UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION
CASE NO. 20-md-02924-ROSENBERG

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION.

West Palm Beach, FL
June 4, 2021

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

FOR THE PLAINTIFFS:

ASHLEY C. KELLER, ESQ.
Keller Lenkner LLC
150 N. Riverside Plaza
Suite 4270
Chicago, IL 60606
312-741-5222

ELIZABETH A. FEGAN, ESQ.
Fegan Scott LLC
150 S. Wacker Drive
Chicago, IL 60606
312-741-1019

JOHN SNIDOW, ESQ.
Walsh Law PLLC
1050 Connecticut Avenue NW
Suite 500
Washington, D.C. 20006

FREDERICK S. LONGER, ESQ.
Levin Sedran & Berman LLP
510 Walnut Street Suite 500
Philadelphia, PA 19106

FOR THE DEFENDANTS:

ANDREW D. KAPLAN, ESQ.
Crowell & Morning LLP
1001 Pennsylvania Avenue NW
Washington, D.C. 20004
202-624-2500

ILANA EISENSTEIN, ESQ.
DLA Piper LLP
one six five zero Market Street
Suite 5000
Philadelphia, PA 19103
215-656-3307

RICHARD M. BARNES, ESQ.
SEAN GUGERTY, ESQ.
Goodell, DeVries, Leech & Dann LLP
One South Street
Baltimore, MD 21202
410-783-4000

THOMAS J. YOO, ESQ.
Holland & Knight LLP
400 Hope Street 8th Floor
Los Angeles, CA 90071
213-896-2400

SARAH JOHNSTON, ESQ.
Barnes & Thornburg LLP
2029 Century Park East
Suite 300
Los Angeles, CA 90067
310-284-3798

Official Court Reporter: Pauline A. Stipes
HON. ROBIN L. ROSENBERG
Ft. Pierce/West Palm Beach, Fl
772.467.2337

THE COURT: Good morning, everyone. We are here for the second day of hearings in the case of In Re: Zantac Products Liability Litigation, MDL 2924. We are here through the Zoom platform due to the COVID pandemic. The hearings yesterday were also conducted in that fashion and no counsel are is here in the courtroom, it is just me and our court reporter, everyone else is appearing remotely.

The first motion that will be heard this morning is the branded Defendants' Rule 12 partial Motion to Dismiss Plaintiffs' three master complaints as preempted by Federal law and incorporated memorandum of law.

As with our format yesterday, everything remains the same, so we will call up -- and this is Docket Entry 3114, and so we can call up Defense counsel, who will be allotted 15 minutes to argue her motion, and she can tell me if she wants any warnings and whether you want to reserve any time for your rebuttal.

MS. EISENSTEIN: Good morning, your Honor, Ilana Eisenstein, I represent Sanofi and the branded Defendants on this motion. I would like five minutes for rebuttal and if I could have a warning at two minutes, that would be good. Thank you, your Honor.

THE COURT: A warning after eight minutes, and you will finish up at ten minutes and reserve five minutes?

MS. EISENSTEIN: That is right, your Honor.

THE COURT: Good morning. You may proceed.

MS. EISENSTEIN: Thank you, your Honor.

The branded Defendants seek to dismiss the Plaintiffs' consumer class action refund claim, their unjust enrichment claims and the failure to warn the FDA claims as preempted by Federal law. Let me start with express preemption.

Express preemption bars Plaintiffs' refund claims in the amended consumer class action and their unjust enrichment claims. Plaintiffs have abandoned any argument that these claims are saved under 379r(e), which was one of their primary arguments in the first round of Motions to Dismiss, and that is for good reason.

These claims, which seek simply a refund of the purchase price of the product, are by no means a product liability claim under the definition that is given by Federal law for that term, or for that matter, any state law definition.

Plaintiffs, moreover, fail to plead a parallel claim. In Wolicki-Gables the Eleventh Circuit made clear that Plaintiffs have the burden to allege the Defendant violated a particular Federal regulation, and they need factual detail to substantiate these crucial allegations.

They make no effort to defend the claims that they had made previously and that are sprinkled throughout their complaint that Zantac was purportedly misbranded because it

was unsafe, and this is in line with this Court's prior preemption ruling that challenges to the FDA approved characteristics of Zantac are preempted to the extent that they are premised on the design of the product, or for that matter, the FDA approved labeling.

Instead, Plaintiffs have shifted onto the thin thread that the FDA approved label itself was misleading by failing to disclose the risk of NDMA, and therefore misbranded. It is a variant of the misbranding claim that they had asserted before.

This theory would be the exception to express preemption that swallowed the rule. It would eliminate decades of well-established precedent that failure to warn claims and similar claims challenging the label are preempted, including the Supreme Court's decision in Riegel which addressed exactly this type of argument.

In Riegel, the Plaintiffs claimed that the product was misbranded by lack of an adequate warning and the Supreme Court in Riegel squarely rejected that argument as a basis for avoiding express preemption, in that case, based on the very analogous and similarly worded medical device amendment 360(k)(a).

Plaintiffs cannot recharacterize their failure to warn theory as a misbranding argument for two reasons. First, Zantac carried the FDA approved label, and as a result, it was

not misbranded. Even if FDA itself could deem its own label was misbranded, that does not permit a private set of Plaintiffs to impose OTC labeling requirements that conflict with the approved label.

Let me start with the first proposition. The FDA approved label does not render a product misbranded. The Plaintiffs are simply incorrect that Section 352 makes it a crime to label and produce a product that complies with the FDA approved label. No court, no enforcement action and no other authority has ever interpreted the misbranding provisions to cover a label specifically approved by the FDA through a new drug application process.

Plaintiffs rely solely on the Government's amicus brief in PLIVA v. Mensing, but the Court in that case found there was no preemption, even assuming such a duty existed to provide an adequate warning, and even assuming that the FDA could in theory find that lack of such a warning rendered the product misbranded.

Misbranding, moreover, is not a catch-all exception to Federal preemption. This Court doesn't even need to reach this theoretical question of whether the FDA could find the Defendants violated 352, because even if they could, Section 379 still preempts private Plaintiffs from seeking a product refund based -- on the basis of a challenge to the FDA approved label.

The case law on regulations are clear here, the generalized proposition of misbranding cannot avoid preemption of claims that seek to add to or differ from specific requirements mandated by Federal law, and this certainly includes the labeling approved by the FDA through an NDA process.

Riegel, as I said before, addressed exactly this issue. It cited to the 360k(a) regulations which provide a helpful guidepost to this Court. Those regulations state that state law misbranding claims are preempted when they have the effect of establishing a substantive requirement for a specific device, i.e. a specific labeling requirement that is different from or in addition to Federal requirements, and the Supreme Court said that means that this express preemption provision preempts a jury determination that the FDA approved labeling for a piece maker violated state common law requirements for additional warnings.

That is exactly what Plaintiffs seek in their consumer class action complaint and their claims for refund.

The cases relied on by Plaintiffs at page 9 of their opposition make exactly this point. Where Federal law specifically regulates the subject matter of a Plaintiff's state law claims, and those claims seek to impose requirements that differ from and are not identical to Federal requirements, those claims are preempted. That is the Canale versus Colgate

case that is cited by Plaintiffs. The same analysis was applied in Zolwinski and Prescott, cases cited by the Plaintiffs.

Moving on to the implied preemption of the failure to warn the FDA.

The failure to warn the FDA claims are rife with problems. You heard yesterday how no state recognizes the attenuated theory of liability that revolves around submission of unidentified adverse event reports to the FDA and depends on a recall which is yet to happen of the product based on those non-pleaded reports.

This is not a warnings claim, it is a flat-out effort to enforce the FDCA requirements, something that is not only inadequately pleaded, but is also impliedly preempted. Implied preemption bars this failure to report to the FDA theory because it relies on the FDCA and the FDA as critical elements of their claim, and it goes even a step further by relying on FDA's discretionary action to have taken a recall or to remove the product in light of information that the Plaintiffs claim should have been reported to FDA.

These principles were applied by the Eleventh Circuit in Mink, in Markland, in Sybaris, and by your colleague in the Southern District of Florida in the TraceAll products liability. In each case, the claims that Plaintiffs should have reported to the FDA adverse event reports, data, or other

information were held to be squarely in the preempted category under Buckman.

Plaintiffs make things worse, not better, for themselves by asserting that they are not trying to enforce duties imposed by the FDCA, but rather state law requirements that would require gratuitous warnings to the FDA that are not mandated by Federal law.

Here, the sole recipient of the information that Plaintiffs claim should have received this unreported information is the FDA itself. This is totally unlike claims that have been recognized in the handful of jurisdictions where the theory is that the FDA would have publicized the information that would have reached consumers or physicians.

THE COURT: That is eight minutes.

MS. EISENSTEIN: Thank you, your Honor.

Rather, the unprecedented theory advanced by Plaintiffs is that the adverse event reports or other information that supposedly should have been given to FDA would have caused researchers to conduct studies of Zantac and the potential to form NDMA, and that that research would have resulted in discretionary action by the FDA to recall the product.

This is squarely in line with Mensing, which held that preemption applies when the manufacturer's ability to comply with state law depends on uncertain Federal agency action or

third-party decisions. It is a variant of the stop selling rationale rejected by the Supreme Court in Bartlett and Mensing, here, based on the idea that FDA would have more quickly or would have ever recalled the product. And the only path to making out this claim runs right through the FDCA and the FDA, its reporting structure and its discretionary decision-making. That is an impliedly preempted theory.

I will reserve the rest of my time for rebuttal, your Honor.

THE COURT: Okay. That was nine minutes and 13 seconds, so you have a little over five minutes left.

From the Plaintiff, if you would state your appearance for the record, and let me know if you need any warnings.

MR. KELLER: Good morning, your Honor, Ashley Keller for the Plaintiffs. I am happy to keep my own time. Can you see me and hear me okay?

THE COURT: I can see you and hear you okay.

MR. KELLER: Very good. Good morning, your Honor. May it please the Court, Ashley Keller again on behalf of Plaintiffs.

I would like to begin with express preemption under Section 379r, and then turn to Plaintiffs' failure to warn through the FDA claims. I know these arguments will have a familiar ring to the Court because the brands have largely repeated assertions they made in the first round of briefing.

Section 379r is the over-the-counter express preemption clause. It only preempts state requirements that are "different from, or in addition to, or otherwise not identical with Federal law." Interpreting similar language in express preemption clauses, the Supreme Court has made two important points to frame our discussion.

First, in cases such as Bates, Lohr, and Riegel, the Court noted once again that preemption is about comparing state and Federal duties. If the duties are the same, or parallel, there is no preemption. If they are different, express preemption applies.

Second, when determining whether state and Federal duties are the same, those same cases emphasis that state law doesn't have to use the same words or have the same naming conventions as federal requirements. Indeed, "it would be surprising if a common law requirement used the same phraseology as its corresponding Federal requirement." That's from Bates, 544 U.S., at 454. What matters is the substance of the duties and whether they match or depart from Federal law.

With those principles in view, let's turn to the state duty pleaded in the amended complaints. Simply put, the state duties we allege throughout the amended consumer class action complaint is to have an accurate label. A drug with a false or misleading label is a breach of that duty under the relevant claims.

Now, it is true the causes of action under state law imposing this duty have different names under various state laws. Some states have a Deceptive Trade Practices Act that forbids false or misleading labels. Some states categorize a false or misleading --

THE COURT: Wait, wait. Mr. Keller, I stopped the clock, so don't worry. We stopped off at some states have -- I think you need to slow down a little bit for purposes of --

MR. KELLER: Of course. I know she has the hardest job in the courtroom. I will start the whole thought over.

It is true enough that the causes of action imposing this duty under state law have different naming conventions. Some states refer to it as a Deceptive Trade Practices Act violation. Some states categorize a false or misleading label as unfair competition. Other states forbid false or misleading labels under a False Advertising Statute, and still other jurisdictions treat a false or misleading label as a breach of warranty.

But the title of the causes of action doesn't matter. What matters is that in substance these state causes of action impose a duty on manufacturers not to have a false or misleading label. That state duty is parallel to the duty imposed by the Federal Misbranding Statute.

The Food, Drug and Cosmetic Act is not ambiguous on this score. The statute makes it unlawful to sell a drug in

interstate commerce if its label is "false or misleading in any particular," or if it "is dangerous to health when used in the dose or manner, or with the frequency or duration prescribed, recommended, or suggested on the labeling thereof." That's from 21 U.S.C. 352(a)(1) and (j).

When you line up state and Federal duties side-by-side, it is obvious they are the same. State law imposes a duty not to have a false or misleading labels. Federal law imposes a duty not to have false or misleading labels. Those requirements are identical. It is therefore straightforward that there is no express preemption under Section 379r.

In response, the brands dust off two points from the last round of briefing, but neither is persuasive. First, as you just heard, the Defendants say that a drug by definition cannot be misbranded under Federal law so long as it matches the label approved by the FDA. In this case, that means the label approved by the agency four decades ago when Ranitidine first hit the market. Ignore new science, ignore new information, ignore new studies. If the four-decade old label is affixed to the drug the manufacturer gets a shield from liability.

The brands, in their briefing, offer two citations in an effort to bolster this definition of a misbranded drug. They turn initially to Beecher, a 1993 District of Minnesota

case, but it is hard for Plaintiffs to see how this case is even relevant, let alone how it supports the brand's definition of misbranding.

The case involved a box of tampons and whether the warning of toxic shock syndrome was placed in a sufficiently conspicuous location on the package. After initially reserving summary judgment on that question, the Court found that the warning was in a conspicuous enough spot that there was no issue of material fact.

The Court never interpreted or even cited the misbranding provision of the Food, Drug and Cosmetic Act, and it never stated or even intimated that a drug is only misbranded if a manufacturer departs from the FDA approved label.

Even more remarkably, the other source of authority that the brands rely on in their opening brief is this Court's prior order. They say that this Court recognized their definition of misbranding. This is their motion at page 10.

Your Honor is, of course, the best arbiter of what you did or did not recognize, so let me simply read to you what your Honor wrote verbatim in that prior order.

"Finally, brand name manufacturer Defendants argued during the hearing that a drug is only misbranded if it fails to contain the FDA approved labeling. Defendants have not pointed to any authority providing that definition of

misbranding. The statute delineating when a drug is misbranded does not contain the definition that Defendants and brand name manufacturer Defendants propose, nor is it apparent that the FDA defines misbranding in such a way."

From Plaintiffs' vantage point, your Honor, it is still true that the Defendants have not pointed to any authority providing their definition of misbranding. You just heard my friend bring up Riegel now at argument based on FDA regulations for medical devices, but where the FDA has regulated medical devices, they point to no regulations similarly for drugs or over-the-counter drugs. That shows exactly our point. The FDA knows how to agree with the brands when it wants to, and it didn't for over-the-counter drugs. All of the actually on-point authority runs in the other direction.

The first source of authority is the plain text of the statute itself, which my friend continues to run away from. The Supreme Court keeps saying so, so it bears repeating again. Where the statutory text is plain, the sole function of the Courts is to enforce the statute according to its terms. A drug is misbranded if its label is false or misleading in any particular.

Those words are clear. Congress never said that FDA approval in the past means that a label cannot be false or misleading in the present. There isn't even a hint of the

brand's argument in the plain statutory text.

And the FDA's interpretation of that text agrees with us, not the brands. As you heard my friend concede just a moment ago, the agency made that view clear in its amicus brief before the Supreme Court in Mensing, and the Supreme Court never rejected the agency's view. The FDA's view is therefore entitled to Auer or Skidmore deference.

Moreover, the FDA promulgated a regulation pursuant to notice and comment rulemaking that gets an even higher level of Chevron deference. In 21 CFR 314.170, the agency reiterated that all drugs, including those that the FDA approves, are subject to the adulteration and misbranding provisions of the Food, Drug and Cosmetic Act. That regulation only makes sense if FDA approval in the past doesn't mean a drug automatically escapes misbranding in the present.

Relying on the agency's view, the Supreme Court agreed with us again in footnote 4 to Bartlett, while the Court reserved the question of preemption, as your Honor noted in your previous order, it also emphatically stated the "misbranding statute requires a manufacturer to pull even an FDA approved drug from the market when it is dangerous to health" as labeled. The label the Court was referring to was the FDA approved label.

The Supreme Court's statement would make no sense on the brands' view. There is simply no authority that supports

the brands' definition of misbranding. Loudly repeating their made-up definition does not make it any more sound.

Unable to establish a conflict between the substance of state and Federal duties, the brands fallback argument is to focus on state naming conventions. They observe correctly that most of our complaints' causes of action don't use the word "misbranding" and that the word misbranding doesn't appear all that often in the complaints.

We have a simple response: So what? The Supreme Court could not have been clearer that when gauging of state law is different from or in addition to Federal law, the phraseology of state law doesn't matter. Bates said this in no uncertain terms. So, it is entirely irrelevant that state law imposes a duty under statutes called, for example, Deceptive Trade Practices Act, while federal law refers to misbranding. The complaints could have never used the word misbranding a single solitary time and the preemption outcome would be the same.

What matters is whether state and Federal law are substantively the same, and they are. State law forbids false and misleading labels. Federal law forbids false and misleading labels. There is no daylight between state and Federal duties, and that is the end of the express preemption inquiry.

Let me turn to our failure to warn consumers through

the FDA claims to show that they, too, are not preempted. Once again we begin the analysis by focusing on duty. As for state law duties, the amended master personal injury complaint pleads for 15 jurisdictions that recognize a traditional common law duty to warn third parties as the most effective way to warn consumers.

Under the law of states such as California, "manufacturers bear a duty to convey warnings to a third party that can reasonably be expected to warn the consumer." That's paragraph 1407. Warning the third party fully satisfies the manufacturer's duty.

By simply telling the warning to the third party, the manufacturer has met its state law obligation goes, regardless of what the third party does with the information.

As noted in the pleadings, the brands could have fulfilled this duty by submitting adverse event reports to the FDA, yes, but they also could have fulfilled the duty "through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting." That is at paragraph 1412. So, emails, phone calls and letters all could have all sufficed as ways to convey Ranitidine's danger to the FDA based on emerging science.

Let's compare the state law duty to the Federal duty to see that there is no conflict. Federal law requires adverse event reports, and according to the FDA, ordinary

correspondence is required as well, but at a minimum, ordinary correspondence is at least permitted. Remarkably, there is no dispute about any of this. As a result, there can be no preemption.

State law says warn the FDA to fulfill your duty to consumers, federal law says you must, or at least may, warn the FDA of risks. Those duties are not in any form of conflict, so the conflict preemption doctrine is not a bar to these claims.

In an effort to undermine that straightforward conclusion, the brands principally rely on the Supreme Court's decision in Buckman and claim erroneously that the Plaintiffs are just bringing a "fraud on the FDA claim" that is based exclusively on Federal law.

That is simply not what Count 5 says. Count 5 rests on traditional state tort law principles. The 15 jurisdictions that recognize this duty don't base it on Federal law at all. Indeed, returning to California as the example, the duty to warn third parties was first applied to a ski manufacturer which had a duty to warn a ski rental shop as the most effective party to get warnings to the ski renters. Federal law was not even a part of the analysis, and there is no Federal law, to my knowledge, regulating ski manufacturers.

It goes without saying that such a claim counts as "traditional state tort law" and that the existence of the Food, Drug and Cosmetic Act is not "a critical element in

Plaintiffs' case." That is from Buckman, 531 U.S. at 353. Indeed, the Food, Drug and Cosmetic Act isn't an element at all, let alone a critical element, in the Plaintiffs' claims. None of the causes of action have an element that depends on the breach of any Federal rule.

To see that, if the Food, Drug and Cosmetic Act were repealed by Congress tomorrow, the state law duties under the common law would be exactly the same. There is no Buckman problem under those circumstances, which is exactly why the unanimous en banc Ninth Circuit in Stengel, the Fifth Circuit in Hughes, the Sixth Circuit in White, and the Seventh Circuit in Bausch have all allowed these claims to survive a preemption defense.

Notwithstanding this wall of appellate precedent, the brands suggest that the Eleventh Circuit went the other way in Mink, but that is an inaccurate reading of the Court's opinion. The first clue that that is an inaccurate reading and that we are correct on this score is that Mink doesn't cite the Ninth Circuit case in Stengel at all, even though it is the leading case in this area, and cites the Seventh Circuit's decision in Stryker approvingly, even though that case is on our side of the ledger.

Typically, a Court of Appeals does not open a sharp conflict with every other Court of Appeals without saying so. It candidly grapples with the competing authority and explains

why it is going in a different direction, but the Eleventh Circuit said nary a word about charting a different path from other Courts.

The reason for that is because the decision turned on the particulars of Florida negligence law. The Court did say that "Florida law recognizes the common law duty of failure to warn as a basis for a negligence claim." That is in the opinion at 1329. But Mr. Mink's theory as pleaded alleged that the manufacturer's "duty is owed to the FDA," and was not "one that state tort law has traditionally occupied." That is in the opinion at 1330.

If the duty is owed to FDA, of course Federal law is a critical element of the claim because only Federal law governs duties that run to the agency. The Court distinguished that theory from manufacturing defect where the manufacturer's duty was owed to Mr. Mink, and was therefore not preempted.

We agree that states which impose duties that run to the FDA or that seek to make a violation of the Food, Drug and Cosmetic Act an element of the state claim are unavailable under Buckman. That is why we carefully pleaded this only for 15 jurisdictions and we did not include Florida on this list.

THE COURT: That is 15 minutes.

MR. KELLER: Very good, your Honor. I finished my sentence, so I will stop there.

THE COURT: Okay. Thank you so much.

You have a little over five minutes left for rebuttal.

MS. EISENSTEIN: Thank you, your Honor. Let me start with the express preemption argument that Mr. Keller just advanced. It makes clear that the issue here is what level of specificity we are talking about.

He wants to have the general rule the specific. He points to the general misbranding regulations, false and misleading, but he ignores the arguments that this would conflict with the specific requirements, mainly the label that was approved by the FDA in the NDA, and he does not address at all the argument that I just made that his own cases make exactly this distinction.

In each of those cases, and I think it is worth a little bit of attention on this, the Canale case for example, turned on exactly this distinction in that case with tooth whitening toothpaste. The question there was whether the false and misleading would govern or whether there was specific Federal requirements that governed the particular statements that the Defendant was making, and it was only because the FDA had not regulated those tooth whitening statements that Canale let those claims go forward.

By contrast, in Riegel, which is the medical device context, but identically worded express preemption provision, the Court found that a challenge to the FDA approved label is squarely preemptive.

The medical device amendments -- regulations make this clear, too, but you don't have to even just go there because the OTC regulations themselves talk about what renders a product "not misbranded," and we cite those regulations at 21 CFR 310.1, .10 and .14. Each of those regulations, and those govern OTC drugs specifically, talk about what renders a drug not misbranded, in essence, following the FDA approved labeling and requirements and applying the monograph in instances of a monographic drug renders an OTC product not misbranded.

Even if there was some argument, and this is -- this Mr. Keller does not address at all -- that a drug could be determined to be misbranded by the FDA, and that is the province of the FDA to do it, there is no way in which the private Plaintiff can claim simply by asserting a drug is misleadingly labeled, or that there should have been additional information in the warning or the instructions for use, that that could avoid express preemption.

It would throw out decades of failure to warn jurisprudence in express preemption context that have held that those claims are preempted all the way up to the Supreme Court.

Let me talk a minute about the failure to warn the FDA claim. Mr. Keller focuses on Coleman and the California Supreme Court, Stengel, Hughes, Bausch, but those claims differed from these claims in an important respect.

First of all, respectfully, I think they were wrongly

decided, but even if they were correct and they, at least in Coleman, established a theory of liability recognized by California law, at least in the intermediary court, the theory of liability there was that the medical device reports would be reported to the FDA, the FDA had a practice of publicizing those adverse event reports on a public website, and that the physician who was prescribing that device would view those adverse event reports and change the prescribing decision as a result.

The theory of liability that Plaintiffs assert is nothing like that. The warning ends with the FDA. It goes to the FDA and it is part and parcel of the FDA reporting process.

In Mink, the Court did not hinge on whether the duty was one that was a state law duty, it was -- was a state law duty, an independent state law duty, it was based on the theory of liability that went through the FDCA and the FDA process, and it was based on a theory of liability, not a duty, that depended on Federal law that Mink held that those claims were preempted.

And to be clear, Mink did not say that this was an issue of an absence of a parallel state law duty, it recognized that Florida had a duty to warn third parties.

This is not a warning claim at all; it is a claim that FDA itself should have been put on notice of purportedly adverse events, of information with respect to risks of NDMA

formation. This is a preempted theory of liability.

In short, your Honor, the branded Defendants ask this Court to dismiss the refund claims and the consumer class action claim, the unjust enrichment claim as expressly preempted, and the failure to warn the FDA claims as impliedly preempted.

THE COURT: Thank you so much. If both counsel can come on, I have a few questions.

Okay. So, this question is for the Defendants, and it most certainly touches on topics that you have addressed, both of you, in your presentation, so if you want to refer me back to what you said, that is fine. If you want to repeat what you said, that is fine, or if by the way I am asking it you have a different way of answering it, that is fine, too.

I think we are all probably talking about the same issue.

So, this first of the questions goes to the issue of the brands' argument theory that an OTC drug can never be a misbranded drug.

So, putting aside for a moment, so in this first question for Defense, putting aside your argument that an OTC drug can never be alleged to be misbranded, put that aside, what do you think a Plaintiff must allege for a product to be Federally misbranded?

In other words, by way of example, are the

requirements for Federal misbranding more than, or different from, what the misbranding statute sets forth in 21 U.S.C. Section 252? And we know from what Plaintiffs have told us before that they are relying in particular on (a)(1) and (j).

So, if so, if the requirements are something different than what the statute sets forth, what is the legal basis for your position? That is the first question for Defense.

MS. EISENSTEIN: Your Honor, the provisions in 352(a) and (j) that the Plaintiffs rely upon are general misbranding provisions, so they are not really a stand-alone set of specifications for how a product must be labeled, what its content or composition would be, or how it is designed.

Typically, these are derivative claims of other violation, so there is some deviation from the FDA rules and regulations in another respect, but then leave the product to be in violation of Federal law and therefore render misbranded, or in a parallel provision, adulterated.

Let me give you an example. If the product were not to carry the FDA approved label, if there were deviations from what the FDA approved, that would render it misbranded. Frequently that 352(a) is also applied to non-labeling claims. So, the Courts have recognized parallel claims in certain instances where Defendants have gone outside the substance of the FDA approved label and made claims that were false and misleading, and that has run afoul at times of the misbranding

provision and constituted a parallel claim. There are situations where other specific regulatory requirements of FDA are violated.

