voluntarily make changes to enhance its warnings without being forced to do so by the FDA and without the FDA saying no, in other words, preemption? And if we start -- here's -- I may not need all these documents because -- Your Honor, may I approach?

THE COURT: Yes.

(Pause in proceedings.)

THE COURT: Thank you.

MR. MILLING: So, this is a 1994 document and it is written to the Extra Strength Tylenol NDA because in 1994, Extra Strength Tylenol was still an NDA

product.

And it is a special supplement changes being effected, and it is saying to the FDA under, "Changes being effected regulation, 'We are taking these steps on our own to change our label for this NDA product.'"

And then if the Court will look at the last page of the document, the third page, then this is -- this will be important later, it's in the second paragraph it says, "If the attached" -- "As the attached letter to Dr. Weintraub indicates, we're also incorporating these same revisions in the labeling for all adult Tylenol acetaminophen-containing products in the monograph."

So what happened, Your Honor, was in 1994, they said we're going to use this "Changes being effected" way, we're going to make changes here in the NDA, but we're going to tell the FDA hey, because we have products over here we want our labels to be consistent, and that's what they did.

"Changes being effected" in the NDA setting is a way in which companies make changes voluntarily. As the court in Wyeth versus Levine said, "Generally speaking, a manufacturer may only change a drug label after FDA approval of a supplement application. There is, however, an FDA regulation that permits a

manufacturer to make certain changes to its label," here is the keywords, "before receiving the agency's approval."

"Among other things those changes being effected," the letter that I just showed you, "provides that a manufacturer is changing to the label to add or strengthen a contradiction, warning, precaution, or adverse event, and it may take the labeling change upon the filing of the supplement application with the FDA. It need not wait for FDA approval." That's what McNeil did and that's the procedure they used under the NDA.

In fact, if you go to the next document, McNeil advertised to the world, we have voluntarily -- Tylenol urges the industry to follow us on voluntarily changing our label to add alcohol. Question for preemption, question for this case, can the company make voluntary changes, absolutely.

Third document, this is interesting because it's 2001. Are you with -- this is the letter to Dr. Ganley.

THE COURT: Dr. Ganley, all right.

MR. MILLING: All right. And the reason that I point out 2001, Your Honor, is because I'm -- we got to go back over here. In 2001, Extra Strength Tylenol is no longer in the NDA. It is a monograph drug, and

the number, the NDA number at the top has changed.

And so here, McNeil is making it, "That changes being effected," if you'll look right over here, "to its extended release product under the NDA," and then it says on the second page, I have it highlighted for you, "These same changes will be made to other Tylenol products of the monograph."

So we are going to make our change over here and then we're going to bring it across to the monograph. And, again, that was perfectly admiss -- perfectly permissible and it was accepted.

Now, so now let me change. That's how you -- that -- this "Change is being effected," Your Honor, is a regulation that we'll look at a little bit, 314.70, but that regulation, again, allows McNeil to make the change voluntarily under the NDA.

Now, let's move to the monograph, and the next document is the document 21 CFR Section 330.10. This is the statute that creates the monograph system. It reads, "For purposes of classifying over-the-counter drugs as generally recognized among qualified experts as safe and effective for use and not misbranded, the following regulations shall apply."

Now, I've highlighted for Your Honor on the first page the commissioner's advisory report followed

by, on about the fourth page or fifth page, actually, further than that, the seventh page, the tentative final monograph.

And then if you'll look at page eight, and this may be a little bit of aside and nuance, but it's something that's come up in motions and has been talked about, it says in paragraph nine, "Final monograph. After reviewing the objections, the entire administration record including all new data," again, the concept of McNeil and other submitting data to the monograph, "and information and comments, and considering the arguments made at any oral hearing, the commissioner shall publish in the Federal Register a final order containing a monograph establishing conditions under which a category of OTC drugs or specific OTC drugs are generally recognized as safe and effective and not misbranded. The monographs shall become effective as specified in the order."

As of today, there is no final monograph for acetaminophen. I'll talk about the final labeling rule, and we should note that this is in Section 330, and, eventually, you'll see the labeling rules in Section 201 because it's not a monograph, it's a labeling rule.

So that's the procedure. In 1988 the next

document is the tentative final monograph. And, as you can see at the top of it that I have it says, "The action is a notice of proposed rule-making." And it says, "Summary: The Food and Drug Administration is issuing a notice of proposed rule-making in the form of a tentative final monograph that would establish conditions for a drug to be generally recognized and effective."

Over on the right-hand column, the legal status of this document is given. "In order to confirm the terminology used in the OTC drug review regulations," and it cites 330.10, the one we just looked at, "the present document is designated as a tentative final monograph. It's legal status, however, is that of a proposed rule."

Your Honor, this is not a law, this is not a regulation, this is a proposal. And so then the question becomes from 1988, we know that Extra Strength Tylenol is operating under the tentative final monograph, can McNeil voluntarily change their label if they determine that there's a signal of safety? Can they change their dosing regimen? Can they change the -- lower the maximum daily dose, all of the things we have talked about? The answer is unquestionably yes.

The next document is a letter to Mr. Gainer actually, who spoke this morning, from the FDA. "When McNeil changed its dose, maximum daily dose, from four grams per day to three grams per day in 2011, after Ms. Hayes died, Mr. Gainer wrote a FOIA request to the FDA and said please send me all the documents relating to this change. And the FDA wrote back and said, "Extra Strength Tylenol is marketed under the IAAA tentative final monograph. Under a tentative final monograph manufacturer's market products at their own risks and are able to make voluntary adjustments taking into account the information presented in the proposed TFM. McNeil's voluntary act to reduce the maximum daily dose is a measure that can be commonly taken by over-the-counter TFMs."

The FDA says of course you can do it. It's just a proposed rule. It's your discretion. You market this at your own risk, and as long as you stay within the borders and the confines of generally what's in the proposal, we're not going to take any regulatory action against you. And, in fact, once again, Your Honor, McNeil wrote a letter to doctors and said look, we voluntarily reduce the dose. There's no preemption.

If that's not clear enough, I believe in the tutorial I stated or showed you a slide of their -- of

their own witnesses. Dr. Anthony Temple testified, "I agree the language is consistent with what's in the regulations. Agency approvals not needed."

Your Honor, we have an expert, Gerald Rationale (ph), who's been challenged as a Daubert, but he actually wrote the tentative final monograph that we're dealing with and can comment on how this process works.

Even the defense expert conceded, of course, under the tentative final monograph, which only has the force of law to propose rule, you can change the label to increase your warnings if you believe it's appropriate to do so.

Now, I want to step back for a second and talk about policy. The FDA encourages manufacturers in many different ways to make changes, and it lays out various standards in various places in the regulations, but they are all designed to do one thing, make sure that the consumer comes first, that safety comes first, and that important information on life-threatening illnesses are not being withheld from consumers.

