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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION

CASE NO. 20-md-02924-ROSENBERG

IN RE: ZANTAC (RANITIDINE) .
PRODUCTS LIABILITY . West Palm Beach, FL
LITIGATION. . June 7, 2021
. .

MOTION to DISMISS PROCEEDINGS (through Zoom)
BEFORE THE HONORABLE ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE and

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1 *THE COURT:* Okay, good afternoon, everyone. We are
2 here resuming the hearings in the Zantac Products Liability
3 Litigation, MDL number 2924. We are continuing with some
4 additional questions and answers with respect to the generic
5 Defendants' Rule 12 Motion to Dismiss on the ground of
6 preemption and incorporated memorandum of law, and that is ar
7 Docket Entry 3105.

8 I will ask all counsel who are arguing that motion and
9 engaging in the question and answer to put your video and audio
10 on.

11 Good afternoon, everyone, I hope you are all well. I
12 hope you had a really restful, relaxing weekend and you are
13 back. So, just to follow up -- and I do appreciate your making
14 yourselves available for a followup day of questions with
15 respect to the motion.

16 Mr. Keller, on behalf of the Plaintiffs, you said on
17 Friday that shorter expiration dates would warn Plaintiffs "not
18 to consume a product" after a certain date.

19 The risk that you have alleged in the complaint,
20 though, is a cancer risk, and you allege that all generic
21 manufacturers knew of the cancer risk.

22 How is the duty, a duty to provide an adequate warning
23 of a products risk or danger satisfied by an expiration date
24 when the risk is a cancer risk? Isn't the warning that the
25 state law requires different than a warning not to consume the

1 product?

2 *MR. KELLER:* Ashley Keller for the Plaintiffs, your
3 Honor, and as Ms. Stipes is probably aware, I am the only one
4 speaking for Plaintiff, so if I forget to reintroduce myself,
5 it is Ashley Keller every time on behalf of the Plaintiffs.

6 No, is the answer to your Honor's question. The duty
7 would be fully satisfied because a manufacturer, behaving as a
8 reasonably prudent manufacturer would, must have an accurate
9 expiration date.

10 When you think about expiration dates for drug
11 products, or for any other product, there is typically not a
12 warning that provides an explanation to consumers as to why the
13 expiration date is set as it is.

14 Milk is the most common example, and it is an example
15 we use in our papers. When a dairy farmer puts the expiration
16 date on a carton of milk, it doesn't further explain if you
17 take it after this date the milk might be sour, the following
18 bacteria are likely to grow in the milk which would be
19 dangerous to you once ingested into your stomach. It simply
20 says this is the expiration date for the milk, and that tells a
21 reasonably prudent consumer don't take the product after this
22 date.

23 So, that is what we are alleging with respect to the
24 expiration date theory of negligence. It is true that
25 separately, under state law and behaving as a reasonably

1 prudent manufacturer would, state law would impose a duty also
2 to warn about cancer risk, but only the brands could satisfy
3 that duty. We fully acknowledge that the generics could not.

4 But the expiration date does provide an important
5 warning to consumers, it is an important warning that state law
6 demanded the generics provide, and it is a state law duty we
7 allege they breached.

8 *THE COURT:* You allege the same state law that you
9 argue imposes one duty on the brand and a separate and/or
10 different duty as to the generic.

11 How do you support a proposition that a duty under a
12 state law, a state law duty can require one thing of one type
13 of manufacturer, and that very same state law duty requires
14 something that is different from a different manufacturer?

15 *MR. KELLER:* That is a very good question.

16 *THE COURT:* Same law, same duty.

17 *MR. KELLER:* A couple of different points because this
18 is a really important area to focus on. First, we allege the
19 duty to have an accurate expiration date for both types of
20 manufacturer Defendants, so it is not just the generics.

21 *THE COURT:* I acknowledge that, yes.

22 *MR. KELLER:* Second, and I think this is the actual
23 heart of your question, and it goes back to something we were
24 talking about on Friday, the duty under most states' law stated
25 at a very high level of generality -- let's take negligence,

1 for example -- is behave as a reasonably prudent manufacturer
2 would under the circumstances. That is going to impose a lot
3 of sub duties.

4 During my relaxing weekend, I spent some time on
5 WestLaw just to confirm that what I said to your Honor on
6 Friday was accurate, and it was. It is totally commonplace in
7 jury instructions for judges to say the Plaintiffs have alleged
8 five theories of negligence, or sometimes the law refers to
9 that as five specifications of negligence. That is just an
10 older term for the same concept, five theories of negligence.

11 And it is really five theories of breach, they did
12 one, two, three, four, and five, and the instructions will
13 typically say you only have to find one breach in order to find
14 that the Plaintiff can recover and that the Defendant is
15 liable. The Plaintiffs don't have to run the table, they only
16 need to win one.

17 The law of the state is the same for all Defendants.
18 Brands and generics both have a duty under Alabama law, for
19 example, to add a cancer warning. The issue is, Federal
20 preemption says generics can't do that. The duty of sameness
21 articulated in Mensing says that specification of negligence,
22 that theory of negligence, though it exists under state law,
23 cannot be applied because of Article VI, clause 2 of the
24 supremacy clause to the generics.

25 So, while the law of Alabama is the same for both

1 generics and brands, we acknowledge that that particular theory
2 can't be asserted legally against the generics. In my research
3 on WestLaw once again confirming our conversation from Friday
4 where I said to your Honor, look at Bates where limiting
5 instructions are articulated as a basis to ensure there is no
6 prejudice and that generics wouldn't be held liable for a
7 preempted theory, that is also completely commonplace.

8 I am happy that I predicted off the cuff the actual
9 practice for State Court jury instructions. Juries are
10 regularly instructed, the state law requires these five things,
11 but because of Federal preemption, the following two things are
12 off the board. I am instructing you as a matter of law, ladies
13 and gentlemen of the jury, you cannot return a verdict for
14 Plaintiff on theories A and B, it has to be the other theories.

15 I know that was a long-winded answer to your question,
16 but we don't think there is any difference in state law between
17 the brands and the generics, but because of Federal law, we
18 have a narrower path that we have to walk against the generic
19 manufacturers.

20 *THE COURT:* Okay. I understand what you are saying as
21 to the brands and the generics.

22 You began your analysis with, to some extent, let's
23 look at Federal law, let's look at Federal preemption, it tells
24 us what one of the manufacturers can't do. So, it sounds like
25 in a way you are then asking the Court to redefine what the

1 duty is based on what the manufacturer can't do because of
2 Federal preemption, as opposed to beginning with looking at the
3 duty that the state law requires and asking, can the
4 manufacturer, in this case the generic, fulfill the duty, and
5 in answering that question one would look to the Federal law to
6 see whether any aspect of the Federal law preempts the state
7 law duty.