But consider this: How would a Defendant be on notice that the label that was approved by FDA through an NDA process was in and of itself misbranded, perhaps has some other violation of Federal law just on some free-floating theory of it being misleading? That kind of vague admonition would be a crime under Plaintiffs' theory, not just a tort and an economic class action, and that just doesn't hold up.

There has to be some specific violation, and that is certainly true in the context of preemption, and that is the Wolicki-Gables lesson, is Wolicki-Gables. You have to point to some specific violation of Federal law, not some generalized notion of the product --

THE COURT: So, is your position that the Statute 352 doesn't impose in and of itself duties upon a manufacturer to comply with the dictates of the statute, it imposes no duties, but rather, there would need to be a violation of a state or Federal law separate from 352 that, if proven, may or would give rise to, therefore, a violation of 352?

MS. EISENSTEIN: So, I think it applies in two instances, your Honor. One is in that instance where there is a violation of some specific Federal requirement, and the other is where it's an area where the FDA doesn't regulate it at all,

and that is the cases that Plaintiff cite at page nine of its opposition that we were just talking about, this Walinski case, the toothpaste case that we were discussing. Those are cases in which the FDA simply didn't regulate along the lines of the area that was being challenged by Plaintiffs.

I think those are two areas where misleading -- that general statement of requirement can have force, but it can't trump the specific requirements that FDA has imposed on a product, and that would create an impossible conflict for the manufacturer to both change its label in a way that rendered it, according to Plaintiffs, not misleading.

So, if that type of conflict between the general admonition and non-misleading label and a specific requirement that have a product with the NDA and FDA approved label, that simply cannot stand in this context.

MR. KELLER: Your Honor, can I briefly respond to that?

THE COURT: I am going to have some questions for you that actually may be very similar.

MR. KELLER: Perfect.

THE COURT: If you will wait, and if I haven't asked the question that allows you to respond, make a note of it and you can, but I think you will find my questions do.

Following up, the first question for Defense, I had asked you to put aside your argument that an OTC drug can be

alleged to be Federally misbranded, and I know on page 8 of your reply you say because OTC Zantac carried the FDA approved label it cannot be criminally misbranded under 352, so I had asked you to put that aside for the previous question.

Do you rely upon anything other than the FDA regulations for your position?

Again, we have been talking about it, so I don't want you to have to repeat yourself. I know you rely upon the FDA's OTC medication regulations which have numerous provisions delineating what renders various OTC products "misbranded and not misbranded," and specified that OTC medications that conform to the conditions contained in monograph are "considered generally recognized as safe and effective and not misbranded," and therefore need not be approved through a new drug application.

One or the other of you cited, I think Mr. Keller may have, to the 21 CFR Section 330.10, as well as the other 330 provision.

So, other than what we have been discussing in the FDA regulations that you cite, is there anything else that you are relying upon for the proposition and the argument that an OTC drug cannot be Federally misbranded?

MS. EISENSTEIN: So, I want to be clear, your Honor, that our position is not that an OTC drug --

THE COURT: FDA approved.

MS. EISENSTEIN: It is not that it can never be misbranded, it is that it cannot be deemed misbranded based on a theory that it has a misleading label where the reason that it is misleading, according to the Plaintiff, is that it followed the FDA approved label through an NDA.

It is really that specific a proposition because the cases that Plaintiffs cite to the contrary are all ones in which the FDA -- it involved areas of activity like homeopathic products that the FDA doesn't regulate at all, or advertising claims that are not part of what the FDA approved or disapproved.

So, to your question, though, your Honor, your question specifically was what authority did we rely on. I think that one of the striking things here is the absence of any enforcement authority, any case that has recognized such a claim. In U.S. versus Smalls the Supreme Court recognized that this type of prosecution history is an empirical fact that the Court can consider when construing a criminal provision.

I think the fact that this is a crime is significant as well in interpreting what it must require of the parties that it seeks to regulate and would indeed subject to criminal liability, the idea that a party could be liable for following the mandates of the FDA and what constitutes a label, without any other violation of Federal law, and that is the point.

Here Plaintiffs, this is the sole basis for their

claim that there is a parallel claim under state law, is that this parallels a misleading component, not that there is any specific violation of Federal law that they can point to.

THE COURT: Following up, why would a consumer be able to question the judgment of the FDA in approving a drug before it becomes OTC, pursuant to Wyeth, 55 U.S. at 575. Quoting, "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness, but then once a drug becomes OTC a jury loses its power to question the FDA."

MS. EISENSTEIN: Your Honor, the argument that we are making is in a very specific context, which is express preemption under 21 U.S.C. 379r. Wyeth versus Levine was an possibility preemption case involving conflict preemption, and it was a products liability case, which is exempted from 379r, as your Honor knows.

The questions are just different from one another, which is, under Wyeth, the question is whether or not a manufacturer was capable of changing its label to include newly acquired information, but here, the fact that a manufacturer may change its label is not the question. That would add to, be different from, or not identical with Federal requirements, and that is a critical distinction with express preemption.

Under express preemption, you have to show that the manufacturer violated Federal law by failing to update its label, not that it was permitted to change its label under

Federal law, and that is the key difference between Wyeth and this case.

THE COURT: Following up further, how is your -- and maybe it is a similar answer because it is sort of a similar question. How is your position a jury cannot decide whether an OTC drug is misbranded compatible with Bates, which expressly held that juries may decide whether a product is misbranded, albeit for a product -- OTC that wasn't an OTC -- for a product pesticide that wasn't an OTC drug? Is it kind of a similar response?

MS. EISENSTEIN: Right. So, in the context of express preemption, it is not that a jury can't make this determination; it is the question of whether this determination adds to, or is different from, or not identical with Federal requirements, not Federal duties, Federal requirements.

Federal law puts a specific requirement on manufacturers to follow the NDA approved label. What Plaintiffs want to do is take a generalized proposition under the misbranding and say that that should have been what was followed, and that's different from the FDA approved label, and that is exactly what Riegel addressed.

The allegation was the device there was misbranded and dangerous, and the Court found that did not avoid express preemption because, first of all, it would impose civil liability in that context based on the jury's finding,

but also because it would impose requirements that were different from the specific FDA imposed requirements on that device. The same is true here.

So, I think in other contexts juries have been recognized to be able to make that determination, but here there is simply a conflict with the specific requirements to which manufacturers were subject under the labeling requirements here.

The fact that they were potentially evil to modify their label would be something they could allege, and have alleged in their product liability claims in the AMPIC, doesn't save their refund claims from express preemption.

THE COURT: You have pointed out that the FDA imposes a duty to follow the label, use the label. Doesn't the FDA also impose a duty to correct a deficient or misleading label?

MS. EISENSTEIN: It does, your Honor. I think that falls into the same category as what we were discussing.

I think it also bears noting that that is a determination that the FDA would typically make if there was going to be either a requirement that the label should have been updated or that it was rendered misleading or misbranded because it was not updated, and that has not happened here.

I think it goes back to the same argument we were talking about before, which is this generalized requirement around avoiding misleading labels versus the specific

requirements of what should be on an OTC label and what was approved in the NDA.

It is also noteworthy, and Courts have focused on this, that where the FDA has failed to make a determination that a product was misbranded or violated that provision, that it is incompatible with or would be in addition to Federal requirements for Plaintiffs to assert such a requirement.

THE COURT: Are you aware of any Court that has expressly found that an OTC drug can never be alleged to be misbranded?

MS. EISENSTEIN: No, your Honor. As I said, I don't think that is what we are alleging here either. There are Court after Court that have said that claims that challenge the --

THE COURT: Can we turn the audio off of the person who is speaking right now. Thank you.

MS. EISENSTEIN: It is not our position that an OTC drug can never be misbranded. In case after case, Plaintiffs have raised claims that the warnings were inadequate, and in fact, in Carter, for example, the claim was that the label was misleading because it misrepresented the safety risk of for children under 12. The Court found that that was a preempted claim.

So, while the Plaintiffs didn't use the term misbranded under Federal law, the result of that case would be

the exact opposite if Plaintiffs' theory was true.

That has been the result certainly in the OTC context and in the medical device context. These claims have been more regularly raised by Plaintiffs and more regularly rejected, including by the Supreme Court in Riegel.

THE COURT: When can an OTC drug be found to be misbranded by a civil jury, not the FDA?

MS. EISENSTEIN: As I said, your Honor, I think it is this question of comparing the generalized obligation of the misbranding statute compared with the specific requirements under Federal law, and that is the exercise that Courts have gone through in evaluating these types of claims with respect to not only what rarely happens in the OTC drug context, but in the analogous context of cosmetics and other over-the-counter products like sunscreens and toothpaste.

Courts have looked at that issue and said that where there is no FDA -- where the FDA hasn't engaged in any form of regulation over the particular activity or conduct in question, then the general misbranding provision can be something that goes to the jury, or where the Plaintiff alleges that the Defendant violated provisions, specific provisions of Federal law that also rendered it misbranded, that can go to a jury.

For example, the advertising, the non-labeling advertising type claims that are different in substance than the FDA approved label have been a good example of where juries

can make the determination that that is violative of the misbranding provisions.

THE COURT: Can you think of a fact pattern involving a drug, not a toothpaste or a lotion or cosmetic, where an OTC drug could be found to be misbranded by a civil jury?

MS. EISENSTEIN: I think I raised this before. If the product carried information on it that was different than what was approved by the FDA, if, for example, the product contained different ingredients than the FDA had approved, and there have been some cases around that where the product was supposed to contain a certain set of ingredients, and the label said as much, but in fact it did not contain those ingredients, that is an example where products have been determined to be misbranded.

Where the allegation is that the product was what the FDA approved, and the label was as the FDA approved it, that is not a situation where misbranding can apply.

THE COURT: Okay. Let me shift gears just slightly. Do you believe that the Mensing decision addressed preemption against brand manufacturers in any way? And if so, what text do you rely upon in Mensing for that proposition? And if not, why do you rely upon Mensing to advance your preemption argument?

I am speaking specifically about your reply on page 5, as well as other pages, where you say Mensing dealt with

impossibility preemption based on generics' duty of sameness, rather than express preemption, nonetheless, it stands for the proposition that misbranding is not some catchall exception to Federal preemption principles.

MS. EISENSTEIN: Your Honor, the reason we rely on the Mensing decision is because one of the only authorities that the Plaintiffs rely upon for their misbranding theory is the amicus brief that the Government filed in that case.

The Court addressed that amicus brief, and while it didn't grapple with the issue that we have just been discussing about whether or not a drug could, in theory, ever be misbranded based on the FDA approved label -- in that case it was the generic's label that was following the label of the branded manufacturer -- it found, nevertheless, that preemption existed even assuming such a duty to update the label existed.

It was exactly a parallel argument, which was that the Government and the Plaintiffs in that case had argued that the duty of sameness was trumped by this duty to have a non-misleading label under the misbranding regulations, and the Supreme Court rejected that as a way in which to avoid, in that case, impossibility preemption based on the generic's duty of sameness.

Now, that doesn't have -- that has an analogy here, because the question here under express preemption is whether Plaintiffs are trying to impose a set of requirements as to the

label that is different from, in addition to, and not identical with Federal requirements, and that is the express preemption provision we have here.

The only way they can get around that is by pointing to some violation of Federal law, and they are trying to use, just like they did in Mensing, the purported violation of the misbranding requirements to say that trumps the duty of identicalness that is imposed by the express preemption provision.

And just as in Mensing, and this is what Riegel said as well in the context of express preemption of the medical device, that theory does not avoid express preemption absent a violation of specific Federal requirements. That is also what Wolicki-Gables requires under the Eleventh Circuit standard for pleading a parallel violation that can survive express preemption.

THE COURT: Okay. I have two more questions. One, I am going to circle back to the exchange we had before I pivoted to Mensing.

Do I understand your position to be that a jury could find a drug misbranded, or it could not find a drug misbranded, OTC, when the manufacturer fully complied with the label that the FDA previously approved? We are in a world where the FDA has approved the label.

What are the ramifications for that in terms of what a

jury could or could not find with respect to misbranding?

MS. EISENSTEIN: I agree with your Honor that the jury could not find that the FDA approved label -- that the FDA approved label was misbranded and therefore avoided preemption. That was word-for-word what the Supreme Court said in Riegel.

Let me read from it. It says "that means the MDA" -- which is the medical device amendment, identically worded to 379r, except that 379 adds identical with, not just in addition to or different from. "The MDA expressly preempts a jury determination that the FDA approved labeling for a pacemaker violated the state common law requirement for additional warnings."

That was directly in response to the Plaintiffs' argument that the label of that device was misbranded and misleading. The Supreme Court looked at the regulations that required a particular label and the PMA approval of that device and said that the MDA preempts that jury determination. The same is true here.

THE COURT: Okay. Assume for argument's sake that I were to conclude, or there was a conclusion that the Plaintiffs' have alleged Ranitidine was Federally misbranded. Would you agree that, upon reaching that conclusion, the Court would then have to turn to carefully comparing the elements of each state cause of action to the Federal misbranding statute, and then decide the extent to which each state claim is

parallel?

MS. EISENSTEIN: I think that is right, your Honor, and in doing that exercise, I agree with Mr. Keller that it is not a question just of a label, it is a question of what substantive requirements the state would impose, and to the extent to which the state would impose a label that is different from that which the FDA had approved, that that would be the preempted.

THE COURT: Again, in a world in which the Court is -- if the Court were to find misbranding, and then turns to a comparison, you are agreeing that the Court would need to compare the elements of the state cause of action to the Federal misbranding statute, that is, undertake a state specific element challenge from the brands if we were to get to that point?

MS. EISENSTEIN: I don't think that the elements of a state law cause of action have to be identical to some elements of a Federal -- there is no Federal claim. I think that the question is what requirements the state law imposes, and whether those would also constitute a violation of specific Federal law requirements.

I want to add one more thing, and this comes from the parallel claim case law. It is not just any violation, it is one that causes the Defendant's injury.

The Courts in the parallel claim arena have been

clear, it is not enough to just point to a specific violation of Federal law that is untethered to the injury of the Plaintiff, it has to be a specific violation of -- a specific violation of both state law duties that also constitute a violation of Federal duties that cause the Plaintiff's injury. So, in doing that comparison, that is what gets beyond, if the Plaintiffs can succeed in that, Federal preemption.

One thing I heard yesterday that sort of concerned me about that in the Plaintiffs' response to the omnibus Motion to Dismiss was, in trying to avoid dismissal on standing grounds, the Plaintiffs seem to be suggesting that the reason they survived express preemption -- sorry, the reason that they survived as a matter of state law was that the product was inherently unsafe.

If that is their theory of liability here, that would still be a preempted theory because it wouldn't be based on a purportedly misleading label that didn't have notice of NDMA formation or a cancer risk warning, but rather, based on the inherent lack of safety of the product.

So, that is an example of where it -- when you get past there is a violation of potential Federal law that also constitutes a requirement under the state law, it's not enough if that is not what caused the purported injury that Plaintiffs are asserting.

THE COURT: Right, but assuming there are allegations

that it caused the injury, would you agree that what the Court has now in its briefing from both parties would not allow the Court to undertake that kind of an analysis?

MS. EISENSTEIN: I agree, your Honor, there hasn't been a state specific analysis of these claims.

THE COURT: So, would that be an issue -- I understand you are saying we don't even get to that, but if in some scenario we got to that, would that be an issue that, for example, under PTO 61, is a state specific issue relevant at a later stage in the litigation and it would be addressed by the parties at that point?

MS. EISENSTEIN: I think potentially, to the extent to which it isn't encompassed in the omnibus briefing on some of these issues with respect to specific unfair competition laws, yes.

THE COURT: All right. Thank you so much.

From the Plaintiffs, what do you think a Plaintiff must allege for an OTC product to be Federally misbranded? Are the requirements more than what the misbranding statute sets forth in 21 U.S.C. Section 252; and if so, what is the legal basis for your position?

That is virtually an identical question that I had asked to Defense and I think that is what you wanted to weigh in on.

MR. KELLER: I appreciate that, your Honor. No, the

Plaintiffs don't have to plead anything more than contained, and just to correct your Honor, I think it is Section 352 of U.S.C.

My friend has referred I think three or four different times to Section 352(a)(1) and (j) as general provisions of law. It is not general provisions, it is the definition of misbranding under the Food, Drug and Cosmetic Act. There are different sections of the statute that set forth the criminal penalties associated with selling a misbranded drug, but that is Congress' definition under the statute.

So, to just say, oh, that is some general stuff, you can't focus on the general when there are more specific things to look at, you do get to focus on the words that Congress chose for the definition of an important provision of a Federal statute.

Now, it is true, under agency law principles, cases like Chevron, the FDA is the agency Congress entrusted to enforce the Food, Drug and Cosmetic Act, has the authority to promulgate regulations that when it is consistent with the statutory text has the force of law.

Here is the crucial point on that, and my friend conceded this, although tries to brush it under the rug, the FDA agrees with us, it interprets its own regulations to say we are right and the brands are wrong, and it went in the different direction with medical devices, and that is fine.

Agencies are allowed to disagree with themselves as to what should apply for a medical device versus a pharmaceutical product, but with respect to the pharmaceutical space, we have the FDA's position, and it is our position.

THE COURT: All right. Are you aware of any case post Bartlett or post Mensing where a claim for a drug, where any claim was not preempted because the Plaintiff alleged that the drug was misbranded?

MR. KELLER: I am not aware of a case in either direction, for us or for the other side.

THE COURT: Regardless of -- so, what I would like for you to do, Mr. Keller, in your own words, is to summarize what your allegations are about the brands' obligation not to sell Ranitidine under Federal misbranding law.

At what point in time did the Federal misbranding law impose a duty on the brands not to sell Ranitidine? Upon what allegations do you rely upon for your position, and relatedly, what inferences, if any, are you requesting that the Court make for your position?

MR. KELLER: Sure, your Honor. The brands had an obligation not to sell a drug, Ranitidine, with a false or misleading label. When they knew or should have known that Ranitidine was false or misleading is a question of fact. We think that we can establish it pretty early in time after the FDA approved the drug, but that is a question that is going to

be subject to a lot of disagreement between the parties based on the different interpretations of the facts.

Once the label became false or misleading, that is where the Federal misbranding statute comes into play. To plead state causes of action that are parallel to the Federal misbranding statute we have to claim there was a breach of duty under various state laws to sell a drug with a false or misleading label.

I hope during my prepared remarks I covered the different types of causes of action that we plead in the amended consumer class action complaint that set forth that you do have a duty when you are selling a product not to sell it with a false or misleading label.

I do want to return to something that your Honor brought up in the last set of questions that you asked my friend, which is, okay, assuming that you believe that the Federal misbranding statute can be violated sometimes and a case can go to a jury sometimes, do we have to carefully look at all of the elements of state law to see if it matches up with the elements of Federal law, and the answer to that is a resounding no.

The only element that you are supposed to focus on for preemption purposes is duty. I think you can consult the Supreme Court's decision in Moore, which was reaffirmed in Bates, for that proposition.

The element of causation, for example, which my friend referenced, yes, under state law we have to plead and prove causation for many of these causes of action. In some states we have to prove reliance, in other states we don't, but that doesn't matter for purposes of 379r and preemption and whether the supremacy clause kills our claims.

The only thing that matters for purposes of section 379r, the Supreme Court has interpreted the word "requirements" to be focused on duty, so we are only comparing the element of duty under state law to see if it matches up with the Federal misbranding statute.

THE COURT: Would you agree that the Court doesn't have briefing on the duty of -- in each of these states where you are bringing the claims, to the extent the Court got to that point, such an analysis would need to be done perhaps pursuant to the agreement that the parties reached that certain issues fall, under PTO 61, for another day?

MR. KELLER: Yes, I would agree with that, your Honor. I don't think the Defendants have briefed whether our state causes of action adequately plead a parallel duty or not. Their position is just that by definition the Federal misbranding statute is not triggered. So, I don't think that they have briefed that, and we, therefore, didn't either.

THE COURT: All right. Okay. Thank you so much, I appreciate it. That was very helpful to the Court and very

much appreciate both of your presentations and carefully thought-out responses to my questions that maybe weren't as carefully thought out as your answers.

So, it was an attempt to try to make sure I understood everything that you were putting forth. It is a difficult issue, so I appreciate your thoughts on it.

MR. KELLER: Thank you, your Honor.

THE COURT: Thank you so much.

MS. EISENSTEIN: Thank you, your Honor.

THE COURT: Okay. The next motion that we are going to go to -- as I had indicated, we might get to the distributors in the morning as well. Let me hear argument from counsel for the retailer and pharmacy Defendants, Motion to Dismiss amended master personal injury complaint and incorporated memorandum of law. That motion appears at Docket Entry 3112.

I am going to hear from Defense and then hear from the Plaintiffs. Then I will ask that counsel for the distributors come up from the Defense, then from the Plaintiff on 3107, which is the distributor Defendants' Motion to Dismiss amended master personal injury complaint and incorporated memorandum of law.

Then I am going to have all counsel come on for those motions and I have questions that I think I can overlap and I would just as soon have everyone there, and then we will be

able to conclude for the morning session and go to the store brand and the generic motions.

Ms. Johnston has her screen on. Good morning. Would you like to use your full ten minutes? Do you want any warning and/or any rebuttal time?

MS. JOHNSTON: Thank you, your Honor, and good morning. Sarah Johnston on behalf of the retailer and pharmacy Defendants. In terms of timing, I think I plan to use only about five or six minutes. In the event that I creep past that, a two-minute warning would be welcome.

THE COURT: All right. You may proceed.

MS. JOHNSTON: Thank you.

Your Honor, my goal here today for the retailers and the pharmacy Defendants -- I am just going to say retailers for brevity -- is to keep this pretty succinct.

We are well into the fourth day of Motions to Dismiss in this MDL and I think at this point, the Court is very familiar with the arguments and the legal principles underlying the retailers' arguments.

For purposes of orienting the Court, and also in the interest of efficiency, I have spoken to Mr. Kaplan, and because there are some overlapping issues in both the retailer and distributor motions, he is going to take on the issues of punitive damages and unjust enrichment because of the overlap in the two briefs and the arguments there, and for my part, I

am going to handle the substance of the retailers' briefing, which is the general negligence claims. With that, I will jump in.

Yesterday, during the first argument of the day, I was struck by something that Mr. Heinz said on behalf of Plaintiffs, and that was a cite to Rule 1 of the Federal Rules of Civil Procedure and the idea that Rule 1 stands for the proposition that the Federal rules are meant to be construed and administered to ensure fairness in the disposition of all cases.

I think the specific language he was referring to is that the just, speedy, and inexpensive determination of every action, but I like Mr. Heinz's paraphrasing the idea of fairness because I think that is a perfect frame for the retailers' overall arguments here.

So, stepping back, let's talk about where we are today.

Back in December, Mr. Keller, who is here again today, he and I argued the original retailer Motions to Dismiss, and those were a very different set of motions. Back then, Mr. Keller and the Plaintiffs conceded that the retailers didn't actually do anything wrong with respect to Ranitidine.

Instead, they argued that the retailers were "absolutely liable." Essentially, this was an argument that the retailers were some sort of insurer or pass through insurer

for the safety of Ranitidine, and Plaintiffs' pleading, their briefing, their argument all conceded that the retailers owed no duty with respect to Ranitidine and were not alleged to have affected the overall safety of the drug in any respect.

When faced with the preemption arguments that were raised during the first motion hearings, Plaintiffs changed their course leaning on a theory of negligence that didn't exist in the first complaint, and essentially, as it was raised during argument back in December, it was sort of a coin flip theory, that either the retailers failed to store Ranitidine at the lowest end of the labeled range or that we collectively and as an entire industry disregarded the label and instead, elected to ship and store Ranitidine however we wanted to.

Following those hearings and in the December 31st order, the Court took a firm line on its preemption findings, and your Honor is well familiar with those decisions, so I won't repeat them. But at bottom, the Court gave Plaintiffs some limited leeway to try to plead this new negligence claim. As I read it, it was basically, fine, if that is your theory, and if you can get around preemption, give it a shot, but as it stands, it is not pled in the complaint.

It is important to remember that the Court's order wasn't open season for Plaintiffs to bring whatever claims they wanted to. Instead, it was a narrow and very specific

directive, and the Plaintiffs were to replead per the order in a manner that reconciled their global theory of the inherent molecular instability of Ranitidine with this new theory that some after-the-fact shipping or storage issue affected the drug in a way that that wasn't preempted.

More importantly, Plaintiffs were told that they needed to plead with specificity with reference made to the specific state law duties that form the basis of their new claim.

And so, in response, Plaintiffs filed the AMPIC, and in response, we got 18 paragraphs. And by "we" I mean 22 retailers and half a dozen distributors together. And whittled down to the actual allegations themselves, we got three paragraphs collectively, industry-wide, and based on information and belief.

So, essentially, Plaintiffs put forth their theory in those three paragraphs that on information and belief the retailers and distributors systematically exposed Ranitidine to "excessive levels of heat and humidity", again, on information and belief that the retailers and distributors failed to implement policies that would ensure that Ranitidine wouldn't be exposed to this "excessive heat and humidity."

Then, finally, a for example that some retailers and some distributors shipped Ranitidine sometimes through the mail, and that was it.

I lost count of the number of Defendants in this case, I think it nears a hundred, but I think it is a fair ballpark to assume that the retailers and distributors collectively make up about a third of the Defendants in this litigation, and we got three paragraphs.

Notably, nowhere in the 600 or so pages of the AMPIC do Plaintiffs define what excessive means, nowhere do they attempt to differentiate among the 25 plus Defendants in various levels of the supply chain to allege any independent actions, any independent existence to support a negligence claim, and nowhere in that 600 or so pages do Plaintiffs identify a single legally recognized duty to support the theories that are based on their information and belief.

This is not what the Court asked for, and it doesn't meet basic pleading standards.

So, going back to the discussion of fairness and efficiency under Rule 1, I think it is important to point out that despite all this, despite two rounds of briefing and two very voluminous complaints, Plaintiffs, in their opposition to our motion, say outright at page ten, "It is true that there is nothing that the retailers could have done that would change whether Ranitidine was unreasonably dangerous at the time the retailers sold it or at any point thereafter through its shelf life."

That is the claim, and back in December the Court very

generously gave Plaintiffs some latitude, and this was to get their claims right. While that leave was narrow, it importantly wasn't narrow in the sense that the Plaintiffs were confined by space limits or page limit restrictions such that they basically didn't have the room or the real estate to get into the factual and legal bases of their claims. They simply elected to focus their energies elsewhere.