One thing you will not find, and Ms. Jones indicated that we had cited a section in the regulations that applies to prescription drugs, and I'll get to that in a second, but the bigger point is

you will not find, as Ms. Jones has not stated and it is not in the regulations, and I think it's intuitive, but there will be nobody that will ever say that the standard before a company has to warn is 100 percent proof of causation.

In fact, there have been drugs taken off the market for three adverse events of serious crazy illnesses without any proof of causation. The standard for warning is far less than causation, and there's no regulation that says that.

If we look at the next document, we started with 330.10 and then -- which is the -- how the monograph system works. We're now at 330.12, "Status of "Over-the Counter Drugs Previously Reviewed Under DESI," that's acetaminophen.

And if you go to the second page, I've highlighted for you at the bottom that kind of goes on to the following page. It says, "Manufacturers and distributors should take notice that the information on OTC drugs provided by drug efficacy study," that's the DESI review, "is valuable information as to 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

which is already in process." That's the monograph process.

It goes on to say, "In the interim, while you're in the monograph process, it is in the public interest that manufacturers and distributors of all OTC drugs affect changes in their formulations," think about our case, "and/or labeling to bring the products into conformity with current medical knowledge and experience."

That's what the regulations says, a general expectation of the FDA for drugs that are in the process. Bring your product if you -- up to the science that you know is available either through formulations, which we know McNeil has been involved in, or through label changes.

Then it goes on, and I don't know if I highlighted yours, but it goes on to talk about the fact that manufacturers may be reluctant to make changes because they make changes.

The FDA may come after them and say you have actually created a new drug, and they may take a regulatory action against the FDA. Does that make sense?

But, what these paragraphs say is "Manufacturers may be reluctant to take these changes

because they might lose their so-called grandfathered status under the monograph."

It says, "To encourage and facilitate prompt changes, the Food and Drug Administration will not take legal action against any OTC drug other than those not deferred based on the charge that the product is a new drug, maybe with an antidote put it in, and not grandfathered as a result of the changes in formulation or labeling," and it tells you the kind.

It says that "The addition of labeling, number one, or warnings, we're not going to take any regulatory action if you add that to your product if you think it's appropriate."

Number two, "Changes in the component, or composition of the drug, we're not going to take any regulatory action if you find that you can make a better and safer product and you do it."

Number three, "Changes in the components or composition of the drug which may reasonably be included to improve the safety of the drug." In other words, the policy behind the monograph system is please make changes, we want you to make changes, we know there's no final monograph yet.

Now, we've now shown Your Honor that McNeil has made voluntary changes under the NDA, they can.

They've made voluntary changes under the monograph, they can.

And I just want to take a second and address something that Ms. Jones said today, which is that the plaintiffs put a standard in their brief that was incorrect. Now, if you can tell, I'm working my way through these documents, so that's good. I apologize.

The regulation that is in front of you, the next document, is 21 CFR 201.57 and, actually, before we get there, is there a way, Your Honor, for you to go back to the very first document that we skipped?

THE COURT: Which is what?

MR. MILLING: It is 21 CFR 314.70. It was at the top of the stack.

THE COURT: Right.

MR. MILLING: 21 314.70 is the regulation on how to do a "Changes being effected," for how to do a CBE. In fact, it's kind of interesting. I read to you -- may I approach, Your Honor?

THE COURT: Yes.

MR. MILLING: I read to you from the Wyeth case. It's in our brief. But after the Wyeth decision explained what a "Changes being effected" was, it cited 314.70 C63, so that's the -- that's what we're now going to look at, 314.70.

THE COURT: And what page are you in your brief?

MR. MILLING: I'm on page 51.

(Pause in proceedings.)

MR. MILLING: And 314.70 is entitled "Supplements and Other Changes to Approved Applications." So here we are with an NDA, an approved application, and this is the regulation that says if you want to do a change like the CBE that we saw them do, you go to 314.70.

And if you go to 3.70, you go to the third page, you'll see a little c, just as The Supreme Court noted, and if you go to the fourth page, I've highlighted number six, which is where The Supreme Court noted, and this is the "changes being effected."

It says six, it says, "The agency may designate a category of changes for the purpose of providing that in the case of a change in such category, the holder of an approved application, like McNeil, may commence distribution of the drug product involved upon receipt by the agency of a supplement to the change." In other words, once we get the letter, you can start distributing the product.

Number three, as the Court said, "Change in the label to reflect newly acquired information to

accomplish any of the following," and this is what they were doing, they were increasing the warnings, "A, to add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for including in the label under 201.57."

So this is a little complicated, but I'm trying to explain why Ms. Jones accused us of giving the wrong standard. This "Changes being effected" regulation says go check out Section 201.57 for the standard. Does that make sense?

And the next document I have for you 201.57, and it is the prescription drug standard, but that's the only place where standards are -- this particular standard is.

And if we look at 201.57 on the sixth page of the document, "Warnings and Precautions," "This section must describe clinically significant adverse reactions, including any that are potential fatal," acute liver failure, "are serious," acute liver failure, "even if infrequent or can be prevented by mitigation through appropriate use of the drug."

Going down to about the middle of the paragraph, it says, "In accordance with 314.70," which we just looked at, "warning" -- of this chapter, "the

labeling must be revised to include a warning about clinically significant hazard as soon as there is reasonable evidence of a causal association with the drug, a causal relationship need not have been established."

Now, we got called out this morning because I cited or our team cited the next document in your stack which is 201.80. 201.80, Your Honor, respectfully, is the new version of 201.57. And if you look at 201.80 on the third page --

(Pause in proceedings.)

MR. MILLING: If you look at 201.80 on the third page under "Warnings," this is what we cited in our brief. "Under this section, labeling shall describe serious adverse reactions and potential safety hazards, limitations, and use by them and steps should be taken if they occur.

"The labeling shall be revised to include a warning as soon as there is a reasonable evidence of an association of a serious hazard with a drug. A causal relationship need not have been proved." The point of me going through this, Your Honor, is to say there are various standards out there.

But, if you go to the NDA standard by which McNeil makes changes, it guides you to the standard for

prescription drugs and it says you don't wait for causation, and that's why we cited that in our brief, and that's why what the jury is going to be listening to on the warnings issue is number one, under the regulations, has McNeil apprised consumers of the current state of its knowledge, whether it be through warnings or redoing the product, as we looked at in the CFR, Section 330.12.

Or has McNeil -- did McNeil -- does the evidence support this in association with a life threatening condition such that it should be warned about, because what I have heard multiple times, respectfully, in the court is a discussion of causation.

Causation, specific causation is the second question in this case. The first question is was the warning appropriate. We now know they can warn. Now I've tried to provide some context for when you warn.

In fact, I next -- next, I have a quote from the defense expert because I was called out or we were called out that this was the wrong standard, and I said doesn't 201.80 in the Code of Federal Regulations talk, and I walked through the standard.

I said, "Are you familiar with that language?" And she said, "Yes, I am." I said, "Isn't

that the standard for when a warning should be place on an NDA drug as promulgated by a government?

"Answer, "It's in the regulation. That's what the regulation says."