8 So, it is kind of what do you look at first, and I am
9 interested in what -- I will hear from the Defense on this as
10 well, but it is sort of the analysis that one undertakes in
11 going through impossibility preemption. The Mensing Court, for
12 example, looked at the duty first to provide a safe label, and
13 then considered that in the context of the Federal regulatory
14 scheme as it applies to generics.

15 Now, it is true that the Court explored different
16 avenues, notifying the FDA, could dear doctor letters suffice,
17 but the Court began by looking at what is the duty.

18 In fact, the Court was so clear about it, in fact, I
19 think the Court even used the word "clear", but at one point
20 the Court says, "To summarize, the relevant state and Federal
21 requirements are these, state tort law places a duty directly
22 on all drug manufacturers to adequately and safely label their
23 products."

24 Taking Mensing and Demahey's allegations as true,
25 state law imposed on the manufacturers a duty to attach a safer

1 label to their generic product, in this case, for purposes of
2 spelling it is M-E-T-O-C-L-O-P-R-A-M-I-D-E.

3 Another part of the opinion, "We find impossibility
4 here. It was not unlawful under Federal law for the
5 manufacturers to do what state law required of them, and even
6 if they had fulfilled their Federal duty to ask for FDA
7 assistance, they would not have satisfied the requirements of
8 state law."

9 And the Court acknowledged that the brand and generic
10 manufacturers had different Federal drug labeling duties, and
11 that is based on the statutory scheme. The brands are
12 responsible for accuracy and adequacy, the manufacturers have
13 the duty of sameness.

14 Let me just see if there was one other provision.

15 Similarly, in that complaint in Mensing, the Court
16 acknowledged that the Plaintiffs pled that the manufacturers
17 knew or should have known that their labels did not adequately
18 warn of that risk. As we know from your complaint, the
19 Plaintiffs' complaint, the knowledge that the generics are said
20 to have, or alleged to have is are the same, you can correct me
21 if I am wrong, as the knowledge that the brands are alleged to
22 have.

23 So, as in Mensing, the generics in our case allegedly
24 have the very same knowledge about the risk of the product, of
25 the drug, the inadequacy of the warning, and the Court

1 acknowledging that the duty is to ensure an adequate and safe
2 label. So --

3 *MR. KELLER:* Yes, your Honor.

4 *THE COURT:* -- consistent with the preemption analysis
5 in *Mensing*, how do we get to where your argument lies?

6 *MR. KELLER:* Very good, your Honor. We completely
7 agree with the Supreme Court's decision in *Mensing*.

8 First, I want to talk about the knowledge allegations.
9 You are not wrong, we do allege that the generic manufacturers
10 had the same knowledge as the brand manufacturers, and if they
11 didn't, they should have had that knowledge. They are charged
12 as being experts in the field.

13 Knowledge is not one of the requirements to which the
14 Supreme Court referred in *Mensing*. Knowledge is not the breach
15 of duty. Knowledge is relevant to the elements of our claims.
16 You can't change an expiration date or have reasonably prudent
17 storage and transport conditions, or an appropriate packaging
18 protocol if you don't know how your product works.

19 So, our knowledge allegations, we think, are very
20 appropriately included in the complaint, but that is not what
21 *Mensing* or preemption is referring to.

22 We also agree with *Mensing* that you start with the
23 duty under state law. You start with -- to quote the language
24 that your Honor just referenced -- the requirements, but state
25 law imposes multiple different requirements on manufacturers of

1 products, a requirement to have an accurate expiration date,
2 the breach of which would be a breach of duty under, for
3 example, negligence where the elements are duty, breach,
4 causation and damages, a requirement to properly store and
5 transport your drug, a requirement to put it in proper
6 packaging, and yes, a requirement to warn about cancer.

7 All of those are requirements, you start with those,
8 then you look at Federal law and say which of these
9 requirements are impossible to square with the Federal
10 regulatory landscape. For the brands, none of those
11 requirements are impossible to square with the Federal
12 regulatory landscape, so all of them can proceed.

13 For the generics, the cancer warning, that requirement
14 is impossible to square with the duty of sameness, but the
15 expiration date requirement isn't. In fact, the very same
16 regulation that Mensing is talking about is the one that
17 articulates that expiration dates are an exception to the duty
18 of sameness.

19 So, we completely agree you start with the duty or the
20 requirement. I think those are synonyms for the same concept.
21 But you do it at a granular level, and the reason you do it at
22 a granular level, or provision-by-provision, to quote the
23 Eleventh Circuit in Paco (phon), is because we are not
24 redefining any of the elements of the cause of action.

25 As I just referenced before, jury instructions in

1 State Court routinely say if you have breached any of your
2 duties that are imposed by the common law of negligence, any
3 one breach is enough to support a Plaintiff verdict.

4 So, they can't point to the fact that they were unable
5 to meet the requirement to add a cancer warning to say that is
6 a get out of jail free card for breaching the requirement to
7 have an accurate expiration date. Any breach of duty under the
8 common law is enough to return a negligence verdict for the
9 Plaintiff.

10 *THE COURT:* Well, with the negligent failure to warn,
11 for example Alabama, paragraph 1180 -- our light just went off
12 in this courtroom.

13 *MR. KELLER:* I can still see you, your Honor.

14 *THE COURT:* We had to move to a different courtroom
15 today because somebody is using our other one.

16 Under Alabama law, a manufacturer has a duty of
17 reasonable care to provide an adequate warning to consumers of
18 a product's danger when used in its intended manner.

19 How are you arguing that changing an expiration date
20 fulfills the generic manufacturers' duty of reasonable care to
21 provide an adequate warning to consumers of a product's danger
22 when you have acknowledged at the hearing on Friday that the
23 expiration date isn't a warning of a product's danger, it is,
24 at best, a warning not to consume?

25 *MR. KELLER:* I respectfully disagree with your Honor's

1 characterization. I do think it is a warning of the product's
2 danger. It is not a specific danger.

3 *THE COURT:* That is not what you said on -- I don't
4 believe that is what you said at the hearing on Friday.

5 *MR. KELLER:* I do have the transcript from Friday, but
6 I don't have that exchange. If I was imprecise, let me try and
7 be more precise.

8 I do not think it is a specific warning of cancer, it
9 obviously isn't that, but I do think it is a warning of danger.
10 It is saying there is a risk if you consume it after this date.
11 It is not telling you what the risk is, it is not being
12 specific.

13 I think if you took a survey, which is obviously not
14 the subject of a 12(b)(6), it is a fact question, almost every
15 consumer would say they don't consume products past their
16 expiration date, they would know to stop taking it because
17 something could go wrong. They can't articulate that something
18 and that is not required. The common law is usually operating
19 at a pretty high level of generality.

20 So, I do think that an expiration date is a warning of
21 danger. It is not as specific as we would like and the brands
22 have a duty to be more specific, and they can comply with that
23 requirement under both state and Federal law.

24 I think an expiration date would go a long way to
25 alerting generic consumers of the dangers associated with

1 Ranitidine, and the fact that the word "cancer" doesn't appear
2 with the dating digits is neither here nor there for purposes
3 of the state requirement at issue in these counts.