The retailers' position is that the Court has given Plaintiffs more than ample opportunity to figure out what they want to allege against the retailers. They haven't done it, they have elected not to, and more importantly, for the reasons we state in our brief, they can't.

We think our briefing adequately lays out the grounds for our position, including why Plaintiffs have failed to satisfy Rule 8, why Plaintiffs have failed to meet the Court's directives, why Plaintiffs claims don't constitute negligence under any construction, why the claims continue to be preempted, and ultimately why those claims should be dismissed.

With that, your Honor, I will stop and reserve the rest of my time. Thank you.

THE COURT: Thank you. That was just shy of eight minutes. All right.

And for the Plaintiffs, you have 13 minutes. Would you like any warning?

MR. SNIDOW: Yes, your Honor, if you would maybe give me a two-minute warning, and I appreciate the extra time.

THE COURT: All right. You may state your appearance for the record and proceed.

MR. SNIDOW: This is JJ Snidow on behalf of the Plaintiffs. Your Honor, I do have a presentation that I will try to show. Your Honor, I hope you can just see a black screen at this point.

THE COURT: I do.

MR. SNIDOW: May it please the Court. Before turning to Defendants' arguments, I want to detail the key allegations in the complaint because we have figured out the nature of these claims and we have pled them specifically succinctly and we have pled them plausibly.

First, the science allegations. Yes, as counsel pointed out, the complaint alleges that Ranitidine always degrades into NDMA, and thus is always dangerous, but the complaint also alleges that the drug degrades into NDMA more quickly and thus becomes more dangerous once exposed to high heat and humidity, and that scientific allegation, your Honor, is at the center of all the claims against the retailer Defendants.

The complaint then specifically links that level of NDMA exposure to the Plaintiffs' cancer. The more NDMA that someone ingests, the higher the risk of cancer.

The label for Ranitidine, meanwhile, contains specific instructions for storage and transport. The label required Ranitidine to be stored at between 68 and 77 degrees and not in the presence of excessive heat and humidity. Here is the crux of the claim which is pled, the complaint alleges that the retailers did not actually follow the label. It alleges that they did not store Ranitidine in the required temperature and humidity range.

Now, Defendants criticize us for not explaining how this happened, but the complaint is actually quite clear on this point. Even though the label said to keep the drug cool and dry, the Defendants shipped it through the ordinary mail and other common carriers, whether in a summer warehouse, in a closed mailbox, left in the sun, or a number of other situations that obviously and foreseeably led Ranitidine to be subject to high heat and humidity.

Finally, the complaint alleges that it is this differential increase in NDMA that led to their injuries. In other words, we allege that Plaintiffs' cancers were caused by the additional NDMA that built up as a result of the high heat and humidity.

Now, Defendants might wish to dispute those allegations during discovery, and that is, of course, their right, but this is a Motion to Dismiss, and that, of course, means that each of the allegations that I just ticked through

must be taken as true.

Defendants call -- in the brief, they say these allegations are conclusory, but the law is clear on the distinction between factual allegations and legal conclusions. Only legal conclusions may be disregarded on a Motion to Dismiss, as Iqbal and Twombly say. The allegations that I just ticked through, each of them, they are not formulaic recitations of the causes of action, they are not legal conclusions, they are facts.

As we say in our briefs, either the Defendants shipped and stored the drug properly or they didn't, but either way, that is a classic factual issue.

What did Defendants say in response? In their brief, though we have heard less of it today, their primary argument is that the factual allegations are unlikely, as they say, or specious. Of course, that is just fighting the complaint. Even if Defendants disbelieved the allegations and, frankly, even if the Court thinks they are unlikely to be proven at trial, they must be accepted as true on a Motion to Dismiss.

Second, Defendants argue that there is not enough detail about their conduct, and that seemed to be the premise of Ms. Johnston's argument today, that even though we had named several Defendants, we have spent not very much time on each of them in the complaint, but that also is not a basis for dismissal.

A complaint does not need to include detailed factual allegations. That is exactly what Twombly says. The complaint makes clear the overall basis for the claim is that Defendants failed to ship and store the drug in accordance with the label and that gives Defendants ample ability to prepare their defense. They know what they are being accused of doing.

Next, Defendants argue the complaint fails to specify the who. They say we didn't allege who failed to ship and store the drug in accordance with the label, but of course, that is just not accurate.

The complaint clearly defines the term "retailer Defendants" as the entities listed in paragraphs 169, 218. In the paragraph cited we list each of the retailer Defendants here from Albertson's all the way down to Winn-Dixie, and then the complaint alleges what each of the retailer Defendants did. Namely, that they shipped and stored the drug in high temperatures humidity levels.

That kind of pleading is perfectly proper and a valid way of stating a claim because when each Defendant is alleged to have done the exact same thing, there is simply no reason to repeat the name of each Defendant before leveling the exact same allegation. Instead, it is perfectly proper to plead against them collectively.

That is also why the complaint does not raise any shotgun pleading concerns. The problem with grouping

Defendants is that it sometimes can create confusion about which Defendant is alleged to have done which act. For example, if the complaint identifies Defendants A, B, C, and D, and then alleges that Defendants did acts X, Y, and Z, it can be unclear whether the complaint is saying Defendant A did act X, or Defendant A did act Y, Defendant A did act Z, or perhaps Defendant A did all three things, and that is a problem because in that situation, the Defendant doesn't actually know what he is being accused of doing and that thwarts his ability to prepare his defense.

That is not what is going on here. The complaint does identify the retailer Defendants, but then it makes clear that each of them did the exact same thing, they failed to ship and store the drug properly.

Turning to preemption, the operative question is probably all too familiar to the Court by now, but it is whether it would have been impossible for the Defendant to comply with the state law duty without violating any Federal law. So, it's a two-step process, identify the state law duty and then ask whether Federal law forbade the Defendant to satisfy it.

The state law duty here is a duty to exercise reasonable care in storage and shipment, and more specifically, to store and ship the drug in accordance with its label. So, having stated the state law duty, the question is this: What

Federal law forbade shipping and storing according to the label? The screen is black because, of course, there is no Federal provision that forbids a Defendant to do exactly that.

To know whether the claim is preempted, Defendants' state law duty is to ship and store the drug in accordance with the label, there is no Federal law duty forbidding someone from doing that, so Defendant can do this without violating this. That means it is not impossible to do both and the claim is not preempted by the Supreme Court's impossibility preemption doctrine.

In response, Defendants say that we are really arguing that they needed to stop selling the drug, but I will say this as clearly as I can, we are not arguing that now, and we didn't allege that in the complaint, full stop. Even though Ranitidine is unreasonably dangerous, our allegation, of course, is that these Defendants could have made it less dangerous by shipping and storing it properly, not that they should have ceased selling the drug.

To support this stop selling argument Defendants basically take a hyper technical reading of this one clause in the complaint, they note the fact that we said the words "unreasonably dangerous." But that paragraph makes clear that we are not suggesting they should have stopped selling.

Now, to be candid with the Court, I suppose we could have said to ensure that the drug was not even more

unreasonably dangerous than it already was, but in context, it is clear what we are saying. In any event, we simply would not have a claim against these Defendants in this complaint if they had shipped and stored the drug properly.

It is even more clear if you look at the state law sub counts which we detail for each of the states in accordance with this Court's rulings. There is no mention of unreasonably dangerous or inherent defects or any of the other phrases that the Defendants cherry pick. The duty is just to ship and store the drug properly and Defendants could have done that without violating any Federal law.

Now, it is true that, under this Court's orders, other state law duties are preempted, like the duty to change the label or redesign the drug, but when analyzing a statute, the fact that one provision is preempted doesn't mean that every provision is preempted, and the exact same thing is true under the common law.

In the Mink case, which is exactly on point, the Plaintiff brought three negligence theories. The Court held that one of the theories was preempted, but the others were not. The same thing is true here.

To illustrate the point, there is actually a spectrum of things that any Defendant could have done to make Ranitidine safer; they could have stored it at lower temperature and humidity, they could have added a cancer warning, they could

have redesigned the drug and, yes, they could have stopped selling it.

Under this Court's rulings, three of those things are preempted, but the fourth one is not. No Federal law forbade Defendants from shipping and storing the drug in accordance with the label, so that claim isn't preempted even though the other ones are under this Court's orders.

Turning to punitive damages, Defendants argue that we haven't pled facts to make that request plausible under Iqbal and Twombly. There are two problems with that argument.

The first is that Twombly and Iqbal don't apply to requests for punitives because those cases are interpreting Rule 882, which applies to claims, and a request for punitive damages is simply a request for a type of relief which is governed by Rule 883, and Twombly and Iqbal don't apply to that provision of Rule 8.

That is exactly what Courts in this district have held. The Doe versus Royal Caribbean case says exactly this, that 882 is about claims, 883 is about relief, and critically, that as a result, a complaint does not need to plead facts underlying a request for punitive damages.

The second reason that argument is wrong is because we have alleged facts plausibly showing entitlement to punitives. We allege Defendants were reckless, we allege that they knew the risk of failing to ship and store Ranitidine properly, and

we allege that they ignored that risk.

Under the law in this Court, that is plainly enough to survive a Motion to Dismiss, as the L.A. versus Royal Caribbean case makes clear. At a bare minimum, we have alleged -- made general allegations of wonton, willful, or outrageous conduct and on a Motion to Dismiss that is sufficient to support a demand for punitives.

Finally, Defendants argue this Court did not permit us to replead unjust enrichment, and on this point, your Honor, I, of course, defer to the Court on the proper interpretation of its prior orders, but we read, I think fairly, the order to only forbid claims based on design for label.

The unjust enrichment claims here are not based on design or labeling, they are based on failure to ship and store Ranitidine in accordance with the label, so we repled it.

For these reasons, the retailer Defendants motion should be denied, and I am happy to answer any questions the Court might have.

THE COURT: Thank you so much. All right. Was there any rebuttal? You had some time left, Ms. Johnston.

MS. JOHNSTON: Yes, your Honor, just briefly because I know that Mr. Kaplan will likely cover some of this.

In terms of pleading, counsel cites to the Guarino case, which I believe is also cited in their brief, for the proposition that they do not need to set forth factual

allegations or other detailed factual allegations in order to properly plead a claim. The portion of that case that they cite is directly followed by a portion that they omit that requires that Plaintiffs must plead enough details -- must contain enough facts to indicate the presence of the required elements of the claim, which they have not done here, and that conclusory allegations then warranted deductions of fact, or legal conclusions masquerading as facts, will not prevent dismissal.

So, the case that they cited in terms of the adequacy of their pleading against this very large group of Defendants proves the point, rather than disputes it.

In terms of preemption, I think the Court is well familiar the principles of Bartlett and Mensing preemption and likely may have some questions on that that we will be prepared to answer.

But the preliminary point that I want to highlight, that counsel and I both agree on, is that the preliminary question to determine is the existence of a duty, which we have outlined at length, and I believe the generic Defendants have as well, that there has not been a legally recognized duty that has been alleged, must less with the specificity the Court has requested.

THE COURT: Okay, thank you.

I am going to call you back up after the distributors

argue and we will have everybody up for questions.

So that I don't lose my train of thought in light of what Mr. Snidow just argued with respect to paragraph 2220 in the AMPIC, I want to give you an opportunity to respond, the allegation that the retailer and distributor Defendants ignored this risk, they did not ensure Ranitidine-containing products were stored at low humidity or within the temperature range on the label.

Instead, some Ranitidine was subjected to excessive humidity and heat during storage, transportation, and shipping, which caused the drug to degrade, leading to the formation of excessive levels of NDMA.

MS. JOHNSTON: Would you like me to address that now, your Honor?

THE COURT: Yes.

MS. JOHNSTON: Certainly. So, starting first from the concept that the retailers ignored the risk, I think it is clear throughout the complaint that there is no allegation that the retailers were aware of the risk of formation of NDMA in Ranitidine.

Throughout both master complaints we have never been alleged to be -- I think we were left out of what was called the knowledge Defendants in the first master complaint and the allegations respecting knowledge in the amended master PI complaint followed that same logic. The retailers were not

alleged to have known of the risk of NDMA in exposure to heat and humidity.

In terms of the allegations regarding exposure to excessive heat or humidity in the shipping and storage process, the first point that I would make on that in response is that Plaintiffs have not defined what excessive heat or humidity is, or what proper storage is. All they have said is on information and belief, here are the label conditions we think sometimes --

THE COURT: You froze there. We will wait for one moment because I am not hearing what you are saying.

I don't know if you can hear me, Ms. Johnston. It looks like we lost Ms. Johnston. Okay.

For the record we will -- oh, you are back.

MS. JOHNSTON: I thought maybe shutting my video off might help.

THE COURT: Now I can see you and hear you. You were right in the middle of a sentence.

MS. JOHNSTON: I am not sure what sentence that was, but setting aside the issue of knowledge, which I think I addressed, the allegations regarding the propriety of storage conditions are all based on this -- the concept that there was an industry-wide disregard to these storage requirements, which is not borne out in any factual way in the complaints as pleaded, specifically as to such a large group of Defendants.

Moreover, Plaintiffs haven't defined why, even were Ranitidine stored outside of the specific labeled range -- they haven't, for instance, given a range of temperatures that would subject Ranitidine to increased likelihood of development of NDMA, nor have they defined what excessive heat would constitute, among the other things that would put the retailers on notice of what exactly they are alleged to have done wrong.

THE COURT: All right. Thank you so much.

So, at this point, if we could have the Defense counsel for -- Mr. Kaplan for 3107, the distributor Defendants Motion to Dismiss, and we are still in the morning hour, good morning. You have ten minutes, do you want any warning or are you keeping your time?

MR. KAPLAN: Good morning, Judge Rosenberg, Andrew Kaplan, I represent Cardinal Health, Inc. I am here to argue the distributor Defendants' Motion to Dismiss, docket 3107.

I would like to reserve maybe a minute of time at the end, and I am happy to keep track of my own time.

THE COURT: Okay. You may proceed.

MR. KAPLAN: Thank you, your Honor, and may it please the Court.

Your Honor, the distributors were not brought into this litigation at the outset. They were first named in the original master complaints as an afterthought. The voluminous complaints barely mentioned the distributors. There were no

direct claims of negligence, as Ms. Johnston pointed out.

After the Court dismissed all of the claims against distributors, most with prejudice, the Court allowed Plaintiffs to attempt to plead essentially one narrow claim, a theory of direct negligence.

More than a month later, the Plaintiffs came back with the AMPIC, a lengthy pleading of more than 3200 paragraphs, of which only three paragraphs attempt to address any purported negligence by distributors, but the three conclusory, unsupported allegations group pled against all six distributors and more than 20 retailers, and conspicuously pled upon information and belief, come nowhere near the level of pleading required under Twombly and Iqbal.

16 months after the commencement of this MDL, and almost a year after the distributors were brought into this litigation, it is clear that Plaintiffs cannot plead a viable claim against distributors.

We respectfully request that the Court grant the distributors' Motion to Dismiss all claims against them with prejudice and release distributors from this litigation.

I will briefly touch on the issues we raise in our motion papers. Most fundamentally, Plaintiffs fail to make any plausible allegation that gives rise to a claim for negligent storage and transportation. As I mentioned, the sum total of the allegations of misconduct are three paragraphs of the AMPIC

in which Plaintiffs allege, upon information and belief, that distributors and retailers purportedly systematically exposed Ranitidine to "excessive levels of heat and humidity," purportedly failed to implement rigorous policies to ensure compliance with heat and humidity requirements on product labels, and purportedly shipped product through the mail, which allowed the product to be exposed to "excessive heat and humidity."

These paragraphs suffer from numerous deficiencies. First, the Court gave Plaintiffs the opportunity to replead their complaint at the outset of this MDL before any Motion to Dismiss practice, but Plaintiffs declined. After voluminous briefing and argument, the Court dismissed all the claims against distributors and specifically cautioned against the improper shotgun pleading.

In its order on the shotgun pleading motion the Court said in no uncertain terms, "The Court is particularly concerned by the way in which the MPIC lumps MPIC shotgun Defendants across entire groups, e.g. retailers grouped with distributors." The order went on to say that the Court understand certain groups to conduct fundamentally different activities than others.

Plaintiffs simply ignored this caution and filed the AMPIC with almost 30 separate Defendants lumped into one count with the same three conclusory allegations made against all.

While it is a technical pleading failure, it also has a practical problem. It allows the Plaintiffs to avoid having to put forth factual allegations about even one instance where any specific Defendant purportedly undertook the alleged negligent conduct.

Second, if Plaintiffs were correct that every distributor systematically exposed Ranitidine to undefined excessive heat and humidity, then it would mean that no distributor handled any of their products correctly, and there is no suggestion that there is a separate Ranitidine-only handling policy. This is implausible on its face as the Court already expressed serious reservations about such a theory in its order on distributors' original Motion to Dismiss.

Third, while Plaintiffs lob the vague and conclusory allegations of exposing Ranitidine to undefined excessive heat and humidity, they notably do not allege anywhere how high the temperatures allegedly were or for how long. This failure is especially important given that the U.S. Pharmacopoeia, or USP, states that controlled room temperature product, which is the category Ranitidine falls into, is allowed to have temperature excursions up to 104 degrees for up to 24 hours.

Plaintiffs have not alleged anywhere that any distributor allowed any product to exceed those allowances.

Fourth, and importantly, the allegations Plaintiffs

make against distributors are directly contradicted by the discovery they have from distributors. By the time Plaintiffs filed their AMPIC, the distributors had completed their document productions under their core discovery agreements and have reduced thousands of pages of policies and procedures regarding storage and transportation. Plaintiffs have since taken multiple distributor storage and transportation 30(b)(6) depositions.

It is troubling that Plaintiffs could continue to argue to this Court that distributors purportedly failed to implement rigorous policies to ensure compliance with heat and humidity requirements on product labels while being in possession of voluminous documents that say just the opposite.

Fifth and finally on this issue, as noted earlier, the allegations of negligence against distributors are made upon information and belief. Multiple Courts in the Eleventh Circuit, including this Court, have stated that the allegations made upon information and belief are not necessarily entitled to a presumption of truth.

The lack of support behind these allegations was highlighted by Plaintiffs' own arguments yesterday. Yesterday, when attempting to support the sufficiency of the economic loss complaint, Plaintiffs' counsel argued that they don't just allege that they "believe" that there is a safety issue with Ranitidine, they plead actual facts in support of their

allegations, such as -- the example was scientific studies.

I leave the issues about the insufficiency of that complaint to my colleagues, but implicit in Plaintiffs' argument is that the Plaintiffs' belief alone is not sufficient to state a claim, and that is all we have here.

I will briefly touch on the other claims against the distributors.

First, the Plaintiffs' state law sub counts fail for the same reason as the general negligence claim. Plaintiffs add no specific allegations for any state negligence claims. Moreover, they don't attempt to tether any state law to any Defendant.

There are, for example, state law sub counts for states where there is not a single Plaintiff asserting a claim against any distributor.

Second, Plaintiffs' derivative claims, loss of consortium, survival, and wrongful death, Counts 15 through 17, must rest upon a viable substantive claim to survive. Because the negligence claim should not survive, these claims must fail as well.

Third, Plaintiffs allege punitive damages against all Defendants. Of course, if the negligence count fails, so does the damages request. But in isolation, the request for punitive damages is still deficient. Plaintiffs' argue that their request for punitive damages is not a claim and therefore

cannot be dismissed under 12(b)(6).

Courts often treat Motions to Dismiss and Motions to Strike punitive damages requests interchangeably. We cite multiple Federal Florida cases in our reply brief on that point.

Whether this Court dismisses or strikes the request for punitives, it should not survive. More important than the mechanism for excising this request is Plaintiffs' inability to sufficiently plead entitlement to such damages.

Plaintiffs' bid for punitives is in paragraphs 473 and 474 of the AMPIC. The alleged misconduct described in those paragraphs has nothing to do with distributors. It relates only to conduct allegedly undertaken by manufacturers, that is labeling, marketing, and purportedly misleading research.

Thus, the argument Plaintiffs make in their briefing is flatly contradicted by their own complaint. They plead no conduct against distributors that could warrant such damages.

Finally, for unjust enrichment, Count 14, this claim suffers from an even bigger problem. The Court dismissed it already with prejudice in its order on the first round of Motions to Dismiss. But even if the Court had allowed Plaintiffs to replead, the amendment fails because once again what Plaintiffs argue in their briefing is flatly contradicted by their own complaint.

Plaintiffs' unjust enrichment count incorporates and

relies on paragraphs 1 through 475 of the AMPIC, which do not allege that distributors had any knowledge of the purported risks of Ranitidine, and the underlying allegedly wrongful conduct that they point to in paragraph 2725 is marketing, promotions, and advertisement, all conduct that does not apply to distributors.

With that, I will yield to Mr. Longer and reserve any remaining time. Thank you.

THE COURT: Thank you. You have about a minute and 20 seconds left. If we could have Mr. Longer come up.

Would you like any kind of a warning, Mr. Longer? You have ten minutes.

MR. LONGER: Can you hear me, your Honor?

THE COURT: I can.

MR. LONGER: A warning would be nice. Give me a minute warning.

THE COURT: Okay. You may proceed.

MR. LONGER: Thank you, and may it please the Court. Fred Longer on behalf of the Plaintiffs.

Your Honor just heard Mr. Snidow present a lot of argument for Plaintiffs, and a lot of it overlapped, as you could hear, between the retailer Defendants and the distributor Defendants.

So, I would just like to address a couple of the points that we just heard, and after that, I will just go into

some remarks, but one of the things that I did just hear is that Mr. Kaplan suggested that a lot of information has been provided in discovery, and we have had depositions, but of course, that occurred after the amended complaint was already filed.

So, to suggest that discovery that was later produced gave us any information about how to plead this amended complaint is not well founded. In fact, a couple of the distributor Defendants have yet to produce any documents, Geri-Care and Golden State. McKesson didn't produce documents in an ununitized manner until after the amended complaint was filled, so the argument about production of documents is unfounded and unhelpful.

So, based on what we did have, the Plaintiffs pled the complaint which provided more than adequate notice of our claims of negligence against the Defendants.

Despite the Plaintiffs taking the Court's guidance to heart and carefully crafting and recrafting our pleading, once again the Defendants' label, the amended personal injury complaint, shotgun pleading, although yesterday I did hear that it was an improvement, so I guess we have done better, but nonetheless, the Defendants' biggest beef is that they are calling our allegations regarding the distributor Defendants a group pleading.

They contend we improperly lumped all the distributors

and retailers together indiscriminately, but the AMPIC is anything but a shotgun pleading. We took great pains to avoid any of the so-called Wyland sins. Our claims in Count 10 are limited to negligence involving storage and transportation outside the labeling range. The distributor Defendants are down the chain of distribution, but they are in the business of storing and moving the products they sell across the country and are properly categorized together.

The distributor Defendants are not confused by the amended complaint. They contend that we are not permitted to plead that all of the Defendants engaged in the same act, such as using the United States Postal Service to ship their products, because they call that circular reasoning that just wouldn't be plausible, but facts are stubborn things, your Honor, and here we alleged a fact that these distributors, each one of them, used common carriers, like the United States Postal Service, to mail their products, and that there was not temperature or humidity control when they did so.

That fact was alleged as to each Defendant. What is not plausible about that fact? Using a carrier that doesn't control conditions makes it more than plausible that temperature and humidity conditions exceeded the product label as to each and every Defendant. They can take issue with that, but that is on a summary judgment motion. Right now they have admitted that fact for purposes of the Motion to Dismiss. It

is to be assumed to be true, and it is supported by examples.

So, there is more than plausibility here, we have given examples of how the fact is actually proven.

The principle case that the Defendants provide in their reply brief is Parker Auto Body. That is an antitrust case, your Honor, it doesn't support them on this point. Magistrate Judge Smith ruled that there are cases in which group pleading is acceptable, and he cites to the Eleventh Circuit case that we cited, Crow versus Coleman, and he said it endorsed the use of group pleading.

Judge Smith even quotes the same quote we quoted: "When multiple Defendants are named in a complaint the allegations can be, and usually are to be read in such a way that each Defendant is having the allegation made about him individually." And the Parker Court noted that provided the Plaintiffs used the Defendants are in fact intended to encompass every single Defendant, then it is acceptable practice to do so.

We also cite in our opposition, your Honor, Sprint Soles at 44 F.3d, a Judge Cohn opinion. He said that Plaintiff may plead claims against multiple Defendants by referring to them collectively, for example, by referring to groups of Defendants as Defendants.

That is exactly what we have done here. The Defendants aren't confused by the pleading, they are taking

advantage of it. They want us to plead evidence, but we are still under a notice pleading standard, and provided the Defendants have adequate notice of the claim against them, that they each failed to ship and store Ranitidine under the temperature and humidity conditions required by the label, then the pleading is adequate.

In the end, your Honor, this is a personal injury complaint. Under notice of pleading, we are only supposed to say, you hurt us. We did more than that. There are so many allegations that give the road map of liability to this litigation.

Instead of owning up to these allegations that we asserted, the Defendants say that they don't understand them, but being purposely obtuse should not be permitted as a defense. This is not a shotgun pleading, your Honor.

We also heard Mr. Kaplan argue that our claims of negligence are not well stated, but we provided all of the elements of negligence, duty, breach, causation, damages, and they dispute the factual assertions.

They suggest that we say each of them separately did these things, and that is implausible, but these allegations, as I mentioned before, are to be accepted as true and entitled to every reasonable inference. If they want to deny the facts, now is not the time.

These allegations put them on notice of our claims,

and in response, they just come up with more challenges. They say that the duty must be pleaded, but in their reply they acknowledge that duty is a matter of law, and that it is a pure question of law.

Yes, this Court in National Fire said that a complaint may be dismissed for failure to establish a duty, but unlike that case, where the Plaintiff failed to plead any facts according to his undertaker liability theory, here we have artfully explained how Defendants failed to maintain proper temperature and humidity, and as I said, we even provided examples.

Paragraph 224 says the distributor Defendants systematically followed a standard practice or policy to allow Ranitidine to be outside the labeled range. They denied that allegation, but the facts that we have pled are not conclusory, they are not postulation, they are not hypothetical, they are plausible. We know that -- we know this, and we pleaded it on information and belief, but we also provided facts to support the allegations.

As I mentioned, the Defendants didn't provide us the documents that Mr. Kaplan said that he provided to us prior to the complaint being -- the amended complaint being filed, so it is not a fair assertion on his part to say, oh, and we are having more discovery. As we go through more discovery, they are confirming our facts.