"Thank you. So to be clear for our judge and jury as it relates to NDA products, a pharmaceutical company has to put warnings on it as soon as there's reasonable evidence of association. They are not allowed to wait until causation is proved, true?

"Witness: That's what the regulations say."

Question down at the bottom, "The regulations of law?

"Answer: Yes."

I'm going to do one more thing and I'm going to talk about Ms. Jones' comment about malnutrition and then I'm going to talk about the final rule. Malnutrition, Ms. Jones says that in 2009 -- well, I'll back up.

(Pause in proceedings.)

MR. MILLING: Ms. Jones says that there is the applied preemption because in 2009, even though at any time from 1980 up until 2009, McNeil could have warned, could have changed the dose, could have done whatever they want.

In 2009, a final rule came out that said use

the word, "severe liver damage." This is very (indiscernible). Why did they choose the language, "severe liver damage"? They did it because that's the exact language that came in the '77 monograph. The FDA was confined to the monograph system. The warning that the FDA said put on in 2009 is the same warning that was recommended in 1977.

McNeil could have put on a higher warning at any time voluntarily between those dates. McNeil could have lowered the dose like it did at any time. But it didn't. And, in fact, it disagreed with the proposed putting "severe" on by saying we don't want the word, "severe," but the FDA insisted on "severe."

But, here's the kicker. Just because the FDA says that you have to put this label on doesn't mean you can't put more. Right above 330.12 that I've got in your packet is 330.11 called an NDA deviation.

That's the procedure you go through if you say you know what, you've given me a rule, FDA, but I want to do more than your rule. I don't think severe liver damage, even that, really tells people that they can die, that they could have a liver failure, like our prescription drug does, like the American Association for the Study of Liver Disease recommended, like the FDA scientist recommended. I want to do more. You can

always do more. The FDA's regulation creates a floor, not a ceiling, and there are regulatory mechanisms for doing it.

As it relates to the issue of fasting, McNeil's brief is pretty aggressive, and it says "The FDA rejected fasting." And Ms. Jones referred to you to page 19397 of the 2009 rule, and I want to refer you to the next page, 19398. Your Honor, fasting has been around in malnutrition.

THE COURT: Well, where are you?

MR. MILLING: It's been around --

THE COURT: Where are you?

MR. MILLING: I'm on the last document, the 2009 rule. I'm sorry. How long ago did I lose you?

THE COURT: And what page?

MR. MILLING: Page --

THE COURT: 19397?

MR. MILLING: 19398.

THE COURT: Okay. Go ahead.

MR. MILLING: All right. To set the -- to set the stage, in 2006, three years before this document came out, Your Honor, the FDA issued a notice of proposed rule making, and it asked for comments from stake-holders about various things, about increasing the warning to severe, about putting a warning on for

malnutrition, about what the maximum daily dose should be, about a lot of things.

And in response to that 2006 notice, that's where the American Association for the Study of Liver Disease responded. It said we agree with the FDA and, in fact, we think that the label should say liver failure, death, et cetera. McNeil wrote in and said we disagree with the FDA, it should not say severe.

In 2009, because McNeil had not done anything to its warning other than say liver damage, the FDA said we're going to require liver warning, but it said we're not going to require fasting. And the way the defense has characterized it is that the FDA rejected fasting, therefore, creating preemption, but it's not the case.

In this Federal Register, what the Court will see, and I don't want to go through it, but I'll just tell you, there were only three documents turned into the FDA on the issue of fasting with the total on page -- of nine cases.

And the part that I've highlighted for you say, "The submitted data are not sufficient to conclude that acetaminophen used a daily OTC doses by malnourished individuals poses additional risk of liver injury in these individuals.

"Therefore, we are not requiring any warning for these individuals," and here's the part the defense has not read, "at this time. If new data becomes available, we will reconsider our position on this issue."

The FDA has never said you cannot put a warning on for malnutrition. The ASLD recommended in 2006, and this document is premised only on three submissions. Malnutrition first came I think 1987 I want to say with an article by Wickman Block (ph). It's been discussed for a long time.

And the jury, if we get into this issue, will see whether or not McNeil turned in all the articles they have in their database on malnutrition to the monograph system.

I'm not going to -- I don't want to tell anybody what the evidence is, but only three submissions came in on fasting, and they said we don't have enough data to make a decision, but there's no implied preemption.

Your Honor, what I've tried to do today is say number one, this is the regulatory scheme. I hope it wasn't too crazy. On both sides of the ledger, McNeil has exercised the way -- has exercised its option and its regulatory ability to say we want to

make changes without FDA approval.

The FDA has never stood in the way of any approval, and even in 2011, McNeil voluntarily reduced the dose. There is no implied preemption. No court has ever found implied preemption, and with that lengthy setting of the table, I'll now have Mr. Tisi, ask him to come up and talk about the genuine issues of material fact on the warnings claim.

THE COURT: Thank you.

MR. MILLING: Thank you, sir.

(Pause in proceedings.)

MR. TISI: Thank you, Judge. If you would give me a moment to get organized here?

THE COURT: Okay.

(Pause in proceedings.)

MR. TISI: To give you a sense of where I expect to go over the completion of the argument, Judge, I want to talk to you a little bit about what was happening with acetaminophen against the backdrop that Mr. Milling was talking about and talked to you about before, what the evidence is with respect to Ms. Hayes, and what her expert testimony is going to be with respect to the inadequacy of the warnings in this case.

But, before I do, I just want to make a

couple of observations, if you would indulge me on that. At its core, the defendant's claim is that what was happening against the backdrop of this regulatory scheme is irrelevant.

It's irrelevant what the American Association for the Study of Liver Disease said, it's irrelevant what the FDA Working Group, which was a group of FDA scientists reporting to the CDR, the director of the Center for Disease and Research portion that covers drugs in this country. It's irrelevant what the scientist was saying. The only thing that's relevant is what's in their files, what they -- what they did, and what the FDA required them to do under the monograph system.

Now, juxtaposed against that, Judge, is in almost every pharmaceutical case that I know I have been involved with and there is a lot of experience in this room, what typically happens is an expert gets on the stand and learned counsel for the defense gets up and says to the expert, Mr. or Dr. expert, how come you are the only one in the world who has figured this out? Nobody has else has figured out what you're now telling the jury. The FDA didn't do it, the scientists didn't do it, nobody did it, okay?

And, in that circumstance, the expert has to

explain why they came to a conclusion with the benefit of hindsight that all the other scientists in the world didn't figure out?

Here, uniquely among cases at least I have been involved with, we have the opposite situation. We have a situation where the experts will get on the stand and their witnesses will agree in almost every instance that this was not a legitimate debate within the medical and scientific community. This was a debate between McNeil and the scientific community.

Who represents that scientific community? The American Association for the Study of Liver Diseases. Scientists like our experts, Dr. Caploids (ph), and Dr. Darren (ph), who published at the time in this area. The Food and Drug Administration, who had not one but two medical advisory committees in the 2000s in order to try and bring these issues out in the public.

