UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: TYLENOL (ACETAMINOPHEN) MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION	)	2:13-md-02436-LS
	)	Philadelphia, PA
	)	July 22, 2015
	)	10:18 a.m.-12:39 p.m.

ORAL ARGUMENTS
BEFORE THE HONORABLE LAWRENCE F. STENGEL

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I N D E X

RULINGS

P R O C E E D I N G S

(Call to Court)

THE CLERK: All rise. The United States District Court for the Eastern District of Pennsylvania is now in session. The Honorable Law Lawrence F. Stengel presiding.

THE COURT: Good morning.

(A chorus of good morning)

THE COURT: Please be seated.

I believe we've worked out the difficulties with AT&T, and all of our listening participants are on the phone, I hope, and Laura and Melissa have given me a list of who's present, so we'll dispense will the roll call.

I've reviewed the reports and your letters of July 17 -- both July 17, regarding the status of the New Jersey cases, and is there anything that counsel wishes to add to those reports?

MR. BERMAN: Good morning, Your Honor, Laurence Berman speaking for the plaintiffs.

Mr. Buchanan did intend to be here this morning, but I understand he had a flat tire in transit, he may arrive yet; however, with respect to the report that was made by the plaintiffs and the defendants, there's an indication in the plaintiff's

report that dispositive motions in the two remaining cases were due to be filed on July 20 by the defendants, and in fact that occurred. The two cases that are still pending in New Jersey with an active work-up for trial are the Taylor and Jackson cases.

THE COURT: Right.

MR. BERMAN: The other three cases that were in a work-up posture have been dismissed.

So eight dispositive motions were filed for each in Taylor and Jackson. And as noted in Mr. Buchanan's letter, responses are due on August 4, and other scheduling matters are identified in his letter with the expert challenge motions due on July 24, which would be this Friday.

We expect that Judge Johnson will probably be presiding over all of those motions somewhere in the early to middle August time frame, August 10 to August 21, possibly, although in limine motions are not -- oppositions are not due until August 25th, so that might carry over a little later into August.

THE COURT: All right.

MR. BERMAN: I don't have anything else to add, I just wanted to update you on the fact that the motions were filed.

THE COURT: Thank you.

And you're still on track for a September 21st trial date?

MR. BERMAN: There's been no change in that.

THE COURT: Okay.

MR. BERMAN: There's still the need for the Court to select which case will be the one to be tried.

THE COURT: Okay. All right.

Anything to add, Ms. Jones?

MS. C. JONES: I don't have a thing to add, Your Honor.

THE COURT: Just eight motions?

MS. C. JONES: Unless you have -- just eight.

THE COURT: Just eight.

MS. C. JONES: But those are only the dispositive ones, Your Honor --

THE COURT: Right.

MS. C. JONES: -- I'm sure that we can -- we'll match --

THE COURT: You're slipping.

MS. C. JONES: We'll match whatever was filed.

THE COURT: I understand.

MS. C. JONES: How about that?

THE COURT: I understand.

Okay. Thank you very much.

All right. So we have a list of motions in limine to discuss this morning. We are working on decisions on motions that have already been argued and expect to have something for you shortly, I guess. I'm not sure what shortly means, but it's shortly for us. It's -- but we have a number of them in the works and I think a pretty good idea where we're going, so it's a question of matching vacation schedules with editing -- the editing process and we're working on that. My vacation schedule actually, don't mean to put that on anybody else.

All right. So let's talk about the fraud on the FDA. The motion in limine number 2, and I wanted to hear first from plaintiff's counsel if I could.

I'm interested in what you want to put in, and then I want to hear from, it looks like it's Mr. Abernethy, as to why that's objectionable. But what it in terms of this fraud issue that the plaintiff hopes to put in at trial?

MR. BERMAN: Your Honor, I'd like to

introduce Frederick Longer, a partner in our law firm --

THE COURT: Good morning, Mr. Longer.

MR. LONGER: Good morning, Your Honor.

MR. BERMAN: -- and he will be the one to argue that motion --

THE COURT: Okay.

MR. BERMAN: -- or discuss any questions you have.

Thank you, Your Honor.

MR. LONGER: Your Honor, good morning.

THE COURT: Good morning.

MR. LONGER: In terms of evidence the -- there is no precise evidence that shows that there was fraud on the FDA. What we intend to introduce are efforts of the defendants to basically water down, delabel, and withhold more information to the public at large, if you will, in terms of the liver toxicity that generates from the acetaminophen.

If you wanted to drill down into specific exhibits I'm not going to be the person to speak to that issue, I'll defer to Mr. Tisi on that, but you know, written large that's the information that we are intending to introduce, and if you want me to speak in terms of the law I can talk to you very

specifically about that.

THE COURT: Well, I'm interested in what it is the defendants are trying to block here. I mean there's a motion in limine that's been raised.

MR. LONGER: Well it's not evident from their motion, that's clear. They have written large as well in terms of this blanket umbrella Buckman (ph) preemption issue, and there is no specificity to their motion.

We have obviously an idea in terms -- and you've seen it in all of our other motions quite honestly -- as to the direction of which plaintiffs are traveling in terms of our proofs going forward and in terms of the failure to warn and failure to warn claims.

So it's really the evidence that supports the failure to warn claim that animates this motion to preclude based on Buckman.

THE COURT: Well you've talked about your anticipated evidence of efforts to water down the label, as you've point to now. What does that mean?

MR. LONGER: I'm going to talk to Chris. I really have to defer there, Your Honor.

THE COURT: All right. Mr. Tisi?

MR. TISI: Yeah, Judge, if you don't

mind. May I approach?

THE COURT: Sure.

MR. TISI: Judge, we're a little bit handicapped here obviously because I think it's the defendants' responsibility to come forward with some -- the evidence that's specifically being challenged, but let me give you some examples of the kinds of things that I think are really important.

In this case, as you learned the last time and as we talked about last time, there are several divisions within the FDA in which you could provide information. One is the NDA process, which is the process in which pharmaceutical -- the prescription drugs are normally under that umbrella, and then there's the office -- the division of over-the-counter drugs, which is a public -- more of a public process.

What we think part of the evidence will show in the case is that oftentimes -- and they're not supposed to communicate with each other. For example, there's a bright line wall, because information that is submitted, for example, to the FDA office of division of new drugs can't share information with the other office. So oftentimes what will happen, it's not an overt, information is not submitted to the OTC

division, it's submitted to the other division. So what often happens is --

THE COURT: By the manufacturer.

MR. TISI: By the manufacturer.

So if you notice, for example -- I don't have the information right in front of me, Judge -- but for example, in the final -- you'll notice in some of the final rules -- excuse me -- the proposed rules and the final rules that are published in the federal register, a lot of the information provided by McNeil is very, very old, and -- because they provide all the information to the other office within the FDA.

And so the division responsible for creating the final rule and creating the proposed final rule and regulating the over counter drugs doesn't get the information that is provided to the office of new drugs.

That's an example of the kind of thing that we expect the jury to hear, is -- because the defendant will come forward with evidence and they will say, well, you know, the FDA is the lion at the gate, it's the one that's the most knowledgeable and understands, and here we're going to be able to have to demonstrate to the jury, and we will demonstrate to

the jury, that very little is actually ever submitted on a scientific and medical basis to the over-the-counter division that actually is responsible for developing the monographs.

THE COURT: All right. And what's that relevant to?

MR. TISI: Well it's relevant to the fact that in this case the defendant is going to come forward with evidence that, well, you know, Judge -- ladies and gentlemen of the jury, that you know, the FDA didn't do certain things, the FDA office didn't -- never followed through on this, never completed this, never made recommendations for this. And part of what we are responsible for showing is, and we will show, is that oftentimes the office of -- and I forget the exact title of the division -- but the division of the over counter drugs is in a position to not get the information that it needs in order to do the final -- create a final rule or timely work on some of these issues.

And frankly that's why oftentimes there is a -- they pull together the advisory committee so that there's an opportunity to publicly air some of this stuff, because they --

THE COURT: So this information that

you're hoping to put in, whatever it is, is not part of your case in chief, it's what you anticipate putting in in response to their defense?

MR. TISI: No, no. It's both, Judge. And part of what we --

THE COURT: So if it's in your case in chief I would expect you'd know what it is.

MR. TISI: Well we need to -- we will explain. For example, we will have a regulatory expert come in and explain the difference between the two offices, the NDA and the other -- and the office of the -- and I'm blanking on the name of the office -- it's the office of over-the-counter drugs or the division of over-the-counter drugs, to explain the process, to explain the fact that information is sent to the NDA and is not sent to the office of the over counter drugs, to explain why -- how the process -- why -- they'll have to go through the regulatory history in order to explain to the jury why, for example, labeling changes can be made, additional instructions could be made, doses could be lowered, and of course as part of the cross-examination that we'll -- I expect will happen, they'll say, well why didn't the FDA do this? Why didn't the FDA do that? And the witnesses will have to explain why that

happened.

So in terms of the quote fraud on the FDA there's really no fraud on the FDA except explaining the FDA's -- the limitations that the FDA has in the various offices within the FDA, to explain to the jury and so that they understand the limitations of the FDA, and the limitations that they have.

Now, you know, there may be evidence in the case, and again, I mean I'm at a little bit of a deficit because I believe that the factual section of this brief was relatively small, it was primarily a legal argument, but I think that the defendant has to come forward with the evidence that they think falls within the Buckman challenge that they make.

So we're left kind of trying to put our hand in the bag, try to understand what marbles they're trying to exclude or not.

But I do know that part of our overarching theory of the case is that there was a lot of foot dragging, there's a lot of we're going to give it to one office and not the other office, we're going to give information relating to one drug to the office of new drugs and the office division. So it's -- that's kind of part of our overall theme of the case.

THE COURT: Okay.

MR. TISI: Thank you.

THE COURT: Got it.

Mr. Abernethy, what is it that you're concerned about?

MR. ABERNETHY: Your Honor, let me take this on by going back to the essence of the relief that we're asking for, and I'll tell you that it's certainly true we did not give you, and I don't think it's our duty to give you in a motion of this nature, a catalogue of testimony that John or Jane will give or a list of exhibits, but we were very clear about the evidence that we're seeking to exclude, and it is an evidentiary motion. This is not a motion arguing that any of the state law claims are preempted.

THE COURT: Uh-huh.

MR. ABERNETHY: It's a motion to exclude evidence, and it's a motion to exclude evidence specifically that we perpetrated a fraud on the FDA or mislead the FDA or withheld evidence or information from the FDA or violated FDA disclosure requirements, things of that nature, and they're very clearly laid out in the motion.