So, at this point, the pleadings are sufficient, your Honor, and the motion should be denied.

THE COURT: That is nine minutes.

MR. LONGER: Fair enough. As to punitive damages, I am going to rely on what Mr. Snidow argued. I thought he did a fine job.

The last point I will address, your Honor, is the contest of the sub counts, and I just think that the Defendants basically ignore the formulaic -- I am sorry, they contend that we simply pled formulaic elements of the complaint without specific allegations of conduct, but those sub counts incorporated the main count where the facts are alleged. So, on that point the argument fails.

Again, this is a master complaint. The Defendants have also argued that there are some Plaintiffs that are not for this -- they have not yet filed claims in certain jurisdictions. This was a master complaint that we were obliged to file under PTO 24, your Honor, so, naturally, because it was a master complaint, there are no individual Plaintiffs in it, so we were pleading broadly --

THE COURT: That is ten minutes.

MR. LONGER: Thank you, your Honor. We were pleading broadly to capture any possibility, is my point. Thank you very much.

THE COURT: Thank you so much.

Could we have everybody turn your video on for the retailers and the distributors, Plaintiffs and Defendants, so we can address questions, which should not take too long and we will be able to have a reasonable lunch break.

MR. KAPLAN: Your Honor, may I --

THE COURT: I am sorry, you're right, you have a minute, 20. Go ahead before we get into the questions.

MR. KAPLAN: Thank you very much, your Honor. Just briefly, the one purported example of the vague excessive temperature argument is this mailing product through common carriers. The mail allegations simply don't apply to distributors. Plaintiffs know that now and they know that from the discovery and the depositions, yet they are still here arguing otherwise.

To correct Mr. Longer, I know Cardinal Health, my client, produced more than 1500 pages policies and procedures before the amended complaint was filed. This is exactly why group pleading is was so problematic, as the Parker Auto Body case says, and Mr. Longer omitted the relevant language.

I would like to just read that and I will finish with this.

As the Supreme Court emphasized in Iqbal, a District Court's task in determining whether a complaint states a claim upon which relief can be granted is a context specific test that requires the Court to draw on its judicial experience and

common sense, but at a minimum, Plaintiffs should allege specific facts specific to each Defendant, or at least each corporate family of Defendants to tie that Defendant to the wrongdoing alleged.

Without those averments it is not plausible to believe that every Defendant made the same statements to every prospective customer, or that every customer who elected to use one of the Defendants preferred shops was unlawfully steered by a Defendant.

Accordingly, I respectfully recommend that all of the claims be dismissed as improper shotgun and group pleadings. Thank you.

THE COURT: All right. Thank you very much, and again I apologize.

This is a question for the Plaintiffs. Do you concede that you have not alleged that the retailers or the distributors had any knowledge of the propensity of Ranitidine to form NDMA when exposed to heat? Do you concede that, acknowledge that?

MR. SNIDOW: That allegation is not necessary for these claims, your Honor --

THE COURT: State your name for the record.

MR. SNIDOW: I'm sorry, JJ Snidow on behalf of Plaintiffs.

THE COURT: I apologize, I think I mispronounced your

name earlier.

I am not asking whether it is relevant or not. You concede that you have not alleged that the retailers or distributors had any knowledge of the propensity of Ranitidine to form into NDMA when exposed to heat; yes or no?

MR. SNIDOW: No, we don't concede that.

THE COURT: What paragraphs in the complaint establish the knowledge?

MR. SNIDOW: Paragraph 1968.

THE COURT: 1968?

MR. SNIDOW: Yes, your Honor.

THE COURT: Any other paragraph?

MR. SNIDOW: That is where that is alleged.

THE COURT: Of the AMPIC?

MR. SNIDOW: Yes, your Honor.

THE COURT: Defendants knew or should have known that it was foreseeable that consumers such as Plaintiffs would suffer injuries as a result of Defendants' failure to exercise ordinary care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Ranitidine containing products?

MR. SNIDOW: Yes, your Honor.

THE COURT: Did you want to follow up?

MR. SNIDOW: There is one more. If your Honor is asking specifically with respect to punitive damages, paragraph

473.

THE COURT: Putting aside, for Plaintiffs, your arguments about retailers and distributors knowing of the need to comply with the temperature ranges on a drug's label, would you agree that without the knowledge of Ranitidine's alleged defect the retailers or distributors could not be found negligent for failing to take steps to safeguard consumers from that defect?

MR. SNIDOW: No, I don't agree with that, your Honor, because the retailers and distributors certainly knew that they needed to comply with the FDA's instructions on the label and we have plausibly alleged that they failed to follow those instructions.

THE COURT: Going back to your paragraph 1968, what part of that allegation puts the retailers and distributors on notice, or that you are alleging they are on notice that they have knowledge of the propensity of Ranitidine to form NDMA when exposed to heat?

MR. SNIDOW: I meant that it was the injuries were foreseeable there. For NDMA specifically I would lean on 473.

THE COURT: You lean on 473. Okay. Any other paragraph?

MR. SNIDOW: That is what I'd lean on, your Honor. I am citing you two paragraphs because your Honor asked if we conceded it, and I did want to point out that these allegations

were made. I do want to emphasize it is not -- those allegations are not necessary for the actual claims that we allege against the retailer and distributor Defendants.

THE COURT: Okay. Let me let Defendants then respond, if you would like, to anything that Plaintiffs have said as to those two questions, because I don't have those questions directed to you. I did want to give you an opportunity to respond if you wanted to.

MR. KAPLAN: Your Honor, Andrew Kaplan. If I may briefly respond to the question of whether knowledge was alleged.

I don't see that in the paragraphs that were pointed to, but importantly, as we note in our reply brief, if you look at paragraphs 439, 504, 505, and 940 through 43, the Plaintiffs allege that the manufacturers hid the issue with -- the alleged issue with Ranitidine from everybody.

So, not only do those paragraphs pointed to not say that the distributors and retailers had knowledge, they in fact allege the exact opposite throughout the complaint.

MS. JOHNSTON: Your Honor, Sarah Johnston for the retailer Defendants. I would just add that the knowledge requirement in the pleadings -- I will give an example. At Paragraph 429, and I think this is repeated at various points throughout the AMPIC, but the allegations related to things like publicly available scientific information and the knew or

should have known of the defect allegations are directed to the manufacturer Defendants and not any other Defendants.

I would also highlight page 9 of the retailer Defendants reply brief at Docket 3504 where we cite to the hearing transcript from the original Motion to Dismiss.

When asked a question on this particular issue, Plaintiffs' counsel stated that "a retailer is not in any position to know if the product is defective, that is particularly so for drugs. Unlike a manufacturer who could have certainly caught that their product was defective, there is nothing a retailer or distributor could do to make that same sort of catch."

That is citing the December 15, 2020 hearing transcript at 107-23 to 108-5.

THE COURT: What is the Plaintiffs' response to that?

MR. SNIDOW: I will address the manufacturing stuff as well. With respect to the manufacturer Defendants, it is a basis of the claim that they had that knowledge. It is not part of the basis of the claim against the retailers and distributors, which is why we don't allege knowledge in the same way we do against the manufacturers.

As for the snippet from the hearing transcript, there, of course, we were addressing an entirely different theory of liability, that was premised on absolute liability for retailers and distributors, and the Court should interpret that

in that context. We were saying in an absolute liability, notwithstanding whether anyone has knowledge or not.

Here, of course, our theory is a very different one.

THE COURT: So, going back, I think what you said was maybe 473, the reckless disregard for human life allegation, Defendants were fully aware of safety risks of Ranitidine. Are you saying that that kind of an allegation is sufficient to put anyone, the public, on knowledge about the carcinogenic risks of Ranitidine?

MR. SNIDOW: No, your Honor. What that paragraph alleges, that the Defendants in particular, not just members of the public, had knowledge. Depending on the state law, the question could be ultimately actual knowledge, it could be constructive knowledge, it could be some sort of imputed knowledge based on testing requirements.

For purposes of these particular claims, what the actual basis is, is not that the retailer Defendants knew that Ranitidine was going to degrade into NDMA, it is that they knew that the FDA required the drug to be stored at the temperature and humidity conditions stated on the label and that that was the specific risk that they disregarded.

That doesn't actually depend on the retailer and distributors knowing exactly what was going to happen if they failed to follow the label. It is enough. With a prescription pharmaceutical product, there are good reasons they should be

stored and shipped in the way that the label says, and disregarding that is negligent for purposes of the claim, and reckless for purposes of punitive damages.

THE COURT: Is there an allegation anywhere in the complaint that there is a state law that somehow imposes a duty on a retailer to test the drugs that they sell? Are you alleging that?

MR. SNIDOW: I think we allege it at a higher level of generality.

Let me take a step back. With respect to the retailers, we are not saying they needed to have tested it in order to know to ship and store the drug in accordance with the label. That was apparent to them from the face of the label, which requires them to ship and store in certain ways.

Again, we don't have that specific allegation as a part of the claims because it is not a necessary part of these claims.

THE COURT: Okay.

MS. JOHNSTON: Your Honor, if I may briefly, just to go into the specific paragraphs that counsel identified, 473 and 1968, 1968 is a part of Count 8 for failure to test, which is not asserted against the retailers or the distributors. 473, likewise, is not incorporated into Count 10, which is the only count asserted against the retailers and distributors.

MR. SNIDOW: Your Honor, I agree with that and that is

why --

THE COURT: But I asked the question as to whether there was an allegation as to these Defendants.

I know you take the position it is not necessary, but that was a bit misleading if you are now saying that 1968 and 473, while there, are not incorporated into the allegations against the retailers and distributors.

Do you agree that 473 and 1968 are not incorporated into the allegations against the retailers and distributors?

MR. SNIDOW: Yes, your Honor, I do.

THE COURT: Going back to my original question, would the answer then be yes? Do you concede that you have not alleged that the retailers or the distributors had any knowledge of the propensity of Ranitidine to form NDMA when exposed to heat? Would the answer be yes?

MR. SNIDOW: With respect to these claims, the answer is yes.

THE COURT: Any claims against the retailers and the distributors.

MR. SNIDOW: With respect to any claims against the retailers and distributors.

With apologies, your Honor, I just want to be clear. I interpreted your question as do we concede as a general matter that, in reality, they didn't have knowledge. I do concede, with respect to the claims against the retailers and

Defendants, we do not level those allegations.

THE COURT: I think you misspoke. You said retailers and Defendants, you mean retailers and distributors.

MR. SNIDOW: That's right.

THE COURT: I do appreciate your position it is not relevant, but on certain specific questions, I just wanted to make sure I got clear answers. Okay.

So, this is a question, and it is a long one, and it is going to be for the Plaintiffs and the Defendants. I don't want to have to repeat it, so I am going to speak slowly and ask you to listen carefully.

Maybe I will tell you what the underpinning to my question is and that might put it all in context.

It is from page 18 of the Plaintiffs' response to the retailers' motion which says that, undersigned counsel was charged with prosecuting viable claims for all Plaintiffs in this MDL, and this claim is more than viable. Counsel cannot abandon viable theories of recovery simply because not every Plaintiff can invoke every one of them successfully.

Plaintiffs, nonetheless, believe common issues of law and fact associated with these claims make an MDL an efficient proceeding to address them.

So, with that backdrop in mind, I would like to hear from the Plaintiffs and the Defendants on this.

The Defendants have asked the Court to dismiss the

negligence claim, Count 10, because it is implausibly pled.

The Court construes the Plaintiff's argument to be that so long as a single Plaintiff could bring a negligence claim, the claim should remain in the master complaint, so one Plaintiff out of well over a thousand, perhaps even over a hundred thousand if the claimants ever file in this case.

I want to understand the Plaintiffs' position as to why a claim, or how a claim should remain in the master complaint even if almost no Plaintiff could plausibly state or bring such a claim. Stated another way, if the negligence claim is implausibly pled for 99.9 percent of the Plaintiffs against the retailers and the distributors, why must the claim stay in the master complaint?

It is my understanding that if I were to find that it shouldn't remain in, that I would not be dismissing any claim from an individual case because this is the master complaint. I wouldn't be precluding such a claim from being prosecuted after remand, nor could I because I lack the authority to do so.

I wouldn't even be concluding that the retailers and the distributors no longer need to defend from Federal claims, only that they no longer face any claims in the master complaint.

What I am looking for is argument about the impact of a dismissal from the master complaint. What is the prejudice

on the Plaintiffs, if any, when a claim is dismissed from the master complaint when nothing would preclude them from seeking to press that claim at a later point outside of the master complaint should a transferee judge permit the claim to proceed for, let's say, the .1 percent of the Plaintiffs that could plausibly state it or plead it?

So, I would like to hear Plaintiffs' position on that first, and then the Defendants' position.

MR. SNIDOW: Your Honor, I think I will start with a couple of cases from the MDL panel, In re Zimmer Duron and In re Denture Cream, which say that issues are -- it is appropriate for an MDL to consider a case even if there is not a majority of overlap of identical factual issues. It is common in most, if not all, MDLs for some issues not to be raised by not just every Plaintiff, but even as these cases say, a majority of the Plaintiffs.

And I would also say that the reason why it is okay to keep these claims in the MDL is because each Plaintiff is essentially choosing allegations and claims from the master complaint to incorporate into their short-form complaint. Some of them will likely include claims against the retailer Defendants, some perhaps not, but I do not think that is a reason not to include it in the MDL because the allegations against the retailer Defendants, they do share common issues of fact.

MR. LONGER: Your Honor, Fred Longer, if I could. The way this is arranged is complicated --

THE COURT: No, Plaintiffs can answer, both counsel, and then I will turn to Defense.

MR. LONGER: I completely agree with Mr. Snidow, but let me also amplify it, which is, the whole purpose of the master complaint in this MDL for the personal injury master complaint, it is not the operative complaint, it really is just the smorgasbord by which persons who register into the MDL or file their own short0form of complaint can choose which claims they wish to assert.

So, this was, I guess, known well from the beginning of the litigation how as to we were going to proceed. There was a lot of discussion before we even got to how Plaintiffs were going to submit a master complaint. There was discussion about the amendment -- I am sorry, not the amendment, but the appending of a short-form complaint as a model, so that it was known how people were going to plead in this complaint going forward.

Your Honor has had several case management orders addressing how to have the Plaintiffs go forward going forward pleading using the master complaint as sort of the template and the short-form complaint as checking boxes and identifying what their claims would be.

The master complaint should remain as is so that in

the future, because there is no prohibition to someone coming in later and filing a new complaint, that they should be permitted to check that box.

So, you know, one point that we had -- and I am making this up, but let's say no one is here from Kansas, but a future Plaintiff may come forward from Kansas and they have to have a box to check, and that is the purpose of the master complaint. It is not the operative complaint, so it is really just the form from which others can come in and say that is what I am asserting in a very abbreviated fashion in the short-form complaint.

So it would be inappropriate, in my opinion, your Honor, for you to dismiss those claims going forward because the future is unknown as to who is going to come in and may be taking from the master complaint, and otherwise, you would be requiring them to separately plead and that defeats the efficiency of the master complaint and this is what all the parties wanted.

So, I find it to be unnecessary and pretty much -- let me just say, it is not needed to be done at this time from a procedural standpoint.

THE COURT: So I understand your response, and then I will turn to Defense, and then we'll wrap it up for lunch.

It is kind of like a case management argument, it is not a dismissal or a prejudice argument because of a

hypothetical dismissal under the hypothetical scenario I posited would be a without prejudice. You are speaking from a case management efficiency, this is the purpose of a master complaint in an MDL standpoint?

MR. LONGER: Yes. What I was saying is, I wanted to amplify what Mr. Snidow was saying, which is there is the practical impact as well, and that ought to be taken into account.

What Mr. Snidow was saying, although I think I just lost him, I don't see him on the screen. There he is.

His point is equally valid. I am just saying there are other valid reasons, and I wish the Court would take that into consideration as well.

THE COURT: Okay. From the Defense.

MS. JOHNSTON: Your Honor, Sarah Johnston for the retailer Defendants, just a few things briefly.

First, we disagree with the concept that the master complaint is meant to serve as a template for short-form complaint serving as the more operative complaint in a litigation of this size. We are months and months of Motion to Dismiss briefing in on these master complaints, and it is disheartening to hear that now they may not actually matter.

I would say that, to address your point on prejudice and using the Court's example of 99.9 percent of the claims not being able to proceed against the retailers and distributors

because they are not plausibly pled, to otherwise hold these Defendants hostage in a litigation where there are no viable claims against them, or virtually no viable claims against them, is extremely prejudiced.

Finally, substantively, the fact that Plaintiffs have had the opportunities that they have had to bring claims that they have attempted to assert here, and after this much time and this much paper, haven't been able to do it, suggests that there is not just a shotgun pleading lack of notice plausibility issue, there is a fundamental problem with the claims as they are pleaded such that it doesn't matter if we are talking about this as an MDL or an individual action, Plaintiffs have had the opportunity to state the basis for their claims, and have not done so.

THE COURT: Thank you. Mr. Kaplan.

MR. KAPLAN: Yes, briefly, your Honor. I want to echo what Ms. Johnston said and amplify it a little bit.

First, we think that nobody, that zero percent could plausibly allege a claim against the distributors, so we don't believe there should be any claim left. We are aware of no authority that allows -- legal authority that the Plaintiffs have cited to in their briefing that allows a master complaint to obviate the rules of civil procedure.

Each Defendant needs an opportunity to be able to challenge the pleadings and to extricate itself from the

litigation if there is no viable claim.

If I heard Plaintiffs correctly, it is astounding that they are suggesting that nothing can be dismissed from the master complaint and that every Defendant must remain in the litigation, incurring costs, under the theory that someone some day could come along and possibly assert a claim that no Plaintiff has yet been able to so far in the 16 months of this litigation. Thank you.

THE COURT: Thank you. Anything further?

MR. SNIDOW: Your Honor, if I may just briefly?

THE COURT: Yes.

MR. SNIDOW: I don't think there is any question that the master complaint is not the operative complaint for the simple reason there aren't any Plaintiffs named in the master complaint. That means it has to be true that when Plaintiffs file short-form complaints they are borrowing from provisions in the master complaint and, in fact, they are barred from doing anything else under the Court's orders.

As to the exact number of Plaintiffs that are going to be able to assert one type of claim against one Defendant, another type of claim against another Defendant, it is far too soon to say that. I don't think the Court, or I, or anyone else knows the exact breakdown. That is simply not a basis for dismissing the claims.

If the claims are plausibly alleged, as they are here,

they need to stay in the complaint. It is not a basis for dismissing a claim just because we don't know exactly how many Plaintiffs are actually going to incorporate those claims in their short-form complaints.

THE COURT: Okay. All right. Well done, thank you, everyone. We will break now for lunch. It is exactly when we broke yesterday.

It is about 12:24 -- it is exactly 12:24. We will come back at 1:25, it is about an hour break for lunch today.

At that point, counsel for the store brand retailer Defendants' Motion to Dismiss should be prepared and followed by the generic.

Have a good lunch. As with yesterday, it worked well, keep your computers logged in if you are going to stay around for the afternoon, turn your mute on and your video off, and we will be back at 1:25. Thanks so much.

MS. JOHNSTON: Thank you, your Honor.

(Thereupon, a short recess was taken.)

THE COURT: Okay, welcome back, everybody, from lunch. We are going to hear 3113 now, the store brand motion.

So, it looks like Ms. Johnston is back with us. Is she coming back on?

MS. JOHNSTON: Is my video working?

THE COURT: No.

MS. JOHNSTON: Okay.

THE COURT: Well, do you want to argue as is? I am okay with that.

MS. JOHNSTON: I am fine with that if you are fine with that, your Honor.

THE COURT: I am. Do you want any warning and do you want to reserve any time?

MS. JOHNSTON: I don't think so. I think this is going to be fairly quick, at least on my end, but I will try and keep track of my own time. If I get into the danger zone, certainly feel free to let me know. All right.

THE COURT: Go ahead.

MS. JOHNSTON: Good afternoon again, your Honor, Sarah Johnston on behalf of the retailer and pharmacy Defendants, specifically CVS, Walgreens, Rite-Aid, and Wal-Mart, who collectively have been deemed the store brand retailers in the master class action complaints.

I will start off by reiterating what I just said, which is that if the goal of our argument on the amended PI complaint was brevity, I think the goal here is to beat that.

The retailers' motion here is styled primarily as a Motion to Strike, and the reason we did that was to highlight an argument that is unique to the retailers that was not captured in the omnibus motions on the class complaints, to which the retailers are also a part and the arguments of which the retailers have, in fact, incorporated by reference.

From our perspective, this is a pretty straightforward inquiry, which is, did Plaintiffs have leave to do what they did here?

That is, were Plaintiffs granted leave to file amended class claims that created a new ancillary tier in the supply chain that restyled certain of the retailers as a hybrid of both seller and of manufacture, and then to bring sweeping claims against these retailers that far exceeded the Court's original orders?

From our perspective, the plain reading of the Court's order makes this an affirmative and very simple no, they did not have that leave.

The Court's order was clear, and it was that claims against retailer Defendants could not be reasserted to more than the general negligence claim across all of the complaints, and more specifically, the Court did not permit any new claims to be asserted against these retailers other than a general negligence count that was premised on Plaintiffs' temperature theory, full stop.

The Court's order that applies here did not make any distinctions regarding leave to amend in the class complaints and leave to amend in the PI complaints. No leave was granted to amend those any differently one from the other, nor did the Plaintiffs seek any leave to amend.

Rather, Plaintiffs' claim that because certain

retailers were previously named as repackagers, the Court's leave to amend granted under the order on the generic and repackagers Motions to Dismiss can be construed as giving Plaintiffs blanket authority to recast these retailers as anything that Plaintiffs want to, and to far exceed what the Court has granted as limited authority to amend.

As the pleadings here and the briefing make clear, the retailers here are not manufacturers, they are not repackagers. So, the order that is applicable as Defendants doesn't have any weight here. The only operative order that can be construed to apply is the retailer order at Docket 2513, and that order did not permit what has occurred here.

So, with that, I will stop and reserve the rest of my time. Thank you.

THE COURT: Okay. Thank you so much. And for the Plaintiffs.

MS. FEGAN: Good afternoon, your Honor, Elizabeth Fegan for Plaintiffs. It is good to see you again. Your Honor, I have a short PowerPoint, I will share my screen if that is okay. I think I can do it.

THE COURT: All right. Yes, you can, you did.

MS. FEGAN: Hopefully you see the white screen.

THE COURT: I do.

MS. FEGAN: I would like to focus for just a moment on what we are talking about here when we talk about the

retailers. We are talking about retailers that are private label distributors. This is a separate category defined by the FDA with respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug, but under whose label or trade name the drug is distributed.

We are not alleging here that the retailers are manufacturers. We are alleging that the four retailers that we have sued in the class complaint are retailers that want to sell a type of product under their own names, that they sought out manufacturers to manufacture these products according to their own specifications, they contracted for the manufacture at those specifications, and they sold these Ranitidine-containing products under their own name and only on their own store shelves.

This is different from a manufacturer brand. A manufacturer brand is a brand that is owned and initiated by manufacturers. For example, Heinz ketchup, neither Winn-Dixie, CVS, Wal-Mart sets any kind of specifications for ketchup, it just orders the ketchup and arranges it on its shelf space.

This is distinct from private label brands which are owned and initiated by retailers. The retailer decides what product it wants to sell under its brand, it decides whether it wants AAA or AA batteries, and it goes to a manufacturer and sets the specifications according to a contract.

For context here in this case, the manufacturer brand

is the Zantac brand, and the private label brands, those that are owned and initiated by the retailers, are the one that we are focused on for these counts. For Wal-Mart it's the Equate brand, for CVS, it's the CVS Health brand, for Walgreens its the Wal-Zan brand, and for Rite-Aid, it's the Rite-Aid brand. These brands are controlled by the private label distributors.

Again, just to differentiate so that we know what we are talking about here, with the manufacturer brand, the manufacturer decides to manufacture the Zantac, the manufacturer sells it to the distributors and retailers nationwide, and it sits on shelves of many different retailers, and those retailers don't pick the specifications. The only thing that they do is set the price and arrange the shelf space.

On the other hand -- and I have put the paragraph numbers here with respect to Wal-Mart, but we do the same for each retailer -- the private label distributor decides to sell the store brand Ranitidine. It goes out to a contract manufacturing organization, it determines the specifications for that product. The contract manufacturing organization manufactures that Ranitidine product for the specific private label distributor.

That private label distributor is responsible for and audits for compliance with CGMPs, current good manufacturing practices, and for quality, and that particular

product is then sold only at that particular store.

Your Honor, here the constellation of the Court's prior orders allowed us to plead these particular counts against these four specific retailers. I would like to walk through the Court's orders.

First, your Honor, what we call the retailer order at ECF 2513, that particular order recognized that Defendants can fall within more than one category of Defendant, and the Court mentioned manufacturers, repackagers, and retailers.

The retailer order specifically focused on the control that a retailer could play over manufacturer branded Zantac. For example, the Court focused on the authority of a pharmacy or retailer to change a label of a manufacturer branded drug, in other words, the liability of a retailer for drugs stocked on its shelves under other brands the Court ordered dismissed.

Similarly, the Court focused on the liability of a retailer with respect to being a dispenser of prescription drugs. Again, those prescription drugs are manufacturer branded drugs.

The retailer order did not consider, and I will concede it is because Plaintiffs did not clearly plead, the private label distributor's responsibility for a product it chooses to have manufactured, for which it sets specifications, for which it audits for compliance for CGMPs, and for which it holds out is safe and effective under its own brand's name.

Then we go to the Court's generic order at ECF 2512, that focused in part on the repackager Defendants. In preparation for today, I went back to the original consolidated class complaint at ECF 889 and confirmed that there we did define the retailers also as repackagers. In the Court's generic order, the Court granted Plaintiffs leave to replead as to the repackager Defendants with respect to non-preempted claims, for example, with respect to expiration dates.

Finally, your Honor, the Court's shotgun order, colloquially, at ECF 2515. There your Honor pointed out the way in which we had lumped Defendants together, we had created confusion, we made it difficult to understand the distinction among groups which conducted fundamentally different activities.

In the original consolidated complaint in just one place we obliquely allege that "many retailers also use their own brand names on relabeled Ranitidine-containing products." That is at paragraph 368. But we did not elucidate what that meant or how that differentiated those retailers from those who just stocked their shelves with manufacturer branded products.

Thus, the shotgun order was right on, specifically encouraging us to plead with precision and granted us leave to replead with clarity.