An almost unprecedented group of scientists who were pulled together by the director of the advisory who said look, tell us what you think. You review the science and you tell us what you think.

So, now because we have a situation where almost all of the scientific and medical community has lined up against McNeil, they have taken the position

in saying well, we don't need to look at what was going on outside.

Well, let's look at what the FDA actually said. In 2006, and I believe you have the document in front of you. In fact, can you bring up the box right here?

This, Judge, I will refer to you is the December 26th, 2006 proposed rule by the Food and Drug Administration published in the Federal Registry, volume 71247, and I believe it's Exhibit 8 to our opposition for motion for summary judgment. May I approach, Judge?

THE COURT: Yes.

(Pause in proceedings.)

THE COURT: Thank you.

(Pause in proceedings.)

MR. TISI: After reviewing -- and just to put this in context, in 2002, the FDA held a medical advisory committee meeting, and maybe I ought to back up for a moment and talk a little bit about what that is.

When there are scientific issues that come up that are -- that are -- that require input, sometimes the FDA reviews it internally, but sometimes what they do is they bring together outside advisors, and then

they have the various stake-holders, companies, scientists come and present, and the FDA actually presents, and then sometimes they meet and try to have a consensus about what needs to be done on the particular issue going forward.

There was a 2002 advisory committee talking about the issue of acetaminophen toxicity, which I think we described in our brief as being a serious public health issue because of the number of deaths, transplants, hospitalizations that were due each year to acetaminophen, which I will remind the Court, I'm sure you've heard this several times, exceeds all other causes of liver failure combined, this one drug.

So after that, the FDA issued a proposed rule and that's what you have in front of you. And on page -- after reviewing what happened at the 2002 advisory committee, the FDA on page 77329 says this,

"The FDA believes that these data support the previous advisory committee conclusion that acetaminophen hepatotoxicity is an important public health consideration and that additional labeling is necessary for it to continue to be recognized as safe and effective."

I want to pause for a second because what it doesn't say is acetaminophen overdose, it doesn't say

acetaminophen suicide, it doesn't say -- it makes the broad statement that there are -- yes, I wouldn't deny that there are -- that there was a problem with overdose and there's a problem with suicide.

But, within the data that they reviewed, there are cases with people who had been fasting, there are cases of people at four grams or less, there are cases of people who took it in combination with other drugs. And what the -- what the FDA was saying was we have a very serious public health issue here that needs to be addressed in part with labeling and instructions, and that's what they said.

So what happened against the backdrop of that? The next thing that happened, Judge, is the American Association for the Study of Liver Diseases looked at this and said you know something, this is something -- we represent thousands of hepatologists throughout the country.

We want our -- we want our -- just like the American Cancer Society, American College of Radiology, American College of Pediatrics, they weigh on issues that are important to them, they took this issue and they wrote a proposal to the FDA, and they said we have, as the hepatology community, reviewed the evidence and we believe that certain things need to be

done. We have described what the -- excuse me.

(Pause in proceedings.)

MR. TISI: May I approach, Judge?

THE COURT: Sure.

(Pause in proceedings.)

THE COURT: Thank you.

MR. TISI: In response to this formal request, the American Association for the Study of Liver Diseases issued a position paper that it filed with the United States government, and you'll see this from the record as you review, it went to the board of directors for the ASLD, and what did they recommend?

Well, the first thing they did was they said, "The ALSD fully" -- paragraph two, "is fully supportive of the agency's conclusion that acetaminophen hepatotoxicity is an important public health consideration and that additional labeling is necessary for the drug to continue to be generally recognized safe and effective." That's the exact same language I just read to you from the Federal Registry -- Federal Register.

So now you have the FDA and the medical community that looks at this stuff saying this drug as labeled in 2006, 2007, is not recognized -- does not communicating what people need to know in order to use

the drug safely.

Now, let me just back up for a second because the label that they're talking about is, in fact, the label that's in issue in this case and I'll demonstrate that to you in a moment.

But, among the things that the -- that the ALSD did is in paragraph three on page two. It says -- it says that a warning -- it proposes an actual warning.

And, again, this is not hindsight, this isn't cherry picking, this isn't plaintiff's experts getting up there and saying gee, you know, we have something that's wild-eyed and we just, you know, made up coming into court.

They looked -- they looked at the evidence in real time and they said this product can cause severe and even fatal liver injury, something that was not on the label at the time. The chance is higher if you have certain things.

Number one, you use this drug at the maximum recommended dose, four grams a day, for five or more consecutive days. They're saying you can have risk at the high -- the recommended dose.

If you go down, it says, the fourth one, you use this drug when water or food intake is restricted

and prohibited. It goes on to say on paragraph four -- excuse me -- and it says some other things that may be relevant in other context, but in this case, those are the big -- those are the big issues. They go on to say at the bottom of this page it says "There is a very narrow therapeutic to toxic ratio for this drug."

Now, I want to stop there for a moment. This issue of margin of safety is a really important issue with respect to this case. If you look back for 40 years, the issue of margin of safety is an issue that has been wrestled with in the medical and scientific community because particularly the over-the-counter drug, you need to make sure you have enough space between the maximum therapeutic dose, the amount that's going to hurt you, and the dose that's going to -- that can cause you harm. And so this issue of what is the difference between the two is and always has been an issue with acetaminophen.

So what they suggest is it might be reasonable to lower the dose from four grams to three grams. And, again, this is three years before Ms. Hayes ever took her acetaminophen.

The next thing that happened, Judge, is that other people, including the Food and Drug Administration, wanted to take a look at this, and so

what they did is they pulled together a group of scientists at the Food and Drug Administration.

And by the way, Judge, all these documents were submitted to McNeil. McNeil knew about all of these things. This wasn't something that was hidden under a rock some place. This was actively provided to McNeil with the hopes that they would make these changes, frankly.

The next issue was following the 2006 proposed rule, the FDA commissioner for this CDR branch that governs pharmaceutical drugs said let's get some of our best and brightest scientists together and look at the data.

By the way, many -- all of this data is data our experts have been looking at as well. They independently looked at this data. But one of the things that experts typically do is not only look at the data, but look at what are people saying about the data at the time? This would be one of those things. And they issued a report by the -- which has been euphemistically called the working group report, and it's Exhibit Number 8 to our --

(Pause in proceedings.)

MR. TISI: It's Exhibit Number 8 to our brief.

THE COURT: We have the working group report, do we not?

MR. TISI: I do have it with me and I'm giving it to you.

THE COURT: Melissa, do we have that? Yes.

MR. TISI: Okay. You don't need a copy?

THE COURT: You can just refer to it.

MR. TISI: So the point is that the -- that the working group made certain proposals, but some of the things that they found were very -- were very important, including, and I'll just make some statements here that -- reading directly from the working group report.

It said, "Acetaminophen has a narrow therapeutic margin and there's little difference between the current maximum recommended dose of acetaminophen and doses that are associated with a potentially elevated risk of hepatotoxicity."