That's distinct from, and I think it's important for us to be clear on what we're not asking

for in this motion, we're not arguing that, for example, the failure to warn claim that plaintiff's counsel just referred to is preempted by Buckman. And we're not -- it's not a summary judgment motion. And it's not an argument that all evidence relating to what McNeil knew or what warnings it gave is excluded.

THE COURT: All right. But you're asking me in a motion in limine, which is an evidentiary ruling in anticipation of trial, to exclude certain evidence, and I'm interested in what that certain evidence is. Or if you don't know then maybe we table this until we hear what the plaintiff is presenting.

MR. ABERNETHY: Well, I think it's impossible in a motion in limine in this kind of setting to give you every piece of evidence that the plaintiff or every exhibit that the plaintiff might present. I guess that you could defer the motion and address specific testimony or exhibits at a particular point in time.

But again, the essence of this motion is that the plaintiff is not permitted, should not be permitted to prove specifically you violated a federal disclosure or reporting requirement that required you to report this piece of information or that piece of

information to the FDA, or you defrauded the FDA by telling the FDA something that was untrue, or that you violated some disclosure requirements.

It is a categorical motion, but I think the categories of evidence that we're seeking to exclude are pretty clearly laid out in the motion.

If you wanted or felt it was necessary to have a specific catalogue of evidence then I think we would have to present the motion in an entirely different way. But I think that --

THE COURT: But where in your motion does it say what you want to exclude?

MR. ABERNETHY: Page 3 of -- the first paragraph of the legal argument describes the specific categories of evidence that we believe should be excluded consistently with Buckman, and it's distinct, those categories, from evidence about what knowledge McNeil had or what notice McNeil had about some specific relevant risk. That's not what this motion goes to.

THE COURT: But I suppose some of that information could be relevant to claims and could come in with a limiting instruction, right?

MR. ABERNETHY: Well, I think any motion in limine of this nature, Your Honor, any

ruling on a motion in limine of this nature has to come with a certain caveat, because I think anyone would have to acknowledge that there may be a specific piece of evidence that comes up at trial that could be relevant to some argument that there was a fraud on the FDA, but some or all of that evidence could be relevant to a specific argument that's being made under a state law theory of liability.

So, I'm not suggesting that Your Honor is going to make a blanket ruling on this motion and that no consideration of a specific piece of evidence at trial would ever affect that.

THE COURT: Yeah. I mean --

MR. ABERNETHY: What we're --

THE COURT: -- I think I have to make --

MR. ABERNETHY: -- essentially arguing, Your Honor, is --

THE COURT: I think I have to make the decision in the context of a particular witness who's about to say something and you contend that that's evidence of fraud on the FDA, which in your view is preempted. I just -- I don't know that I can make a ruling on a blanket categorical motion.

So what I'll do is I'll deny this

without prejudice and you can raise this in the context of specific witnesses or specific exhibits or specific evidence as it comes up.

MR. ABERNETHY: There is a -- there is one other broad issue that I just want to highlight for Your Honor, and I realize that you're suggesting that you want to deal with all of these issues at trial, but there's an argument --

THE COURT: No, I'm not suggesting I want to deal with all these issues --

MR. ABERNETHY: Yeah.

THE COURT: -- at trial, I'm saying this is too broad for me to make an intelligent ruling on. Period.

MR. ABERNETHY: Okay.

THE COURT: So what else do you want to say?

MR. ABERNETHY: I only wanted to highlight that there's an issue that I think we're going to have to address at the appropriate time about whether these specific areas are relevant to punitive damages, because there is also an argument in the plaintiff's brief that their -- that they should be allowed to prove all these things on a broad basis in support of the punitive damage claim, and if punitive

damages are in the case then obviously we would want to address that at the appropriate time.

THE COURT: All right. All right. Thank you.

MR. ABERNETHY: Thank you, Your Honor.

THE COURT: All right. There is a motion then -- motion in limine 13 to exclude evidence on foreign labels and regulatory actions.

Well, I'm interesting in hearing from the plaintiff what -- again, what you want to put in so that I know what it is they're trying to -- specifically to keep out.

I mean do you have an intention to put in evidence of foreign labels or regulatory actions taken in other places?

MR. BERMAN: Good morning, again, Your Honor.

THE COURT: Good morning.

MR. BERMAN: Laurence Berman.

That's actually how my response argument was written out to address, which is what is really at issue here and what is it that the plaintiffs actually want to introduce? And I think I can really simplify this quite a bit.

The plaintiffs do not have an intent to

introduce evidence about how foreign governments come to decide how labels should be written, how they should be prepared, or to delve into foreign regulatory processes.

We agree this is a United States product, and what's at issue is the conduct of McNeil and Johnson & Johnson and how they labeled their product.

And Exhibits C and D of Defendant's motion provide Your Honor with two forms of a Tylenol Extra Strength label. One is a 2010 version, one is I believe a 2009 version.

And the relatively narrow evidence that the plaintiffs wish to present is that the Canadian label, and I have a -- sort of a color pictorial if I may present that to the Court.

THE COURT: Sure.

MR. BERMAN: And I have a copy for defense counsel.

THE COURT: Thanks.

MR. BERMAN: And this is actually attached in our brief as well as Exhibit 1, but it's a print version rather than what I prepared as a PowerPoint.

But I pulled out of the text of the

exhibit and highlighted the wording that was used in the Canadian label. "Smallest effect of dose and may result in severe or possibly fatal liver damage."

Now this is a label that's being used in Canada, it's a label that defendants have knowledge about, particularly Johnson & Johnson, as they are the -- a defendant here and they are the worldwide company.

If you will look at our Exhibit 10, this is from Pat Gussin (ph), also known as Pat Stewart (ph), it dates back to April 1996, but it speaks about Johnson & Johnson attempting to standardize labeling for all of their over-the-counter products country to country.

Our point will simply be that the defendants had notice about the risk of sever liver damage prior to the time of Ms. Hayes' usage of the Extra Strength Tylenol, yet in the United States a label that did not contain as a significant a warning was used.

As you know from the dispositive motions argued at the last hearing relating to failure to warn there's going to be a constellation of a number of different items of evidence that will attempt to establish by the plaintiffs that there was

a failure to warn, and part of that is the notice question. What notice, what knowledge did the defendants have relating to these risks? And as I said, there's a variety of different evidence.

This is a small piece, a very small piece admittedly of the issue.

Again, we are not seeking to have witnesses testify about foreign regulatory processes or even how or whether a foreign government mandated this label. That's not the issue. The issue is in fact there was a label with stronger warnings of which the defendants had notice, stronger than in the United States, and it's part of the notice and knowledge component to the failure to warn claim that we have.

Again, as you had mentioned with respect to the Buckman motion, and we have this at the end of our brief, this can easily also be addressed at the time at trial when the proffer is made, but the proffer is intended to be relatively small and minor, Your Honor.

THE COURT: Do you have any other evidence of foreign labels?

MR. BERMAN: We have no intent to use other foreign labels, Your Honor.

THE COURT: So it's this one.

MR. BERMAN: It's just the Canadian label.

THE COURT: Okay.

MR. BERMAN: Thank you.

THE COURT: All right.

MR. BERMAN: If you have no other questions, Your Honor.

THE COURT: No, that's good. Thank you.

MR. BERMAN: Thank you.

THE COURT: Ms. Jones?

MS. C. JONES: Frankly, Your Honor, I would think at one point that perhaps Mr. Berman would have laid to rest many of our concerns when he suggested that it's only this one label, but frankly his statement that we don't intend to put before the jury any of the foreign regulatory processes or procedures by which they get to labels, demonstrates the flaw in the argument, if you will.

THE COURT: Uh-huh.

MS. C. JONES: Because in fact what we have here -- and I'll just deal with the Canadian label since he's represented that that's all we're talking about.

What we have here is a Canadian label

that was promulgated pursuant to the Canadian regulatory authority, which has different rules and different procedures from the FDA, and in this case where we have a very specific over-the-counter label that's been considered on multiple occasions by the FDA, and we now have a final rule from the FDA, what we clearly know is that the FDA came to a different conclusion and doesn't have that same language.

And I suggest to Your Honor that if we have to deal with that label we have to put it into that context and it becomes a trial within a trial, which is the reason that the vast majority of cases, and I think it's -- I'm not -- I can't represent to the Court that it's all of the MDLs that have looked at that --

THE COURT: Uh-huh.

MS. C. JONES: -- but certainly the vast majority of MDL judges who have looked at this question in the case of the Sara Quell (ph) or Triason (ph) or all of these different judges having different drugs that have been considered by FDA have come to the conclusion that foreign labels do not come in, and that foreign regulatory processes do not come in. As one, they are irrelevant to the claims before the Court, and two, to the extent they had any relevance,

would be barred under 403.

But what I think is perhaps most important and most telling is that the vast majority, if not all of the citations that the plaintiffs have put in their brief suggesting that this information ought to come before the jury, are all based upon the argument that Mr. Berman just made, which is that information may come before the jury if there is a question of what the defendant knew when, or there's a question of scienter, if you would --

THE COURT: Uh-huh.

MS. C. JONES: -- in terms of whether or not that's an error -- an issue in this particular case, Your Honor.

It's basically been stipulated by the parties that at least as early as 1977 the risk of liver damage associated with excess dosages of Tylenol has been well know, and so we don't have here the situation where other courts may have had a different situation or concern at whether or not a company knew or didn't know of the potential of an adverse event and that that was the subject of a different warning. That's not the issue at all.

Knowledge for all intents and purposes of the risk of potential liver damage associated with

an overdose has all but been stipulated in this case, and it's pretty clear in terms of looking at everything that the FDA has considered.

So under those circumstances you don't have the rationale for admission of a foreign label that you would have and have had in some of the other decisions.

The second part goes really directly to the FDA's procedure. We talked the last time, and the last thing I want to do is to go back through the warnings issues and the fact that we got to the final warnings, but it is important to note that this -- the product that we're dealing with here is an over-the-counter product in the United States, and as an over-the-counter product in the United States the FDA has promulgated like a drug fax label, and every product that relates to area over-the-counter product has a label with a certain form with certain information.

And I won't represent to the Court that I have reviewed every over-the-counter label that's out there, but fatalities are generally not mentioned on over-the-counter product labels in the U.S. There's a reason for that, and the reason is you have to go back to the early discussions about what was perceived to be the importance of making information

available to consumers, and to make it available in such a way that it would prompt them to go see the doctor under certain circumstances but would otherwise make that available.