Your Honor, that is what we have done here, we have excised all but four retailers from the class complaints and we

have excised all claims against those retailers, except those tied to their roles as private label distributors, and rather than lump those allegations into the general fact section, we separated the allegations out as to each private label distributor, Walgreens, Wal-Mart, CVS, and Rite-Aid, starting at paragraph 912, and we narrowed the claims to ensure that we stayed within the confines of permitted claims in the generic order, expiration dates and package sizes, two areas in which we allege the private label distributors could exercise independent control or control independent of the FDA, and consistent with their Federal and state law obligations.

Dismissing the retailers at this point, based on arguments that contradict allegations of the complaint is not permissible. Plaintiffs allege that the private label distributors control the quality, the expiration dates, the package size of the products that they have chosen to have manufactured for their store brands.

Finally, Defendants attempt to seek dismissal on the Court's prior orders when these allegations were not previously tested or clarified should be disfavored. As Justice Brandeis remarked in the Eleventh Circuit, quoted in Graham versus R.G. Reynolds Tobacco, "Sunlight is said to be the best of disinfectants and electric light the most efficient policeman."

We ask that these allegations be tested by the light and not dismissed on a technicality. Therefore, we ask that

the store brand retailers' Motion to Dismiss be denied.

Thank you, your Honor.

THE COURT: Thank you. Okay, Ms. Johnston, did you have any rebuttal?

MS. JOHNSTON: Briefly, your Honor. I will start by saying that, you know, the Court's orders are pretty straightforward, they are clear. The first slide that counsel showed was the definition of private label distributor, which is 21 CFR 207.1. We highlight this in both our brief and I believe also in our reply, and where Ms. Fegan concedes that private label distributors are not manufacturers, she left out the part that private label distributors are also not repackagers.

So, again, whatever we are styling these Defendants as, they are not manufacturers, they are not repackagers. The order applicable to those Defendants doesn't apply here, and respectfully, counsel's arguments are not a whole lot more than an attempt to rewrite the Court's order as it exists.

Secondly, I would say that I think that as a matter of common sense, the idea that these four retailers are somehow unique and distinct from the larger group of retailers is just not correct. Private label products are not unique to these four retailers. Gas stations and retail stores sell private label products.

So, the attempt to turn these retailers into a unique

classification of Defendants is an end around the Court's existing orders with respect to both scope and authority that was granted.

And I think, finally, I would say that in the slides that we saw that cite back to the paragraphs of the master complaint, I think it is tellings that the support for the positions -- and I'm specifically thinking of the upside down pyramid slide. It is telling that the positions here are citing back to the allegations in the complaint themselves, not to actual legal authority.

So, in other words, based on counsel's own allegations, if we were to substantively consider these claims as accurate -- the Court is being asked to accept as true the idea that there is an entirely new group of Defendants with authority to do more respecting labeling and testing.

But where Plaintiffs only cite back to their own allegations without any legal authority cited and, you know, whether these -- whether these retailers sold private label products or engaged in a contractual relationship with an actual manufacturer of those products doesn't usurp FDA regulations and does not change the analysis that the Court has already gone through on multiple occasions.

In other words, the fact that a contract may exist that says, you know, that a retailer wants a label to say something or wants a manufacture or do something with respect

to design or testing or something else, it doesn't alter the existing regulatory landscape. And so, while there are a lot of allegations here, there is not legal authority to support it.

In closing, I will go back to the original point, which is, your Honor, you know best what the scope of the orders as written was. We, in reading those orders, believe that they did not give the leave here to add new claims against a new group of Defendants.

THE COURT: Okay, thank you.

All right. So, I have a few questions, if Ms. Fegan wants to come back on. We know Ms. Johnston is here by audio only, and that is fine. Most of my questions are directed to Plaintiffs in this regard.

So, I want to be clear, is it correct that when it comes to the AMPIC, your storage -- the Plaintiffs' storage and transportation claims against CVS, Rite-Aid, Walgreens, and Wal-Mart are brought under Count 10, the negligent storage and transportation count against retailers?

MS. FEGAN: That is a very good question, your Honor, and I would have to defer to my mass tort compatriots. I have been referring to the consolidated class action complaint where we have focused on these claims with respect to expiration dates.

I have gotten a text that says claims against the

store brand retailers may not be in the AMPIC, but I am doing this by text. I can get you an answer on this, your Honor.

THE COURT: All right. Why don't you monitor your channel of communication there and see if you can get me a definitive answer one way or the other.

MS. FEGAN: Okay.

THE COURT: Turning to the MMC, which does not name a category of store brand retailer Defendants, Plaintiffs raise negligent storage and transportation claims against the four Defendants, CVS, Rite-Aid, Walgreens, and Wal-Mart, that, to the Court's reading, are similar to the negligent storage and transportation claims against the manufacturer Defendants in the MMC. Is that correct?

MS. FEGAN: Yes, your Honor.

THE COURT: So, for the purpose of the negligent storage and transportation claims, are the Plaintiffs intending that these four Defendants be treated as retailers under the AMPIC, and to be treated similarly to manufacturers under the MMC, understanding that in your opening statements you are not alleging that they are manufacturers? So, I need clarity on that.

MS. FEGAN: Your Honor, with respect to the store brand products, we are not alleging that they are manufacturers. They did have obligations with respect to storage and transport and with respect to setting

specifications, and in the class economic loss complaint we focused only on expiration date and package size allegations. We do not include storage and transport in the economic loss class complaint, which is the citations that I provided you today.

And I am told in the AMPIC, we do not categorize the retailers that way, just as retailers and distributors in Count 10.

THE COURT: So, CVS, Rite-Aid, Walgreens, and Wal-Mart are retailers in the AMPIC under Count 10.

MS. FEGAN: I believe that is correct.

THE COURT: Okay. Are you suing the store brand Defendants in the MMC for negligent storage and transportation of the API, not only the finished Ranitidine products?

You are alleging that these stores were negligent because they did not ensure that the manufacturers cooled API in the manufacturing process. That is at like paragraphs 967, 969, 971. Can you explain that to me?

MS. FEGAN: Your Honor, I believe it is because, with respect again, the control starts at the top. The store brand retailers choose to have a particular product manufactured, they contract out for those services. As a result, they are responsible for the specifications of the particular product.

That includes storage and transport, that includes the quality of the API used, and ultimately, each of the retailers,

as we allege, has an audit process in place, some of them hire third parties to conduct those audits, but an audit process in place to ensure that the CGMP is complied with at each stage in the manufacturing process.

THE COURT: Is the answer, yes, that you are alleging that these stores were negligent because they did not ensure that the manufacturers cooled API in the manufacturing process?

MS. FEGAN: I believe so, your Honor.

THE COURT: Plaintiffs bring claims in the MMC and the ELC against CVS, Rite-Aid, Walgreens, and Wal-Mart that are based on failure to shorten expiration dates and improper product containers, like in paragraphs -- in the MMC, paragraphs 430 and 431. You do not bring claims based on failure to shorten expiration dates and improper product packaging against those Defendants in the AMPIC.

So, am I correct about that, or do you want to wait for a message on that one?

MS. FEGAN: I believe --

THE COURT: What is that show where you get a call -- phone a friend.

MS. FEGAN: Yes, exactly. I believe that is correct, your Honor. I believe that the focus here with respect to package size -- misrepresentation based on package size with respect to these four store brand Defendants, as well as -- specifically expiration date are in the economic loss

complaint.

THE COURT: So, is it correct that for the purpose of analyzing the expiration date and product container claims, the Plaintiffs intend these four Defendants be treated differently under the AMPIC than under the MMC and the ELC?

MS. FEGAN: Your Honor, I don't know that it is treated differently. Maybe I need to back up and -- I do wish I could phone a friend.

The product liability claims are broader and allow a broader range of conduct and damages than were allowed on the non-physical injury claims because of the preemption orders. What we tried to do here in the economic loss context was thread that needle and focus on that conduct which we can bring for pure economic loss.

So, it is a subset of the overall negligent conduct that is alleged in the AMPIC, so it may not be alleged with as much precision as we have alleged in the economic loss complaint, but I don't want to foreclose the idea that the negligence alleged in the AMPIC is broad as to the conduct at large that is not otherwise preempted because that is allowed in the product liability context.

We, in the economic loss complaint, I think really, because of the confusion we created on the front end and trying to plead with precision, really focused in and tried to walk the Court through the misrepresentation in terms of labeling

and packaging so that it was very clear that we were complying with or excising the preempted claims.

THE COURT: It is just a practical question, not necessarily a pleading question, but how does that play out, say, at a trial? Same Defendants, but different theories for different --

MS. FEGAN: Ultimately, if we think about what happens here, I think there was a recent stipulation among the parties that for purposes of the class claims, post class certification they will get remanded back for trial in the Defendant's home state. For example, the case against Wal-Mart in Arkansas, I think, isn't going to happen contemporaneously with or alongside a particular bellwether trial that may happen before your Honor, or that may happen in a place where someone was injured.

So, I don't think it is inconsistent with the idea here, I think it probably provides a more narrow path in discovery for the class side as we move forward with the retailers, but I think that that is consistent with MDL Court's charge in marshaling us through discovery to a place where either the cases are tried before you or remanded back to the particular locations.

So, I think it doesn't create a conflict here in this MDL.

THE COURT: Okay. You name this category of store

brand Defendants that you maintain are not exactly like manufacturers, repackagers or retailers, and you allege that the store brand Defendants had, for example, a duty to use reasonable care to adequately warn of the risk a product posed, a duty to use reasonable care in choosing and making product containers, and a duty to use reasonable care in transporting and storing products, and that would be, for example, in the MMC, paragraphs 7519, 7534, and 7548 by way of example.

What legal authority supports the existence of these duties under state law? That is, are Plaintiffs relying on authority providing duties for manufacturers, for retailers, or is there authority providing state law duties for store brand Defendants?

MS. FEGAN: Your Honor, with respect to package size and with respect to expiration date, and focusing on the economic loss complaint, we are specifically focused on Consumer Protection Act and warranty claims. In that context, the Consumer Protection Act claims, for example, the majority of them are considered what are called little FTC acts, and that is in part why we have referred here to -- and cited in our complaint, for example, at paragraph 947 provisions that are parallel both between the FDA and the FTC as to how package size can be misleading or deceptive.

That particular type of claim is then incorporated into state law Consumer Protection Act claims that recognize

that something is deemed to be misleading in the Federal context here, FTC, FDA, that is also deceptive or unfair under particular state laws.

It is not that, for example, the Consumer Fraud Act specifically named store brand retailers. They talk more generally about the type of conduct that can be considered deceptive or misleading, borrowing from Federal law, and that is what we have focused on here, your Honor.

THE COURT: Okay. Do you have authority for the proposition that non-ANDA holders have the duties of ANDA holders? I will ask the question again.

Do you have authority for the proposition that non-ANDA holders have the duties of ANDA holders?

MS. FEGAN: Your Honor, I knew this question would come, and it is one of the most difficult question, I will concede that.

There is not a direct statement to that effect, but what I do have for your Honor -- certainly what we could plead if necessary are FDA warning letters where the FDA has sent warning letters to private label distributors and specifically said things like, as a distributor that contracts with other manufacturers to manufacture a package or label, that your firm releases for distribution under your firm's name, your firm has an obligation to know what and how manufacturing activities are performed so that you can make decisions related to whether to

sell the product or release the products for distribution.

So, certainly I could provide your Honor with the FDA warning letters that incorporate this duty into its statements.

There isn't a specific CFR cite that I can give you, but we believe that -- that is why we have kind of painstakingly gone through not just alleging the duty, but alleging how that duty is elucidated through the regulations on misbranding.

THE COURT: I don't know if the answer to this question that I am about to ask is the same as the answer you just gave, but I will ask the question and see.

Do you have authority for the proposition that store brand Defendants have duties to instruct manufactures to manufacture products in a particular way, to instruct them.

MS. FEGAN: That would be the same, your Honor, in terms of the warning letters that the FDA has said, you are going out and choosing the contracting organization, you are instructing them on what you want, and you have a duty to ensure that they comply with CGMPs.

What we have also done is to back end that in our complaint, we have also then alleged what the Defendants publish, what they do to comply with those duties. So, we haven't just alleged the duty itself, we have tried to bolster that with the actual published information, for example, Wal-Mart and Walgreens have as to how they could fulfill those

duties.

We have actually alleged and quoted from their websites, we have quoted how they use third parties in their own words, so that makes it more plausible with factual allegations and actual facts of how they are fulfilling these duties to kind of show that the duties exist in the first place.

So, it is not just us saying it, it is coming out through FDA warning letters, but then also demonstrating that, in fact, these store brand retailers are taking on those duties and demonstrating how they comply with them.

THE COURT: To be clear, the legal duty that you are speaking of to warn, for example, comes from an FDA warning letter?

MS. FEGAN: No, it doesn't come from the FDA warning letter. The FDA warning letters demonstrate the existence of it.

THE COURT: But it doesn't come from a regulation?

MS. FEGAN: The regulation generally requires -- let me see. What we are generally talking about are the CGMPs, and the CGMPs require each person in the distribution scheme to comply with those CGMPs based on what they have control over.

What is important here is that the private label distributors have control at the outset of the decision not just to sell the drug, but to have the drug manufactured in the

first place.

Ultimately, although we don't have them yet -- during discovery, one of the things that we will get are the contracts that elucidate the duties and elucidate who had primary responsibility. One of the key things here is that this isn't a matter of these Defendants having just one manufacturer, they went out and chose the manufacturers and we have alleged at different times they hired or contracted with Perrigo, Apotex, Dr. Reddy and others.

They chose the manufacturer, they went out and said this is what we are looking to do. They chose the package size. That is not a manufacturer set item. And they could have chosen, for example, to only have 14 days -- they could have had package sizes of 28 pills, but they chose to, for example, sell packages of 220 pills or 90 pills.

So, the idea here is control, and that is what the CGMPs recognize and that is what we have pled.

THE COURT: So, are they contractual duties?

MS. FEGAN: No, I am sorry, they are delegating their duties through their contract with their contract manufacturing organization. Delegation of those duties doesn't remove the requirement that they comply in the first place.

THE COURT: I want to make sure I understand the answer. Where do the duties come from?

MS. FEGAN: From, in part, the Current Good

Manufacturing Practices.

THE COURT: Is there a particular provision of the Good Manufacturing Practices and a paragraph where you allege that?

MS. FEGAN: For example, we allege at paragraph 938 in the economic loss complaint, 21 CFR 210.1, which talks about CGMPs that apply to manufacturing, processing, packaging and holding. 21 CFR 211.142, which talks about warehousing, and I think the idea here is that these CGMPs don't apply to -- they don't say this only applies to manufacturers or it only applies to distributors. It is the idea that a drug through the system has to -- any person in the system needs to comply with the CGMPs.

I can't give your Honor a cite to a particular CFR that says private label distributors must X.

THE COURT: Okay. Could the particular Plaintiffs that you allege were injured by the store brand Defendants' Ranitidine products and are suing the store brands for failure to shorten expiration dates also sue the manufacturers of those same products for failure to shorten the expiration dates?

That is, is the duty to shorten expiration dates in this instance on the store, the manufacturer, or both?

MS. FEGAN: We have sued the manufacturers also for the same claims. So, immediately after our store brand retailer claims, we then allege claims against the store brand

manufacturers, the ones I just named. So, we are suing both, and it may be that the two point fingers at each other, and that will come out during discovery, and there may be a time where that choice gets made in some way or that liability shared, but certainly we understand that they both can and may play a role.

THE COURT: So, that was my last question on that topic. Does the existence of the store's duty to shorten expiration dates relieve the manufacturer of the same duty?

MS. FEGAN: I don't believe so, your Honor.

THE COURT: Okay. You allege -- the Plaintiffs allege that the store brand Defendants knew or should have known of the risk of Ranitidine degrading into NDMA such as, for example, in paragraph 939 where it is alleged that the Defendants knew or should have known that Ranitidine had an inherent risk of degrading, and it goes on in paragraph 939.

How do you plausibly allege that the store brand Defendants knew that Ranitidine products could degrade with time and exposure to humidity such that they would have known to instruct manufacturers to shorten the expiration dates and to use different product containers?

MS. FEGAN: So, I think that this is what, in part, differentiates these allegations from the discussion this morning.

Again, if there is a manufacturer branded product, I

don't think that necessarily -- well, Wal-Mart would not have opened Sanofi Zantac and tested it. Here, because of Current Good Manufacturing Practices, we have alleged, for example, that Wal-Mart requires its suppliers to submit to audits -- I am looking at paragraph 929 -- through a third party chosen by Wal-Mart to actually do these tests under the Current Good Manufacturing Practices, to ensure that they comply and to provide particular certifications.

And, for example, in 930 we talk about items showing nonconformance to standards requires submission of corrective measures. I am quoting from Wal-Mart's requirements. The idea here is that during the manufacture audits and testing are done on the product, so that, had the proper testing been done, should have revealed the presence of NDMA because we see later when Valisure does its testing and the FDA does its testing, this information comes out.

There is the opportunity -- this isn't a matter of a boxed product showing up at a retailer, and I am not saying they need to open it and do some kind of testing. I am saying that this testing was supposed to be done along the way, because there is a requirement that the CPMGs be followed, and the retailers actually say that they were doing these audits, so they should have put them on notice of the presence of NDMA.

THE COURT: You are not saying that Wal-Mart had the legal duty to test, for example, but through the Good

Manufacturing Practices, it had --

MS. FEGAN: I am sorry. It did have a duty to test its own products.

THE COURT: Wal-Mart had a duty?

MS. FEGAN: Yes, and it fulfilled that duty by hiring, according to its website, a third party to do that testing, but that was its duty and that is how it was fulfilling its duty.

THE COURT: That is the premise on which the store brand Defendants knew or should have known of the risk?

MS. FEGAN: That is correct.

THE COURT: I don't have any particular questions for the Defense. Is there anything that was said, if you wanted to just respond.

MS. JOHNSTON: Yes, your Honor, just a couple of things. The Court's questions on the interplay, or rather, the inconsistencies across the complaints is an important one.

We heard this morning in the last argument that the allegation that the retailers had any knowledge regarding the inherent risks of NDMA formation in Ranitidine, that they are not alleged to have that knowledge.

That is important because the personal injury complaints involve these same four retailers, and the personal injury complaint isn't exclusive to any Ranitidine product, it includes store brand Ranitidine. The retailers are not alleged to have any duty to test, they are not alleged to have been the

NDA or ANDA holders for any NDMA product, and they are not alleged to have the ability to exert any control on the labeling, design, testing of those products. That is consistent with everything in the master PI complaint, which is not exclusive of any particular Ranitidine product, including a private label one.

So, to now claim that these four retailers selected as selected arbitrarily among countless store brand products, not only have this knowledge that was disclaimed a couple of hours ago, but are now under a significant obligation to direct generic manufacturers to do the very things that generic manufacturers themselves can't do is really hard to reconcile.

I think that -- going to the issue of whether there is legal authority for any of these things, I don't agree with the position that there is no authority that addresses this that is on point. This is exactly the discussion that we had back in December respecting the abilities to alter the design and labeling of a product under Bartlett and Mensing.

At the end of the day, when we are talking about a generic product that is manufactured by a generic manufacturer and then sold by a retailer as a seller, then we are clearly in Bartlett Mensing territory and Bartlett and Mensing don't apply to PI cases.

I think that the recent supplemental briefing that Plaintiffs submitted on a number of issues on a number of

different states is telling here because there are states that Plaintiffs submitted authority for that expressly do not recognize the ability to sue a seller of a product simply by virtue of the fact that they put their own name on the product, a private label product.

Alabama is one of the three states that the Court had Plaintiffs brief, and Alabama is one of those states. It is a common statutory provision, it doesn't show up anywhere in Plaintiffs' briefing or in their pleadings, and it essentially ignored for purposes of making this argument, that is not supported by the regulatory landscape.

Again, we are going back to, well, if we get into discovery and contracts are produced and the contracts say that Wal-Mart said that it could make all of its packaging out of bubble wrap, that doesn't change the fact that the regulatory landscape still exists. That trumps the contract.

So, this is not an issue for discovery or for further analysis down the road; this is an issue that not only has the Court has decided, but is pretty well settled law.

THE COURT: Okay.

MS. FEGAN: Your Honor, may I respond briefly?

THE COURT: Yes.

MS. FEGAN: Your Honor, this is beyond what Defendants have briefed, and if we were going to get into state law issues, just as an example, California jury instruction civil

9.23 says that a seller who puts out as its own product a product manufactured by another has the same duty of care as that of the manufacturer.

So, it is not well settled that private label distributors have no liability. If for example, Amazon Basics, battery excluded, Amazon Basic, Amazon would be liable for that.

This goes beyond what the retailers -- the private label distributors chose to focus on here, and going back fundamentally to the briefing of these issues, we focused in large part on the Court's orders, and I appreciate that our original pleadings didn't have the clarity that they do now, but that is why we tried to go back and replead and focus.

And finally, your Honor, with respect to one thing, these four retailers were not chosen arbitrarily, they were chosen based on market share. So, this didn't make sense for us in the class complaint to go against every gas station that might sell a particular product, but we focused on the largest given that we are focused on class chains.

THE COURT: If the Court wanted to see GMP cites, are you able to give those to the Court?

MS. FEGAN: Yes, your Honor. For example, we allege them in our economic loss complaint, so I can direct the Court in the Wal-Mart section, and we do this for each retailer, but just using this as an example, at paragraphs 938, 939, and then

separately with respect to containers, that is a slightly different provision, it is not the CGMPs. It is 21 -- at paragraph 947, it is a reference to the U.S. Code, 21 U.S.C. Section 352i(1).

But they are in our complaints because we did try to walk through it because we knew this was going to be a focus of the Court.

THE COURT: All right. Thank you both very much, I appreciate it. I think we have covered store brands.

MS. JOHNSTON: Thank you, your Honor.

MS. FEGAN: Thank you, your Honor.

THE COURT: Okay. Last, but certainly not least, the generic Defendants' Rule 12 Motion to Dismiss on the ground of preemption and incorporated memorandum of law, Docket Entry 3105.

If we could have the Defense put your videos on. We have 23 minutes allotted for you, if you want to tell me how you want to divide your time.

There is 23 minutes because I understood you have an LDC and/or next gen attorney, but I don't see that attorney on the screen. Are the two of you going to be arguing?

MR. BARNES: Yes, we are actually in the same room now.

THE COURT: Okay. How do you want your 23 minutes split up?

MR. BARNES: I think we can handle the split. Halfway through my argument, Mr. Gugerty will take some of the argument, then I will end the argument. We will just reserve any time at the end to the extent we have some extra time for rebuttal.

THE COURT: Okay. So, I don't need to do anything?

MR. BARNES: Just relax and enjoy the ride.

THE COURT: Okay.

MR. BARNES: Thank you. This is the last argument of the day, and I appreciate that your Honor has had a very grueling few days, so I thought I'd start off with a little levity.

Good afternoon. This is Richard Barnes on behalf of Perrigo and co-liaison counsel for generic manufacturing Defendants.

In its preemption ruling this past December this Court applied the holding of Mensing and Bartlett for generic drug preemption and this Court summarized those holdings as follows: "If a Defendant cannot independently, and while remaining in compliance with Federal law, do what needs to be done to avoid liability under a state cause of action, the cause of action is preempted." That is at page 37 of your order.

Applying that standard, the Court held that all Plaintiffs' claims in the original master complaints were preempted because they required either warning about

the presence of NDMA in Ranitidine or else changing Ranitidine's basic design. Those actions are barred by Federal law for generic manufacturers.

Importantly, this Court did not prune away preempted warnings and design allegations out of Plaintiffs' original claims. Instead, this Court held that including preempted allegations within a count required that the count be dismissed in its entirety.

This is what is required by Bartlett. The Bartlett Court found that a New Hampshire tort cause of action required taking remedial actions, such as changing labeling or design, that were prohibited by a Federal law for generic manufacturers. The Supreme Court held that this direct conflict between state and Federal law required that the whole cause of action be preempted and dismissed.

Courts routinely hold that when a generic manufacturer cannot avoid liability under a state law cause of action without violating Federal law, the entire claim is preempted and must be dismissed.

Examples of this include the Eleventh Circuit's decision in Guarino, the Fourth Circuit's decision in Drager, and the Fifth Circuit's decision in Morris. All these cases were extensively briefed last year in connection with the first round of motions practice before your Honor.

So, even though the original complaints claims were

dismissed, this Court let the Plaintiffs replead, but it instructed them to separate each count, while clearly identifying "the elements under each state's law and what state law would require of Defendants to avoid liability." That is at page 37 of your order at Docket Entry 2512.

Each substantive count in the AMPIC asserts that state law required generic Defendants to do one of two things; one, warn consumers about all of the alleged risks of Ranitidine use, or ensure that Ranitidine products were safe from those risks.

The generic Defendants could avoid state law liability only by taking preempted actions. Plaintiffs allege that Ranitidine always risks forming NDMANDMA no matter how it is stored or transported, or when it is ingested. They allege that all Ranitidine when ingested breaks down to form NDMA in the stomach. That was the subject of our PowerPoint slide yesterday from Plaintiffs' counsel.

Plaintiffs allege that Ranitidine always risks forming NDMA no matter how it is stored or transported or when it is ingested. They allege that all Ranitidine when ingested breaks down to form NDMA in the stomach, so that the Ranitidine molecule by its intrinsic nature is never reasonably safe to use due to the inevitable degradation into NDMA.

In this regard the amended complaints do not differ from the original complaints. Because the Plaintiffs allege an

inherent design flaw, generic Defendants could only meet their state law duties by issuing a cancer warning, changing Ranitidine's design, or stopping all sales of the product.

But generic Defendants could not do any of these things without violating Federal law. That is why Plaintiffs' claims are preempted.

We saw and heard of a spoiled milk analogy yesterday from Plaintiffs' counsel, but like their complaint, this example really does not defeat a preemption. Your Honor, milk is safe to drink at the outset, it only transitions from safe to unsafe if it sits too long or it is mishandled.

In contrast here, the Plaintiffs allege that Ranitidine is fundamentally different from spoiled milk. They claim that Ranitidine is defective and unsafe from its inception. In their view, it is never safe. It is ingested, the action in the stomach breaks it down into NDMAGeneric Defendants could not avoid state law liability for a product that is allegedly never safe without taking preempted acts, issuing warnings, changing the formulation, or stop selling. That should end the case as it relates to the generic Defendants.

I will turn this over now to my associate, Mr. Gugerty, to walk through the allegations in the complaint that further demonstrate these points. Thank you, your Honor.

THE COURT: Thank you.