Also, they concluded -- with respect to warnings and instructions, they made these follow conclusions. "Number one, consumers perceive that over-the-counter medications are extremely safe and not likely to lead to serious toxicity. The marketing of over-the-counter drugs emphasizes safety and the perception may be reinforced by the availability of

package sizes with large numbers of pills."

Again, there was no drug that was more aggressively marketed over the past decades than Tylenol, Extra Strength Tylenol. It comes in packages of -- Ms. Hayes bought a package that had 100 tablets in it.

Number two, they said, "Consumers are not aware that acetaminophen can cause serious liver injury, in part because the product labels do not adequately warn of the problem."

Judge, this is in real time what people looking at the evidence were seeing. So this idea of warning about liver damage, what they're finding is that that doesn't tell people very much.

Number five, and this is all from page five of the document, "Consumers are not aware" -- I'm sorry. "Some populations may be more susceptible to hepatic injury."

They also say that patients may take more than they -- than is on the package, and that's foreseeable because that may reflect a lack of knowledge that acetaminophen can be toxic to the liver and that other products may also contain acetaminophen.

So they made very specific regulations, including change the label because the label wasn't

good enough, and they added -- they said warnings and instructions need to be added in order to use the drug safely, among them, lower the dose from four grams to something less than four grams.

Number two, lower the individual dose, how much you can take at one time. They recommended -- and, in fact, this had really implications for this case because if followed through, this would remove Extra Strength Tylenol as an issue in favor of the alternative, which is regular strength Tylenol, from 1,000 milligrams a day, which is two tablets of Extra Strength Tylenol, to 650 milligrams, which is two tablets of regular strength Tylenol.

The point is, Judge, by the mid-2000s, there was a crystallization of thought in the medical, scientific, and regulatory community that this was a serious, serious public health issue that needed to be addressed and that consumers like Ms. Hayes were not getting the information on the risk and how to reduce the risk.

(Pause in proceedings.)

MR. TISI: Now, Mr. Milling went through a lot of discussions about the regulatory scheme, and what I hoped to really do was to graft upon that, that there are genuine issues of material fact that not only

could they change the label to add additional warnings and instructions, that's what Mr. Milling talked about, but that there was adequate evidence and adequate -- there was more than enough information.

I haven't even begun to cover what was in the published medical literature at the time that would say that against this regulatory scheme, a reasonable and prudent manufacturer would change its label through either of the mechanisms that Mr. Milling talked about, either through make a change to the new drug application -- the NDA for Extended Release Tylenol, and then making all of the monograph products that it had out there, including Extra Strength Tylenol, consistent with what was in the -- what was in the NDA, which is one regulatory pathway to make those changes, or to do what they did with respect to lowering the dose ultimately, which is simply to do it under the monograph, which you can do under tentative final monograph.

Either of those regulatory pathways were available, and we believe that there is more than adequate evidence from which a jury can find that they should have used one or two of those pathways in order to make changes.

Let me talk about Ms. Hayes. She was

51-years-old and according to all of her doctors, died of acetaminophen acute liver failure, according to her doctors and according to our experts.

Now, they have indicated they have another theory about what her diagnosis was. Clearly an issue for the jury to decide. The evidence was she was taking between three and four grams a day for five days. Ms. Jones mentioned ten days. I don't think that's supported by the record.

She was, and I'll give you a record here, Judge, that indicates that she was released from the hospital after having had some physical therapy, et cetera, from a lumbar laminectomy that she had.

She was given a drug called Lorcet, which is a narcotic similar to Vicodin. She took that for a couple of days, decided that it was not something that she felt good about taking, as a lot of people do, and she switched to Extra Strength Tylenol, and she took it for five days before she ultimately went into the hospital on the 29th of October -- excuse me, the 29th of August 2010.

Judge, this is the -- I brought the wrong record here. If you -- if you don't mind, Judge, I would like to be able to supplement the record with the record of that, if you don't mind. I have the hospital

record which indicates she took three to four grams and that she was -- on the 29th.

At the time, here sister indicated that she had purchased a bottle of Extra Strength Tylenol following a gastric bypass surgery which occurred in the prior year of August of 2009, okay. She purchased that bottle. It had 100 tabs and that was the only bottle that she and her sister had between the time of August of 2009 and August of 2010.

Now, just by way of background, this is a little bit of a different family situation than we typically have. These two sisters lived together for their entire adult life from the time that Ms. Denise Hayes was approximately 21-years-old to the time that she passed away at 51-years-old. They lived together exclusively for that time and they split the duties of keeping house together.

And as it turns out, Denise, who was deposed in this case, did all the shopping, got all the medications, was the one who picked out all the medication, was the one who went to the store, was the one who bought Extra Strength Tylenol, so she's the one who actually made that call.

The evidence was that Ms. Hayes was not eating or drinking for the period of time that she was

taking Tylenol. They indicate she was vomiting, she was nauseous, she was drinking soup and broth, there was -- and at the time, there was nothing on the label, and the label from 2000 -- actually, I have to clarify the record here.

On Saturday, the 28th of August, 2010, Ms. Hayes, Denise Hayes, was finishing up here -- the end of that 100 pill bottle that they had bought the year before and she asked her sister to go out and get another bottle.

There is no indication that that bottle was ever even opened, much less used, okay. So what the -- the only evidence in the case of the drug that she took was from a bottle that she shared with her sister that was purchased in the summer of 2009. And so the label was the one -- the first one that Ms. Jones pointed out, the one without the word, "severe." And, interestingly, that's not the only difference in that label of significance.

(Pause in proceedings.)

MR. TISI: That label indicated, which is not on the next year, it indicated that which the marketing message had been for 30 years. It has a box on it that says, "How Tylenol products are different. Recommended by most doctors and used by most hospitals."

What they didn't tell you was that most doctors, according to their own surveys and, in fact, with their own witnesses testified that they never give Extra Strength Tylenol at the maximum daily doses. They use two or three grams, not four grams as recommended by acetaminophen -- by McNeil. And, in fact, the evidence in this case will be that even defendant's own experts recommend to their patients that they don't exceed two to three grams a day.

It also says, "The makers of Tylenol do not manufacture store brands," and as -- "this is safer than" -- implies that it's safer than other drugs like aspirin and those kinds of things. And those are the same marketing messages that Ms. Hayes indicated that both she and her sister had seen for years.

THE COURT: What's your position as to how this label on this 2009 box is inadequate?

MR. TISI: It's inadequate in multiple days, Judge, and we list that --

THE COURT: Give me a couple.

MR. TISI: We list that -- we list that in the brief.

THE COURT: All right.

MR. TISI: Number one is it doesn't indicate -- it talks about liver -- "liver damage" --

"liver damage with overdose." Number one, it doesn't indicate that you can have severe liver -- severe fatal injury leading to death. It doesn't tell them what the consequences are.

Number two, it doesn't tell them that they're at risk if they take it as directed. It only tells them they take it -- there's a risk if they take it in overdose.