And I -- and so, I say all of that because that history and that consistent -- is consistent with the FDA regulatory process in the United States that we are obligated to comply with --

THE COURT: Uh-huh.

MS. C. JONES: -- and to -- and it's a different system in Canada, and you know, and how they got to that labeling.

And so to the extent I respectfully suggest that even if it had any probative value at all, and I don't think it does in this case because of the issues here, that it would be barred under 403 as these other courts have come to that conclusion. Because any probative value, as the judge in the Sara Quell case said, is simply overmatched by the danger of -- as that judge said -- jury confusion, wasted time, and prejudice by dealing with, you know, foreign issues that are not at issue here.

THE COURT: Well, I guess the -- one point I think the plaintiffs are trying to make is that this language was used by Johnson & Johnson,

albeit in Canada, why couldn't it have been used here in the U.S.? It's a stronger warning as I understand their position.

MS. C. JONES: But it was -- I'm sorry.

THE COURT: Do you have -- and I know we've been around on this issue in other context -- but what's your client's ability to modify the label once it's approved by the FDA? I mean does that create a floor and you can use stronger language or do you have to use the language that's approved?

MS. C. JONES: In this context, Your Honor, and specifically in dealing with the acetaminophen --

THE COURT: Uh-huh.

MS. C. JONES: -- in, you know, following the promulgation of the final rule in 2009 --

THE COURT: Uh-huh.

MS. C. JONES: -- our responsibility is that we must use that language.

Now there is a provision in the federal regulations that you can seek permission to make a difference, but they have some variance associated with that, but you cannot implement it without specific approval.

THE COURT: Right. Okay.

MS. C. JONES: So that's what that is.

But I think the point is, Your Honor, that if you have to look at the Canadian label you have to look at the format of the label, who's dispensing the drug, the fact that it is -- I frankly can't remember whether Canada is sold behind the counter or not and that's a label that comes --

THE COURT: Uh-huh.

MS. C. JONES: -- from the pharmacist as well as the consumer -- but all of those issues become relevant then to explaining that issue, and that's part of the reason that courts have concluded that generally, even if it seemed to have some degree of relevance, that it ought to be excluded, because you have to put it into the context of the regulatory scheme, the marketing scheme, and the culture scheme, and the country in which it is -- it's there and sold.

And it's -- you know, McNeil itself dealing with the product we're talking about here functions in the Untied States subject to those regulations. And you have -- it's not -- I think we even cited it in our brief that we have different subsidiaries or different members of the Johnson & Johnson family of companies that are actually

organized under, for example, the laws of Canada, or another company, that they must follow that regulatory scheme as set out.

THE COURT: Okay. All right. Thank you.

MR. BERMAN: May I respond or reply, Your Honor, to a few points, if Your Honor thinks --

THE COURT: I think I understand your position and I understand the defendants' position.

Let's move on. This motion in limine 11 to exclude evidence regarding the inadequacy of the FDA regulatory process.

All right. Ms. Jones, are you going to argue this one?

MS. C. JONES: I'm going to argue this one too.

THE COURT: All right.

MS. C. JONES: I was waiting to see --

THE COURT: Well, I was trying to get some insight if I switched up the order, but I'm striking out here. So go ahead, it's your motion.

MS. C. JONES: Well let me first of all say that I think I can explain very clearly to you what we're seeking to exclude --

THE COURT: Okay.

MS. C. JONES: -- and I won't identify every document that falls within this category, but the plaintiffs actually filed as part of their response the documents that are of a type that we're addressing, and those are the documents, that's the general accounting office report, and then there is a separate report entitled FDA Science Admission at Risk. There are a host of other similar documents. I don't think that when the plaintiffs attached only these two they meant to suggest that it was only those two that they would offer --

THE COURT: Uh-huh.

MS. C. JONES: -- but I think they're in enough of a format, there's one by the Institute of Medicine and so forth.

What I think is important to understand about those reports, Your Honor, the FDA Science Admission at Risk report, for example, is a report that was prepared by a subcommittee of an outside advisory committee to the FDA commissioner.

So for our purposes here I really don't want to argue whether or not they meet the foundations for being a government record subject to admissibility, because even then you have to establish relevancy. We have arguments about that, but I don't

think that's the key argument here.

The key argument here is clearly that these documents are not relevant, and even if they had any probative value, should be excluded under Rule 403 because of the danger of unfair prejudice, jury confusion, and misleading the jury.

To put this into a little bit of context. The FDA Science Admission at Risk that's attached here is dated 2007, and the GAO report that is attached here is dated 2006. I think that's important, because first of all we're dealing with a product, acetaminophen, that's been available and on the market since 1955, and so picking out one or two reports at a given period of time is just a snapshot, and whether or not any of the comments that are included within any of these reports -- and let me backtrack. I don't know if Your Honor has had any opportunity to look at these reports, but let me just in --

THE COURT: Uh-huh.

MS. C. JONES: -- an overview I will simply say that these reports general criticize the operation of the FDA, and they suggest that the FDA may be underfunded, lacks sufficient manpower, doesn't have the appropriate decision-making processes in

place. They make some recommendations for funding and some predictions as to what will happen, and to some extent they're dealing with the new development of drugs of a different type that are just now in today's world coming to the floor and how the FDA is going to deal with that.

THE COURT: And they also have some witnesses who want to talk about that right? As well, right?

MS. C. JONES: I'm confident that they have a couple of witnesses that -- Dr. Bloom (ph) --

THE COURT: Right.

MS. C. JONES: -- that would like to talk about that, and you know, and the argument -- I mean in all candor, what I think that the plaintiffs intend to do would be to have Dr. Bloom, you know, testify, and to suggest, well, you know, we all know that the FDA doesn't have sufficient manpower to get out there and really study these issues, and therefore the fact that they did or didn't do something is -- you know, you can't give much credence to it. That of course --

THE COURT: And how does that come in? Does that come in in response to your position that McNeil and J&J have complied with the FDA?

MS. C. JONES: Well that's the issue, is I don't think it comes in at all.

THE COURT: Okay.

MS. C. JONES: But the reality of it is that it's not -- what the plaintiffs will say is that when we say we complied with the FDA regulations --

THE COURT: Right.

MS. C. JONES: -- and it's found to be safe and effective, they want to say in return, well, yeah, but that doesn't mean anything.

THE COURT: Right.

MS. C. JONES: I mean I'm putting words in their mouth, but that's what I anticipate that they're going to do. And my response to that is, but this is a regulatory system under which we operate and you're not suggesting that we didn't comply with the regulations, you're simply saying we don't believe that Congress has appropriately funded the FDA to allow it to deal with these issues, or we don't believe that the FDA has set up the appropriate mechanisms to evaluate these issues. And that becomes a separate trial on the FDA and how the FDA is organized, funded, works, which in and of itself I think creates the whole risk of confusion for the jury and misleading the jury and certainly for a longer

period of time.

And the reason I say misleading the jury, Your Honor, is that these documents that we're talking about are very broad documents. They're talking about the FDA in some cases in all of its functions. Its food function, its, you know, agricultural function, all of those different functions that have absolutely nothing to do with this case.

I think that I am correct, and I'm confident that counsel will point out if I'm wrong, but I do not believe that either of the documents that they've attached as exhibits mentions McNeil, mentions Tylenol, acetaminophen, or focuses on over-the-counter regulations and products. It certainly doesn't focus, Your Honor, they don't focus on drugs that have been on the market for 60 years and repeatedly evaluated in different formats, whether as a new drug application or under the drug efficacy study evaluation or any of those other studies.

So what you have is you have a blanket indictment and, for example, one of them take several drugs like Vetra and goes through their regulatory history and, you know, questions whether or not the FDA acted timely on certain things. Those have

nothing to do with Tylenol, have nothing to do with regulation of over-the-counter drugs and, you know, ultimately what they do is they put simply a jury in a position of second guessing or evaluating the FDA and the FDA's actions.

We've had a number of courts that have looked at the admissibility of these issues. In New Jersey, Judge Johnson looked at it and granted a similar motion saying essentially that the agencies regulations are legal benchmarks which are presumed valid and properly enforced and, otherwise, it could be any trial to the contrary.

The Plaintiffs have cited a number of opinions that suggest that this evidence is admissible and the ones that they cite primarily are the decisions, for example, in the Wyeth v. Levine case in the Supreme Court because they suggest that the Supreme Court says that these are issues to be considered.

But what I would call your attention to is that what they quote repeatedly in their brief is a footnote by the FDA that cites -- I'm sorry, not by the FDA -- by the Supreme Court that cites some of these issues, but it relates to nothing about the admissibility of this evidence at trial. It's simply,

in the context of considering the issues that were then before the Court, it footnotes that, and it makes absolutely no evidence or suggesting that that evidence, in fact, should become relevant or admissible in a trial before a jury.

THE COURT: Okay. I think I understand your position.

MS. C. JONES: So I'm perfectly happy to go on, Your Honor, and to answer any questions, but I think that that's the heart of the argument.

THE COURT: Thank you.

MR. TISI: Judge, Chris Tisi for the Plaintiff.

THE COURT: Yes.

MR. TISI: Really, the question is where the Defendant in a pharmaceutical case relies heavily on the FDA process, as the Defendant does in this case, should the Plaintiff be permitted to show the limitations that even the FDA itself and the federal government have acknowledge about the FDA's power to regulate both over-the-counter and prescription drugs. In this case, as the Court knows, the question is whether or not there was adequate information about acetaminophen-induced liver disease

and whether the instructions provided to patients and consumers was adequate.

The Defendant in this case claims that they did every single thing that the FDA ever required. They complied with every regulation. They did it scrupulously. The Plaintiff in this case claims, look, you know, this is a drug that despite of oversight by the over-the-counter division of the FDA, a final monograph has never been finalized and that there are reasons for that including the limitations that the FDA itself has acknowledged.

Let me give you a couple of examples, Judge. The FDA itself has recently determined, using acetaminophen as the poster child, that the process that the FDA process for the monograph system needs to be completely revamped because it cannot get anything done within that process. The institute of medicine, the United States Congress, the Executive office -- I mean, these are documents we have not attached but these are examples.

The FDA itself has concluded that it did not have the power to force companies, whether it be over-the-counter companies or prescription drug companies, to take action to change their label and, in fact, they relied upon companies to make those

changes. And I must tell you, I mean, I've tried -- like Ms. Jones, I've tried cases involving drug litigation and in almost every case this comes in. They point to Judge Johnson and, frankly, candidly, I think Judge Johnson got this particular issue wrong.

Recently, in the Gadolinium litigation, Judge Polster in the Northern District of Ohio allowed that kind of evidence to come in. It came in before Judge Fallon in the Vioxx litigation. So there are multiple -- you know, if the Defendant came up here and said, you know something, we're going to try this case on the merits of what we knew and did not know and we're not even going to mention the FDA, they might have an argument.

But if they put the FDA as the 800-pound gorilla in the middle of the courtroom, the jury needs to have an understanding as to whether or not that 800-pound gorilla has limitations or not, especially if the 800-pound gorilla acknowledges the limitations. And so it's not -- you know, as a practical matter, I think that Ms. Jones, and she's done an excellent job of trying to present this issue, however, the point is this is not a trial within a trial, this is part of the case.

I bet, Your Honor, if you look back at every single status conference, every single phone call, and you do a search of the FDA, the Defendant brings up the FDA and what it did to comply with the FDA. If I don't hear the word FDA 100 times in the opening statement by Ms. Jones, I would be shocked.

And then we're going to be hamstrung in explaining to the jury, well, you know, you may have thought that the FDA does clinical trials or epidemiologic studies, but would it be surprising to you that it doesn't? That it doesn't have the funding to do it? It's not part of their job.

Would it surprise you that the FDA itself has limitations in the ability to force a company like McNeil to make a change to the label? Would it surprise you to know that even though this drug has been on the market for 60 years that the company still has -- that the FDA has still not gotten around, despite numerous regulatory actions, to finalize the monograph for this drug? We're not going to be able to do that.

That seems to make us try this case with one hand tied behind our back and I think that that would be unfair. This is clearly relevant. It's clearly probative of the issues in the case

particularly when the Defendant places the FDA in the center of this courtroom. Unless you have any more questions, Judge, I think I'm pretty clear where I think the Plaintiff is on this.

THE COURT: What evidence do you expect to present on the limitations on the FDA?

MR. TISI: Well, let --

THE COURT: Is it Dr. Blum?

MR. TISI: Yes, Dr. Blum. Dr. Blum, for example, and Mr. Rachonelle will testify to two things. First of all, Dr. Blum ran a pharmaceutical company for years and years and years and knows the limitations, knows the relationship between the FDA and industry. And she will testify that there are limitations that the FDA has and explain why the FDA has not done certain things.

Mr. Rachonelle, who worked within the office of -- I have to apologize, I'm just blanking on it -- the over-the-counter division responsible for developing the monograph will testify as to the limitations and the process of getting a new -- I mean, the process of getting public comment, the process of finalizing a rule, the process of getting a tentative final monograph in process, and he will testify as to what the limitations are. So going into

the Defendant's case, and defense case, the jury will have at least a bar understanding of not only the regulatory framework relevant to this case, but also the practical limitations that the FDA has.

So those will be the primary witnesses, but I'll also tell you, and I have not reviewed the video cuts for this, but the Defendant themselves, I believe I questioned Dr. Temple, and I could be wrong about this, but I questioned Dr. Temple, you do understand that the FDA has limitations? They don't do clinical trials. They can't force you to do a label change. So it may come in through other witnesses, as well. But this is all part of any pharmaceutical case, Judge. This is really not that -- this is not a cutting edge legal issue. This is pretty standard stuff.

THE COURT: All right. Thank you.

MR. TISI: Thank you very much, Judge.

MS. C. JONES: Your Honor, may I respond only to one thing to perhaps clarify? There is no doubt that the FDA regulatory process and what the regulations are are going to come into evidence and what the FDA does and doesn't do.

THE COURT: Right.

MS. C. JONES: And Mr. Tisi is absolutely correct, that comes in on every case. What doesn't come in in every case is the report of the subcommittee of an advisory committee that has certain opinions in it that it's basically an indictment of the entire FDA process. And that's what those documents are that we have talked about.

THE COURT: Right. Well, the documents probably have a hearsay problem.

MS. C. JONES: They do.

THE COURT: Also there's a relevancy issue, but what if a witness wants to testify about her or his experience with the FDA process and points out to the jury that there are limitations to that?

MS. C. JONES: Well, in all candor, Your Honor, it becomes a bat issue on an individual witness is on the witness stand probably becomes a closer question in the sense that you have to take it in the context of what it is. If what the witness is saying is I have a problem with the FDA and the way the FDA makes decisions or I have a problem with the FDA and the way the FDA is structured, then at that point I think they're getting to the point that they're infringing upon a congressional authority to govern the FDA and those processes and procedures.

If what the witness is saying is the FDA does not do clinical trial, that's a fact. That's not something that -- I mean, what I'm trying to do is to distinguish that for Your Honor because I know --

THE COURT: If this was a crash worthiness test, crash worthiness case involving a car, and the Defendant would say the car complies with all federally mandated testing requirements, couldn't the Plaintiff's experts say, yeah, but they used 150-pound crash test dummies and they don't go through the windshield but the 250-pound crash test dummy does and the Plaintiff here was a larger person? I mean, those kinds of distinctions are made all the time in product liability litigation.

MS. C. JONES: That's right.

THE COURT: You can question the approval process.

MS. C. JONES: Well, I don't know enough about the National Transportation and Safety related to wrecks, but there's a difference between saying -- there's a difference in what I'm saying in the sense that -- if we put it in the context of drugs, for example. There are case after case where even though the drug has been found to be safe and effective, the Court has allowed it to go to trial. I

mean, that decision is not preempted. And we understand that and that's an understanding that we've got the ability to challenge that.

But what you're not doing is actually challenging the process. You're not challenging the agency. You're saying we still believe that this product was defective, but you're not going in and saying, you know, the FDA has connections with the drug company or the FDA is under-manned and they couldn't study this or the FDA doesn't have a proper decision-making process or the FDA doesn't have enough manpower to consider it. Do you see the distinction that I'm -- I see you don't, but I'm --

THE COURT: Well, I'm struggling with that because I think the -- if there's a process that has approved a drug or a car or a car seat or something and the defense is we're fully in compliance with that regulatory body then can't the Plaintiff say, well, but the regulatory body has certain limitations?

MS. C. JONES: But when the defense says we're in compliance with this, the courts and the evidentiary things say that is evidence of reasonable conduct.

THE COURT: Right.

MS. C. JONES: That's what comes in. That's the evidence of reasonable conduct.

THE COURT: Right.

MS. C. JONES: It's not saying this is a fool-proof system that's (indiscernible).

THE COURT: Right. But it's up to the jury to decide if they accept that evidence of reasonable conduct, right? I mean, that's why you offer it.

MS. C. JONES: Well, you offer it because we complied with the rules that we were required to comply with. Whether or not you agree with those rules or disagree with them, you know, whether you think that the FDA ought to have, you know, a different regulatory scheme, the fact is that as long as the regulatory scheme that's there is in place, we have to comply with it.

And that's a different issue altogether from saying the FDA doesn't do its job. And that's what these documents and, you know, that general thing is about.

THE COURT: Right.

MS. C. JONES: So I understand Your Honor's concern when you've got a witness on the witness stand and I think we still have the same

arguments that the process itself, the regulatory process itself is not on trial here. Those issues don't go specifically to any issue in a product liability case that is here. But when you look at the context of the documents, it's much easier to see that than it is when you're talking about --

THE COURT: I'm not -- I mean, I think I may agree with you as to the reports and I think you have a big hearsay problem with those reports unless it goes to notice or state of mind or something like that with respect to a particular person who is testifying for the Defense. But if it's an expert who is talking to the jury, instructing the jury on what the FDA approval process really means, why can't we hear that?

MS. C. JONES: I think that a proper qualified expert witness can certainly -- I mean, there may be some limitations on it, but can certainly address the FDA regulatory process. And what they can or cannot do, I think the issue is when it gets to be -- when it gets to be a further statement that, for example, the FDA didn’t have sufficient manpower to consider this so you must disregard this finding, that, I think, goes a little bit beyond what they're appropriately allowed to say.

What they can say is here's what the regulatory scheme is and go a little bit beyond that. But what our motion was focused on primarily were those documents and that type of evidence coming before the jury that are criticisms of the FDA in general that have nothing to do with the issues before this Court in terms of it being either acetaminophen or an over-the-counter product or those things.

THE COURT: I think I understand your position.

MS. C. JONES: All right. Thank you.

THE COURT: Thank you.

MR. TISI: Judge, if you'd give me --

THE COURT: Sure.

MR. TISI: I want to address your particular concerns. First of all, again -- well, I don't want to say again. The issue of hearsay, let me just address that issue really, really briefly. First of all, these are government reports and so they would fall within the exception of 803-8 and they are also the business records of the agencies that are involved.

Number two is even if they were hearsay, an expert can -- if it's the type of evidence that an expert typically relies on, they can testify

to it. Okay. So the question about whether or not it's hearsay or not hearsay, I don't perceive that as being part of -- that wasn't part of what the argument is. It was really a relevancy argument. Okay. We can deal with those issues at the time of trial, I think. Okay.

THE COURT: Right.

MR. TISI: The overarching question that's raised by this motion is to whether or not the Plaintiff's basically have to sit on their hands. The truth of the matter is, okay, the FDA itself has issued a formal report. The United States Congress has issued reports. The FDA has proposed changing its regulations because of the acetaminophen in part, okay, because it takes too long to get a final rule done for the over-the-counter drug.

These are reports by the FDA. So if the Defendant is going to put these at issue, the question about whether they're relevant, they clearly, clearly are. The question about whether any particular item of evidence, frankly, is at issue for trial.

Let me give you an example, Judge, about why this is important. You raise the issue of crash worthiness as an example. If I could, I'll give

you another example. The FDA regulates food. The FDA has inspections of meat packing plants, Nebraska and Iowa and all over. If the FDA, in a food poisoning case, if the Defendant came in and said, as the Defendant would say in this case, well, we complied with all inspection regulations. We inspected our plants three times a day that's required by the regulations. You know, the FDA is involved and protects our food supply. The FDA does all of this.

If the FDA had a report, its own report, or Congress had issued a report, that said, you know, we just don't have enough people to inspect the plants, we don’t have enough people to actually go in and test the meat, sample test the meat, we should be able to present that kind of evidence in a trial involving tainted food.

It's the same issue. They're putting the FDA -- is Ms. Jones were to stand up here today and say we don't intend to talk about the FDA at all in this case. This is only about acute liver failure and acetaminophen and we'll try the case on the science and on the merits and on what proper risk mitigation would be without FDA regulation, she might have an argument.

But she's clearly put the FDA in the center of the wheel here and we're entitled to -- if the FDA says, you know something, yes, we have these regulations, we have these powers, but you know, when we did our own audit of our process, we did not have the manpower to enforce this. We cannot force label changes on companies. We cannot do certain things. And therefore, we rely on companies to do the right thing. We're allowed to do that.

And, frankly, you know, I recently tried the Gadolinium case and all of the documents they had indicated, they all came in. They not only came in on the basis of being a government record, they came in as evidence. The witnesses were -- the experts were entitled to explain to the jury and did in fact explain to the jury, you know, this drug was approved by the FDA. They repeatedly looked at it. You know, all that stuff. But the FDA has limitations.

This is about deciding this case on the merits. It's not about weighing it on one side or the other. And if they're going to put the FDA here, let's talk about the FDA.

THE COURT: I understand your position.

MR. TISI: Thank you.

THE COURT: Thank you. Does anyone need a recess? Take a five-minute break?

MS. C. JONES: Yes.

THE COURT: All right. Let's take a five-minute break.

THE CLERK: All rise.

(Recessed at 11:27 a.m.; reconvened at 11:39 a.m.)

THE CLERK: All rise.

THE COURT: Please be seated. The next motion in limine is motion in limine number 3 which has to do with a request to exclude evidence and argument related to the September 2002 and June 2009 advisory committee meetings.

Good morning.

MR. HEWES: Good morning, Your Honor. Michael Hewes on behalf of Johnson & Johnson and McNeil. This is our motion, Your Honor, to exclude evidence and argument relating to the September 2002 and the June 2009 advisory committee meetings.

And for context, Your Honor, the advisory committee meetings are meetings periodically called by the FDA in all the contexts, food, drugs, or what have you, to discuss and obtain independent advice on scientific, technical, and policy issues.

The two advisory committee meetings at issue here related to acetaminophen occurred in 2002 where the FDA wanted to have an advisory committee meeting to discuss acetaminophen safety. The 2009 advisory committee meeting was called to discuss liver damage and acetaminophen.

And in particular, as it relates to these two advisory committee meetings, Your Honor, the discussions, the presentations, and the transcripts, and the votes made by the committee are not relevant. And as I will show in the argument and as we show in the paper, Your Honor, the discussions and the context and the arguments lack the required indicia of truthfulness and lack reliability. Moreover, they appear hearsay and, finally Your Honor, which seems to be the catchall argument that we've been seeing in the motions, they do not constitute notice for a number of reasons which I'll discuss.

And if I could first, Your Honor, discuss the September 2002 advisory committee meeting and the discussion that went on there. The main element --

THE COURT: Just to clarify, Mr. Hewes --

MR. HEWES: Yes.

THE COURT: McNeil was represented at those meetings, right?

MR. HEWES: McNeil was present at the meetings and --

THE COURT: Right. Who was present for McNeil?

MR. HEWES: In 2002, Dr. Tony Temple was present and he actually spoke at the advisory committee meeting.

THE COURT: Right.

MR. HEWES: And in 2009, I believe Dr. Ed Kuffner was present, Your Honor. And there may have been some other people from McNeil who were present at the time and spoke at the meetings.

The main area of discussion that the Plaintiffs want to address from the 2002 advisory committee meeting is a presentation made by Sarah Erush and, in fact Your Honor, if you seen the deposition designations, you'll know she is one that they have designated from. Ms. Erush is a PharmD or Dr. Erush, shall I say, is a PharmD who worked as a pharmacist at a hospital and she purported to present data to the FDA regarding 46 --

THE COURT: Here in Philadelphia, right?

MR. HEWES: Yes, sir.

THE COURT: Yes.

MR. HEWES: She works at the Children's Hospital right now. She purported to present evidence to the FDA regarding 46 acetaminophen overdoes cases and she told the FDA that 23 of those cases represented unintentional overdoses where the individual, for whatever reason, overdosed with a therapeutic intent or not really meaning to overdose for purposes of self-harm or suicide.

Well, at her deposition we asked her to identify the doses for 23 of those 46 cases and at deposition she couldn't identify the doses. And at deposition we asked her to admit which of those 23 cases were truly unintentional and at deposition she couldn't admit it. And as we go to the reliability of this evidence, the key testimony from her deposition, Your Honor, dealt with her interaction with McNeil because prior to the 2002 ad com, McNeil contacted Dr. Erush and they said we'd like to see the data, we have to produce the data, we have to report the data to the FDA. She didn't give it to McNeil.

After the advisory committee meeting, McNeil wrote her a letter and said we'd like to have the data you presented to the FDA. Not only did she

not give it to McNeil, Your Honor, after McNeil asked for it a second time, she destroyed it. And at the deposition we asked her these series of question. If Your Honor will indulge me for about a minute so I can put this in context. And here's the question:

"Q. Let me just make the record clear, Doc. Just so the jury understands the timeline as to when this data was destroyed and when McNeil asked for it, okay?

"A. Correct.

"Q. You were asked by the FDA in July 2002 to do this analysis of the data of your adverse event reports, correct?

"A. Correct.

"Q. And you presented it in September 2002, correct?

"A. Correct.

"Q. And prior to your presentation, McNeil called you and asked you for the data, correct?

"A. Correct.

"Q. And subsequent to your presentation, McNeil sent you a letter and asked you for the data, correct?

"A. Correct.

"Q. And you didn't give it to them on either instance, did you?

"A. I did not.

"Q. And that was before the data was destroyed, correct?

"A. It was.

"Q. And so there was an opportunity for you to provide McNeil with the underlying data and you chose not to, correct?

"A. Correct.

"Q. And subsequent to that the data was destroyed, correct?

"A. Correct."

This is the type of information and this is the type of data the Plaintiffs want to use the ad coms as a conduit to get before the jury. This is data that is unsupported. This is data that was never peer reviewed. This is data that was never published. And therefore, Your Honor, in addition to the fact that after McNeil asked for it, it was willfully destroyed. And the Plaintiffs would have Your Honor believe that because it was presented at an advisory committee meeting therefore it has some additional reliability and therefore it should be put before the jury and we submit that it should not.

THE COURT: Well, you had somebody important from McNeil present in the room, right?

MR. HEWES: There was somebody, yes, Your Honor.

THE COURT: And there were discussions of adverse events involving acetaminophen and the liver at that advisory committee meeting, right?

MR. HEWES: Yes, Your Honor.

THE COURT: So it seems to me that it's some evidence. It might not be conclusive. It might be evidence that you can certainly attack. But it seems to me that it's some evidence that McNeil was well aware in 2002 that there were these adverse events and there was this study and it was important enough for an advisory committee to be convened, right?

MR. HEWES: Well, the --

THE COURT: All that is significant. I mean, you can -- it seems to me that what you've outlined in the deposition testimony of Dr. Erush would be effective cross-examination of the doctor, if she testifies, or anybody else who testifies about that advisory committee meeting. But just like the Plaintiffs want to attack the FDA process, I mean, you can attack the advisory committee process, can't you?

MR. HEWES: It's not an indictment of the advisory committee process, Your Honor. It's a

discussion f the data that's presented therein and as the FDA has recognized in the context of adverse events, adverse events, especially with acetaminophen, are inherently unreliable. And the Plaintiffs would like to get these adverse events before the jury without anybody having had the opportunity to look at them to see if they are valid adverse events and to see if they do have the underlying data that do more than temporally relate an ingestion of acetaminophen to an adverse event.

And while the cross-examination is there, the opportunity to examine the data that was presented to the FDA at the time is lost and now it's lost forever because she destroyed the data. And because of that --

THE COURT: So that's her bad and that makes that process look a little tarnished, right?

MR. HEWES: Right. And the data shouldn't come in though, Your Honor, before the jury. Why would something come before the jury that nobody has had a chance to look at for the jury to consider or the Plaintiffs to present it as data relating to adverse events or valid adverse events related to acetaminophen?

THE COURT: Okay.

MR. HEWES: The 2009 advisory committee meeting, Your Honor, suffers from similar problems in that the main event that the Plaintiffs would like to advance from the 2009 ad com meeting is a vote taken by the committee. And the ad com members, Your Honor, are not members of the FDA. They are an external group of researchers and scientists who have an interest or who have knowledge on the topic to be discussed.

And prior to the presentation in 2009, the FDA had an internal committee prepare a report -- which you've heard or read about in most of the briefs called the 2008 CDER, it stands for Center for Drug Evaluation and Research -- a 2008 CDER working group which basically set the table for the conversations to take place at the advisory committee meeting.

And at the ad com meeting, at the end the scientists and doctors and researchers, taking the cue from the 2008 CDER document, voted on a series of questions related to acetaminophen and liver damage. And the questions related to whether the package should be changed, whether the dosage should be changed, whether different things should happen relating to the over-the-counter product versus the prescription product.

And after considering this, Your Honor, to date, since 2009, the FDA has not adopted one of the recommendations made by the ad com committee as it relates to acetaminophen over-the-counter products. And this very issue was before Judge Johnson in the Lyles case in September. And Judge Johnson said the FDA recruits a group of people to solicit their advice, this group gives their advice, and the FDA doesn't act on it.

And there have been cases in New Jersey, that we cited in our brief, where the courts repeatedly excluded ad com testimony and ad com discussions as hearsay. And the fact that the FDA has not adopted the votes of the advisory committee, that goes to its credibility.

And the Counsel for Plaintiff would like to downplay the fact that the FDA has not adopted the over-the-counter recommendations from the ad com and they cite the Wyeth v. Levine case and state that the manufacturer bears responsibility for the content of its label. But our responsibility, Your Honor, lies in compliance with the federal regulations, not with speculative votes by an outside committee that were never adopted by the FDA.

As to hearsay, Your Honor, it is pure hearsay. The opinions and discussions by the ad com committee are not subject to peer review. They're not subject to cross-examination.

THE COURT: What if they're offered not for their truth, but just that they happened and that McNeil was in the room and they can do what they want to do with it?

MR. HEWES: For notice purposes?

THE COURT: It's notice, state of mind, right?

MR. HEWES: In order to have a valid notice argument, Your Honor, the discussions taking place in terms of the liver damage need to be substantially similar to the damage at issue in the case here. And it's citing the Barker case from the Third Circuit. And in this case here, Your Honor, the Plaintiffs have advanced as a key element of the liability, as to the specific causation with the decedent as advanced by their expert, Tim Davron (ph), that Ms. Hayes, a year prior to her death, underwent gastric bypass surgery and because she underwent gastric bypass surgery, her stomach was essentially cut down to a fraction of its original size therefore affecting its ability to absorb acetaminophen and

therefore putting her at a higher risk than other patients who may not have had the gastric bypass surgery.

We don't think that's a valid science and we make that argument in our daubert motions, but that is a key peg they hang their hooks on in this case. And nothing in the 2009 ad com discussion, nothing in the 2002 ad com discussion remotely addresses increased risk of individuals who have had gastric bypass surgery and who have gone on to suffer acute liver failure and death.

Moreover, Your Honor, from a notice perspective, as Ms. Jones said earlier, the FDA had notice. The original discussion about the monograph happened in '77. The monograph came online in '88. And the FDA adopted a final rule in April of 2009. The FDA not only had the benefit of McNeil's reports, but the FDA had the benefit of these ad com reports. The FDA had the benefit of receiving adverse event reports from all the other acetaminophen manufacturers.

And the FDA, having analyzed the same material McNeil analyzed and the FDA, having seen the 2008 CDER working group document, came to the ultimate conclusion that was reference in the final rule. And

the final rule is a final monograph for the purpose of that section, Your Honor. We've heard today a lot of it took 40 years and they still don't have a final monograph, but a final rule was implemented in 2009.

And the notice that the FDA had is the same notice that everybody else had. And what the FDA did is they identified and mandated a label that contained a liver damage warning. And the liver damage warning that they put on there was similar to a liver damage warning that had already appeared on the Tylenol label in 2004. The FDA added the word severe and changed some of the order around.

So in the context of notice, the evidence and the data that the Plaintiffs would say put McNeil on notice should turn back into what the FDA had notice had notice of and what the FDA ultimately concluded. And McNeil should be held to the standard of what the FDA ultimately concluded. And what you won't hear today, Your Honor, or anywhere during trial is where the FDA cited McNeil for improper labeling or for not following the FDA regulations as it relates to its Tylenol label. So the notice --

THE COURT: Well, we already know that McNeil is free to petition for a change in the label

using language perhaps stronger than what the FDA required, right?

MR. HEWES: After the final rule there appears to be a provision, Your Honor, but that is a provision that requires, as I understand it, a new drug application which is a whole nother process which requires a whole long review and assessment of the data that's out there. And so McNeil is not free to change or strengthen its label now just on its own and just decide it wants to add additional language to its label.

We also believe, Your Honor, that to allow this unreliable evidence in would prejudice McNeil and the jury and make it credence to the discussions of the advisory committee meetings as if they were the FDA making the pronouncements themselves.

THE COURT: Of course, we could change with a limiting instruction or you could argue that, right?

MR. HEWES: We certainly could, Your Honor. And finally, Your Honor, the 2008 CDER working group document was a document prepared by FDA employees. It too constitutes hearsay, Your Honor. It does not reflect an official agency or viewpoint.

As a matter of fact, the CDER policy manual for its employees specifically states a scientific review shall be considered a reviewer's own work.

As I said earlier, the 2008 CDER working group document set the table for the 2009 ad com and as Judge Johnson stated when discussing the CDER working group document in the Lyles case, he said the study group's recommendations and the entire discussion are a step removed from a step prior to the advisory committee. And the advisory committee, I'm of the opinion that that's hearsay. This is hearsay, hearsay never acted on by the FDA.

And for those reasons, Your Honor, we believe that the 2002 and 2009 testimony and arguments related to the advisory committee should be excluded. Thank you.

THE COURT: Mr. Tisi?

MR. TISI: You're going to get tired of me today, Judge. In MIL No. 3 and without any real specificity other than broad examples, McNeil seeks a pretrial motion and order in limine preventing plan from introducing or referring in any way or in any form important pre-2010 evidence it was aware of concerning things like acetaminophen toxicity, the

appropriate does, the narrow margin of safety or any risk factors associated with acetaminophen.

THE COURT: Well, they've stipulated that they've known that acetaminophen overdoses --

MR. TISI: Correct. And that was --

THE COURT: -- can cause liver toxicity and they've known that for many years.

MR. TISI: Absolutely, they have. And in fact -- but that kind of begs the question, well, if that was so well known, why did the FDA get so active in the 2000s if that's been known forever? Why would they go through the process of calling all these advisors in and issuing reports and doing the kinds of things they did? Because the risk profile and the safety profile for acetaminophen, was known by acetaminophen, was evolving and became alarmingly different in the 2000s and the late 1990s than was known in 1977.

Now, each of these issues that the Defendant seeks to exclude, the 2002 advisory committee, the 2009 advisory committee evidence and the FDA working group documents, importantly occurred before Ms. Hayes' death. All of these issues, all of these events occurred with either the input of McNeil, the participation of McNeil, or in the case of the FDA

working group, a reaction by McNeil as I'll illustrate in a second.

Now, all of these categories are admissible in this case for several reasons. None of which, frankly, were addressed by Judge Johnson as I'll talk about in a moment.

First, the evidence, and as I'll demonstrate, all the evidence related to this pre-2010 key events are non-hearsay under 801, Federal Rule of Evidence 801. As Your Honor pointed out, this is classic, or at least intimated, but this is classic notice evidence because the Defendant participated in the discussions surrounding the risk and safety profile of acetaminophen.

In 2002 they were present in the advisory committee, 2009 they were present in the advisory committee, and they received the FDA working group document all of which discussed not only the toxicity of acetaminophen, but the appropriate dose at which acetaminophen is capable of causing acute liver failure and liver injury in some people.

It referenced the problems with patients not understanding the label. It referenced -- all of these issues referenced -- all these events referenced the fact that patients did not understand

or appreciate the risk associated with over-the-counter drug.

All of these issues, all of these events that were put in McNeil's lab call into question McNeil's reasonableness in responding to that evidence.

Second, the evidence relating these key events can come in -- can come in for the truth of the matter asserted as hearsay with an exception under Federal Rule of Evidence 803(6), which is the business records exception, particularly with respect to the working group document and 803(8), the government records exception, and as a matter of fact, 807, the reliability exception, the catch-all.

Third, this kind of evidence is exactly the kind of evidence that experts in the field of hepatology, risk management, and regulatory affairs rely on and testify to regularly. As I pointed out when we discussed the failure to warn argument, if we were -- if the shoe were on the other foot, okay, and the FDA had repeatedly come down and the FDA advisory committee come down with a vote of 20 to 0 against Plaintiffs, it would be justifiable for the Defendant to get up and say, you know, Dr. Bloom, you're a genius sitting there with hindsight, sitting there

telling the jury about all of this stuff. You know, we had a bunch of people who sat here at the request of the FDA who heard the same evidence you're telling the jury about and 10 to 0 they voted against you -- against the position you're taking before this jury. That might be proper examination for her, okay. This is exactly the same kind of thing. These are the kinds of things that experts in the field, hepatologists, regulatory people typically rely on.

Now, before addressing these issues in particular, I'd like to address what appears to be McNeil's suggestion that this court simply follow the decision reached by Judge Johnson in the Lyles case. The answer to that is respectfully simple. The New Jersey court decided the evidence was hearsay, but did not perform the analysis and decide whether or not it was an exception, did not decide whether or not this is the kind of evidence that experts typically rely on and did not -- did not really analyze whether or not this was a proper question for notice. In short, because of the time constraints, I would respectfully suggest the Court simply made a ruling and moved on.

So and to drive the point home, the analysis of the judge -- of Judge Johnson seemed to be predicated on his notion that a mistaken notion that

the FDA never took any steps following any of these meetings, therefore suggesting to the jury and suggesting to him that this didn't -- that this evidence was unreliable.

Let me just quote you what the judge said. He said -- as Mr. Hewes pointed out the FDA recruits a group of people to solicit their advice. The group gives their advice. The FDA doesn't act on that. I don't know what to make of that. So what is the jury supposed to do?

So one of the guideposts I use as a judge is if I'm confused, the jury might be confused. Well, of course the judge didn't -- Judge Johnson did not hear the evidence in context, so the issue of whether or not it makes sense in the context of testimony was not before the judge. But number two, is he was under the mistaken assumption that the FDA never took any action as a result of any of these issues.

Let me give you an example. After the 2002 advisory committee -- and that advisory committee was not simply about hepatoxicity and acetaminophen -- as the evidence will show in the case, the 2002 advisory committee and I focused on Dr. Erush's testimony, but it was much more comprehensive than

that. They discussed all the published literature in the case, six studies from the acute liver failure study group in which they showed a dosing range between approximately 2 grams and greater. So they were discussing whether or not there was a risk at or near 2 grams. They also looked at the internal adverse event database that the FDA had and analyzed those adverse events and looked at whether or not there was a dose range, and in fact that there were.

They also looked at risk group factors, and in fact the presentation made at the 2002 advisory committee noted that many of these people were malnourished, many of these people had alcohol, many of the people who had a risk at or near 4 grams were people who had -- and you'll hear more testimony about this -- depleted glutathione stores in their body, which is the body's reaction that detoxifies the drug. Okay. It wasn't just about Dr. Erush, as you might be led to believe.

As a result of all of that, okay, the FDA published the results of this in the CFRs and that's Exhibit, I'm sorry, it's Exhibit 4 to our motion. It's a December 2006 where it reviewed and published in the CFRs in exquisite detail the evidence that was presented, not only to McNeil, but to the FDA

in which it considered and it reached the conclusion that acetaminophen toxicity, not acetaminophen overdose, but acetaminophen toxicity was an important safety issue for which additional labeling needs to be changed, needs to be addressed. Now, and that would be on page 7732 of the Code of Federal Regulations of the December 2006 advisory committee. So the point is the FDA did take action following the 2002 advisory committee.

Now that --

THE COURT: Mr. Tisi, what -- how do you anticipate this will come in in your case?

MR. TISI: I anticipate this comes in several ways. Okay, first of all it comes in -- it comes in, I believe, for the truth of the matter as a --

THE COURT: I mean, what --

MR. TISI: In other words --

THE COURT: -- what actual --

MR. TISI: There is a risk --

THE COURT: No. Will witnesses testify about it --

MR. TISI: Yes.

THE COURT: -- or will you put the report -- the physical report into evidence?

MR. TISI: Yes. The physical report -- we believe that the Code of Federal Regulations of -- there are several -- that's the problem here is I think the McNeil and I understand the problems with bringing your motion in limine that sometimes it's hard to list all the documents, but for example there was a PowerPoint which we attached to the -- to our motion. I can give you the exhibit number, but it's a PowerPoint from the 2002 advisory committee, in which the FDA presenters synthesize and now analyze both the published and unpublished literature with respect to dose and intentionality of whether or not people were just trying to feel better and get a liver failure.

THE COURT: Uh-huh.

MR. TISI: We believe that that comes in as -- certainly as notice to the Defendant, notice to the Defendant about what the thinking was in the medical and scientific community about the risk range and the dose range too. Some documents, like the Code of Federal Regulations may come in actually as a physical exhibit. Some things, like testimony at the advisory committee, may be used to impeach. So it depends upon the kind of evidence, frankly, that we're talking about here, but the overall gist of the 2002 advisory committee -- I haven't moved into the others

as well -- the overall gist is this was -- these advisory committees are not just let's get together and talk about things over coffee. These are authorized by the Code of Federal Regulations; these are regulatory committees that the FDA calls.

There are over 30 of the committees that stand at any particular time and the FDA calls them in the normal course of business to answer questions and to review data and to issue reports to the commission or the FDA, but they don't do that in secret, they do it in consult with the sponsor and the manufacturers of the drugs.

Let me, if I could, move on to the next issue and so really actually let me respond if I haven't concretely to what you're asking. The way in which any individual piece of evidence relating, for example, to the 2002 advisory committee comes into evidence in this case depends upon the evidence that's being submitted.

There are a lot of documents surrounding the 2002 advisory committee. If it's an e-mail from the Defendant saying, boy that was -- that was a terrible presentation, we don't believe any of it, okay it comes in a statement of a party opponent, the e-mail comes in. If it's evidence from the FDA,

for example, a PowerPoint, it may come in as a -- it may come in as notice to what the FDA was presenting to the company. If it's -- you see what I mean, it depends upon the category of evidence.

THE COURT: Right.

MR. TISI: Okay.

THE COURT: I get that. I was interested more in what physical evidence you anticipate introducing.

MR. TISI: Oh, there are -- oh, I apologize. I apologize.

THE COURT: I think I -- no, I think I understand.

MR. TISI: I apologize, Judge. If you want me to list some of the items --

THE COURT: You have the report; you have people who will testify about the proceedings of the advisory committee?

MR. TISI: Correct.

THE COURT: All right.

MR. TISI: Let me move on to the 2008 FDA working group report. The 2008 working group report and I think there's a little bit of a misperception. The 2008 working group report was not developed for the advisory committee in 2009. I don't

know if this is important or not, but I think it's important to understand the record. It grew out of the 2002 advisory committee. As a result of the investigation that the FDA did in 2008, they decided to reconvene another advisory committee.

So let's talk about that report that working group document for a moment. As a result of the public health issue identified in the 2002 advisory committee and the things that had happened between, the FDA commission -- the FDA commission -- director for the Center for Drug Evaluation and Research, which is the division of the FDA involved in this case, decided to ask an interdisciplinary group of scientists at the FDA to conduct a comprehensive evaluation and make a formal, final report to the director of that division. That was initiated in 2007, but the report was not issued to the commissioner for over a year.

In February of 2008, after a year of work -- and this is -- if I could refer to the report is Exhibit No. 2. There's an appendix in the back in appendix B which talks about the timeline for the development of this particular report and the very last it talks about the division, the members of the committee.

And the reason why that's important is this isn't just some employee who writes down a report somewhere. This report was issued by one, two, three, over ten members of the committee from the Office of Nonprescription Drug Products, the Office of Regulatory Policy, the Office of Surveillance and Epidemiology, the Division of Anesthesia, Analgesia and Rheumatology Products, controlled substance staff and the Office of Medical Policy. Okay, this was a high level report that was generated in the normal course of business for the commissioner.

It finally, on page 4 of the report, it describes the genesis of the report and I don't want to go into detail, but it says, "recognizing the continued of occurrence of acetaminophen toxicity as a significant public health problem, Dr. Steven Galson, the former CDER director, charged the working group within CDER to recommend to the FDA interventions" and it describes all of the things that they reviewed in connection with the development of this report.

This was a very -- the point of me bringing that up, this was a very comprehensive year-long report that was ultimately issued at the highest levels of the FDA.

Now, the next thing that happened of

importance, and they might have an argument -- McNeil might have an argument to exclude this if that's as far as it went, but the truth of the matter is, on May 27th, 2009, McNeil got a copy of the report. It was sent not only -- not just to McNeil, but to Colleen Goggins, the president of Johnson and Johnson.

McNeil not only received and reviewed it at the highest levels, it was called the worst case scenario by -- and they planned a media outreach in order to neutralize what the FDA report was saying. And I'm going to refer you to Exhibit No. 7, which is an e-mail from Dr. Kaminski (ph) to Dr. Goggins dated May 27th, 2009 at -- and it describes the report. But it says, "Colleen if you're still awake, I got a copy of the FDA report. It's close to worst case scenario." And he talks about all the things that they're going to do to address this report. So not only did they receive a copy of it, they reacted to it and they reacted to it rapidly and they reacted to it in real time.

So now the question becomes whether or not the FDA working group report is a -- if it is going to be referred to in this trial, how it is going to be referred to and how it is going to be presented to the jury. We would submit that at the very least,

this is notice evidence, important evidence and important evidence -- and I want to be concrete here. It's important evidence of several things, not just for the recommendations that are made, which of course, McNeil could have implemented any of those recommendations at any time, including until today.

The other important thing is the basis upon which those recommendations were made. For example, on page 11 of the working group report, the working group formally makes a recommendation to increase the margin of safety for acetaminophen that the dose ought to be lowered from 4 grams to something less than 4 grams. It acknowledged the argument that the Defendant is making in this case. Well, there's no -- there's no peer reviewed study, there's no clinical trials. You only rely on case reports.

The FDA working group said exactly what our experts say. They say, you know, when we look at the case reports and the case series and we look at the totality of the evidence, we look at the clinical trial data showing elevations of ALTs in clinical trials. When we look at the totality of the evidence on balance, we don't believe what McNeil is saying. We think it's misplaced and that's on page 11 and 12 of the report.

The point of this is, Judge, for the purposes of notice, okay, the jury is going to be called upon to try and appreciate whether or not McNeil's actions were reasonable under the circumstances, okay. If this group of scientists telling McNeil that you know something, your view of the science was "X," you say it's "Y," the jury is going to have to decide whether or not they reasonably responded to the information that was provided to them, so that's notice.

But we believe the information comes in for more than notice. Okay, we believe that it is kind -- even if it was hearsay, okay, the report of an -- a report of an FDA committee of this high level and of this high stature involving people and divisions within the FDA that were involved in this report, okay, is the very kind of evidence that an expert would rely on in this case and not just any expert, a hepatologist would say, you know something, we've been studying this for years and you know something, you know, this is our experience. And you know something, these other people looked at case reports, case series, clinical trials, experimental animal data and concluded that there was a risk at 4 grams. That's the kind of things that they would rely on, okay.

As a regulatory person, Dr. Bloom, for example, could come in and say, you know something, you know, I believe that it was reasonable for the company to change their label to provide additional warnings, to lower the dose, to do the kinds of things that we believe ought to have been done in this case, okay. Well, what's the basis of that? Well, I've looked at all the evidence and I've concluded that. Anything else, Dr. Bloom? Well, you know, other people looking at the very same evidence reached the same conclusion I did, okay. That's the kind of a thing that experts typically rely on.

Further, even if it was hearsay, okay, this is clearly, we believe, a public -- this falls into the public records exception for 803(8). It's data collected and reported in the official capacity of the FDA in the normal course of business. They're factual findings from a legally authorized investigation. McNeil has not shown or even attempted to show in its briefs that the -- that they may disagree with the conclusion, but they don't in any way suggest that the FDA was wrong or misguided in any way in the evidence that they relied on. And this is, in fact, the final report of a government agency.

For example, there are cases which I've

pulled up and I'm happy to provide them to the Court. There's a Musgrove case. There's a case called Guthrie -- and I can provide the Court with the cites -- where these kinds of things typically come in.

So whether it's for notice, whether it's in order for the experts to talk about it under Rule 703 or whether a -- as a exception under the hearsay rule, it comes in in this case. And I just -- I oftentimes try to -- as an officer of the Court, I think one of the things we try to do is yes, we're advocates, but I think looking at things at a 10,000 foot view and trying to decide whether a jury can decide issues in fairness, it boggles my mind, Judge, that with all of this activity involving acetaminophen and the FDA -- this kind of dovetails with the argument we made before -- that this jury would not hear about significant issues and significant events like this and they would be precluded. They wouldn't be able to reach a fair and reasoned result.

Let me turn to the 2009 advisory committee meeting again. Oh and let me stop here for a moment. None of the --

THE COURT: I want you to wrap this up in a few minutes, okay. I get the point.

MR. TISI: Okay. None of the analysis

I just did was performed in the New Jersey case and I just would add that.

THE COURT: I got that.

MR. TISI: The 2009 advisory committee McNeil presented again to the FDA, they were involved in the case. There were several recommendations made to McNeil and by McNeil to reduce the risk. The committee voted, okay. And the formal results of that vote were published by the FDA itself and I believe -- and if I could provide this to the Court, because I think we provided the wrong -- oh. This is the actual formal report of the FDA of the vote because I think that becomes important for evidentiary purposes and that's the FDA's reporting of the vote that was taken in connection with this issue.

Again, this is the kind of a thing experts rely on. This was why they reported. The fact that all of these people go together and decided and voted the way that they did, I think is some indicia of the reliability of our expert's opinions in this case.

Now, Mr. Hewes and frankly, Judge Johnson in New Jersey make much of the fact that of the suggestion that the FDA never did anything following this report and I'd like to address that for

a moment. Number one, that is not a criteria for admission for relevancy whether or not the agency ever did anything or not, but the truth of the matter is the FDA did do things following this.

Following this 2009 advisory committee the FDA met with McNeil repeatedly and out of those discussions grew McNeil's voluntary change of the label to lower the dose in 2011 after Ms. Hayes. Following that was -- following those discussions, following this meeting, there was a flurry of activity relating to risk reduction and whether or not, you know, and you'll hear about that during the course of the trial.

Number two, the FDA did take action where it could. Let me give you an example. On one of the recommendations that the advisory -- that the both the working group and the advisory committee made was that the dose be lowered from 500 milligrams to 325 milligrams, from extra-strength Tylenol to the equivalent for regular strength Tylenol. Now because of the vagaries on the OTC side, they could not force that, but on the prescription side where the FDA has a lot more power, okay, the -- on the prescriptions it told manufacturers, for example, of Vicodin and Percocet and others which have components to lower

their dose from 500 milligrams to 325 milligrams.

So even though the -- even though the threshold test for admissibility is not did the person or the FDA or anything do anything as a result of the statement, okay. It was a misperception and frankly, an inaccurate statement of the facts to suggest that following the meeting, everybody went home, nobody's ever done anything related to the recommendations made of this committee and much ado about nothing. The truth of the matter is and the evidence will show in this case that a lot was being done that could be done. So I think unless you have any questions, Judge, I think you understand where we are in this case.

THE COURT: I think I understand both sides of this --

MR. TISI: Thank you.

THE COURT: -- very interesting issue. Thank you.

MR. HEWES: Your Honor, could I just have --

THE COURT: Quickly.

MR. HEWES: Thank you, Your Honor. I will be very brief. One thing I neglected to mention at the beginning was these advisory committee meetings

are not sworn statements and they're not sworn testimony. And Mr. Tisi made my point for me, they intend to offer out of court, unsworn statements for the truth of the matter asserted, Your Honor. That is classic hearsay and it's not -- and it's a hearsay that cannot be cured by citing some exception, especially when there's evidence that the material is unreliable. And if you look at the Sarah Erush transcript as an example of why the hearsay rules exist as to why something should be reliable and -- when it goes to a jury.

The second point, Your Honor, I'll make and then I'll sit down is the 2008 CDER working document is not a final document. 21CFR10 dictates the requirements for a final federal document. It dictates who must sign it, it dictates what type of foundation must be laid for it to be a final document and it is not a final document. And it is clearly not a document that represents the opinions of the FDA, because the recommendations made in that document, again, were not adopted by the FDA. And when the FDA rose the document to the level of an advisory committee meeting, the advisory committee meeting recommendations, likewise, were not adopted by the FDA. Thank you, Your Honor.

THE COURT: Okay. Thank you. Let's turn to motion in limine 8. This is the evidence of other lawsuits and settlements. Good morning or good afternoon.

MS. A. JONES: Now we're in the afternoon. Motion in limine number 8 is our argument that lawsuits, other lawsuits, claims, and settlements should be excluded. As the Court is aware, there are hundreds of lawsuits pending before this Court. There are additional lawsuits filed in New Jersey related to other claimant's use Tylenol.

There have historically been lawsuits involving claims related to Tylenol. Some of those which -- some of those for which have other injuries alleged and none of these claims have any bearing on Mrs. Hayes' claims that are before this Court.

Those other lawsuits and other claims have been resolved, some through jury trial, some through settlement, some, as this Court is aware, have been even voluntarily dismissed. Another person's claim is not relevant to the question presented in this matter, which is Mrs. Hayes uses of Tylenol, Mrs. Hayes' knowledge and the warnings that were provided to Mrs. Hayes and whether Tylenol caused her injuries.

This is a 401-403 analysis as to

relevancy and whether any probative value would then be outweighed by the confusion to the jury of other lawsuits. The lawsuits, as the Court is aware, allegations, they are complaints that have not been proven in court and therefore they lack any probative value.

We cite the Court to the Foster (ph) and the Wolfe case out of the Eastern District of Pennsylvania and in fact, the Plaintiffs also cite to the Wolfe case in which the Court granted the motion without prejudice.

The -- I'll respond quickly to what the Plaintiffs raised in their response. Plaintiffs infer that perhaps because the wrongful death act provides for punitive damages that there is some willful and intent conduct that should give rise to evidence such as other lawsuits and claims that would then make it relevant to punitive type conduct, and that in fact, is not the standard. Plaintiffs did not cite to any Alabama cases that would raise the standard into an intentional or willful conduct. The standard is negligence.

Plaintiffs also try to couch the lawsuits as other similar incidents and we would submit that the requirement would then be

substantially similar incidents. And I'll stop there, because the Plaintiffs draw correlations in their response to other claims and lawsuits and settlements as adverse events and try to couch them as all related to a notice element. And in fact, this motion in limine which seeks to exclude the other lawsuit's claims and settlements is not directed towards adverse events.

If, however, you were to entertain the notice requirement, they would in fact, have to be substantially similar and they would have to have the same element of usage, same product, same warning at the time, the same cofactors that we see here as presented in Ms. Hayes' case and the same injuries. And in fact, Plaintiffs could not be able to do that with each and every lawsuit or evidence related to the lawsuits for claims.

The Plaintiffs also -- the Plaintiffs raised they tangential point of adverse events that somehow would be a similar incident related to the lawsuits for the claims. That motion is covered by Defendant's motion in limine number 1. The Plaintiffs also raise tangential points related to recall type evidence as well as evidence related to other McNeil products, such as children's motion and those -- that

type of evidence is covered by motion in limine number 7, which is recall related and governmental investigation type evidence.

The specific type of evidence that we are seeking to exclude are other lawsuits, reference to other claimants that have filed lawsuits. Media reports or any other tangential type evidence that refer to the other lawsuits, that they would not come in as irrelevant, they would be irrelevant to Mrs. Hayes' claims in this lawsuit and not probative.

THE COURT: What if witnesses who testify in this trial were called in other trials and said something different? Couldn't there be a reference to those other lawsuits?

MS. A. JONES: So certainly the Plaintiffs would be entitled to admit other sworn testimony by a particular witness for impeachment purposes, however, that can be done with the protection of a jury from other lawsuits.

THE COURT: Without identifying -- right.

MS. A. JONES: Right, that you wouldn't want the jury to be subjected to statements qualifying the testimony such as in the 200 other lawsuits that have been brought, you wouldn't say this or something

to that effect.

THE COURT: Okay. Anything else?

MS. A. JONES: No, I do not have anything else.

THE COURT: All right. Thank you. Mr. Tisi, what is it that you hope to introduce with these lawsuits?

MR. TISI: I'm going to -- I'm going to be as blunt as I can be. I have no intention of bringing in complaints and stacking complaints about -- from plaintiffs. I am concerned, though, Judge, and you know, I think this one of those things that has to be kicked down the road a little bit to see what happens at trial. I'll say, for example, there was a case and it's a case that went up to the Fourth Circuit, a case by the name of Benedi, okay. As a result of the Benedi case, I because -- and I'm not going to mis -- but I believe that that was part of the catalyst for voluntary changing the label for alcohol, for example. And we believe that the ability to change a label, for example, and the reasons for changing the label and the ability to do it voluntarily may be important.

Now, whether or not the Benedi case comes in and reference to it as the catalyst for that,

you know, I think that has to come out during the context of the case, but I will tell you as a general matter, the Plaintiffs and maybe I could have saved Ms. Jones some problem. The problem is the motion was so brief, we didn't know what it covered, okay. So if the complaint is that we are going to come in with stacks of complaints and see look at all these people who have filed claims against McNeil, we have no intent of doing that, Judge.

THE COURT: Okay. How long have there been lawsuits, over what period of time have there been lawsuits --

MR. TISI: Oh my goodness, there have been --

THE COURT: -- involving liver damage from Tylenol?

MR. TISI: There have been lawsuits going back decades, frankly. And most of the early lawsuits were related to -- this question would probably be better directed to McNeil, but most of the lawsuits that I am aware of, Judge, were in the early days related to alcohol use and either people who take a couple drinks a day who are not alcoholics or people who were using alcohol.

The Benedi case, for example, was I

think a 1996 case that went to trial in Virginia, went up to the Fourth Circuit and involved, I believe, an advisor to President Bush at the time who used to drink two, I think two glasses of alcohol a day, developed acute liver failure and died and there was a verdict there. So that was 1996. So that gives you a sense of how long these suits have been pending.

THE COURT: So you're not going to suggest in your case in chief, that the fact that there have been -- there's been so much litigation involving Tylenol and liver failure, that that's another element of this notice or state of mind argument?

MR. TISI: No. I mean, I think that the fact that there are people who had acute liver failure, okay, is notice. The fact that they filed a lawsuit or not, to me is, you know, again as, you know, as an officer of the Court I try to tether it to something that I think is -- the jury needs to understand. Whether or not the person filed a lawsuit is probably depends upon if something, you know, unusual comes up on the context, but as a general matter, I would not, you know, if I referred to a patient, for example, there are patients, for example, who are published in the peer review literature who

had a acute liver failure at 4 grams, while in the hospital being given 4 grams. I mean, under the supervision of a doctor.

Whether or not those patients filed lawsuits or not subsequently, I mean, to me the important thing is for notice purposes, for that kind of a case is that they had liver failure at 4 grams under the supervision of a doctor. That's the important part.

So, you know, I can see, as you said, there may be times when a blanket ruling, you know, did you testify in the Jones case back in 1997, I don't want to be stuck violating an in limine order because I've asked a witness, tried to impeach them. So I guess I would say to Your Honor is we don't have any intent to do that as a general matter, but there may be issues as it comes up in the context of a trial.

THE COURT: We can deal with those at trial.

MR. TISI: Exactly.

THE COURT: And you have no intention of bringing in any settlements at all?

MR. TISI: Oh, no. No, no, no. At least not in this case for sure.

THE COURT: Okay.

MR. TISI: I could have probably saved everybody time if I was --

THE COURT: I should have let you go first. Okay. Thank you.

MR. TISI: Thank you very much, Judge.

THE COURT: Thank you very much for your arguments on these motions. We have another conference scheduled in August, I believe?

MR. BERMAN: August 26th, Your Honor.

THE COURT: Right.

MS. C. JONES: And I just want to advise the Court while I'm thinking about it, I will actually be in trial on August the 26th, so I would request leave to be excused.

THE COURT: That's fine.

MS. C. JONES: Alyson will also be out at that point. Mr. Hewes and Mr. Abernethy will be available. I just am asking that we be excused for that hearing if at all possible.

THE COURT: I think that's fine. Our hope was to have another list of motions to argue and make some progress on these pending motions.

MS. C. JONES: That's fine.

THE COURT: Okay.

MS. C. JONES: We'll be here -- we'll -- my colleagues will be here and ready to handle it.

THE COURT: Okay.

MS. C. JONES: Thank you.

THE COURT: All right. Anything else?

MR. LONGER: Your Honor, just a point of personal privilege, my son is here in the courtroom and I'd like to introduce him to you after the hearing.

THE COURT: All right. Good morning or good afternoon. Okay. Good, thank you very much. That closes our record.

(A chorus of thank you)

(Proceeding concluded at 12:39 PM)

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CERTIFICATIONS

We, Dawn South, Debra C. McCostlin, and Melissa Looney, certify that the foregoing is a correct transcript from the official electronic sound recording of the proceedings in the above-entitled matter.

Dawn South

AAERT Certified Electronic Transcriber CET**D-408

Debra C McCostlin

Debra C. McCostlin

Melissa Looney

Melissa Looney
AAERT Certified Electronic Transcriber CET-607

Date: November 6, 2015