MR. GUGERTY: Thank you, your Honor, Sean Gugerty appearing on behalf of Perrigo. I have have a few slides that will put on the screen in a moment.

As Mr. Barnes mentioned, I am going to go through the AMPIC and show how each count against generic Defendants would require generics to take preempted acts to avoid state law liability. I will start with Count 4, negligent failure to warn through proper expiration dates.

In Count 4, Plaintiffs assert that generic Defendants should have included a shorter expiration date on Ranitidine labels. The Plaintiffs do not allege that a -- excuse me -- a shorter expiration date alone would satisfy the state law duty to warn.

Instead, in paragraph 1162, Plaintiffs assert a duty to warn of "the risks associated with the use of Ranitidine." The supplemental authorities Plaintiffs recently filed are just as clear on this point.

For example, for their Alabama sub count for Count 4, Plaintiffs cite to Richards v Michelin Tire, which held that under an Alabama negligence cause of action a manufacturer has a duty to give adequate warnings of "any dangers known to it." That is at 21 F.3d., at 1058.

And Plaintiffs are equally clear as to what risks and dangers they allege were present in Ranitidine.

In paragraph 1167, within Count 4, Plaintiffs again

allege that generic Defendants needed to warn about the dangerous risks associated with Ranitidine, and in the very next sentence they say that those risks included "the carcinogenic characteristics of NDMA."

Plaintiffs also allege in paragraph 1150 within that count that Ranitidine degrades to form NDMA as it breaks down in the human digestive system.

So, to sum up, Plaintiffs allege in Count 4 that the generics had a duty to warn of the risks associated with ingesting Ranitidine, specifically including NDMA forming and allegedly causing cancer when Ranitidine is ingested, but a shorter expiration date does not warn about that cancer risk. It is just a string of six digits.

For all the consumer knows, the expiration date could simply mean the date by which the product will lose its potency. Instead, avoiding liability under Count 4 would require a written warning that this product may form an alleged carcinogen, which Plaintiffs allege is NDMA, and because adding that type of cancer warning would violate Federal law, Count 4 is preempted.

Plaintiffs' other expiration date claims, Counts 3 and 7, have the same allegations and are preempted for the same reasons as Count 4.

Plaintiffs' negligent storage and transportation claim, Count 11, and their negligent product containers claim,

Count 9, are also preempted.

In those counts, Plaintiffs allege that generics should have taken certain actions to reduce exposure to heat and humidity, and both counts are based on a duty of care to ensure that consumers received a reasonably safe product.

For example, in AMPIC paragraph 2453, within Count 11, Plaintiffs allege that the state law duty is a duty to exercise reasonable care in the storage and transportation of Ranitidine, both API and finished products, to "ensure the products are not unreasonably dangerous to consumers and users."

And in their notice of supplemental authority, for their Alabama storage and transportation count, as well as for their Alabama product container sub count, Plaintiffs cite to this pattern jury instruction stating that, "Negligence is the failure to use reasonable care to prevent harm to others."

I want to highlight this instruction, your Honor, because you heard earlier today during the discussion on the retailers' motion, Plaintiffs' counsel showed your Honor an Alabama sub count for the storage and transportation sub count against the retailers, which is substantively similar to that brought against the generics for storage and transportation. Plaintiffs' counsel argued that the duty under Alabama law was limited to "a duty to exercise reasonable care in transporting and storing products."

Based on Plaintiffs' own submission to the Court in response to your Honor's order for supplemental authority, that is not accurate and the actual Alabama duty is much broader, a duty to use reasonable care to prevent harm to others.

The problem for Plaintiffs in both the negligent products containers count and the storage and transportation count is that the changes they call for wouldn't meet that sate law duty.

Plaintiffs incorporate into these counts an allegation that Ranitidine degrades to form NDMA over time even in "normal transport and storage," and that is at paragraph 389.

So, Plaintiffs are alleging that Ranitidine is never safe to consume, even if stored and transported appropriately.

Given that allegation, generic Defendants could not meet the state law duty to ensure a reasonably safe product unless they took other actions that would violate Federal law, like changing the drug's design, so both of those counts are preempted.

Plaintiffs also bring a negligent failure to test claim for just two states, KansasKansas and Texas. As was pointed out in the Omnibus Motion to Dismiss, neither state actually recognizes a negligent testing claim, but even if they did, it would still be preempted.

Plaintiffs assert that additional testing would have prompted actions by third parties, such as the FDA issuing a

recall, but as the Supreme Court held in Mensing, the question for impossibility preemption is whether the private party could "independently do under Federal law what state law requires of it." That is at 564 U.S. at 620.

Here, generic Defendants could not independently avoid liability under the testing claim without taking preemptive acts, so the testing claim should also be found preempted.

Plaintiffs' final remaining substantive claim in the AMPIC as to the generic Defendants is for failure to warn the FDA, Count 5. Of course, that count depends entirely on actions that FDA might have taken, which are in turn dependent on the exercise of the FDA's judgment.

So, that count, too, is preempted under a straightforward application of Mensing.

To sum up, your Honor, I have now gone through why all of the substantive claims in the AMPIC brought against generic Defendants are preempted.

Plaintiffs have also filed, as your Honor knows, an amended ELC and a new MMC. The claims in those class complaints rely on the same underlying facts and theories of liability as the AMPIC claims, at least as to generic Defendants.

So, the class complaint claims are also preempted under Mensing and Bartlett.

In addition, Plaintiffs' storage and transport claims

and their product containers claims are also separately preempted under the "major change" regulation, which is 21 CFR 314.70(b)(2), and we have outlined our major change argument in detail in our briefing.

We also fully agree with the arguments that Ms. Eisenstein went through this morning regarding Buckman preemption for Plaintiffs' failure to warn FDA claim and on Section 379r, express preemption for OTC drugs, and we incorporated those arguments into our briefing.

And now I will transition back to Mr. Barnes to address how Plaintiffs have failed to effectively rebut Mensing and Bartlett preemption of all of their claims.

MR. BARNES: Richard Barnes on behalf of generic Defendants.

Your Honor, Plaintiffs' arguments opposing preemption do not survive scrutiny under Supreme Court precedent and as applied by dozens of Federal Courts.

Plaintiffs first argue that this Court should ignore the duties and requirements of their causes of action that conflict with Federal law. So, for example, Plaintiffs argue that the Court should ignore the duty to warn of the risks of NDMA and cancer, even though that duty is an essential part of the expiration date causes of action that Plaintiffs have pled.

First, that approach is contrary to the preemption rulings this Court has already made. The Court held that if a

Defendant could not independently do what needs to be done to avoid liability under a state cause of action without taking acts that are barred by Federal law, the entire cause of action is preempted and it should be dismissed.

If you read the Supreme Court cases, which I know you have, the Plaintiffs' position lacks legal support. Plaintiffs seize upon a single statement appearing in English v General Electric, 496 U.S. at 79, that "state law is preempted to the extent that it actually conflicts with Federal law." But the Supreme Court in Bartlett quoted that very language from English and reached a completely opposite conclusion than Plaintiffs.

Specifically, the Bartlett Court held that when a state cause of action imposes a duty to take remedial measures that are barred by Federal law, the entire cause of action is preempted and must be dismissed. That is found at 570 U.S., pages 490 to 492.

In Bartlett the Supreme Court carefully analyzed "the content of the duty" under New Hampshire design defect cause of actions, and specifically with reference to a generic manufacturer. That is found at page 482. And in looking at that, the New Hampshire duty was the duty not to sell an unreasonably dangerous drug, the same duty as many of Plaintiffs' claims assert here.

Because the only way to satisfy the state law duty was

to change warning labeling or change the design, the entire state law cause of action for design defect was held preempted.

The same approach was taken by the Supreme Court in Mensing, which held that Minnesota and Louisiana state law causes of action for failure to warn were preempted because the state law duties conflicted with Federal law. Similarly, the more than 150 Federal Courts that have applied Mensing and Bartlett in generic drug cases apply preemption to dismiss entire claims, not to partially preempt certain requirements within the claims.

Plaintiffs have not provided a single example of a Court at any level that has applied conflict preemption to ignore or strike certain parts of a state law cause of action and allow a Plaintiff to proceed on what remains.

None of the Supreme Court cases cited in the footnote at page one of the Plaintiffs' opposition reached that holding.

I will spend a minute on the Cliff versus Payco case, which the Plaintiffs rely on, and that is at 363 F.3d 1113, a 2004 decision.

This case does not assist Plaintiffs' cause. Cliff involved a Florida consumer protection statute that had a long list of prohibited debt collection practices, each with its own subsection, and the Florida statute provided a private right of action to enforce any one of those subsections.

In analyzing conflict preemption, the Eleventh Circuit

limited its analysis to a single subsection at issue in the Plaintiffs' cause of action, and it found that specific subsection, that specific subsection did not conflict with Federal law so the action was allowed to proceed.

It was not material that another subsection not at issue in the Plaintiffs' cause of action may have conflicted with Federal law.

When the Cliff Court talked about applying conflict preemption on a provision-by-provision basis, it was in reference to that specific section in which the provision has its own separate and distinct cause of action. The Cliff case is entirely consistent with the generic manufacturers' position before your Honor, each substantive count requires its own preemption analysis.

But the problem for Plaintiffs is that all of their counts contain requirements that conflict with Federal law, so all of those counts are preempted.

One last thing I will comment on, your Honor, about Plaintiffs' approach to preemption is that it would also contravene the Erie Doctrine. There has been a lot of discussion about Erie yesterday and today, but the Plaintiffs, when they ask the Court to prune away preemptive elements, they are really violating Erie.

What the Court should realize is that it would become the first Court to actually recognize a new claim that

materially differs from the claims that are recognized by state courts. Plaintiffs have not shown any authority that any state would recognize, for example, an expiration date claim divorced from the actual state law duty to give an adequate warning to consumers of the risks of injury, or a negligent storage and transportation claim divorced from the duty of ordinary care to ensure a product is not unreasonably dangerous.

I'll spend a moment on the failure to warn FDA claim. I will add a few points to Ms. Eisenstein's argument this morning. I will focus on two arguments that we made in our reply brief, and there are several others, I'll refer the Court to our briefing.

But the first one is, I point the Court to the Eleventh Circuit case of Guarino versus Wyeth, 719 F.3d at 1245, and there are other Courts that have held any state failure to warn claim brought against a generic drug manufacturer is preempted. A failure to warn FDA claim is still a warning claim based on traditional state failure to warn principles and should be preempted.

No Court has held that a failure to warn FDA claim in a generic drug case evades preemption under Mensing and Bartlett. As the Supreme Court held, Courts cannot accept arguments that effectively render the whole body of preemption case law all but meaningless. This Court previously relied on that language and rejected Plaintiff's earlier

parallel misbranding theory against the generics. It should do the same for Plaintiffs' failure to warn FDA claim here.

Second, as set forth in Mensing and in this Court's own preemption order, only actions that a manufacturer can independently take to avoid liability under state law are relevant to the preemption analysis.

Of course, a failure to warn FDA claim requires a jury to speculate as to what the FDA might have done at a prior time given certain information by the generic manufacturers, so the failure to warn FDA claim is also preempted for that reason.

So, your Honor, in conclusion, Mensing and Bartlett drew a very bright line, if generics must violate Federal law to avoid state law liability, the claim is preempted.

The Court told Plaintiffs explicitly what they needed to do on repleading: Present state law causes of action with elements that generic Defendants could fully satisfy without violating federal law. Plaintiffs have failed to do that.

Instead, they presented an assortment of discrete actions that a generic manufacturer allegedly could take without violating Federal law. That is not enough. Plaintiffs expiring, storage, transportation, and packaging claims are all preempted because generic manufacturers cannot avoid state law liability unless and until they redesign Ranitidine, add a cancer warning, or stop selling. Each of those remedies are preempted as a matter of law.

For these reasons, the claims against generic manufacturers should be dismissed with prejudice as to all three master complaints.

I will reserve any remaining time for rebuttal. Thank you, your Honor.

THE COURT: Thank you. You have about a minute and a half left. Okay. From the Plaintiff.

MR. KELLER: Good afternoon, your Honor. It is Ashley Keller on behalf of the Plaintiffs, and though I can't see her, for Ms. Stipes' benefit, I want you to know that I switched to decaffeinated coffee, so hopefully that will slow me down some, but by all means, interject if I am still going too fast.

THE COURT: She will.

MR. KELLER: I hope she will, but hopefully it also won't be necessary. I will keep my own time, your Honor.

THE COURT: Okay.

MR. KELLER: Once again, Ashley Keller on behalf of the Plaintiffs.

I want to begin with the main event, which is the scope of preemption, because that is obviously a source of significant disagreement between the parties on what the state of the law is.

But let me begin instead by noting some areas of common ground. Accepting the amended master personal injury complaint as true, it is a fact that Ranitidine breaks down

into NDMA in multiple different ways, and it is a fact that NDMA exposure causes multiple forms of deadly cancer.

Remarkably, the generic manufacturers no longer dispute that there were at least some actions they could have taken consistent with Federal law that would have reduced Plaintiffs' exposure in NDMA.

In a complete reversal from the first round of Motion to Dismiss briefing, generics now concede that they could have lawfully used the CBE process to shorten expiration dates; that they were at perfect liberty to test Ranitidine to determine if it had NDMA; or that FDA regulations required them to provide adverse event data, and required -- or at least allowed them to informally correspond with the agency to apprise it of new and emerging risks.

Generics, similarly, do not dispute that each of those actions were required under the law of some or all states. The generics agree that the common law of failure to warn requires accurate expiration dates; that the common law of negligence requires reasonable testing of potentially dangerous products; and that the law of some states requires warnings to third parties as the most effective way to disseminate warnings to the end consumer.

Those points of agreement between the parties should be the beginning, middle, and end of any impossibility preemption argument. It can't be impossible to do under state

law that which the Defendant concedes is possible or even required under Federal law as well.

Yet we are still talking about preemption because the generics have, without a single solitary case in support, invoked a rule as illogical as it is imaginary. The generics claim that if they cannot meet every requirement imposed by a state common law cause of action, then it must be impossible for them to perform any requirement imposed by that cause of action.

Let me state the generics rule as a syllogism. Premise one, we can comply with some things required by state law. Premise two, we cannot comply with all things required by state law. Conclusion, we therefore can comply with no things required by state law. An amateur logician could spot that fallacy a mile away.

Since Congress passed the Pure Food and Drug Act in 1906, state tort law has complimented Federal regulations and played a crucial role in ensuring patient health and safety. The FDA has repeatedly noted and approved of this dynamic. So did the Supreme Court in Wyeth versus Levine.

But if the generics rule were accepted, it would preempt virtually every pharmaceutical case. It would disrespect federalism principles and undermine state sovereignty, and it would convert the supremacy clause from a narrow provision that displaces state law only to the extent it

differs with Federal law into a sweeping provision that shields Defendants from liability even where holding them accountable serves, rather than undermines, Congress' policy aims.

The generics are so obviously wrong that there are multiple different ways to see it. The first way is through common practice.

Federal Courts routinely hear challenges to state law either under the Federal Constitution or Federal statutes. Your Honor no doubt has experience with such challenges. Regardless of which source of Federal law is invoked, the supremacy clause is doing the analytical work in these cases, because it is the supremacy clause that makes Federal law, be it constitutional or statutory, supreme over state law.

Think about any such challenges your Honor has heard in the past. If your Honor believed that some aspect of state law was unconstitutional, would you strike down the entirety of the state law? No. Just the opposite is true.

Federal Courts routinely apply the severability doctrine, which has existed since the dawn of our republic. What is the severability doctrine? It is a presumption that, absent manifest intent by the state law giver to the contrary, the portions of state law that are preempted can be severed, leaving in place the portions that do not conflict with Federal law.

The generics say in the first page of their reply

brief, and you heard it just a few moments ago, that you can't take a blue pencil or prune away offending provisions of state law. But that is precisely what Federal Courts do, and that is the whole point of the severability doctrine. Courts only preempt any thing in state law that offends Federal law under Article VI.

The severability doctrine has been applied to state law in every area the Court can think of, from telecommunications rules to state antitrust law to abortion statutes to firearm ordinances to healthcare regulations. The bottom line is always the same, absent clear state law to the contrary, the Court severs the preempted aspects of state law. The aspects of state law consistent with Federal law remain fully in effect.

That is why binding precedent emphatically rejects the generics' newfangled distortion of preemption doctrine.

Every time the Supreme Court lays down the rule for preemption, it says the doctrine applies only "to the extent of the difference" between state and Federal law. What do the words "to the extent of the difference" even mean if not that the generics' approach is incorrect?

The Eleventh Circuit's decision in Cliff v. Payco illustrates the principle. In that case, Cliff sued a debt collector under the Florida Consumer Collection Practices Act. There were 17 different subsections of the law that regulated

how debt collectors interacted with debtors.

The Eleventh Circuit acknowledged that many of them seemed incompatible with the Federal statute. That is because Federal law gave certain protections to debt collectors who were seeking to collect student loan debt of the type that Mr. Cliff owed, but the particular provision Cliff sued under was not inconsistent with Federal law.

The Eleventh Circuit said that preemption must be analyzed "provision by provision" under the statute. Because the particular provision Cliff invoked was not preempted, his case was allowed to proceed.

That holding is incompatible with the generics' position. Recall that the generics say the entire cause of action is preempted if you can't entirely avoid liability under the relevant provisions of state law. But as the generics point out themselves on page 4 of their reply, the Florida law prohibited a person for failing to comply with any provision of the statute. Because many of those provisions did conflict with Federal law, there was no way for a debt collector to meet all of its state law responsibilities. Nonetheless, the provision-by-provision approach embraced by the Eleventh Circuit meant that Cliff's non-preempted theory based on a single breach of duty could proceed.

Now, it is true Cliff dealt with a statute, not the common law, but the preemption analysis is precisely the same

for both. To see that, let's apply the logic of Cliff to the law of negligence. As every first year law student knows, negligence is a state common law cause of action, the elements of which are duty, breach, causation, and damages.

What is the duty created by the common law? At a high level of generality, it is to behave as a reasonably prudent person would under the circumstances, the so-called reasonable man or woman standard.

Applying that high level standard to the particular facts and circumstances of any individual case, there may well be 17 different duties imposed by the common law, just as there were 17 different duties under the Florida Consumer Collection Practices Act. To name but a few common law duties that would apply to a reasonably prudent manufacturer of Ranitidine, it had a duty to warn that the drug causes cancer, and a duty to warn of the proper expiration date, and a duty to redesign the molecule to make it safer.

It is true enough that the generics could not perform two of those duties consistent with Federal law, but the crucial point is that a failure to perform any one of them is sufficient to support the element of breach for the cause of action in negligence.

It is just like the statute in Cliff where violating any one of the 17 provisions of Florida law allowed Plaintiff to obtain a recovery.

So, I want to be really clear on this point, your Honor, because it is extremely important. We are not asking the Court to redefine the elements of negligence or any other cause of action. Negligence still requires duty, breach, causation, and damages.

We are simply saying that the generics cannot ask the Court to ignore the element of breach under one theory, failure to have an accurate expiration date, just because another theory of breach, for example, failure to add a cancer warning, is concededly unavailable.

The entire cause of action for negligence does not fall to preemption just because one theory is foreclosed, just as the entire cause of action under the Florida Consumer Collection Practices Act was not preempted just because some theories were.

The Court doesn't have to speculate about this. The Eleventh Circuit has already agreed with us in Mink, which is a case the generics have invoked time and time again when they think it suits them. In Mink, the Eleventh Circuit noted that Mr. Mink brought three theories under a cause of action for negligence. Two were preempted, one was not.

Did the entire cause of action for negligence fail even though, as pleaded by Mr. Mink, the Defendant Smith & Nephew could not comply with all of the duties imposed by state negligence law? No. Just the opposite holding obtained. The

preempted theories were disallowed, the viable theory could proceed. That is Mink, 860 F.3d at 1329.

There is no doubt that we plead a non-preempted theory of negligence. For instance, in Count 3 of the amended master personal injury complaint we plead state by state that "the warnings included on each Ranitidine containing product were inadequate because the expiration date improperly instructed the Plaintiffs that Ranitidine containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time." That is paragraph 965.

We then plead in the very next paragraph that that breach of duty is what caused the exposure to NDMA for the Plaintiff that in turn caused the Plaintiffs' injuries.

Yes, the generics could not also have warned on the label about cancer while still meeting Federal obligations. Yes, their failure to do so would be considered negligent under state law. But just as in Mink, the inability to pursue that theory has no bearing on whether we have pleaded a viable, non-preempted claim that can proceed.

The final way to see the error of the generics rule is that it leads to absurd results. We illustrated this through straightforward examples in our opposition. The generics say that our examples are inapt, but they did not grapple with them at all in their reply or in the presentation that you just heard.

First, they ignore the point that your Honor allowed us to replead design defect claims against the brands. That begs a simple question: Why did you do that? Recall that in many states design defect imposes at least two different duties, to redesign an unsafe drug, which the brands could not do, and to add appropriate warnings to the label, which the brands could do using the changes being effected regulation.

But if the entire cause of action fails when you cannot meet all of the duties imposed by state law, repleading was a waste of time. Preemption was already conclusively established.

Of course, repleading was not meaningless, and not even the brands were brazen enough to move to dismiss our repleaded design defect claims. Your Honor allowed repleading because our labeling based theory is not preempted and your Honor was simply following the path set forth by the Supreme Court in Bartlett, where the Court considered both design defect theories and found both preempted before concluding that the Plaintiff lost.

So the generics have Bartlett exactly backwards. Bartlett's decision to consider the labeling theory was a waste of time if the entire design defect cause of action failed once the Court concluded that the generic could not redesign the molecule. Your order, too, would have been a waste of time on the generics' logic, but, of course, your Honor was correct to

let us replead and the generics are mistaken.

Adding to the absurdity of the generics' position, their rule would require the Court to dismiss even the core failure to warn claim against the brands affirmed by Wyeth v. Levine. If the state failure to warn cause of action requires any warning that the brands couldn't act, for instance a colder temperature range on the label, or a black box warning with a skull and cross bones, or the big bolded font example from our brief, then the entire cause of action would fail.

This despite it being undisputed for purposes of this Motion to Dismiss that the brands could have used the CBE process to add a cancer warning, as required by state failure to warn law. The generics rule would render Wyeth effectively meaningless in virtually every case, including this one. As your Honor has previously noted, that cannot be the law.

Let me transition, if I could, to the generics' argument about our storage and transportation claims. I think we are ships passing in the night here, your Honor. The generics believe that we are asking them to change the temperature range on the label. This is in their reply at 12. That is not the duty we allege. We are saying they didn't even comply with their own lab's temperature range.

Count 11 makes this clear in paragraphs 2446 and 2449 of the amended master personal injury complaint. It should go without saying that it is not impossible to comply with the

generics' own FDA approved label.

Our disagreement is starker with respect to packaging. The complaint alleges that the generics had a duty to reduce the number of pills in each container and to switch to blister packs, both of which would have reduced Ranitidine's exposure to excessive humidity.

The generics pretend that these would have been major changes that would have required FDA pre-approval. To support that argument, they selectively quote 21 CFR, Section 314.70(b)(2)(iv) to say that any change that "may affect the impurity profile" of the drug is a major change.

That is simply false, your Honor. All of the specific examples contained in the (b)(2) category are a subset of the sorts of changes that count as "major changes." The standard for what counts as a major change is stated in 21 CFR 314.70(b)(1), not (b)(2). A manufacturer needs pre-approval from FDA for changes that have "a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency" of the drug.

Respectfully, omitting the word "adverse" conceals the most important part of the standard. Changing from multiple dose packaging to single dose packaging or switching to a blister pack has virtually no chance of having an adverse effect on Ranitidine.

Yes, it can affect the purity profile of the drug, but

only in a salubrious, not an adverse way. That is exactly the sort of change that belongs under Sections 314.70(c) or (d) for moderate or minor changes that do not require FDA pre-approval. Don't take our word for it, your Honor, just ask the FDA.

That is exactly the position the agency took in its 2004 guidance document to NDA and ANDA holders. It says that the sort of changes we propose can be done in an annual report because they are minor changes that do not require FDA pre-approval.

The generics ignore this and claim that the FDA really says that if there is any doubt as to a reporting category, a manufacturer should use the higher standard, but that is not what the FDA said. It instead said that if a manufacturer is submitting more than one change at once, and one falls into a higher category and another in a lower category, the agency recommends that the manufacturer submit them both in the higher category.

That has nothing to do with ambiguity. The FDA does not consider the changes we are talking about ambiguous in the first place. The law is instead is clear. Plaintiffs allege that the generics have a duty to use safer packaging. Federal regulations allowed them to switch to safer packaging without pre-approval. It was thus entirely possible for generics to meet their state law duty without violating Federal law. There is no impossibility preemption under these circumstances.

Finally, your Honor, let me address the Plaintiffs' failure to warn through the FDA claims. We have already discussed these claims in the morning session, particularly with regard to Buckman and objectives and purposes preemption. I want to emphasize here that nothing about these claims runs afoul of Mensing and the impossibility preemption doctrine.

Once again, preemption is about comparing state and Federal duties. In Mensing, the state law duty Plaintiffs allege was to change the label of a generic drug to add a warning, but that was impossible under Federal law as it would violate the duty of sameness. The Supreme Court agreed that if the FDA were told about the drugs' risks, it might order generics to change the label.

The Court further agreed that telling the FDA about the risks was something the generics could do, but that permissible action, telling the FDA about risks associated with a drug, would not have satisfied the manufacturers' state law duty.

As the Court said, "Although requesting FDA assistance would have satisfied the manufacturers' Federal duty, it would not have satisfied their state tort law duty to provide adequate labeling. State law demanded a safer label, it did not instruct the manufacturers to communicate with the FDA about the possibility of a safer label. Indeed, Mensing and Demahy deny that their state tort law claims are based on the

manufacturers' alleged failure to ask the FDA for assistance in changing the labels." That is at page 619 of the opinion.

As the Court noted in the next page of its opinion, "The question for impossibility is whether the private party could independently do under Federal law what state law requires of it." Then at page 524 of the opinion the Court noted that where state law imposes a duty to add a safer label and Federal law imposes a duty only to warn the FDA, the Federal duty is "not a matter of state law concern."

For the 15 jurisdictions pleaded in Count 5 to the amended master personal injury complaint, state law imposes a duty to warn consumers through the FDA. As paragraph 1408 --

THE COURT: That is 20 minutes.

MR. KELLER: Very good. I will pause there and wait for your questions.

THE COURT: The Defendants have about a minute and a half left.