Number three, it doesn't tell them that in order to use the drug safely, what you do is what it says to do on the Motrin label, and we have a copy of that if you want to see it, which is take the lowest effective dose. Take one and if one doesn't work, take two. It doesn't tell them take only no more than three grams a day. It says you can take four grams a day.

It tells them -- that's just -- those are just some of the ways and those are listed in our brief. And what Ms. -- what Ms. Hayes testified to, and this is important, and I can provide you with the testimony. It's attached to our brief. She said number one is I never would have bought it in the first place. There are plenty of other options out there. I never would have bought it.

Number two is I know my sister. We lived together for 30 years. She was -- she was very careful

about her medications. She read -- I know she read the label that was on -- the inadequate label, so I know she would have read the other label.

And, you know, I'm kind of deviating from my outline here, but under Alabama law, Alabama does not have what's called a heeding presumption. In many states, I believe Pennsylvania actually has it, which says that where there's an adequate instruction, there is a rebuttable presumption that a -- that the warning would have been seen and read. Alabama doesn't have that and we can see that, Judge.

On the other hand, what Alabama does say is you can infer that they would have been read -- that they would have been -- especially with somebody who is no longer here, through other evidence.

And what it comes down to is if the plaintiff had not read the inadequate warning, there is no evidence that they would have read a proper warning. If there is evidence that they read the inadequate warning, then you can infer that that's part of the evidence in which you can -- the jury can consider whether they would have read and heeded a proper warning.

THE COURT: Well, you don't have any evidence here at all as to what she read or didn't read.

MR. TISI: Well, her sister testified repeatedly that she read instructions on all of the medications she took. She testified that she would have -- that she knows her sister and she would have -- her habit and practice would be not only to read the instructions, but to follow them.

The evidence in the record was -- is that she -- that she, in fact, followed instructions. In fact, the document I hope to give you, which is the -- when she went into the hospital on the 29th, indicates she was taking four grams -- between three and four grams a day.

It indicates there is also -- in fact, I asked the hepatology experts in the case, you reviewed all the medical records in this case, Dr. Brown, Dr. Flamm (ph), is there any evidence that she was not compliant with her medications? And Dr. Flamm said there is no evidence. It appears that she was compliant with all -- with the things that she did. Dr. Brown demurely said I see no evidence saying she was compliant, non-compliant, but I'm not going to go so far as to say she was compliant.

So even the defendant's experts indicated that she was scrupulous in the way in which she used medication, the way in which she followed doctors'

instructions.

There is evidence in the case, and every witness was asked, is there any indication she was reckless in how she used Tylenol? No. Is there any evidence that she intended to harm herself? No. Okay.

There is one -- there is -- there is one record, one note, that her sister says that she may have taken on a Wednesday when her pain was particularly bad. She may have taken one more dose bringing it up to five grams, five grams a day on one occasion. But that's -- as the evidence will show, that's a foreseeable use that McNeil was well-aware of in how that drug was being used.

The totality of the evidence, Judge, when you see the totality of the evidence, as we pointed in our summary judgment motion is that, unfortunately, Ms. Hayes is not here to testify for herself. But, the circumstantial evidence by the one who knew her the most, which is her sister who she lived with for 30 years, is that -- is that she followed instructions. Her doctors indicates she followed instructions.

And so I think under the cases -- and we've provided those to you in our brief, under Alabama law, there's more than enough evidence from which a jury can conclude that a warning would have been heeded and a

warning would have -- would have been read.

Which brings us to the third issue, which is if they had been heeded and read, would she have avoided her -- avoided her acute liver failure? Well, number one, if she had -- if she had not taken it at all, which is what her -- which is really what Rebecca Hayes, her sister testified to, is if she knew there was -- there was plenty of other pain relievers out there.

If she knew that there was a risk of, you know, death or acute liver failure, that's not the pain reliever that anybody would choose. In fact, the evidence would be in the case that's why they didn't -- that's why McNeil didn't want to included it on the label, because they didn't want people to see other drugs as being safer than theirs.

So, clearly, if she didn't take acetaminophen, she wouldn't have had acetaminophen induced liver failure. Number two is if the warnings and instructions had indicated that they -- she take the least effective dose possible, the evidence is really -- is really clear as you get to the lower dose range the risk is almost -- is almost minimal and that she -- the chances of her getting acute liver failure were infinitesimally small.

The risk is as you get to the higher levels of this dosing range for several days, and particularly when your body is under the kind of stress that her body was, having just undergone surgery, that's what the evidence will be and that's what the experts will testify to.

I want to make one other -- one other point about the adequacy of the label because it -- I think it will weave into the Daubert motions as well. Our expert in this case on warnings and instructions will be -- well, there will be three of them that kind of work together.

It will be Dr. -- Mr. Rakanau will talk about what Mr. -- what Mr. Milling talked about, Dr. Goldberg will talk about the effect of marketing, but Dr. Bloom, who will also testify -- and she's given a report that indicates all the ways in which the warnings were inadequate. And I quoted her on page --

(Pause in proceedings.)

MR. TISI: -- page 18 of her brief from her report, and it summarizes her opinion after going a lot of pages -- after many, many pages of her report. It says, "Not only did acetaminophen induced liver risk, including failure and death, not fully described in the non-prescription packaging, patient subgroups were --

vulnerable patient subgroups were not identified, the total daily dose was not reduced from four grams, there was no dose titration," meaning take the lowest effective dose. If you take one, if it works, don't take two, and it talks about advertising and those kinds of things. So we will have expert testimony that the label was inadequate.

I will tell you that Dr. Bloom has recently been affirmed by the Sixth Circuit Court of Appeals in a case called Decker versus GE Healthcare, where she did the very same kind of analysis that we talk about here.

And I have those cases in here and I think those are in -- and I'll provide them for the record. I think those are important cases for the Court to consider because it's the district court case, it was another MDL, and it talked about -- talked about pharmaco vigilance and how that weaves into warnings and the inadequacy of the warnings. And those cases are at 956 F.Supp 809, and that's Northern District of -- I have copies here, Judge, if you want -- THE COURT: Sure.

MR. TISI: -- Northern District of Ohio, and the Sixth Circuit opinion which affirmed Dr. Bloom's methodology and the way in which he analyzed the label

was at 770 F.3d 378214, and I have copies of those if you -- if you want me to provide those to you so you don't have to look them up --

THE COURT: Sure.

MR. TISI: -- on Lexis as well.

THE COURT: Do we have them?

LAW CLERK: I have (inaudible).

THE COURT: Sure. I'll be happy with a copy.

MR. TISI: I'll provide it on our break. The short of it, Judge, is the standard for motion for summary judgment is well-known and understood. It's whether or not there is -- there is enough evidence from which a jury can decide the three questions that Ms. Jones identified up front.

Was the warning label inadequate? Would a proper warning have made a -- would have been read and understood, and would it have made a difference? And we believe that the evidence will show that there's more than enough evidence that that would have been the case.

THE COURT: Okay.