4 Your Honor, if I could just add, even if you didn't
5 consider it a warning of danger, it would be very easy to say,
6 under the reasonably prudent man or woman standard, a
7 manufacturer obviously has a duty to have an accurate
8 expiration date. If they are putting an expiration date on the
9 product, it has to be accurate.

10 So, I think it counts as a warning, the expiration
11 date, but even if you didn't, the expiration date would still
12 support a breach of a state requirement that isn't preempted or
13 inconsistent with Federal law.

14 *THE COURT:* Well, at page 40 of the transcript from
15 the Friday hearing you say, "As I said before, I don't think
16 that an expiration date is itself a warning about cancer, it is
17 a warning when a consumer should not continue to take the
18 product."

19 *MR. KELLER:* And I stand by that. I hope there wasn't
20 an inconsistency, but I think that is what I said this
21 afternoon as well.

22 *THE COURT:* You went on to say, "But the expiration
23 date itself is just a warning to a consumer not to consume a
24 product."

25 *MR. KELLER:* Correct.

1 *THE COURT:* That goes back to my question of how,
2 then, does a generic meet the duty under Alabama law to provide
3 an adequate warning to consumers of a product's danger?

4 *MR. KELLER:* I think, even though it is not providing
5 a cancer warning, it is not using the word "cancer," it is
6 alerting consumers that there is danger if they consume it
7 after the proper expiration date.

8 So, though it is not as specific a warning as would be
9 possible under state law, it is still a warning of danger, and
10 a reasonable manufacturer would provide a reasonable expiration
11 date, and we, I think, plead the allegations that, if accepted
12 as true, demonstrate the generics didn't do that.

13 *THE COURT:* So, is it your position that a shorter
14 expiration date would satisfy the state law duty to warn?

15 *MR. KELLER:* Yes, your Honor.

16 *THE COURT:* And from the Defense, would an expiration
17 date satisfy the state law duty to warn; and if yes, why? If
18 no, why?

19 *MR. YOO:* Thank you, your Honor, Thomas Yoo for the
20 generics.

21 An expiration date would not satisfy the alleged state
22 law duty to warn. As the Court has already pointed out, the
23 duty, as articulated by the Plaintiffs and as referenced in the
24 authority submitted by the Plaintiffs, is a broad duty to act
25 reasonably to provide an adequate warning of the risk of the

1 product's danger.

2 Here, that alleged risk is cancer and exposure to
3 NDMA, and notwithstanding the exchange with the Court just now,
4 I think the Plaintiffs are quite clear in both their papers and
5 statements on the record during the hearing that they concede
6 an expiration date is not a cancer warning.

7 Again, not to sound repetitive, but the touchstone is
8 not what could a Defendant have done to mitigate some of the
9 risk, it is what must a Defendant have done to avoid liability
10 altogether.

11 So, an expiration date, a new a set of four to six
12 digits, is not a cancer warning, I think the Plaintiffs concede
13 that, nor is there any plausible way to see how a new set of
14 digits would warn consumers about the alleged risk of cancer
15 from using Ranitidine.

16 In this sense, I don't think it is very different from
17 the milk analogy in that when we look at an expiration date on
18 a carton of milk, people think different things. Some people
19 may think it may result in something like an upset stomach, but
20 no one looking at a set of dates would assume that there was a
21 clinical risk of a serious adverse event associated with the
22 expiration date.

23 Same thing with Ranitidine. Absent instructions and
24 an actual clinical warning about the risk of cancer, no
25 consumer, or even physician, would look at an expiration date

1 and assume that if they don't use it before the expiration
2 period, that the patient is going to be exposed to a risk of
3 cancer.

4 I think the Plaintiffs' amended complaints bear that
5 out where they make it quite explicit that the alleged duty on
6 the generics is to not only provide an expiration date, a
7 different expiration date, but to provide instructions and a
8 warning of cancer such that consumers and physicians are made
9 aware of this alleged risk of cancer that the generics
10 supposedly have known all along and failed to disclose.

11 So, an expiration date is absolutely not a cancer
12 warning and would not be sufficient to satisfy the state law
13 duty.

14 I would also add, your Honor, that the allegation
15 regarding an expiration date is fundamentally irreconcilable
16 with the Plaintiffs' claim as to why Ranitidine is defective.

17 An expiration date would not matter at all but for the
18 Plaintiffs' allegation that Ranitidine degrades into NDMA, and
19 does so not only under normal storage conditions, but simply by
20 being ingested and digested in the human body.

21 So, it matters not that the Plaintiffs say they
22 believe a better expiration period would have been two months
23 because they are still alleging that that Ranitidine still
24 degrades into NDMA when consumed.

25 *THE COURT:* Let me ask you a question. What do you

1 think provides the contours of the duty imposed upon the
2 manufacturer, the generic manufacturer in this instance -- when
3 you are talking about negligence, negligence failure to warn or
4 general negligence, it is very broad. There are probably many
5 things that a manufacturer can do just in any ordinary
6 business. A storekeeper could do many things in the store to
7 keep the store safe.

8 How do you suggest that the analysis is to be
9 undertaken to determine the breadth of obligations that the
10 generic manufacturer has under a -- whether it be a general
11 negligence theory or a negligent failure to warn?

12 Is it every single thing that could possibly be done,
13 and if a generic manufacturer couldn't do but one of those
14 things, it couldn't comply with state law duty because one of
15 those things, perhaps, is preempted? Or do you go about
16 defining the contours of the analysis for what a duty is, and
17 therefore what obligations a generic manufacturer has, in a
18 different way?

19 *MR. YOO:* I assume that is for me, your Honor?

20 *THE COURT:* Yes.

21 *MR. YOO:* Thank you, Thomas Yoo again for the
22 generics.

23 I think the analysis is much more straightforward than
24 that, as the Supreme Court instructs in *Bartlett* and did in the
25 *Mensing* decision, and that is to look at what it is the

1 generics would have to do in order to avoid liability
2 altogether.

3 If that, according to the Plaintiffs, one thing, you
4 look at one thing. If it is three things, then you would have
5 to satisfy all three things. If any one of the three things is
6 not possible because of the strictures of Federal law, then the
7 entire claim is preempted.

8 *THE COURT:* Okay. So, if Plaintiffs are saying that
9 they are alleging that the manufacturers only had to do three
10 things to ensure that the product was safe, three things that
11 they could do, does that define the duty for the generics?

12 *MR. YOO:* Well, your Honor, instead of looking at
13 it purely abstractly, what the Plaintiffs have alleged here is
14 that there are things that the generics could have done to
15 reduce any additive risk related to a container or an
16 expiration date.

17 But what they continue to embrace is the primary
18 allegation that all of those things are relevant because of the
19 inherent defect of Ranitidine.

20 And so, when those things matter, according to the
21 Plaintiffs, because all Ranitidine is defective and all
22 Ranitidine, no matter how you handle it, and as soon as you put
23 it in your body turns into a carcinogen, then you would have to
24 take care of all of those issues in order to avoid liability.

25 That is the point that we are trying to make, your

1 Honor, and that is why all of these claims are preempted under
2 Mensing and Bartlett.

3 This is not a case of simply some handling practice
4 resulting in some risk that otherwise Plaintiffs say would not
5 be present.

6 This is the Plaintiff saying there is a unique
7 molecule here that becomes a carcinogen in the body, and
8 everyone who handled it, made it, sold it is liable, including
9 the generics, and on top of that, we think there are a couple
10 of additional things that we can pin on the generics. It
11 doesn't matter whether those additional things could have been
12 satisfied or not when doing those things wouldn't allow the
13 generics to avoid liability.

14 The Plaintiffs would not concede, your Honor, that a
15 Ranitidine product manufactured by a generic with a two-month
16 expiration date would not degrade into NDMA in the human body.
17 To the contrary, they say the opposite.

18 So, it is still has in tow as a necessary part of the
19 claim the design of the product, and ultimately, the lack of a
20 cancer warning, and that is what makes this preempted.

21 *THE COURT:* If they were at trial and they were
22 limited to arguing the manufacturers were -- the generic
23 manufacturers were negligent, and the only way in which they
24 were negligent was failing to have a proper expiration date,
25 and ladies and gentlemen, as you can see, the evidence shows

1 that the expiration date can cause someone to ingest more NDMA
2 than they otherwise would and that then causes cancer, and the
3 jury instruction is the standard jury instruction on
4 negligence, negligent failure to warn, ladies and gentlemen, if
5 you find that the generic manufacturer expiration date that was
6 on the label caused the Plaintiffs to ingest more NDMA and that
7 caused cancer, then you may find the generic manufacturer
8 negligent.

9 So, the Ranitidine molecular composition isn't being
10 argued as the basis for negligence, design isn't being argued,
11 the cancer warning. It is, ladies and gentlemen, in order to
12 find the generic manufacture negligent, or having negligently
13 failed to warn, you may do so only if you find that the
14 expiration date was inappropriate, was too long.

15 MR. YOO: Thank you, your Honor, Thomas Yoo again for
16 the generics.

17 That would not be their argument, your Honor, because
18 the argument would have to be, you would find the generics
19 negligent because of an incorrect expiration date because
20 Ranitidine is a drug that forms NDMA, because Ranitidine
21 happens to be a molecule that degrades into the components of
22 NDMA and forms NDMA in the body.

23 That is just the nature of Ranitidine as the
24 Plaintiffs allege. So, the generics would still be penalized
25 for making the drug they were required to make under the ANDA

1 approved by the FDA.

2 Put another way, your Honor, in your discussion with
3 Mr. Keller, I believe he articulated what the Plaintiffs view
4 of the duty is on the generics as what a reasonably prudent
5 manufacturer would have done, but the second half of that
6 equation is, given that Ranitidine degrades into NDMA, and
7 there is an increased risk of cancer.

8 And there is a reason, your Honor, why in the decade
9 of jurisprudence since Mensing no Court has recognized an
10 expiration date exception or a container exception to Mensing
11 preemption because Plaintiffs, at the pleading stage, could
12 easily add such allegation to any pharmaceutical
13 product liability case.

14 Whether it is tardive dyskinesia in Mensing or
15 myocardial infarction and stroke or a birth defect, they could
16 take some alleged inherent clinical risk of a drug, and then in
17 order to bring in the generics industry, add a cause of action
18 that says at the pleading stage, we believe that an incorrect
19 expiration date or the failure to use blister packs may have
20 contributed to this risk.

21 That is not how the law works, and no Court has done
22 that.

23 *THE COURT:* I am not sure these arguments have been
24 made before. I don't disagree that there have been no cases
25 that we could find where, since Mensing, a claim has been made

1 that survived preemption against a generic, but then again, I
2 also haven't seen a case, and no one has brought to my
3 attention, where such arguments are being made or such theories
4 of liability are being put forth.

5 Let me continue, and if there is anything to add, I
6 will allow the parties to do so.

7 I asked the question would a shorter expiration date
8 satisfy a state law duty to warn. The Plaintiffs said yes,
9 Defense said no. I want to complete the question as to the
10 other two claims.

11 For the Plaintiff, would changing the product
12 container satisfy the state law duty of reasonable care; yes or
13 no?

14 *MR. KELLER:* Yes.

15 *THE COURT:* From the Defense?

16 *MR. YOO:* No, your Honor, for the same reasons we have
17 discussed.

18 *THE COURT:* I am assuming the same answer for would
19 changing the storage and transportation conditions satisfy the
20 state law duty of reasonable care. From the Plaintiff?

21 *MR. KELLER:* Yes, your Honor.

22 *THE COURT:* From the Defense.

23 *MR. YOO:* No, your Honor, for the same reasons.

24 *THE COURT:* Plaintiffs, if a shorter expiration date
25 helps, but doesn't fully satisfy the state law duty, wouldn't

1 the entire state law cause of action, a cause of action for
2 failure to warn, be preempted?

3 *MR. KELLER:* I am sorry, your Honor, could you repeat
4 your question? I want to make sure I heard it right.

5 *THE COURT:* If a shorter expiration date helps, but
6 doesn't fully satisfy the state law duty, wouldn't the entire
7 state law cause of action, that is the cause of action for
8 failure to warn, be preempted?

9 *MR. KELLER:* No, your Honor, it wouldn't be preempted.
10 It might fail under state causation principles, which would be
11 something the Court could address when the question of fact and
12 causation was presented.

13 Many states have complicated causation law,
14 particularly in the area of exposure to carcinogens, and so it
15 is possible under many state laws that if it would have helped
16 and reduced the amount of NDMA exposure below a certain level,
17 even if there was still a lot of NDMA that the Plaintiff was
18 exposed to, causation could be legally established.

19 That is a tricky question on causation. I don't think
20 it is tricky on preemption because, as your Honor previously
21 remarked, preemption is about comparing duties or requirements,
22 and if the duty that we are alleging they breached is to have a
23 proper expiration date, and the premise of your Honor's
24 question is the expiration date they actually had was improper
25 because a shorter one would have helped, then we have already

1 established a breach of duty, and that is the only focus of the
2 preemption inquiry.

3 *THE COURT:* Where do you allege in the complaint, just
4 an example of either the expiration date or the container or
5 the storage and transportation, that that failure to have a
6 proper expiration date or a proper storage condition or a
7 proper container caused, not contributed to, or didn't
8 mitigate, or didn't in some way impact the volume of
9 consumption, and therefore the harm, but actually was the cause
10 of the ingestion of NDMA and/or the cause -- that led to the
11 cause of cancer?

12 I know you said it on Friday, you used the word
13 legally sufficient. Where in your complaint do you allege that
14 for any one of those claims?

15 *MR. KELLER:* Sure, your Honor. The complaint is
16 actually replete with those allegations. We have always been
17 picking on Alabama because they have the perils of being first
18 in the alphabet.

19 Since I have it handy, paragraph 1182, for example:
20 Plaintiffs or their doctors would have read and heeded these
21 warnings. As a result, Plaintiffs would not have consumed the
22 volume of NDMA they ultimately did and would not have been
23 harmed by NDMA.

24 That is the factual allegation that we are making and
25 you can see that throughout the sub counts. There is a

1 causation type paragraph associated with all of the expiration
2 date claims and all of the packaging claims and all of the
3 storage and transport claims. Ultimately, of course, we will
4 have to prove that, but for purposes of a 12(b)(6), that
5 factual allegation has to be accepted as true.

6 *THE COURT:* Thank you.

7 *MR. YOO:* Your Honor, would you like me to respond on
8 that point?

9 *THE COURT:* Sure.

10 *MR. YOO:* Thank you. Thomas Yoo for the generics.

11 The Plaintiffs actually not only have not alleged that
12 changing the expiration date or using a different container
13 would have allowed the generics to avoid liability or prevented
14 a harm; to the contrary, they lumped those things into all of
15 the other things we have been talking about premised on the
16 inherent risk of Ranitidine to turn into NDMA.

17 The amended personal injury complaint at paragraphs,
18 for example, 951, 1167, 1753 allege that the Defendants knew or
19 should have known that Ranitidine posed a great risk of harm
20 and they failed to exercise reasonable care to warn of the
21 risks associated with the use and exposure to
22 Ranitidine-containing products.

23 The dangerous propensities of Ranitidine products and
24 the carcinogenic characteristics of NDMA as described above
25 were known to the manufacturer Defendants, but were not known

1 to end users and consumers such as Plaintiffs.

2 That is mostly a direct quote, your Honor, I have some
3 ellipsis in my notes, so I think I left out a few phrases. But
4 further in the amended personal injury complaint at paragraphs
5 959, 1175, and 11 -- excuse me, 1761, Plaintiffs go on to
6 allege, had the manufacturer Defendants provided adequate
7 warnings and instructions and properly disclosed and
8 disseminated the risks associated with the Ranitidine products,
9 Plaintiffs could have avoided the risk of developing injuries
10 and could have obtained or used alternative medication.

11 This is not tethered to a different set of digits that
12 comprise the expiration date, this is talking about a change to
13 the clinical warning in the FDA approved label.

14 As to negligent containers, nowhere do the Plaintiffs
15 say simply changing the containers would have prevented all
16 harm or allow the generics to avoid liability. To the
17 contrary, in the amended personal injury complaint at
18 paragraphs 1992 and 1997, for example, Plaintiffs talk about a
19 different container would have reduced the amount of NDMA
20 consumed by the Plaintiffs.

21 At paragraphs 2001, 2005, 2009, and others, the
22 Plaintiffs allege the manufacturers breached the duty by
23 failing to utilize containers that would minimize the NDMA
24 produced in its Ranitidine-containing products.

25 But again, your Honor, the test is not what could a

1 generic have done to minimize the risk or lower the risk; it is
2 what would it have had to do to avoid liability altogether.

3 *THE COURT:* Okay, let me ask Mr. Keller about that
4 because I had seen that in the complaint, and I know Mr.
5 Keller has just pointed me to 1182 paragraph as it relates to
6 the expiration date, and he is relying upon, presumably,
7 similar type paragraphs for each of the states as it relates to
8 the allegation of the causation between expiration date and
9 harm by NDMA.

10 But with respect to container and storage and
11 transportation, would you acknowledge that that is the nature
12 of the allegation of causation, if you will, that it is a
13 causation that relates to minimizing NDMA with respect to
14 container and/or reducing the amount?

15 I don't know whether it is the same for storage and
16 transportation. Maybe I cut Mr. Yoo off too quickly if you
17 were going to also point out that similar language is used with
18 respect to storage and transportation.

19 *MR. KELLER:* So, your Honor, we -- sorry.

20 *THE COURT:* Let me just get clarity. Is that where
21 you were going, Mr. Yoo, that that same language is used with
22 storage and transportation?

23 *MR. YOO:* Your Honor, I believe the allegations in the
24 complaint as a whole would hold that to be true. I don't have
25 specific language quoted in front of me with regard to storage

1 and transportation.

2 I think, as the Court pointed out earlier, the storage
3 and transport allegations do include very broad and general
4 allegations regarding a duty to ensure that the products are
5 not unreasonably dangerous.

6 So, again, there is nothing in there I could say
7 that -- where the Plaintiffs have said a different storage and
8 transport method or better adherence to the labeled transport
9 and storage conditions would ensure that the Plaintiffs were
10 not exposed to a risk of cancer. They don't say that.

11 *THE COURT:* Mr. Keller.

12 *MR. KELLER:* Thank you, your Honor.

13 A couple of points to unpack here. We are not
14 alleging that the Defendants had a duty to get NDMA levels down
15 to zero. As they re so wont to point out, bacon and beer have
16 NDMA in it at some level just given the nature of the molecule
17 that couldn't have been completely eliminated, but that is not
18 the relevant test for causation.

19 So, for product containers, look at, for example,
20 paragraphs 2001 and 2002, again for Alabama, each manufacturer
21 Defendant breached its duty by failing to utilize containers
22 that would minimize, not eliminate, but minimize the
23 NDMA produced in its Ranitidine-containing products.

24 Then to paragraph 2002, as a direct and proximate
25 result of this failure, excessive levels of NDMA built up in

1 the Ranitidine-containing products each manufacturer Defendant
2 sold. These high levels of NDMA caused Plaintiffs' injury.

3 So, we are not accusing the Defendants of breaching a
4 duty to get the exposure to nothing; we are accusing them of
5 breaching duties that allowed a level of exposure that was high
6 enough to be a legally sufficient cause of the Plaintiffs'
7 injuries.

8 We are well before the point where we need to point
9 out what that particular level is. At some point in the future
10 your Honor is going to hear plenty about that from the experts
11 in Daubert.

12 I just want to pause on this point because Mr. Yoo --
13 I applaud him for taking his position to its logical conclusion
14 and reiterating that if there is any breach of any state law
15 duty that they couldn't satisfy, there has to be preemption.

16 I just want to point out for the Court, and I say this
17 with a little trepidation because I know that it has sweeping
18 ramifications, that argument would apply to the brands, too,
19 and the brands couldn't redesign the molecule either. We all
20 agree that, under Federal law, they couldn't redesign the
21 molecule post FDA approval.

22 Mr. Yoo was referring to the last complaint where we
23 talked about how Ranitidine was inherently defective. We
24 excised those allegations because we took your Honor's
25 misbranding decision seriously, and he wants to go back to

1 those allegations, but regardless, to the extent that the
2 argument is you couldn't comply with all of your state law
3 duties, and therefore every state law duty is preempted, the
4 brands should be out of this case, too, because under design
5 defect law you have a duty to reasonably design your molecule
6 and redesign your molecule --

7 *THE COURT:* But isn't one way to do that, to fully
8 comply, is to change the label, is to make the label safe, and
9 they can do that?

10 *MR. KELLER:* No, your Honor, it would not fully
11 comply. Many states would say you also have to redesign this
12 molecule. Even adding a warning doesn't fully eliminate all of
13 the risks associated with the product, and there is a different
14 design that you could offer to make it safer. You have to do
15 that, too.

16 Nobody disputes that the brands can't do that, and the
17 brands don't try and to dismiss our repleaded design defect
18 claims, even though they couldn't comply with that redesign
19 theory. That should tell you something about Mr. Yoo's
20 argument. He does go to his logical conclusions, but that is
21 not how preemption works.

22 *THE COURT:* Doesn't the restatement say if you can't
23 change the design, then do it through the label?

24 *MR. KELLER:* If you can't change the design as a
25 matter of state law, it is not talking about Federal

1 preemption. They could certainly change the design as a matter
2 of state law, they could tinker with the molecule all they
3 wanted.

4 *MR. YOO:* Your Honor, may I provide a brief response?

5 *THE COURT:* Yes.

6 *MR. YOO:* Thank you. Thomas Yoo for the generics.

7 I am not looking at the prior complaint, I am looking
8 at the amended complaints where the Plaintiffs allege in the
9 amended personal injury complaint at paragraphs 343, 1957,
10 1989, the Ranitidine molecule itself contains the constituent
11 molecules to form NDMA.

12 Paragraphs 6, 346, 935, 1150, 1737, that the
13 Ranitidine molecule internally degrades to form NDMA.

14 Paragraphs 953, 1169, 1755, the medical monitoring
15 complaint at paragraph 871, for example, that at all relevant
16 times the Ranitidine-containing products were defective at the
17 time they left Defendants' control.

18 Amended personal injury complaint paragraph four,
19 there is no recommended daily dose of NDMA. The ideal level of
20 exposure is zero.

21 The consumer economic loss complaint, paragraph 341,
22 the medical monitoring complaint paragraph 209, NDMA is a
23 genotoxic which interacts with DNA and may subsequently induce
24 mutations. Genotoxins are not considered to have a safe
25 threshold due to their ability to alter DNA.

1 It goes on and on and on, your Honor. There is
2 nothing has been excised out. As I said on Friday, your Honor,
3 I don't think this is an exaggeration, the Plaintiffs have
4 doubled down on the notion that NDMA -- excuse me, Ranitidine
5 is inherently defective because it turns into NDMA during
6 normal conditions and when ingested and digested in the human
7 body.

8 *THE COURT:* Okay, thank you.

9 This is a question for Plaintiffs. On page 20 of your
10 opposition you offer "as a judicial admission that the only
11 inaccurate warning complained of by Counts 3, 4, and 7 of the
12 AMPIC is the expiration date."

13 The judicial admission is not part of the complaint.
14 How is the complaint, standing on its own, clear as to what
15 these counts are based upon? Are they clear or are you relying
16 upon your judicial admission to make clear that which you did
17 not believe is clear in your complaint?

18 *MR. KELLER:* To be clear in my answer, your Honor, we
19 think the complaint is crystal clear, and admittedly that
20 language from our opposition is some frustration. We think the
21 generics are deliberately confusing the issues.

22 The title of these counts, which are extremely
23 granular because, again, we wanted to provide a lot of
24 specificity in light of the Court's prior shotgun pleading
25 order, all specifically say, for example, negligence, failure

1 to warn consumers through proper expiration dates, and then
2 each of the sub counts goes through -- states what the
3 particular jurisdiction's law is at a high level, and then more
4 granularly says that the exposure to NDMA caused by the
5 expiration dates is what caused the Plaintiff's injury.

6 So, we don't think the judicial admission is necessary
7 at all. We offered it as sort of an exasperated final -- if we
8 have done anything unclear, let this brief serve as a public
9 document for us to say we really, really mean it, we are only
10 talking about these particular theories of breach, expiration
11 date, product containers, storage and transport.

12 So, I think the amended master personal injury
13 complaint is more than adequate on that score. We don't need
14 the judicial admission. We sort of viewed that as gilding the
15 lily if absolutely necessary.

16 *THE COURT:* So, paragraph 1168 that is incorporated
17 into your sub counts for negligence, failure to warn, that,
18 among other things, alleges "manufacturer Defendants failed to
19 warn and have wrongfully concealed information concerning the
20 dangerous levels of NDMA in Ranitidine-containing products, and
21 further, have made false and/or misleading statements
22 concerning the safety of Ranitidine," that stands on its own?

23 *MR. KELLER:* In context, your Honor, with the rest of
24 the allegations and recalling that we make these claims against
25 both categories of Defendants, yes, I still think the generic

1 manufacturers know exactly what we are accusing them of in
2 these counts.

3 It is true that they had all sorts of knowledge, and
4 as we have discussed before, knowledge is relevant to whether
5 we can establish a breach of duty.

6 I don't think that isolating paragraph 1168 robs the
7 generics of notice of what these claims are really driving at.

8 *THE COURT:* Maybe, then, the way for me to understand
9 this is that this paragraph, for example, tells me the
10 Plaintiffs are alleging that in fact the generic Defendants,
11 which is encompassed -- they are encompassed with the
12 manufacturer Defendants. I believe that is how you have
13 defined manufacturer Defendants.

14 *MR. KELLER:* Yes.

15 *THE COURT:* That the generic Defendants in fact had a
16 duty to warn, that they wrongfully concealed information
17 concerning the dangerous level of NDMA, they made false and/or
18 misleading statements concerning the safety of Ranitidine, and
19 they failed to warn about all of those things, and they had a
20 duty to do all of those things, but Federal preemption law says
21 they couldn't do some of those things.

22 They had the duty, but, under Federal law, they
23 couldn't do some of those things, so, they had to do this
24 thing. Is that --

25 *MR. KELLER:* Yes, your Honor, just like State Courts

1 announcing the common law start with the broadest statement of
2 duties and then get to the specific, that is what happened
3 here. We talk about the general things that reasonably prudent
4 manufacturers are charged with doing, and then we get to the
5 very specific thing that they could have done under state law
6 and Federal law and we don't allege against them the things
7 that admittedly they could not do consistent with Federal law.

8 *THE COURT:* But that they had a state law duty to do.

9 *MR. KELLER:* Yes. We cannot run from the fact that,
10 under state law, they had a duty, for example, to add a cancer
11 warning.

12 *THE COURT:* Okay.

13 Question for Plaintiffs. The generic manufacturer
14 Defendants argue on page 31 of their Motion to Dismiss that
15 AMPIC Count 14, the count for unjust enrichment, is a
16 derivative claim that cannot survive absent a substantive state
17 law claim.

18 I don't think the Plaintiffs responded to that
19 argument in their opposition. Do you agree that Count 14 is a
20 derivative claim that must be dismissed if all other claims
21 against the generic manufacturer Defendants in the AMPIC are
22 dismissed?

23 If you don't agree, please explain.

24 *MR. KELLER:* Especially in the context of this
25 preemptive argument, your Honor, yes, I agree with that,

1 meaning I agree the Defendants are correct, that if you dismiss
2 all of the other claims against them, the unjust enrichment
3 claim can't stand on its own.

4 *THE COURT:* All right. Can you stand by for just a
5 few minutes? I am going to just take a few minutes, make sure
6 I review my notes so I don't have to bring you back again, and
7 maybe you can give thought to whether there is anything you
8 wanted to say that you didn't feel you were able to, maybe I
9 cut you off. Maybe ten minutes or so?

10 *MR. KELLER:* Of course, your Honor.

11 *THE COURT:* Okay. Thank you.

12 (Thereupon, a brief recess was taken.)

13 *THE COURT:* Okay, counsel can rejoin if you are there.
14 All right. All accounted for.

15 So, this is a question for Defense. It is a little
16 bit following up from Mr. Keller's -- one of his comments
17 toward the end about sort of the implications of maybe taking
18 the Defendants' argument to a certain point, so to some extent,
19 I am following up on that.

20 I think I'm understanding the Defendants' position to
21 be that the generics on the negligence claims have immunity
22 from any liability on these negligence claims, in some respects
23 because of the way the complaint is pled, the allegations are
24 set forth with respect to Ranitidine and its composition and
25 how it acts with heat in the stomach, etc.

1 I guess I would like to understand, if that is your
2 position, that there is sort of is a degree of immunity because
3 of preemption as to all of these negligence claims for the
4 reasons that I think I have understood you to say, which are
5 based on how this particular drug case is pled, the particulars
6 of this case of Zantac and NDMA and what it is and how it acts
7 as alleged.

8 If I have understood that correctly, I am trying to
9 think through -- if you are able to comment on the implications
10 for such a finding of immunity as to negligence claims in other
11 cases. In other words, are there boundaries to such immunity
12 as it relates to negligence claims being brought against a
13 generic manufacturer?

14 *MR. YOO:* Your Honor, Thomas Yoo for the generics.

15 I think in this case, and in other cases like it,
16 which, frankly, I think are most pharmaceutical product
17 liability cases, where the alleged injury and risk are inherent
18 clinical risks associated with the drug for whatever reason,
19 generics are preempted.

20 I don't know that I have looked at it as some type of
21 immunity, per se, but I understand what the Court is asking. I
22 think it is for this reason that you don't see any cases that
23 are excepted from *Mensing* and *Bartlett* based on a container
24 theory or an expiration date theory or something else that the
25 Plaintiffs say is ancillary to their claims.

1 To the contrary, under Guarino and Savarez (phon), and
2 other cases that have been cited to the Court since the first
3 round of Motions to Dismiss, Courts have routinely looked at
4 creative theories, alternative wording for the claims, and in
5 the words of the Guarino Court in the Eleventh Circuit, the
6 Courts have looked at it as just another garb that the
7 Plaintiffs are trying to dress up, what is inherently a case
8 about an inherent clinical risk of the drug itself.

9 When that is the case, as it is here, the claims are
10 preempted, and that certainly applies to negligence.

11 *THE COURT:* So, then, potentially read into your
12 answer, putting it in the context of my question, arguably,
13 then, a boundary as to whether it is immunity or preemption
14 might be a complaint that is not based on all -- in the drug
15 context, is not based on, to use your words, inherent clinical
16 risks of the drug itself.

17 *MR. YOO:* I think conceptually, theoretically, your
18 Honor, that is correct. So, as applied to this case, if the
19 Plaintiffs are not saying that Ranitidine is inherently
20 defective, if the Plaintiffs are not saying that Ranitidine
21 degrades into NDMA, if the Plaintiffs are not saying that
22 Ranitidine turns into NDMA in the digestive system, and they
23 wanted to bring an entirely separate lawsuit based on something
24 specific to an expiration date, we would have to look at those
25 allegations.

1 But it is not what has been pled here today or what
2 this MDL was slated to be, which is, again, what they have
3 embraced to this day, which is it has to do with the molecular
4 structure of Ranitidine and what happens in the body under
5 normal conditions.

6 *THE COURT:* Okay. While you have the mike, so to
7 speak, because I am going to be concluding now, were there any
8 final comments that you or your colleagues wanted to make?
9 Then I will turn to Mr. Keller.

10 *MR. YOO:* No, your Honor, we don't have any further
11 comments. Thank you very much.

12 *THE COURT:* Something like beating a dead horse, we
13 have arrived there? Okay. And Mr. Keller?

14 *MR. KELLER:* I'm sorry, your Honor, I have to
15 talk just one or two more times, but I will take less than 90
16 seconds.

17 First, let's go back to expiration dates and the sort
18 of warning they provide. We talked about milk. My kids drink
19 Horizon milk. If the expiration date on their carton of milk
20 was improperly stated as two months when manufacturer should
21 have known it was four weeks, and they drank it at six weeks
22 and got sick, even though the expiration date doesn't say
23 anything about why they got sick or the bacteria that was
24 forming, it provides no further information, if we were just
25 talking about milk, I don't think anybody would dispute there

1 is a state cause of action there for negligence, and so I think
2 the same thing applies here.

3 *THE COURT:* Isn't milk safe, though, when it is made,
4 and isn't the allegation in this complaint that Zantac isn't
5 safe even when it is made?

6 *MR. KELLER:* Milk by its inherent nature degrades over
7 time. I think that that is inherent in the design of milk, and
8 the same thing applies to Ranitidine, it degrades over time,
9 which is actually a good segue to the final point that I --

10 *THE COURT:* Just so I am sure I understand, isn't it
11 Plaintiffs' allegation not only that Ranitidine degrades over
12 time, but from the very, very inception, just the way it is
13 chemically made up, it is just dangerous right from the get-go,
14 right from the get-go?

15 *MR. KELLER:* Right from the get-go, your Honor, milk
16 is going to start to degrade. Ranitidine degrades into NDMA,
17 which is more dangerous than the things milk degrades into, but
18 we don't dispute that some background level of exposure to NDMA
19 is okay. People are allowed to eat bacon and drink beer.

20 We are not suggesting that Ranitidine, because it has
21 a propensity to degrade right from the get-go, is necessarily
22 problematic, and the FDA approved it, but I do want to focus on
23 this point because --

24 *THE COURT:* But I thought the Plaintiffs' allegations
25 included that if the FDA knew some of the things that it should

1 have known had the Defendants been forthcoming with studies and
2 whatnot, it wouldn't have been approved, it shouldn't have been
3 approved, it couldn't have been approved. Isn't that the
4 Plaintiffs' position?

5 *MR. KELLER:* Ranitidine has been recalled and so we do
6 look at --

7 *THE COURT:* From the outset though.

8 *MR. KELLER:* We are not alleging a fraud on the FDA
9 theory against anyone, not the brands or the generics. So, I
10 want to make that point crystal clear.

11 *THE COURT:* Is it the Plaintiffs' position that the
12 drug should not have been approved, and would not have been
13 approved had the FDA been aware of all of the information that
14 the Defendants allegedly knew, but didn't conceal -- or didn't
15 reveal, that they did conceal?

16 *MR. KELLER:* We have not taken a position on whether
17 FDA would have approved the product. We are only bringing
18 theories against the Defendants based on what they could have
19 done, and FDA yanking it or not approving it at inception is
20 not one of those theories.

21 The inherent propensity of Ranitidine to degrade -- I
22 heard my friend, Mr. Yoo, bring this up a couple of times, so
23 this is a point to close with -- that is precisely why the
24 theories that we allege against the generics here, which you
25 don't typically see against generics, are viable.

1 It is true that there are no cases that say that
2 expiration date theories can go forward, and there are no cases
3 that say they can't. Your Honor has to decide that question of
4 first impression based on the law and the well-pleaded
5 allegations, but I pretty strongly disagree with Mr. Yoo's
6 slippery slope fear that this is going to open the floodgates
7 to people bringing expiration date claims against the generics.

8 Take any other pharmaceutical MDL, take Truvada, for
9 example, where the allegation is that an HIV drug causes
10 osteoporosis, and the users weren't warned of that. The
11 expiration date has nothing to do with it. It is not a
12 function of the molecule degrading over time that causes the
13 bone problems with Truvada, it is just that is how the drug
14 works.

15 Maybe it would have been still a good risk/reward for
16 someone HIV positive to take it and to absorb the risk of their
17 bones thinning out, but they weren't warned of that.

18 You couldn't plead an expiration date claim or a
19 packaging claim against the generics in that MDL, or just about
20 any other. It is precisely the unique facts of how Ranitidine
21 turns into NDMA over time that allows the theories we have pled
22 against the generics to be viable.

23 This is not going to be open season on generic
24 manufacturers in the future because most drugs don't look like
25 Ranitidine. They should not get off Scott free in this MDL

1 because of the unique facts and circumstances of this case
2 where we have pled requirements under state law consistent with
3 Federal law just because they are used to getting out in other
4 cases.

5 *THE COURT:* Mr. Keller, I want to go back to something
6 you said.

7 I am sure you are familiar with your paragraphs 407,
8 408, 1519, for example. Do they not allege studies from 1981,
9 Dr. Silvio de Flora publishing results of experiments in the
10 Lancet showing Ranitidine produced NDMA in combination with
11 gastric fluid and nitrates? This study put all future
12 manufacturers of Ranitidine on notice of the risk of consuming
13 Ranitidine in combination with high nitrate foods.

14 *MR. KELLER:* Yes, your Honor, they do say that. If
15 what your Honor is getting at is, how is that consistent with
16 our theory or us not taking a position on whether FDA would
17 have approved Ranitidine, it is still consistent.

18 The FDA might have approved it with a different label
19 that said only take this product for two weeks, or four weeks,
20 and don't take it with high nitrite food, but that is not the
21 same thing as saying the FDA would have never approved it at
22 all.

23 *THE COURT:* Is the Plaintiffs' position, through its
24 allegations in the complaint, that Ranitidine was always
25 misbranded?

1 *MR. KELLER:* I do not believe that is our position in
2 the amended complaint, your Honor. In fact, we have made no
3 misbranding allegations other than with respect to the
4 over-the-counter sales of Ranitidine and the economic loss
5 Plaintiffs in the class action complaint.

6 The amended master personal injury complaint does not
7 contain any allegations of misbranding, and none of our
8 theories rest on misbranding.

9 *THE COURT:* Was that the position, then, in the prior
10 complaint, that Ranitidine was always misbranded, but that is
11 not the allegation in this complaint?

12 *MR. KELLER:* In our prior original complaint, your
13 Honor, which again, just to be clear, is not the operative
14 pleading, but to directly answer your question, we did make a
15 misbranding allegation in the previous round.

16 I don't think we locked ourselves in to when
17 Ranitidine became misbranded, and so I don't think that we took
18 a position on whether it was right away, or if new science had
19 to come out since the original FDA approval that would have
20 subsequently made the drug misbranded because the label became
21 false or misleading in any particular.

22 So, yes, we alleged misbranding previously, but I
23 don't think we took a position on timing.

24 *THE COURT:* What about in this complaint, what is the
25 timing of the allegation as to when Ranitidine, or the drug

1 became misbranded?

2 *MR. KELLER:* To be clear, your Honor, when you say
3 this complaint, I assume you mean the amended consumer economic
4 loss complaint? Because in the amended master personal injury
5 complaint we do not allege misbranding at all.

6 For the economic loss complaint, I still do not
7 believe we have taken a position on when temporally the label
8 became false or misleading in any particular. That is a fact
9 question that we are still exploring through discovery.

10 *THE COURT:* But, while you may not use the word
11 misbrand in the AMPIC, you, yourself, have said that it is not
12 about the label, it is not about what you call something. Many
13 state laws have different variations of sort of the same
14 concept.

15 You are alleging other types of causes of action that
16 directly and indirectly suggest that the product, at a minimum,
17 was mislabeled. If it is mislabeled, would you say that that
18 meets the definition of misbranding?

19 *MR. KELLER:* Yes.

20 *THE COURT:* Okay. So, even though you might not have
21 used the word misbranded, aren't you making those types of
22 allegations in the AMPIC?

23 *MR. KELLER:* We do allege that the label, particularly
24 against the brands, needed to have different warnings, and with
25 respect to the generic manufacturers, needed to have an

1 accurate expiration date. That is the, I believe, only
2 labeling-based theory we allege against the generics.

3 You are also correct that I pointed out from Bates
4 that the substance of the duties is what matters, not the
5 naming convention, but even in substance, when it comes to the
6 labels we have not pinned down a particular time when we allege
7 the label should have had different information on it. That is
8 still a factual issue for discovery.

9 So, we are not yet locked into starting at this date
10 in 1980, whatever, the label should have changed.

11 *THE COURT:* Okay. All right. Thank you so much, nice
12 seeing everyone again. I don't have any more questions.

13 *MR. KELLER:* Thank you, your Honor.

14 *THE COURT:* I appreciate it very much, have a nice
15 rest of the day.

16 *MR. KELLER:* You as well.

17 *MR. YOO:* You, too.

18 *(Thereupon, the hearing was concluded.)*

19 * * *

20 I certify that the foregoing is a correct transcript
21 from the record of proceedings in the above matter.

22
23 Date: June 11, 2021

24 /s/ Pauline A. Stipes, Official Federal Reporter

25 Signature of Court Reporter

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