MR. GUGERTY: Thank you, your Honor. I just have a few brief points. So --

THE COURT: Hold on. Restate your name for the record.

MR. GUGERTY: I apologize. For the record, Sean Gugerty appearing on behalf of Perrigo.

So, Mr. Keller stated that the Supreme Court in many cases have stated preemption applies only to the extent of the

difference. The lead case that says that, and a frequently quoted one, is the English opinion, but as pointed out in our briefing, in the very first line of the English opinion it states that the decision before the Supreme Court is whether Federal law preempts a state law cause of action.

So, in line with the crystallization of the bright line rule in your Honor's preemption order, and in line with the holdings in Mensing and Bartlett, English in fact supports that preemption -- although preemption applies to the extent of the difference, the Court looks to preempt entire causes of action if there is a conflict between the duty element and Federal law, and, of course, that was the holding in Mensing and Bartlett.

The duty in Bartlett was actually to avoid -- the same as in many of Plaintiffs' counts, to avoid actions that would be unreasonably safe. In that particular instance there were two ways to satisfy that, two theories. So, contrary to what Mr. Keller is stating, our argument is totally consistent with Bartlett, it would not prevent claims against brand manufacturers.

Lastly, I would just say, your Honor, that we welcome the comparison to the Cliff case. The Cliff cause of action, as is made very clear in the opinion at page 1127, that was a cause of action brought just to enforce subsection 9 of the Florida statute, only that, and it was only that duty that the

Court in section -- subsection 9 that the Court looked at, for that reason, and because the duty was preempted --

THE COURT: Time.

MR. GUGERTY: Thank you, your Honor.

THE COURT: Thanks. Okay. What we are going to do is, I have one or two questions that I want to ask now and then we are going to take a break, our mid-afternoon break. If we could have all counsel come on the screen with your videos on. Just a few questions, and then we will take our break and I will have additional questions.

Plaintiffs, the Court wants to be sure that it understands the way you have pled your claims in the AMPIC. Take the claims for failure to warn through proper expiration dates, for example, such as -- well, Counts 3, 4, and 7. You allege that "Plaintiffs or their doctors would have read and heeded these warnings referring to shorter expiration dates. As a result, Plaintiffs would not have consumed the volume of NDMANDMA they ultimately did and would not have been harmed by NDMA." That is coming from paragraph 966.

Are the Plaintiffs alleging that the expiration date being too long was the only reason that Plaintiffs came to consume NDMA, and therefore the only reason they were harmed? And if that is not your allegation, can you explain to the Court what you are alleging?

So, if you can answer the first question first.

MR. KELLER: No is the answer to the first question, your Honor.

THE COURT: So, you are not alleging that the expiration date being too long was the only reason that the Plaintiffs consumed the NDMA and were harmed. That is not what you are alleging in that paragraph?

MR. KELLER: This is Ashley Keller for the Plaintiffs. That is correct, your Honor.

THE COURT: So, then, can you explain just that?

MR. KELLER: Yes, I can. The key word that your Honor focused on that I took to heart is "only". You were asking if the too long expiration date was the only reason that the Plaintiff consumed too much NDMA that ultimately caused their injury, and I said no to that.

We are alleging that the NDMA that the Plaintiffs consumed because the expiration date was too long was a legally sufficient cause of the Plaintiffs' injuries, and the causation inquiry is going to vary state by state. Some states have a but for cause, some have a substantial contributing factor standard for causation.

We are alleging that there was enough NDMA that the Plaintiff consumed because the expiration date was too long to be a legally sufficient cause of their injury, but it was not the only reason.

THE COURT: Okay. A legally sufficient cause for the

Plaintiff to have consumed NDMA and to be harmed.

MR. KELLER: Correct, your Honor.

THE COURT: Okay. Just so I am clear, the Court has the same question for the failure to warn claims brought only against the brand manufacturers for lack of adequate labeling, the negligent product container claims, and the negligent storage and transportation claims, such as Counts 1, 2, 6, 9, 10, and 11.

MR. KELLER: Same answer, your Honor, exactly the same answer.

THE COURT: Okay. So, if my question is, are the Plaintiffs alleging that the inadequate labeling was the only reason that Plaintiffs came to consume NDMA, and therefore the only reason they were harmed, the answer would be no, but it is a legally sufficient reason to have caused them harm.

MR. KELLER: That is precisely correct, your Honor.

THE COURT: And the same goes for improper product containers?

MR. KELLER: Yes, your Honor.

THE COURT: And improper storage and transportation conditions?

MR. KELLER: Yes, your Honor.

THE COURT: Okay. Are Plaintiffs pleading the causes of harm in the alternative? For example, you may know what I mean, but just to be sure you know what I mean, are you

pleading that Plaintiffs got cancer because Ranitidine products' labeling was inadequate, Counts 1, 2, and 6, or alternatively, because products' expiration dates were too long, Counts 3, 4, and 7, or alternatively, because product containers were improper, Count 9, or alternatively, because the products or their ingredients got too hot, Counts 10 and 11, or are you pleading that some or all of the alleged defects pled in these counts in combination caused cancers?

MR. KELLER: Your Honor --

THE COURT: Put it in your own words, because if I --

MR. KELLER: I think your words were perfectly fine, and I understood the question. I hope you don't consider this too cute of an answer. The latter is what we intended, meaning that we think each source is a sufficient legal cause of a Plaintiff's injuries.

However, you still shouldn't dismiss, even if you disagree that we haven't pleaded that adequately, because we are allowed to plead in the alternative. It is not our intention to plead in the alternative here.

We think that each count provides a sufficient basis to establish causation as a matter of law, and when multiple different sources of a harm are present factually, the law in most jurisdictions would allow a recovery, and that hasn't been briefed here, as your Honor is aware, and we haven't gone through a 50-state causation analysis.

Even if you disagree with that, we are, of course, allowed to plead in the alternative. The counts could stand as an alternative basis for the exposure to NDMA even if you didn't agree with my first proposition.

THE COURT: But as pled, it is not pled in the alternative.

MR. KELLER: That is correct.

THE COURT: Why don't we take a break until 3:30. We will have the same group come back on with your videos and I will continue with the questions. Thanks so much, have a good break.

(Thereupon, a short recess was taken.)

THE COURT: All right. If we could have our attorneys arguing the generic preemption motion come on. Okay.

All right. Most of these questions are for the Plaintiffs, actually, so you don't have to state your name each time, Mr. Keller.

Plaintiffs, Mr. Keller, most of the state law duties that you plead for the failure to warn claims require in some iteration an adequate warning of the product's risks or danger.

Would the law of any state consider an expiration date a warning of a cancer risk for the purpose of satisfying that duty?

MR. KELLER: I think the answer is yes, your Honor, to the extent that the reasoning behind the expiration date being

shortened was to aver to Plaintiffs' exposure to a carcinogen. The common law which imposes a requirement to behave reasonably on manufacturers would encompass that.

I don't think that the expiration date would have to explain with extra words why it was being shortened, even if the manufacturer would privately know those reasons. Simply shortening the expiration date could satisfy the duty.

THE COURT: And would the law of any state consider a shorter expiration date an adequate warning of a cancer risk for the purpose of satisfying that duty?

MR. KELLER: Depending on the amounts involved, your Honor, that were formed as a result of the longer expiration date and that were formed as a result of the shorter expiration date, yes, I think the law could consider that adequate.

THE COURT: Are these legal questions for a Court to decide or factual ones for a jury to decide?

MR. KELLER: The existence of duty is a question of law for the Court.

THE COURT: So, now would be the stage, at the pleading stage, for the Court to determine whether, as a matter of law, any state would consider a shorter expiration date to be an adequate warning, or even that an expiration date is a warning of a cancer risk?

MR. KELLER: To the extent that your Honor thinks that the Defendants have adequately briefed the issue and moved to

dismiss on the basis of each jurisdiction's duty juris prudence, then you could address it as a matter of law at the pleadings.

That is not how I read their papers, but it is a question that theoretically could be addressed on a 12(b)(6) because the existence of duty is a question of law, and the contours of duty is a question of law.

THE COURT: Is there any legal support that you have found in any of the allegations that have been made in the complaint upon which state duties you are relying that -- and state laws, common law, that encompass duties that an expiration date is a warning of a cancer risk?

MR. KELLER: No, your Honor. As I said before, I don't think that an expiration date is itself warning about cancer, it is warning when a consumer should not continue to take the product and it doesn't provide the explanation behind it. In this particular case, it is obviously because of exposure to a carcinogen, but the expiration date itself is just a warning to a consumer not to consume a product, but I think it is worth pausing on this point.

The common law, which is what all of these causes of action are, is usually stated by the state common law courts at a pretty high level of generality. You then have to get to the specific facts and circumstances of a particular case to apply that general standard.

For example, paragraph 964 of the amended master personal injury complaint -- I am just jumping up a few paragraphs from the one that your Honor cited before. Under Alabama law, a manufacturer has the duty to provide an adequate warning to consumers of a product's danger when used in its intended manner.

That is going to be the sorts of statements that you see throughout the common law courts. There might be slight variations jurisdiction to jurisdiction, but they are not going to get to the specific issue of expiration dates count as a warning unless the facts of a particular case presents it that way, but there is no reason to think that Alabama's Supreme Court wouldn't recognize an improper expiration date that told the consumer, you can consume this for two years, when it is only reasonable to consume it for six weeks, and say that is not tripping that general statement of the duty.

I think it is important to understand how the common law actually operates in practice.

THE COURT: So, hypothetically, if this case is remanded and you are in Alabama, and you are arguing to the jury that the Defendants breached their duty under Alabama law to provide an adequate warning, you would envision arguing to the jury that the way they violated that duty was by not having a shorter expiration date.

MR. KELLER: For this particular count, your Honor,

and the ones that incorporate expiration dates, absolutely, that is how I would envision it.

MR. YOO: Your Honor --

THE COURT: Yes. Defendants, do you want to respond on this point?

MR. YOO: Yes, your Honor, thank you. This is Thomas Yoo on behalf of the generics.

Your Honor, I think it is important to look at the allegations that the Plaintiffs have actually made with the --

THE COURT: Well, I am going to get into other allegations, and be assured that if you haven't had a chance to say what you want to say, since most of my questions are for the Plaintiffs, although I will try to give you an opportunity to respond, but for purposes of the question, if you want to respond to the particular question, I appreciate that if you want to, but I will give you an opportunity if there is something you haven't been able to say generally. I don't want to go off on tangents and lose my focus on these particular questions.

MR. YOO: Thank you, your Honor. I don't want to interrupt the Court's train of thought. I will take the opportunity later to look at the specific allegations the Plaintiffs have made, but for purposes of this issue, I will say at this time that the Plaintiffs have very much alleged that the Defendants needed to provide more than a series of

four or six digits, a new expiration date.

Their complaint is replete with allegations that the Defendants actually needed to provide a clinical warning about cancer in order to meet their state law duties.

I think there is a disconnect between what Mr. Keller is telling the Court for purposes of opposing this motion and what the Plaintiffs have actually done. I would be happy to review the specifics at another opportunity.

Furthermore, to the extent -- I think Mr. Keller is saying that the Plaintiffs would view a new expiration date as a type of warning that would somehow communicate the risk of NDMA or cancer to consumers. If that is the purposes of a new expiration date, I would dispute the notion that that is something that could be accomplished by a CBE 30.

An expiration date, as was discussed earlier with the Court, serves various purposes and is based on stability testing that goes to things like color, hardness, dissolution, et cetera, of the drug product.

The purpose of an expiration date is not to cover the risk of a serious adverse event like or cancer, and the Plaintiffs like to say, let's look at what the FDA actually did. I would remind the Court that if you do look at what the FDA actually did, the FDA did not tell manufacturers, go ahead and pick an expiration date and put your Ranitidine products back on the market.

To the contrary, as Mr. Petrosinelli covered with the Court yesterday, the FDA said we are going to do testing, we, the FDA, we are going to analyze the data. So, for now, we request that everyone who hasn't already withdrawn the product, do so.

So, this notion that we all each independently could determine what is a safe expiration date in order to prevent the risk of cancer, slap that on the side of a box and continue to sell Ranitidine, I think is a fallacy.

MR. KELLER: Your Honor, I don't think that Mr. Yoo was responding to what I was responding to. I think you heard a lot of different arguments there, which I would be pleased to respond to if you want to give me the opportunity, or we can go on to other stuff.

But I don't think that he stayed within the confines of what he promised you when he started his answer.

THE COURT: You can briefly respond to the point. I do have other questions, but if you would like an opportunity to briefly respond.

MR. KELLER: I would, your Honor, and I really appreciate that.

First, on the CBE process, the generics are now backtracking from their briefing. They made the argument about the CBE regulation and how they couldn't change expiration dates without the FDA's special permission and assistance in

the first round of Motion to Dismiss briefing. They completely dropped that in this round and now you have just heard Mr. Yoo resurrect it.

Relying on your order and Excelsior, I think that is completely inappropriate to get sandbagged by that for the first time at oral argument.

Second, we are not saying that the expiration date was designed to warn consumers about the NDMA that they were going to consume. An expiration date, just as a matter of common sense, tells a consumer, don't take the product after this particular date. It doesn't matter what the reasons are at that point. If you didn't properly warn them that it wasn't safe for whatever reason to take the product after a particular date, justified by the facts, then it was an inadequate warning.

There is a stark disagreement that we were candid about in my presentation. Mr. Yoo is correct, state law would also require the generics to do more, it would require them to add a cancer warning, but we cannot plead that against them because of preemption, and that is not what our theory is based on with respect to expiration dates.

Again, if you look, for example, at paragraphs 963, 64, 65, and 66, which is the sub count for Alabama in Count 3, the only one that I think you could fairly say suggests that they also had a duty to warn about cancer is the one that we

were talking about, paragraph 964. Under Alabama law, a manufacturer has the duty to provide an adequate warning to consumers of a product's danger when used in its intended manner.

Yes, that would also, under state law, include a cancer warning, but we weren't going to conceal that general statement of the duty from your Honor just to avoid preemption.

THE COURT: Is that an example of you couldn't make that claim under Alabama law because of the way the duty is phrased, an adequate warning to consumers of a product's danger?

You would concede, wouldn't you, that changing an expiration date doesn't warn the consumer about the risk of cancer or even -- I mean, or even not to consume, maybe, arguably, not to consume after a certain period of time, right?

MR. KELLER: I absolutely concede that an expiration date by itself would not warn the consumer of the risk of cancer, of course that is true. It would, as your Honor just suggested quite correctly, suggest to the consumer don't consume it after this date, and if that is causally connected to the Plaintiff's ultimate consumption of too much NDMA that leads to cancer, we have pled enough for causation.

Effectively what I would say, your Honor, is because the common law is stated at a high level of generality, paragraph 964, which we think states the duty under Alabama

law, actually imposes at least two duties on manufacturers.

The reasonably prudent manufacturer would, number one, provide an accurate expiration date, and they failed to do that. The breach of that by itself is enough to support the element of breach for the cause of action.

It would, admittedly, also impose a duty under purely state law to warn about cancer. We can't support that theory because it is preempted and we agree that if we tried to go to a jury with that we should get JAMOLed. That would be an improper theory and an improper set of facts to present to the jury because the inadequacy of the cancer warning is not something that the generics could fulfill.

THE COURT: You are still claiming you could pursue a non-preempted claim under Alabama law, given that Alabama duty?

MR. KELLER: Yes, your Honor.

THE COURT: So, can we assume that an Alabama jury instruction would sort of match that duty, so it would be along the lines of, you know, a duty to give an adequate warning of a product's danger, and so -- you know, most Courts don't like to modify their jury instructions, so if a standard jury instruction was given, how would that work?

MR. KELLER: That is a fantastic question, your Honor, I am glad you asked that. Typically, you are correct, you shouldn't tinker with the pattern jury instructions, but look at the Supreme Court's decision in Bates. It specifically

addresses this and says that if the Defendants are concerned that the Plaintiffs are going to try and veer into preempted territory, they are entitled to limiting instructions in the jury instructions to make sure the Plaintiffs stay in the non-preempted lane.

That is exactly what could happen here. I would also say it would be improper for us to submit evidence to the jury of any sort of failure to provide a cancer warning, and if we did, that evidence should be excluded and the jury could once again be instructed, you can't consider that.

THE COURT: That was another lingering question I had. So, would you envision that trials against generics and brands would be severed, they would have to be tried separately? Because clearly you would acknowledge that the level of evidence that you have at least -- the allegations that you have made against the brands -- but I am going to get to another point, which is that many of the allegations have also been made against the generics, but just assume for a moment everything that you have alleged against the brands and you believe is not necessarily preempted and hasn't been challenged as being preempted, that could not -- it is not relevant in a generic lawsuit, and in fact could be very prejudicial, how would that work?

MR. KELLER: That is another great question, your Honor, not least because I have to confess I hadn't even

thought of that yet.

Speaking off the cuff, I think your Honor would certainly, if it was a trial that you were conducting, would have discretion to sever under the rules for precisely the reason you just indicated. The arguments that we're permitted and the proof that we're permitted to put in varies by categories of Defendant, and if you thought it was too prejudicial vis-a-vis a particular category, you could sever them out of the case so that we could only present the evidence against them that would be appropriate under preemption.

A different possibility is that juries are typically trusted to follow the instructions that the Court gives and to adhere to what the Court says is the law, and through jury instructions you could cure any prejudice.

I would have to concede, again just off the cuff here, that your Honor would have ample discretion, if you were concerned about this issue, to say that brands and generics can't be tried together. That is only going to be relevant, of course, for a Plaintiff, at least on the personal injury side, who has consumed both branded and generic Ranitidine, but there are admittedly many Plaintiffs in this MDLMDL who fall into that dual Defendant category.

THE COURT: So, another followup question, putting aside whether brands and generics come together or they're separate, whether there are limiting instructions, modification

to jury instructions, et cetera, et cetera, there are many allegations that you have made in the complaints that are incorporated into the allegations of the causes of action against the generics, albeit you have parceled out some of them, or many of them that were in the previous complaints for reasons, I'm sure, to try to conform to the Court's orders.

But nevertheless, I mean, it is further down in my questioning, but -- I will get more particular when I come across it, but flowing from this conversation, you have charged the generics with such knowledge of -- through your allegations of the danger of Zantac, of how it was manufactured, of the heat, of the breakdown, of the degradation, the carcinogenic elements of NDMA.

I would imagine you would anticipate bringing such evidence into a trial against the generics, but yet, how does that relate to very -- so, it is okay for the generics to know what Ranitidine does in the stomach, but they can sell it anyway, just have a shorter expiration date and --

MR. KELLER: Yes, is the answer to your Honor's question. All of that evidence is relevant to what the expiration date should have been, and you will instruct, we would suggest --

THE COURT: Sorry to interrupt, but I am not just talking about evidence about expiration date. I would think that evidence about expiration date would be relevant to the

claim based on expiration date, but there is a lot of other allegations that go beyond expiration date as to the molecular composition of NDMA, what it is, what it looks like, how it acts, not just within an expiration date period after one to two months and before 24 months, everything else you have put into the complaint.

So, how do you take all of that information, impute that knowledge to the generics through the incorporation of those allegations, but proceed on fairly narrow grounds given the gravity, the enormity of the dangers and the safety risks that have been alleged in the complaint?

MR. KELLER: I completely understand, or at least I think I do, your Honor, the thrust of your question.

Obviously, we are here on a 12(b)(6), and we are pleading facts against the generics that we think help establish our claims. All of the ultimate evidentiary decisions that your Honor, or a trial court would make if these cases are remanded, as to what gets in, what is prejudicial, and what ticks off the boxes of being fairly in play for the elements of the claim is for a later day.

I actually, very respectfully, want to disagree that all of those knowledge allegations that we allege, again, just focusing on expiration dates, for example, are not relevant to just that claim. The generics' knowledge of the Ranitidine molecule, their knowledge about how it reacts to heat and

moisture under ordinary circumstances, all of that is relevant to what they should have been testing for to set the proper expiration date based on the actual life cycle of these drugs on a grocer's shelves and then ultimately in the consumer's possession.

You could import that over to the claims about their packaging, should they have used blister packs. Their knowledge of how Ranitidine degrades more quickly under conditions of excessive moisture are absolutely relevant to the fact that they should have make a change and consider to do so, using the CBE process or the minor change update in the annual report.

So, I would respectfully submit that even though those are broad allegations that accuse the generics of pretty serious misconduct, they are relevant to the narrower set of claims that we are allowed to bring against them.

I can see how logically you would say it is even more obviously relevant to the brands because they could have actually added the cancer warning, but I still think the expiration date claim, again sticking with that, ties in well with all of those knowledge-based allegations.

THE COURT: Response from the Defense. If you don't have one, that's fine. I just want to give you that opportunity.

MR. YOO: Your Honor, I do have a response. I will

try to keep it short.

This is the primary point of our motion, your Honor, that the Plaintiffs, as Mr. Keller just admitted, have made extremely broad allegations about all of it, the inherent risk, the inherent defect, our supposed knowledge, et cetera, and you just heard Mr. Keller clarify, if the Plaintiffs' pleadings weren't clear enough, that they view it as absolutely relevant to the generics, and they intend to present evidence to the jury on all of it.

So, how is this not an attempt at an end run around Mensing and Bartlett?

Thank you, your Honor, I will stop there for now.

THE COURT: All right. Let me -- for the Plaintiffs, Mr. Keller, in the AMPIC Count 9, you alleged under the law 52 jurisdictions, "A pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products." That's, for example, if we are sticking with Alabama, paragraph 2000 under Alabama law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

The Court wants to be sure that it is clear as to the Plaintiffs' position. Is it your position that Count 9 as a negligence claim, that the duty at issue is the typical negligence duty to use reasonable care, and that one factual way that the Defendants could have satisfied that duty is by

using appropriate containers for their products, or is it the Plaintiffs' position that any jurisdiction has a separate cause of action for negligent product containers with its own special legal duty?

MR. KELLER: The former, your Honor. The reason we pleaded it as the title of the cause of action negligent product containers, we were just trying to be really specific in view of your Honor's previous order and wanted to get to that level of granularity, but this is just a negligence claim.

THE COURT: Okay. Maybe I asked for this then.

MR. KELLER: I didn't say that, your Honor

THE COURT: Just following along just to be clear, same question for AMPIC Counts 10 and 11, where Plaintiffs allege "a duty to exercise reasonable care in transporting and storing products." So that would be, we will pick on Alabama, paragraph 2461 under Alabama law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

Is it the Plaintiffs' position that those counts are negligence claims with the legal duty being to use reasonable care, and that a factual way to satisfy the duty to use care is to use care in storing and transporting?

MR. KELLER: Exactly right, your Honor.

THE COURT: Okay. I never really saw that in the briefing, this notion of a factual way to satisfy a duty. It

was a bit unclear as to whether it was its own duty or, as you are saying now, it is a general duty, it is a negligence ordinary care duty, reasonable care, an ordinary manufacturer -- reasonable manufacturer using ordinary care, and that this is a factual way.

So, is the factual way to satisfy the duty becoming the duty or -- again, you have this very broad duty to use reasonable care. You have allegations about the dangerous nature and the propensity of what Zantac does, can do.

There would be many things, arguably, that, again, generics being charged with this knowledge of these dangerous propensities, would have to do to fulfill a general ordinary care, reasonable care duty, and I am not -- you know, to think of it as a one-way, a factual way as being elevated to the duty, I am just trying to see how you are connecting the dots.

I guess on that point -- I know you pointed to Mink, and I am aware that Mink was pled as a -- in the second amended complaint, Count 1, as a negligence count, and the Court did, among other things, say of Mr. Mink's three theories of liability for his negligence claim, only the manufacturing defect theory may proceed. The improper training theory is barred by Florida law and the failure to report theory is impliedly preempted.

I am not sure -- by the way, that was not an impossibility preemption case, as you know, so I did want to

hear on how you analogize Mink when it really wasn't grappling with impossibility preemption, but that is kind of a second question I had about Mink.

But I see you saying that there is a factual way that the generics could comply with a broad duty, and I see Mink as negligence and different theories of how the Defendants were negligent, and a couple theories went away, but one theory remained.

There weren't factual ways in which a duty couldn't be complied with, at least I didn't see it that way, but admittedly, you just made the argument about Mink before the break, so this was a short review, although I am familiar with the case. I don't think you had made that argument before, that I recall, so I would want to look at it with a little more time. But what is your response to that?

MR. KELLER: Sure, your Honor, a couple of different points to unpack there. First of all, the buck stops with me on the briefing, so if there was anything unclear, it wasn't the amazing team that you helped assemble, that was on me. I apologize if it was unclear.

What we are trying to aim at is not elevating a particular factual way of stating the duty, we are talking about a theory of breach, which is, of course, an element of the cause of action, and I think it is useful to think about this in the branded context, for example.

If you look at a high level, the common law of most of the states, there may be some slight variation in the word choice, but it is going to say you have a duty to reasonably act to warn consumers of known or knowable risks.

No Court is ever going to consider the particular factual warning that the Defendants are proposing in a case like Albrecht, for example. There is not going to be that level of specificity. So, it is the same point with respect to all of these counts.

The high level standard that is going to be the announcement of the common law from the State Supreme Courts and intermediate Appellate Courts is never going to be considering the particular facts and circumstances. So, that is why -- and I would commend to your Honor giving Mink a more careful look -- each of our the different possible ways of recovering against the generics is a different theory of the element of breach.

We are not trying to redefine any of the causes of action, we are not trying to say that the common law says there is such a granular cause of action that it is titled failure to have an adequate expiration date. It is still going to be just the general common law failure to warn, but there is a specific way on the facts and circumstances of this case that the generics behaved unreasonably.

The way that we are allowed to plead, for example, is

that they didn't have an adequate expiration date. That ticks off the element of breach. We still have to prove causation and damages, and all of the other things that you would expect for the elements of these torts. We are not trying to redefine any of them, but in Mink, I think that is what happened.

Mr. Mink tried to plead three different theories of negligence, the Court said one is okay, and two are not. The entire negligence cause of action didn't fall away, just the two impermissible theories were disallowed.

You are correct, by the way, your Honor, Mink was not an impossibility preemption case, but it was both an express and implied preemption case, and I would actually say that impossibility is a much more difficult standard for the generics to satisfy than the objectives and purposes implied preemption doctrine under Buckman.

Objectives and purposes lets the Court say here is what Congress was really getting at, the policy aims of Congress. Even though it is not technically possible for the Defendants to comply with state and Federal law, we are still going to find preemption because it would frustrate Congress' purpose to let the claims proceed.

Impossibility is much stricter than that, it has to actually not be possible for the Defendant to do its state law duties consistent with Federal law.