MR. TISI: Unless there's any questions -- I know I've gone on for a long time, but it is an important issue and this is the heart of the case.

THE COURT: Right.

MR. TISI: I appreciate your indulgence --

THE COURT: Right.

MR. TISI: -- on this.

THE COURT: Thank you, Mr. Tisi.

MR. TISI: Thank you very much. And I'll get you those cases as well.

THE COURT: Okay.

(Pause in proceedings.)

THE COURT: Ms. Jones?

MS. JONES: I'm going to bring reinforcements next time, Judge.

(Pause in proceedings.)

(Ms. Jones was not close enough to the sound system to be heard clearly, therefore the following colloquy contains inaudibles.)

MS. JONES: I'm going to see, Your Honor, it's been a long day and I'm going to try and make this short and sweet, so if I am making it too short and sweet, if you'll stop me, I'll be glad to go back and regroup.

I want to talk just briefly about this whole chart. To some extent, a limited extent, it is correct. It is correct that Extra Strength Tylenol was initially approved under the NDA process. It is correct that that new drug application was removed or

withdrawn subsequently and it proceeded under the monograph product, the tentative final monograph. It is also correct that McNeil voluntarily, as I told Your Honor this morning, made some changes to the label under the tentative final monograph.

What is not correct about this chart that Mr. Milling stated are two things. One, if you go back and you look at his arguments under 201.57 and 201.80, those are specific doc -- regulations that apply to prescription drugs and biologics by their very title.

It is true that under some new drug applications, you can have an obligation to revise a label as soon as there is reasonable evidence of an association of a hazard. But that -- that applies to prescription drugs and most (inaudible) process which Extra Strength Tylenol clearly was not governed by by 2009.

By 2009, Extra Strength Tylenol was on the market (inaudible) of the (inaudible) final monograph. And what Mr. Milling never really addressed was that in 2009, the FDA promulgated the final rules applicable to the content of the label that deals with the liver damage.

And under that final rule, McNeil is required to use that label and, in fact, their expert, Mr.

Rakanau acknowledged that, testified to that, and his testimony is attached as an exhibit to our motion.

That's the only area, Your Honor, that we have raised for Your Honor's consideration at this time, the issue of implied preemption. It is on that narrow aspect of the post-2009 implementation of the federal -- of the final rule.

(Pause in proceedings.)

THE COURT: Does that 2009 final tentative monograph --

MS. JONES: Well, it's -- let me see if I can -- because I know this gets confusing. The entire -- the monograph in its entirety is still tentative.

THE COURT: Yes.

MS. JONES: However, the rule that was codified in 21 CFR 326 is the rule on what must be included in the label on liver damage (inaudible), and that is a final rule and it has the final full force and effect as though the -- as though the entire monograph had been finalized.

THE COURT: All right.

MS. JONES: Does that make sense? That portion of the rule has become final so --

THE COURT: Okay. And even though that's

final, does that preclude McNeil from modifying the warning label to include maybe a stronger one?

MS. JONES: As to the context of what's covered in that final rule, yes, it cannot do that without final approval.

Now, what we're talking about -- let me see if I can -- is that that final rule -- and that's the reason, Your Honor, that the Wyeth versus Levine argument doesn't apply here, is that because you don't have applicable here what might become a "Changes being effected" provision, which is what Mr. Milling argued was from the 314.70, is that you can change the label without prior approval. Well, that's not applicable here because that's a final ruling.

THE COURT: Wait a minute. The 21 CFR 326?

MS. JONES: 326 is the final rule --

THE COURT: Final rule.

MS. JONES: -- on what must --

THE COURT: So you can't modify --

MS. JONES: -- be on the label.

THE COURT: They can't modify --

MS. JONES: Cannot modify.

THE COURT: -- their label as long as it's covered by that final rule?

MS. JONES: That's right.

THE COURT: All right.

MS. JONES: That's what the testimony will do.

(Pause in proceedings.)

MS. JONES: Mr. Milling talked about policies and the -- and, frankly, Your Honor, this doesn't go all directly to the issue of the failure to warn, but it kind of -- I think it (inaudible) understand the entirety of this case.

The policy of the FDA is that the public health thinks that it -- that the public health in the United States demands that drugs be available over-the-counter without the necessity of having to go to the doctor's.

And what the FDA has done over a period of time and, indeed, it will probably come into evidence in this case, is that in 1998 it implemented what's called the drug facts label.

And the drug facts label is just a format, if you will, of exactly what must be in an over-the-counter drug. So that every over-the-counter drug arguably has the same format where you look at X place for directions and X place for warnings and whatever.

It's been the policy of the FDA that that

language be written for a consumer and written so that it would prompt the consumer to consult a doctor under certain circumstances.

For example, in this case, if a consumer took an overdose of Tylenol would prompt them to consult a doctor, and the FDA's policies and procedures have generally been that that's what we want to do as opposed to explaining to the consumer the details of the medical complications it might cause.

THE COURT: All right.

MS. C. JONES: I don't think -- that really, truly is not an issue in this, but I think it's helpful to kind of understand some of the background about that.

Going back to the three questions that are important for the Court to consider, which at least I think both parties agree on this, is --

THE COURT: Yes. Yes.

MS. JONES: -- whether or not the label was inadequate, two, whether or not an adequate label would have been, or a different label would have been read and heeded, and three, whether or not it would have made a difference in the outcome.

If we go back to the first one, whether or not it was inadequate, what I suggest to Your Honor is

that Mr. Milling and Mr. Tisi went through all of the history that spanned a period of 40 years before 2009 and clearly set forth -- everything they set forth was information that the FDA had when it implemented the final label in 2009 and implemented the warning with respect to the liver damage that was implemented.

I suggest to Your Honor that under Alabama law and everything else that we've seen that, in fact, the warnings on their face are adequate because they do, in fact, advise the consumer of exactly the condition that they claim the decedent had, acute liver failure, albeit in layman's terms in this instance, liver damage.

And when you look at the Alabama law, if you look specifically at the Gurly case, I think the Gurly case sets stance for the very proposition that when you warn of the very event, if you will, of which you're at risk, then the warning is adequate because it doesn't have to be perfect in the sense of setting forth all of the various mechanical and scientific and medical terms that you might want to set out for a doctor, or that you might want to set out for (inaudible). The point is we revised the definition.

The fact of the matter is we've taken the

position, and I think it's the correct one, that -- the testimony is that a bottle of Tylenol was purchased in August of 2006. That testimony comes from the decedent's sister. They also said they had one they purchased in 2009. But immediately after the death here, immediately after the death, the plain -- the sisters file an insurance claim in which they said there was an overdose of Tylenol that lead to the death.

That's important for two reasons. On the day of her death, the sisters knew arguably of a claim against McNeil and Tylenol and yet (inaudible) the bottle of Tylenol that was supposedly new was disposed of.

And rather than us having the benefit of knowing exactly what it is, since we don't, I think it is appropriate for us to presume that it was in 2000 -- the post-2009 label that I showed you on the 2010 because that's certainly what would have gotten -- been purchased at that time.

But, more importantly or just as important, when we get to the second prong of the labeling issue is whether or not the decedent would have read and heeded the warning, there is no proof (inaudible), the plaintiffs cannot meet that requirement, and the reason

they can't is the following.

First, the plaintiff's doctor, and this is uncontroverted, recommended that she take regular strength Tylenol, not (inaudible) that recommendation. Two, the plaintiff's sisters filed a claim saying she had taken an overdose, so she didn't follow that (inaudible).

Three, Mr. Tisi says -- I'm sorry, wow. Mr. Tisi said that she didn't take it for ten days, but the plaintiffs admitted in their brief the material fact -- our material fact, based upon the evidence that was there, was that plaintiff alleges that decedent, Denise Hayes, ingested Extra Strength Tylenol from August 12th to 29. That's 17 days. And the plaintiff's response was to admit that.

So we believe, based upon the evidence and based upon their admission, she took it for 17 days rather than the ten days that are suggested there.

THE COURT: Now, how should I approach that on summary judgment? I mean that's all -- that's all factual, right?

MS. JONES: That's all factual, but it's admitted. It's not controverted.

THE COURT: Right. But my point is there are factual questions here about whether she would have

heeded the warning, even whether the warning was adequate, I'm not sure if I can decided that as a matter of law. And I think, you know, your Celotex burden is that you raise the motion, they come forward with the evidence that shows that there is -- that there's a question of fact here, and you have to show that there's really no question by fact. And we have an awful lot of information developed in discovery. We have talked about experts and we have talked about the sister and depositions. I mean it seems to me that there's a lot factual question to be resolved here.

MS. JONES: Your Honor, I think you are correct in the sense that if -- that -- with all due respect, I think there's one issue in your analysis that I think --

THE COURT: Oh, feel free.

MS. JONES: -- is a little bit off, is that they must come forward with admissible evidence --

THE COURT: Okay.

MS. JONES: -- to create a question of fact.

THE COURT: And what about the testimony of the sister? Is that inadmissible?

MS. JONES: I think it is. I think it's -- I think the testimony of the sister --

THE COURT: It's character evidence?

MS. JONES: It would either be character evidence and doesn't come in under 404, or it's pure speculation as to what, you know, she would have done. It becomes self-serving evidence that there's really no way to contradict it --

THE COURT: Yes.

MS. JONES: -- other than to point to other ways that she did not follow the direction. But I think it's inadmissible as either speculation, lack of personal knowledge, or character evidence, so it doesn't come in at all. That's the -- that's the basis for saying that there's no question of fact on that. And then --

THE COURT: So if the sister is out, then there's no -- your position is there's no evidence that she would have heeded the warning --

MS. JONES: That's correct.

THE COURT: -- and that a better warning would have prevented the harm?

MS. JONES: That's right. In fact, there's no -- there's no evidence whatsoever, no expert testimony, there's nothing that suggests that a different warning would have led to a different result and would have prevented the harm.

THE COURT: Okay. All right, thank you. I

said I would keep you until 3:30 so -- sit down, Clay.

MR. MILLING: Your Honor, can I just have one minute?

MS. JONES: Please.

THE COURT: One minute.

MS. JONES: Your Honor --

THE COURT: Aren't you outraged?

MS. JONES: I am outraged. I am outraged that they have had four times as long as I have and you're letting him have another minute.

MR. MILLING: You're awesome for doing it for me, Christy, I appreciate it. Your Honor --

THE COURT: You can have a minute.

MR. MILLING: Your Honor, I just have to say you asked the question. If in 2009 when the final rule on the label, which was not a monograph rule, it was a labeling rule, could you do more? And it's in your papers at 330.11, it's in your lap. It's called an NDA deviation and it's done all the time.

It says, "NDA deviation from applicable monograph. A new drug application requesting approval of an OTC deviation in any respect from a monograph that has become final shall be in the forms required by Section 314.50 of this chapter, but shall include a statement that the product meets all conditions of the

applicable monograph except for the deviation for which approval is requested and may omit all information except that pertinent to the deviation."

Mr. Rakanau explained it's a letter, you're right. And for defense to get up and say you can't change it when it's right -- when everybody, even Judith Jones notes, every expert notes, NDA deviation is also called a citizen's petition, there are multiple ways. But common sense also tells us whether it's in the trucking industry, the auto industry, the government regulations set the floor, not the ceiling.

THE COURT: All right. And what's -- where do I find that NDA deviation?

MR. MILLING: It's on -- I gave it to you.

THE COURT: Okay.

MR. MILLING: It's -- we talked about 330.12, and it's on the top of that page, Section 330.11 called --

THE COURT: All right.

MR. MILLING: -- "NDA deviation."

THE COURT: Thank you.

MR. MILLING: It's in your materials.

THE COURT: Ms. Jones?

MS. JONES: Your Honor, I think your question to me was specifically whether or not it could be

changed. It cannot be changed without prior approval of the FDA. It cannot be. That doesn't -- that provision doesn't change that.

MR. MILLING: That doesn't -- that's not the issue on preemption, Your Honor. The issue is can it be changed. It can be changed.

THE COURT: All right.

MR. MILLING: And to be clear, this is not the vaccine case that Your Honor provided over where the FDA said we will not allow the change in the back scene. I think it's called the Sykes case.

THE COURT: All right. Okay. Thank you very much. We didn't get through our entire list, not surprisingly. We have one more summary judgment motion to argue. Let's schedule that for our next case management conference. Does that work. Okay.

MR. MILLING: Your Honor, on behalf of the plaintiffs, first of all, we thank you for your time and what you've done today for us today and for everybody.

We were talking at lunch and I have not had a chance to run this by Christy, but I know part of your goal has been to get through the motions in limine so we can get our deposition cuts better, and I would say on behalf of the -- we've talked about on behalf of the

plaintiffs, we would welcome the opportunity if the Court is interested to argue those by phone, for you to put limitations on time for us, to tell us which ones to do and which ones you don't -- you're not interested in hearing argument on.

Our goal is to get the answers on the motions in limine, and if the Court has an hour any time, you know, if you want to say ten-minute limit or something, we would be fine with that to get through those motions.

THE COURT: All right, I think we can do that.

MS. JONES: Well, I move for a time limit on the plaintiffs.

THE COURT: I think that's a good idea.

MS. JONES: Secondly, Your Honor, I do think it would be helpful for us to get through the dispositive motions before we do that.

We will, of course, do whatever Your Honor requests with respect to the rest of them, but I do think the dispositive motions may have some impact on what we do with respect --

THE COURT: Okay.

MS. JONES: -- to the rest of those.

THE COURT: All right. We're in agreement

with that. Okay. All right, thank you very much. Really excellent work all day today. Thank you.

MS. JONES: Thank you, Your Honor.

ALL: Thank you, Your Honor.

(Proceedings adjourned, 3:36 p.m.)

* * *

CERTIFICATION

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

7/6/15
Date

Brad Anders