

1 UNITED STATES DISTRICT COURT
2 EASTERN DISTRICT OF PENNSYLVANIA

3 IN RE: TYLENOL)
(ACETAMINOPHEN) MARKETING,) 2:13-md-02436-LS
4 SALES PRACTICE AND PRODUCTS)
LIABILITY LITIGATION)
5) Philadelphia, PA
6) July 22, 2015
7)
8) 10:18 a.m.-12:39 p.m.

9 ORAL ARGUMENTS
10 BEFORE THE HONORABLE LAWRENCE F. STENGEL

11 APPEARANCES:

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24
25

1 ECRO OPERATOR: LAURA BUENZLE

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RULINGS

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1 P R O C E E D I N G S

2 (Call to Court)

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

7 THE COURT: Good morning.

8 (A chorus of good morning)

9 THE COURT: Please be seated.

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

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

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

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

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

6 THE COURT: Right.

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

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

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

22 THE COURT: All right.

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

1 THE COURT: Thank you.

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

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

6 THE COURT: Okay.

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

10 THE COURT: Okay. All right.

11 Anything to add, Ms. Jones?

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

14 THE COURT: Just eight motions?

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

17 THE COURT: Just eight.

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

20 THE COURT: Right.

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

23 THE COURT: You're slipping.

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

1 THE COURT: I understand.

2 MS. C. JONES: How about that?

3 THE COURT: I understand.

4 Okay. Thank you very much.

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

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

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

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

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

3 THE COURT: Good morning, Mr. Longer.

4 MR. LONGER: Good morning, Your Honor.

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

7 THE COURT: Okay.

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

10 Thank you, Your Honor.

11 MR. LONGER: Your Honor, good morning.

12 THE COURT: Good morning.

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

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

1 specifically about that.

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

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

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

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

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

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

24 THE COURT: All right. Mr. Tisi?

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

1 mind. May I approach?

2 THE COURT: Sure.

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

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

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

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

3 THE COURT: By the manufacturer.

4 MR. TISI: By the manufacturer.

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

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

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

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

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

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

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

25 THE COURT: So this information that

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

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

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

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

1 happened.

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

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

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

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

1 THE COURT: Okay.

2 MR. TISI: Thank you.

3 THE COURT: Got it.

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

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

16 THE COURT: Uh-huh.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 THE COURT: Yeah. I mean --

14 MR. ABERNETHY: What we're --

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

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

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

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

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

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

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

11 MR. ABERNETHY: Yeah.

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

15 MR. ABERNETHY: Okay.

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

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

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

3 THE COURT: All right. All right.

4 Thank you.

5 MR. ABERNETHY: Thank you, Your Honor.

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

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

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

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

18 THE COURT: Good morning.

19 MR. BERMAN: Laurence Berman.

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

25 The plaintiffs do not have an intent to

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

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

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

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

17 THE COURT: Sure.

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

20 THE COURT: Thanks.

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

25 But I pulled out of the text of the

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

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

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

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

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

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

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

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

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

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

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

25 THE COURT: So it's this one.

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

3 THE COURT: Okay.

4 MR. BERMAN: Thank you.

5 THE COURT: All right.

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

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

10 MR. BERMAN: Thank you.

11 THE COURT: Ms. Jones?

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

20 THE COURT: Uh-huh.

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

25 What we have here is a Canadian label

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

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

16 THE COURT: Uh-huh.

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

1 would be barred under 403.

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

11 THE COURT: Uh-huh.

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

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

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

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

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

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

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

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

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

9 THE COURT: Uh-huh.

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

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

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

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

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

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

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

14 THE COURT: Uh-huh.

15 MS. C. JONES: -- in, you know,
16 following the promulgation of the final rule in
17 2009 --

18 THE COURT: Uh-huh.

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

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

1 THE COURT: Right. Okay.

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

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

9 THE COURT: Uh-huh.

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

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

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

4 THE COURT: Okay. All right. Thank
5 you.

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

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

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

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

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

17 THE COURT: All right.

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

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

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

25 THE COURT: Okay.

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

12 THE COURT: Uh-huh.

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

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

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

1 think that's the key argument here.

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

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

20 THE COURT: Uh-huh.

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

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

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

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

12 THE COURT: Right.

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

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

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

3 THE COURT: Okay.

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

7 THE COURT: Right.

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

11 THE COURT: Right.

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

1 period of time.

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

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

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

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

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

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

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

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

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

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

11 THE COURT: Thank you.

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

14 THE COURT: Yes.

15 MR. TISI: Really, the question is
16 where the Defendant in a pharmaceutical case relies
17 heavily on the FDA process, as the Defendant does in
18 this case, should the Plaintiff be permitted to show
19 the limitations that even the FDA itself and the
20 federal government have acknowledge about the FDA's
21 power to regulate both over-the-counter and
22 prescription drugs. In this case, as the Court knows,
23 the question is whether or not there was adequate
24 information about acetaminophen-induced liver disease
25

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

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

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

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

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

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

15 But if they put the FDA as the 800-pound
16 gorilla in the middle of the courtroom, the jury needs
17 to have an understanding as to whether or not that
18 800-pound gorilla has limitations or not, especially
19 if the 800-pound gorilla acknowledges the limitations.
20 And so it's not -- you know, as a practical matter, I
21 think that Ms. Jones, and she's done an excellent job
22 of trying to present this issue, however, the point is
23 this is not a trial within a trial, this is part of
24 the case.

25

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

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

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

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

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

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

7 MR. TISI: Well, let --

8 THE COURT: Is it Dr. Blum?

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

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

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

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

17 THE COURT: All right. Thank you.

18 MR. TISI: Thank you very much, Judge.

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

24 THE COURT: Right.

25

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

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

10 MS. C. JONES: They do.

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

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

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

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

15 MS. C. JONES: That's right.

16 THE COURT: You can question the
17 approval process.

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

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

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

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

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

25 THE COURT: Right.

1 MS. C. JONES: That's what comes in.

2 That's the evidence of reasonable conduct.

3 THE COURT: Right.

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

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

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

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

22 THE COURT: Right.

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

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

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

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

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

9 THE COURT: I think I understand your
10 position.

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

12 THE COURT: Thank you.

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

14 THE COURT: Sure.

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

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

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

7 THE COURT: Right.

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

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

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

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

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

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

25

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

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

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

24 THE COURT: I understand your position.

25 MR. TISI: Thank you.

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

3 MS. C. JONES: Yes.

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

6 THE CLERK: All rise.

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

9 THE CLERK: All rise.

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

15 Good morning.

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

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

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

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

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

23 THE COURT: Just to clarify, Mr. Hewes

24 --

25 MR. HEWES: Yes.

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

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

5 THE COURT: Right. Who was present for
6 McNeil?

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

10 THE COURT: Right.

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

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

24 THE COURT: Here in Philadelphia,
25 right?

1 MR. HEWES: Yes, sir.

2 THE COURT: Yes.

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

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

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

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

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

10 "A. Correct.

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

14 "A. Correct.

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

17 "A. Correct.

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

20 "A. Correct.

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

23 "A. Correct.

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

1 "A. I did not.

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

4 "A. It was.

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

8 "A. Correct.

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

11 "A. Correct."

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

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

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

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

6 MR. HEWES: Yes, Your Honor.

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

15 MR. HEWES: Well, the --

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

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

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

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

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

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

25 THE COURT: Okay.

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

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

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

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

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

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

25

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

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

9 MR. HEWES: For notice purposes?

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

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

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

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

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

22 And the FDA, having analyzed the same
23 material McNeil analyzed and the FDA, having seen the
24 2008 CDER working group document, came to the ultimate
25 conclusion that was reference in the final rule. And

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

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

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

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

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

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

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

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

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

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

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

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

17 THE COURT: Mr. Tisi?

18 MR. TISI: You're going to get tired of
19 me today, Judge. In MIL No. 3 and without any real
20 specificity other than broad examples, McNeil seeks a
21 pretrial motion and order in limine preventing plan
22 from introducing or referring in any way or in any
23 form important pre-2010 evidence it was aware of
24 concerning things like acetaminophen toxicity, the
25

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

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

5 MR. TISI: Correct. And that was --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 Let me give you an example. After the
21 2002 advisory committee -- and that advisory committee
22 was not simply about hepatotoxicity and acetaminophen --
23 as the evidence will show in the case, the 2002
24 advisory committee and I focused on Dr. Erush's
25 testimony, but it was much more comprehensive than

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

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

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

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

10 Now that --

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

13 MR. TISI: I anticipate this comes in
14 several ways. Okay, first of all it comes in -- it
15 comes in, I believe, for the truth of the matter as a
16 --

17 THE COURT: I mean, what --

18 MR. TISI: In other words --

19 THE COURT: -- what actual --

20 MR. TISI: There is a risk --

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

23 MR. TISI: Yes.

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

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

14 THE COURT: Uh-huh.

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

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

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

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

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

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

5 THE COURT: Right.

6 MR. TISI: Okay.

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

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

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

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

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

19 MR. TISI: Correct.

20 THE COURT: All right.

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

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

6 So let's talk about that report that
7 working group document for a moment. As a result of
8 the public health issue identified in the 2002
9 advisory committee and the things that had happened
10 between, the FDA commission -- the FDA commission --
11 director for the Center for Drug Evaluation and
12 Research, which is the division of the FDA involved in
13 this case, decided to ask an interdisciplinary group
14 of scientists at the FDA to conduct a comprehensive
15 evaluation and make a formal, final report to the
16 director of that division. That was initiated in
17 2007, but the report was not issued to the
18 commissioner for over a year.

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

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

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

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

25 Now, the next thing that happened of

1 importance, and they might have an argument -- McNeil
2 might have an argument to exclude this if that's as
3 far as it went, but the truth of the matter is, on May
4 27th, 2009, McNeil got a copy of the report. It was
5 sent not only -- not just to McNeil, but to Colleen
6 Goggins, the president of Johnson and Johnson.

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

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

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

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

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

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

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

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

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

25 For example, there are cases which I've

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

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

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

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

25 MR. TISI: Okay. None of the analysis

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

3 THE COURT: I got that.

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

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

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

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

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

14 Number two, the FDA did take action
15 where it could. Let me give you an example. On one
16 of the recommendations that the advisory -- that the
17 both the working group and the advisory committee made
18 was that the dose be lowered from 500 milligrams to
19 325 milligrams, from extra-strength Tylenol to the
20 equivalent for regular strength Tylenol. Now because
21 of the vagaries on the OTC side, they could not force
22 that, but on the prescription side where the FDA has a
23 lot more power, okay, the -- on the prescriptions it
24 told manufacturers, for example, of Vicodin and
25 Percocet and others which have components to lower

1 their dose from 500 milligrams to 325 milligrams.

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

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

17 MR. TISI: Thank you.

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

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

22 THE COURT: Quickly.

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

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

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

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

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

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

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

25 This is a 401-403 analysis as to

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

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

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

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

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

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

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

1 type of evidence is covered by motion in limine number
2 7, which is recall related and governmental
3 investigation type evidence.

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

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

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

20 THE COURT: Without identifying --
21 right.

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

1 to that effect.

2 THE COURT: Okay. Anything else?

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

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

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

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

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

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

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

15 THE COURT: -- involving liver damage
16 from Tylenol?

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

25 The Benedi case, for example, was I

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

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

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

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

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

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

19 THE COURT: We can deal with those at
20 trial.

21 MR. TISI: Exactly.

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

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

1 THE COURT: Okay.

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

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

6 MR. TISI: Thank you very much, Judge.

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

10 MR. BERMAN: August 26th, Your Honor.

11 THE COURT: Right.

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

16 THE COURT: That's fine.

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

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

24 MS. C. JONES: That's fine.

25 THE COURT: Okay.

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

3 THE COURT: Okay.

4 MS. C. JONES: Thank you.

5 THE COURT: All right. Anything else?

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

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

13 (A chorus of thank you)

14 (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

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