THE COURT: Brief response.

MR. YOO: Your Honor, I hope we are not confusing Mink's express preemption portion of the holding with the Mensing analysis because, as I think we went over on the last round of the Motion to Dismiss, those are distinct areas of law.

We cited Mink for the proposition that as it relates to Buckman implied preemption, the allegation that the Defendants are liable because they failed to report adverse events to the FDA is preempted under Buckman.

THE COURT: No, I know it was raised in the context of failure to warn the FDA, but it was mentioned by Mr. Keller before the break as it relates to this negligence claim and three different theories. So, I wanted to pull the case up again and pull the complaint up and try to follow his thinking.

MR. YOO: As to the broader point, your Honor, if I may, I think Bartlett included a statement about doing a straightforward analysis under Mensing to arrive at the result that the Court did.

I would say the same thing applies here. We don't need to get afield of Mensing and Bartlett and those opinions themselves in order to find the right result here because the touchstone, as your Honor knows and as your Honor pointed out in the December order, is what must a Defendant do, according to the Plaintiffs' allegations, in order to avoid liability.

It is not, as Mr. Keller suggested earlier, what could

a Defendant have done, what was possible or impossible for a Defendant to do to minimize exposure to NDMA or to mitigate risk. That is not the test. It is what is it, all of it, that a Defendant needs to do in order to avoid liability altogether, based on what the Plaintiffs have alleged.

What is clear not only from the amended complaints themselves, but the discussion we are having today, is that the Plaintiffs have doubled down on this idea that the generics are responsible for everything that they are saying about Ranitidine, a fact that as a part of the normal digestive system Ranitidine becomes NDMA. That is knowledge they want to charge us with.

Then they want to tack on expiration dating and containers and everything else.

Back to Mensing, what is it, according to the Plaintiffs, that we needed to do to avoid liability? It is to have taken care of all of that, which, as my colleagues pointed out earlier, is, in summary, either change Ranitidine, provide a cancer warning that the Plaintiffs would deem adequate, or don't sell it, and the Court ruled in December that those are all preempted claims and allegations and theories.

Here we are right back to square one, and I think it has been made clear in argument today that the Plaintiffs absolutely intend to continue to embrace those primary allegations against the generics, and that is why all of the

claims are preempted and should be dismissed.

THE COURT: Let me ask, did Mr. -- did you intend to put your video on? You should probably turn it off, then.

Mr. Yoo, if -- Plaintiffs have said they have not done this, but if Plaintiffs, hypothetically, had alleged in the alternative a narrow theory with only one thing wrong with Ranitidine, the expiration date, what then?

MR. YOO: Well, putting aside for the moment, your Honor, our argument about under Buckman, and some of the things that they are alleging being major changes that we could not independently do --

THE COURT: Let's just take expiration date.

MR. YOO: I would say this, your Honor. If the Plaintiffs -- the Plaintiffs would have to concede and make it very clear that, as to the generics, no Ranitidine made pursuant to an ANDA is defective, could not have caused the Plaintiffs' cancers and could not be a basis for liability against the generics.

THE COURT: Is that really a pleading issue, though, or is that a factual question, you know, for another day?

I am just talking about pleading right now.

MR. YOO: I believe it is both because Mr. Keller, for example, made clear today that they have pled it because they view it as absolutely relevant and they intend to present evidence on all of this at the time of trial.

I think the pleadings would have to make clear that the Plaintiffs are limiting their claims against the generics solely to cancers that they could prove were caused by some additive level of NDMA associated with an expiration date beyond the two months, or whatever it is that they were positing the other day, and that these Plaintiffs would not otherwise have gotten cancer.

Unless they are going to limit themselves to that, all they are doing is taking claims that are clearly preempted under Mensing and Bartlett, tacking on, in the words of the Guarino Court, an additional garb, and saying that those preempted claims are no longer preempted and they can present evidence on all of it at the time of trial.

MR. KELLER: Your Honor, can I respond? Because it actually may be useful to limit some of the issues between us.

THE COURT: Okay. Wait. It's Mr. Keller.

MR. KELLER: I'm sorry, Ms. Stipes.

I actually agree with Mr. Yoo, for our expiration date claims only -- let's not think about packaging and failure to warn the FDA. For our expiration date claims, we have to prove that because of the negligent or strict liability improper expiration date, the amount of NDMA that that particular Plaintiff was exposed to caused his or her cancer. So, we completely agree with that.

But there is a difference under the law for what the

duty is, which is the subject of preemption inquiry, and what evidence is admissible in a trial proceeding, which is not the subject of a 12(b)(6), this is not a Motion in Limine, but what evidence are we allowed to submit to show that the generics breached their duty and had too long of an expiration date.

So, conflating the evidence that we are allowed to present ultimately to the trier of fact, and you may decide that we are not allowed to present as much as we think we should be able to present, that is absolutely a question for a different day.

We agree with Mr. Yoo on what we are going to ultimately have to prove for these claims. We don't agree that we have to excise from our complaint all of the knowledge that the generics had because we think those are factually relevant pieces of information that would go into how they are supposed to set the expiration date.

THE COURT: Why did you limit your agreement with Mr. Yoo just to expiration? What about the other two?

MR. KELLER: Only to make sure linguistically I said it the right way. For, for example, the blister packs claim, we would agree that for that count that Plaintiff, in order for her to recover, would have to show that the amount of NDMA that she was exposed to was the legal cause of her cancer because the generics failed to comply with their duty to use blister packs.

So, for each of the claims that we are alleging against the generics, we would limit it in that same principled way.

THE COURT: Mr. Yoo, putting aside evidentiary rulings, Motions in Limine, what evidence comes in at trial, if Mr. Keller is agreeing that the intent of the pleading -- now, we are talking about in the alternative right now, because that was my hypothetical. I will pivot in a moment.

But let's assume a world in which these claims against the generics are pled in the alternative, and all that Mr. Keller is actually agreeing would be put to the jury, regardless of what evidence comes in, is did the failure to short -- the failure to shorten the expiration date caused the Plaintiff to have cancer, and that is the claim against the generic.

Is there a preemption argument there?

MR. YOO: There is, your Honor, because I don't think the Plaintiffs could survive the pleading motions because they still have the problem with their allegation that all Ranitidine to some extent turns into NDMA in the body, and that is the nature of Ranitidine, which was approved by the FDA, and we were given ANDAs to make that very molecule.

So, how could we be charged with liability for making a drug that we were authorized to make which is, because of its nature, the basis of the Plaintiffs' allegation that it exposed

users to cancer?

THE COURT: Right. I guess I am focused on, for preemption purposes, what it is that the Plaintiffs in this world of an alternative theory of pleading -- let's even assume for a moment that there aren't allegations that -- or facts that come in, evidence that comes in as to what happens in the stomach when it is mixed with nitrates, you know, whatever it is that ultimately is presented to the Court as to the evidence, the science behind why it is an expiration date causes cancer. It is not before the Court today, so I am not going there.

But, you know, this is like a one count complaint, let's pretend it is a one count complaint against the generics, and the allegation is that the generics were negligent because they didn't change the expiration date, and it would be -- you know, the Plaintiffs would have to prove that. They would have to eventually get past Daubert and whatever it is to be able to get to a jury to make the case that it was the expiration date and the expiration date only that caused the cancer.

MR. YOO: Your Honor, I would say if that is the narrow path that the Plaintiffs are going to be permitted to walk, then that should be made clear in the pleadings, because the pleadings currently are the exact opposite of that.

THE COURT: We can put that aside and I didn't say permitted. I am not saying anything. I want to know what your

legal position is on that. This is all about preemption, so I just want to understand, because it really wasn't briefed. So, what is the legal position of the generics in that world?

MR. YOO: We are, obviously, talking about hypotheticals here. I think we would have to look at that, but if what you are saying is the Plaintiffs would not be able to plead anything related to the nature of Ranitidine, which was approved by the FDA, and we were allowed to make with our ANDAs, and that it was a stand-alone cause of action based solely on an allegation that an expiration date should have been X months as opposed to Y months, then we would have to look at that, and perhaps there is an Iqbal/Twombly challenge to be made on plausibility, but we would have to assess that separately.

THE COURT: Right.

MR. YOO: That is, obviously, not what we are presented with currently.

MR. GUGERTY: Your Honor, this is Sean Gugerty for the generics. May I be heard very briefly on this point to elucidate something that was in our briefing?

THE COURT: Yes.

MR. GUGERTY: Thank you, your Honor. As I understand your Honor's hypothetical, it's a one-count complaint on expiration dates, and in the alternative to everything else. If the Plaintiffs included the allegations about notice as part

of that complaint, notice from --

THE COURT: Somebody has their audio on who should not. If you could please turn it off. Thank you.

MR. GUGERTY: If the generics were on notice that Ranitidine has a propensity to degrade based on its very molecular structure, as Plaintiffs have consistently alleged, and the state law duty is a negligence for failure to warn, there is no such thing, your Honor, as just a negligence for failing to have expiration dates, and to create such a claim would contravene Erie.

THE COURT: Mr. Keller has acknowledged there is no such thing.

MR. GUGERTY: Right. If the Plaintiffs' one-count complaint included any allegations about notice of Ranitidine's molecular structure, anything about its propensity to degrade, anything about --

THE COURT: Well, what if their argument was that was relevant to the expiration date? All they were going to argue is the expiration date, but we are not making Motions in Limine rulings today, or at the pleading stage, nor should you be expected to make such arguments, but point well taken. I think maybe there is an argument that the Plaintiffs can make that some of this stuff is relevant to how you get to being able to present to a jury why the expiration date should be shortened.

Suffice it to say that if the claim is just about the

expiration date, the Court should be allowing only that evidence which the Plaintiffs have successfully argued to the Court is relevant and, you know, not unduly prejudicial to make the claim to the jury.

MR. GUGERTY: Of course, your Honor. The basic point I was trying to make is that, based on the jury instructions and other information that the Plaintiffs recently submitted in response to your Honor's supplemental order, the duty is to warn of all the risks that we knew about.

Of course this is a factual matter and would depend, as Mr. Yoo was just saying, would depend on the nature of what was pleaded. It is a little hard to discuss in the abstract, but the point that I was trying to make is that I think it would take a very strangely constructed complaint to create a universe where the only fact, the only risk that we knew of and the only warning that we had to give would be consume this a little bit more quickly. It would sort of go completely contrary to the entire theory of this case from its very inception.

That was why I wanted to stand up and make that point. Perhaps I should sit down.

THE COURT: No, no, that is fine. I don't think that is, you know, a point that is escaping any of us, and I think maybe, Mr. Keller, that is one of the problems.

The complaint began one way, the Court made certain

rulings and, you know, to the Plaintiffs' credit, they took advantage of the ability to replead and have tried to find a way to replead that is consistent with the Court's rulings and the law as the Court has interpreted the law, but certain aspects of the complaint really haven't changed, certain fundamental allegations about the nature of Zantac, the molecule, the causation theories of cancer.

In fact, they didn't necessarily need to change for certain Defendants, like the brands, so it is not surprising that they didn't change, but we do have the brands and the generics together in the complaints, and that may be what is causing such -- so many challenges, I suppose, is that there is a lot in there. There were labeling charges initially and allegations of design defect, and much went away, but it is kind of like the essence of the dangers and the safety risks are still there.

And then again, when you go back to sort of negligence, you think of the duty to use -- a reasonable manufacturer using ordinary -- reasonable care -- it is late in the day, so I am getting my reasonable and my ordinary -- duty to use ordinary care, so it is kind of a hard concept to -- maybe this is where the Court is struggling and the generics are struggling.

How are they expected to, you know, meet the duty, the common law duty with the common law jury instruction, the

pattern jury instruction on an expiration theory only, let's say? We are in the world now of just the expiration date.

MR. KELLER: I totally understand your Honor's question. Trust me, I know that the amended master personal injury complaint has a lot of information, and it is not a tiny document. So, I acknowledge that.

A couple of points. As a technical point, I think it is important to forget what transpired before, there is only one operative complaint before your Honor, it is the amended master personal injury complaint. That is what the Defendants have moved to dismiss.

We did take very seriously your Honor's previous orders, so they can't point to theories that existed in an old document that is no longer operative. We have to take the amended master personal injury complaint on its own terms.

To the pattern jury instruction point, again, we recognize that the common law is broader than all of the things that the generics could actually do, and I think limiting instructions or modifications to those pattern instructions would be appropriate to make sure that the Plaintiffs can only obtain a recovery from a jury based on a permissible non-preempted theory.

But I keep hearing that we shouldn't be allowed to plead against them that they knew that Ranitidine was dangerous, and they knew how it breaks down, and again, I

appreciate that this is not a Motion in Limine, and I definitely don't want to convert it into one, but just thinking about how a manufacturer would set the expiration date for any product, a drug or something else, how would they do that if they don't know about the nature of the product?

If they are not charged with knowledge about how the product works and degrades over time -- some of those factual allegations have got to be relevant for the expiration dating duty, and there, in this Motion to Dismiss, is no dispute that the generics could have changed the expiration date consistent with the duty of sameness.

So, my friends on the other side keep bringing up Mensing, but they don't actually have the courage of their convictions. They are not arguing anymore that they couldn't have changed expiration date, so Federal law is off the table.

The only question is state law, and under state law, we think that the common law incorporates through reasonable behavior the obligation to behave as a reasonably prudent person would, putting an accurate expiration date on your label. They have to know something about Ranitidine to set the expiration date.

I don't know how in any product you could say that you have to put an expiration date on it, but you don't have to know anything about how the product works or degrades. That doesn't make any sense.

THE COURT: So, for example, in Florida, the jury instruction 401.4 on negligence reads "Negligence is the failure to use reasonable care, which is the care that a reasonably careful person would use under like circumstances. Negligence is doing something that a reasonably careful person would not do under like circumstances, or failing to do something that a reasonably careful person would do under like circumstances."

So, let's say the jury has read that jury instruction in Florida on the negligence claim and the argument that the Plaintiffs are making, based on their pleadings, so they would be limited to what they pled, and let's just say this world of the one-count expiration date, that is what you are arguing to the jury as why the generics failed to use reasonable care, but at the same time, maybe if you are successful in your Motion in Limine practice, all of this other evidence comes in about how Ranitidine works, and the jury comes back and finds that the Plaintiffs -- the Defendants were negligent.

How would we know that the jury was basing their finding of negligence on a non-preempted reason as opposed to a preempted reason when they are hearing a lot of other things, and then particularly if the generics are being tried with the brands? Look, most Courts don't look for ways to sever cases.

MR. KELLER: Plaintiffs don't typically like that either, your Honor.

THE COURT: They do it in certain situations, but it is not the norm. So, how could the generics be assured that they weren't being found negligent for preempted activity, because they are hearing about these things and they are maybe thinking to themselves, gee, why didn't they put a warning on there at a minimum, or why did they let it go off into the shipment process knowing what heat and humidity can do? Why did they design it this way?

MR. KELLER: That is a completely fair question and the generics would be entitled to raise it. And again, we are not at the jury instruction phase, and as you know, the law would say they have a duty to propose limiting instructions and there would be a whole process.

What I would suggest to your Honor is look at Bates, which specifically talks about this in the preemption context and says that limiting instructions are appropriate. I didn't have the Florida instructions at my fingertips, but they are very similar to the instructions that you see for negligence in other cases.

So, what I would say off the cuff to your Honor, not turning this into a jury instruction exercise, is after reading those instructions verbatim, you would then say if you were the trial court judge, and I am instructing you as a matter of law for reasons that you don't need to know about that the only way, in your hypothetical, your Honor, where we have only

brought the expiration date claim, for example, the only way that the Plaintiffs can recover is if you find that the generics breached their duty because the expiration date on the product was too long, and that was their failure to engage in reasonably prudent behavior.

If you find that they were not reasonably prudent for any other reason, you must return a Defense verdict.

You wouldn't say it exactly the way I did, there would be more careful back and forth to make sure that that language was accurate, but that is what I would envision. All the evidence that you referred to that could be prejudicial, you know, we would try, as Plaintiffs do, to get everything in, and you would say you have to put in only these things, but we would be allowed to put in evidence that showed that the generics should have had a shorter expiration date and that they had enough information to shorten their expiration dates.

We don't have to argue anymore about exactly what the contours of that are, but I still would submit to you that it has to be something, they have to be charged with knowledge of how Ranitidine works and degrades and how it operates in order to set an expiration date.

And by the way, the FDA presumes that ANDA holders, just as much as NDA holders, have that information. That is why they are allowed to have separate and shorter expiration dates from the reference list of drugs. So, we are not

conjuring this out of thin air; the Federal regulatory landscape requires them to have this sort of information.

THE COURT: Just back to in the alternative, you haven't plead in the alternative. You said you could or you would, if need be. What do you think, given this discussion -- and then I will turn this question to the Defense -- the result of pleading in the alternative versus not pleading in the alternative has on the topic of preemption and -- I am hearing you say each independent theory stands on its own and supports a breach of a duty that causes cancer.

It is not as if you would be seeking multiple recoveries for a claim. So I am trying to understand, is there prejudice to the Plaintiffs to plead in the alternative? And then I am wondering whether it is the Plaintiffs or the Defense who answers this question. What does pleading in the alternative do or not do to address the preemption issues we have been discussing?

Maybe Plaintiffs first and then Defense.

MR. KELLER: Sure, your Honor. Let me start with the preemption question. Whether we plead in the alternative or not I think has no bearing on preemption. The claims that we allege against the generics, your Honor will either find that they are impossible or expressly preempted, or you won't. Hopefully you will say that all of the ones we pleaded against the generics are not preempted because that is what we think is

supported by the law.

But whether they can comply with their state duties and their Federal duties simultaneously, that is a pure question of law for the Court and it doesn't depend on whether we are offering these as alternative theories.

The pleading in the alternative I think goes to the element of causation. To the extent that your Honor believed that the only plausible way for us to recover would be to say it was either the expiration dates or the blister packs, but not both, that is a causation issue, and respectfully, I don't think that issue has been briefed by the other side because this is a preemption argument. So, I think that they would agree with us that the alternative issue is not a preemption concern.

If you did want briefing on that, we would show your Honor that the law of many states says that where there are more than one cause of an injury, each one of which is sufficient to provide enough exposure to, for example, a cancer causing compound to cause a Plaintiff's cancer, each one of those is independently actionable.

That is a pure question of state law. We could get into the restatement, it is Restatement Third of Torts, physical harm, Section 27, comment D and comment G, and many states have adopted that. I don't think that that is an inquiry that we need to go into further here because it is not

properly teed up before your Honor.

THE COURT: Okay. From the Defense.

MR. YOO: Your Honor, I think it is clear from everything that has been said and the allegations that Plaintiffs have made that it is not possible for any Defendant to meet the alleged duty of reasonable care to ensure that consumers are not exposed to the alleged inherent risk of Ranitidine regarding a carcinogenRanitidine and cancer through expiration dating. Even Mr. Keller stated during this argument that an expiration date is not a cancer warning.

So, I think the Court can make the conclusion under Mensing, and Mensing looked at what it would take to satisfy the alleged state law requirement, and what would a Defendant have to do to avoid liability.

I think the Court could look at everything that has been presented to the Court and make the determination that it is impossible through expiration dating to meet this alleged duty of reasonable care to ensure that people are not exposed to the risk of cancer with regard to a drug that is alleged to inherently turn into a carcinogen in the human body.

THE COURT: Okay. Let me just -- I have a couple of questions here. Plaintiffs, you mention on page 20 of your opposition to the motion the generics' ability to satisfy a portion of the duty. You say Plaintiffs only allege the duty or a portion of the duty that could be satisfied.

What did you mean when you said "a portion of the duty?"

MR. KELLER: This is the part of my previous answer, your Honor, when I said that state common law typically announces the duty at a high level of generality and then basically creates different sub duties for the specific facts and circumstances. That is what we meant by a portion of the duty.

Behave as a reasonably prudent person would in particular circumstances is going to impose a lot of different duties on a manufacturer of a pharmaceutical product, of which expiration dating and proper packaging are two examples, but they are not the only examples.

THE COURT: Thank you. You mentioned reducing risks and reducing the danger, for example, on pages 14 and 15 of your opposition where you say they could have done something, reduced risks and saved lives, and you say these simple measures would have reduced the danger.

Are you arguing that any state imposes a duty on drug manufacturers to, for example, reduce the risk or mitigate harm, or is it your position that a state imposes such a duty, you know --

MR. KELLER: Yes, your Honor.

THE COURT: Have you pled that?

MR. KELLER: I think that states requiring parties

like the Defendants to behave reasonably requires them to take action that reduces risk, even if they can't eliminate it entirely. So I think that is completely compatible with state law, what a reasonable person would do.

THE COURT: So, that is also under the ordinary negligence standard?

MR. KELLER: Yes, your Honor. I think ordinary negligence law would impose that obligation.

THE COURT: So, just to reduce the risk, but not to get rid of it altogether?

MR. KELLER: Yes, your Honor. I think there are lots of circumstances where you can't completely eliminate risk, and state law would then say reduce it.

THE COURT: Does Defense have a response?

MR. YOO: Your Honor, that is not any law the Plaintiffs have cited. Even the things we have looked at during the hearing, everything from the jury instructions to what Plaintiffs have alleged is a duty on the generics, according to the Plaintiffs, is avoid, prevent, make sure consumers are not subjected to the risk of an unreasonably unsafe product. No one gets a pass because they tried and mitigated some of the risk.

The test is whether a Defendant acted reasonably and prevented a Plaintiff from being subjected to an unreasonable risk.

This takes us right back to Mensing, your Honor. The test is what must we have done to avoid liability, to eliminate that risk to the Plaintiffs altogether, not simply to reduce (inaudible) -- mitigate some of the alleged harm.

MR. KELLER: Your Honor, can I offer a very simple example that used to be the sort of thing that was in the pattern complaint in the Federal rules before Iqbal and Twombly?

THE COURT: Yes.

MR. KELLER: Imagine someone is driving and they are speeding, and then they swerve into my lane without using their blinker and they cause me injury. I can sue them for breach of their duty under common law negligence for not using their blinker. I don't also have to sue them for speeding as my theory of recovery, even though they were also speeding, and that would also be a breach of the common law duty.

This is ordinary practice in State Court, Plaintiff gets to choose the theories of recovery that they are going to pursue, and preemption doesn't change that.

The entire cause of action from negligence in that hypothetical wouldn't fall away because I didn't also sue for speeding.

MR. GUGERTY: Your Honor, may I briefly be heard in response to this? Sean Gugerty on behalf of generics.

THE COURT: Yes.

MR. GUGERTY: I do agree that Plaintiffs get to choose the causes of action that they bring under state law, but I don't think -- and I believe that Erie stands for the proposition that neither this Court nor the Plaintiffs, through the type of judicial admission that they offer in their brief that your Honor was asking about just a moment ago, can rewrite what those duties would be within a particular cause of action.

I think that is effectively what Mr. Keller is proposing with some of his reconstruction of just expiration date count that is completely divorced from the underlying duty to warn, or just change storage and transport practice, that is divorced from the duty to deliver a reasonably safe product.

I don't believe that the Plaintiffs have shown in their AMPIC, in their pleading -- excuse me, in their briefing to this Court, or in their supplemental responses to this Court's order that there is any state that recognizes a duty just to reduce harm.

I think, in fact, that several of the jury instructions and cases submitted in response to your Honor's supplemental order are directly to the contrary of that. The duty is -- for the failure to warn is to warn of all of the risks, as one of the Plaintiffs' cases say, or to deliver a product that is safe from any latent dangers, as another case stated.

Thank you, your Honor.

THE COURT: Thank you. Okay. Plaintiffs, generic Defendants argue on page 31 and 32 of their Motion to Dismiss that all of the claims against them in the ELC are necessarily preempted if the claims against them in AMPIC are preempted.

Do you agree with that?

MR. KELLER: I believe I do, your Honor.

THE COURT: Your claims against the generic Defendants in the ELC for OOTC products are based on improper expiration dates and product containers.

When it comes to express preemption under 379r, do you maintain that the expiration dates and product containers rendered Ranitidine products misbranded?

MR. KELLER: I would maintain, your Honor, certainly that the expiration date rendered the product misbranded because the label would be false or misleading in any particular.

THE COURT: What about product containers?

MR. KELLER: Based on your Honor's previous order which limited the scope of misbranding to just the label, I think I would have to concede that the product container is not the label itself, and so the product container would not count to satisfy the misbranding definition.

THE COURT: Anything that Defense wanted to say in response to any of the last answers?

MR. YOO: No, your Honor.

THE COURT: Okay. All right. Here is what I am going to do. I think that it is a good time to conclude for today because I think we've gone over a lot, and in fairness, I want to give you a break because it has been a long time that you have been on call to answer my questions.

You have been patient and I appreciate that, and I think that some things have come up that maybe hadn't really been delved into, you know, in the four corners of your briefing, and maybe much prompted by the Court's question.

I had asked the parties, all parties, to keep the Monday open in case the Court had any followup questions, and I think what I would like to say at this point is, really, actually only as to this last motion might the Court -- might the Court have followup questions for Monday.

There are no other counsel for any other parties, for any other motions, in other words, that need to be on standby for Monday, but I would like to ask all counsel who have been responsible for arguing this last motion of the day, the generic motion, if you could be available beginning at one o'clock on Monday.

I will endeavor to try to get word as soon before then if I know that we are not going to need to have you come back to answer any questions.

We would be using the same Zoom link because that was already part of the plan, and that was already set out, so

nothing new, same instructions.

I just think it would be a good idea to take a break now and I would just hate not to have you on standby, and then there is a question or two that I wanted to get clarification on and I didn't have the opportunity to do so. By the same token, it may be that you have exhausted the topics that I wanted to cover and there will be no need.

Does that sound like an acceptable plan to counsel?

MR. KELLER: Yes for Plaintiffs, your Honor

MR. YOO: And for the generics as well. Thank you, your Honor.

THE COURT: Okay. Assume you will log on at 1:00, until or unless I communicate, in all likelihood through the special master, that it won't be necessary. Okay?

MR. YOO: Yes, your Honor.

MR. KELLER: Yes, your Honor.

MR. YOO: Thank you very much.

THE COURT: Okay, thank you all. That will conclude our hearing for the day. Everybody have a very nice weekend.

Again, for those who argued today, thank you, and everybody did a very, very good job, I appreciate it. I appreciate the patience and time that has been devoted to arguing the motions that I know has taken a lot of time over these last two days.

Thank you, and have a great weekend.

(Thereupon, the hearing concluded.)

* * *

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

Date: June 10, 2021

/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter