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
December 15, 2020

MOTIONS TO DISMISS HEARING (through Zoom)
BEFORE THE HONORABLE ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

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THE COURT: Good morning, everyone. We are here for the second day of hearings in the Motions to Dismiss that have been filed in In Re: Zantac Products Liability Litigation, MDL number 2924.

A couple of matters I want to take up first. For all presenters, following your presentation, if you would kindly email your presentation if you have written it out, I suspect most of you have, to Ms. Stipes, Pauline Stipes, she is our court reporter. Her email address is pauline_stipes@flsd.uscourts.gov.

The reason for that is, while she, of course, is transcribing only that which is said in your presentations, and certainly is not relying upon your written presentations because you may have varied from it, if there is a question she has about the pronunciation of a name, or a case, reference to your presentation will aid her to ensure she will put together the most perfect record possible. Those are her standards and those are my standards and I am sure that is what each of you want as well.

We don't need them before your presentation, but after you have given your presentation, if you email them to Mrs. Stipes and this will aid her so there are as few unintelligible or inaudible references in the record as possible. Zoom has worked very well for all of us during this litigation, but it is not perfect.

When attorneys are here in court and Ms. Stipes is not able to hear something, she is able to stop me or counsel and we can get it corrected right in the moment. With the Zoom setup, we are separated, in fact, we have a plexiglass between us, it is not so easy. I appreciate your accommodation, and I expect that everybody will comply with that request.

MR. GILBERT: Judge, would you repeat that email address please?

THE COURT: Pauline_stipes@flds.uscourts.gov.

Now I would like to take up one last matter that we were going to circle back to today. I think Mr. Agneshwar is going to be able to answer that question and we wanted to get to that this morning. As I understand, you also have another matter, so I hope this doesn't pose any conflict for you, it is just the one remaining question.

Good morning, Mr. Agneshwar, how are you?

MR. AGNESHWAR: I am good, your Honor. How are you?

THE COURT: Good. Thank you. Happy holidays, I see a festive tree there in the background.

So, for the benefit of the record, my last question yesterday when I was addressing the issue of innovator liability and speaking to Mr. Cheffo, I had asked the following question: According to paragraph 35 of the master personal injury complaint, Defendant Patheon Manufacturing Services LLC, referred to by the Plaintiffs within the category of Sanofi

Defendants, is a citizen of Massachusetts because its sole member, Thermo Fisher Scientific, Inc. has its principal place of business in Massachusetts. Thus, Massachusetts would have the general personal jurisdiction over Defendant Patheon Manufacturing Services. Massachusetts is one of two states that recognizes Plaintiffs' theory of liability, albeit in a limited way, Plaintiffs must allege Defendants acted recklessly.

My question was, do you -- and whether that is directed at you, Sanofi, Patheon Manufacturing LLC, but ultimately the question is, does Patheon Manufacturing Services LLC dispute that it is a citizen of Massachusetts?

MR. AGNESHWAR: Yes, your Honor, so I am Anand Agneshwar, and I represent Sanofi. The jurisdictional allegation about Patheon's home are correct, about its principal place of business and state of incorporation. What is not correct about the complaint is any suggestion that Patheon is part of Sanofi.

Sanofi and Patheon are separate companies. Sanofi is incorporated in states other than Massachusetts, and Sanofi is the brand manufacturer that joined in the innovator liability motion. Patheon manufactured some product for Sanofi, an arm's length business relationship, but it is just not part of the Sanofi entities.

The real problem with these allegations, it is not

correct to allege that Patheon is part of the Sanofi family.

THE COURT: So, Sanofi is disputing that Patheon is part of the Sanofi affiliates, but you are representing that Patheon is a citizen of Massachusetts.

MR. AGNESHWAR: That is correct, but I think it is irrelevant to this particular motion because innovator liability, as the Court well knows, is a theory that is directed at the NDA holders of the product, the brand manufacturers. Patheon was never a brand manufacturer or an NDA holder of the product. It's not an innovator. So, the motion doesn't apply to Patheon at all, so its residence doesn't matter to the scope of this motion.

THE COURT: Okay. Okay, all right. Thank you.

That takes care of that followup question, I appreciate it. Thank you for making yourself available this morning.

MR. AGNESHWAR: Absolutely, your Honor. Thank you.

THE COURT: Take care.

Now we are going to turn to the motions for today. I have received the revised schedule that the parties have agreed to in terms of your allotment of time, so thank you for agreeing. I always like it when parties can work things out together, it is important to me, it is important to the litigation, and hopefully you value the importance of it as well.

The first motion that the Court is going to hear argument on this morning is Docket Entry 1582 it is styled The Generic Manufacturers and Repackagers Rule 12 Motion to Dismiss on the Grounds of Preemption and Incorporated Memorandum of Law.

And I see that Defendants have been allotted 23 minutes and the Plaintiffs have been allotted 20 minutes.

So, if I could have the Defendants turn -- counsel for the Defendants turn your audio and video on and introduce yourselves for the record. Then let me know if you want to divide your time up; and if so, how, and whether the Court giving you any warnings is of any help to you.

MR. BARNES: Good morning, your Honor, this is Rick Barnes, I am appearing on behalf of the generic manufacturers. I will be taking about 18 to 19 minutes. My associate, Mr. Gugerty, will be handling the arguments pertaining to loss and the repackager preemption argument, and Mr. Yoo will take the lead on responding to your Honor's questions, and if there is any time for rebuttal, he will handle that. I anticipate there will be limited time for rebuttal.

THE COURT: Is that Mr. Gugerty in the room with you?

MR. BARNES: Yes, your Honor.

THE COURT: Is Mr. Yoo just going to come on for the questions?

MR. BARNES: Yes, your Honor.

THE COURT: So, how did you want to divide your 23 minutes in terms of -- I might have missed that -- your opening versus rebuttal?

MR. BARNES: I think I am going to take about 18 minutes and Mr. Gugerty will take the rest. If we have any time left, it will be two minutes for Mr. Yoo. I do not expect there will be any time left over, so let's not plan on any rebuttal. It will probably be spent in the arguments. Mr. Gugerty will probably take about four to five minutes on the remaining arguments. I am handling implied preemption of state law claims.

THE COURT: All right. Did you need any warning or do you have that under control?

MR. BARNES: I've got it under control, your Honor.

THE COURT: All right. Take it away.

MR. BARNES: Good morning, may it please the Court.

The generic manufacturers' Motion to Dismiss on preemption is based on the two landmark Supreme Court decisions that Your Honor is very familiar with, PLIVA versus Mensing and Mutual Pharmaceutical v Bartlett. Your Honor, as we set forth in our briefing, the Supreme Court established a very straightforward analysis for implied preemption as it relates to generic drugs and generic manufacturers.

The analysis goes like this, it's a three-step inquiry. First is, the Court has to examine the requirements

that exist under Federal law as to the generic manufacturers, so what does Federal law require.

Second, the Court asks what the generic manufacturer did do to avoid liability under the Plaintiffs' state law claims.

And third, if Federal law prohibits a generic manufacturer from independently taking the action needed to avoid State Court liability, then the claim is found to be preempted.

Under Federal law, the duties for generics are very clear, they are set forth in the briefing, and yesterday several times counsel referred to the duty of sameness and that.

So, I won't go through the duty of sameness, your Honor is well acquainted with it, but, essentially, it requires the generic manufacturers to follow precisely the brand manufacturers' labeling and to match in equivalence the design of the molecule, in this case Ranitidine. So there is no deviation, the duty of sameness requires a faithful following of the brand label and the molecule.

I think it is conceded that the accuracy and adequacy of the label for Ranitidine is the sole responsibility of the brand manufacturers. The generic's duty is simply to follow the brand. Yesterday, I think Plaintiffs conceded during argument that the brands were the only ones who could change

the label and they are obviously correct in this.

So, in Mensing and Bartlett the Supreme Court held that any Supreme -- I am sorry, any State Court law claim that required a generic drug manufacturer to change the warning labeling or the formulation of a drug conflicts with the duty of sameness and is impliedly preempted. This is called impossibility preemption.

The Bartlett Court, when it addressed this issue, added an additional holding is that the Defendants cannot comply with any State law duty and the Federal law duty by simply not selling, or ceasing to act, or never selling the medicine at all.

So, Mensing was decided nine years ago and Bartlett was decided seven years ago, and in the intervening time, your Honor, there have been at least 125 Federal District Court decisions that have dismissed claims against generic drug manufacturers on implied preemption grounds. At last count, there have been 25 Federal Circuit Court decisions that have affirmed such dismissals.

I think it is fair to say, when you spend the time reading the decisions, it is fair to say that the Courts apply Mensing and Bartlett broadly to give effect to the supremacy clause.

What they do is they perform a functional analysis, really, they look at the complaint and they say, well, at their

core what are they alleging? And usually these claims really fall within adding new warnings, changing a drug's design, and manufacturers never should have participated in manufacturing and selling the product.

A good example of how the Federal Courts look at that is the Eleventh Circuit's decision in Guarino versus Wyeth and the quote goes something like this, no matter the garden in which the Plaintiffs present the causes of action for warnings, they all are barred and cannot escape Mensing's grasp.

I think the Courts have basically seen the three-step analysis and have applied them uniformly to find preemption in favor of the Federal law of supremacy.

All three complaints here -- I want to go back first to the principles, if I might, your Honor. We are here today because the allegation is that every single Ranitidine product, every dose, every drop of syrup, every tablet, every capsule is defective because of chemistry, it is alleged to have an inherently unstable design, molecule. The molecule is foreordained to degrade and it does so, according to the complaint, under normal anticipated circumstances.

This is the core allegation that set off this MDL, is the very nature of the Ranitidine molecule itself.

With this core allegation as the factual predicate the Plaintiffs' claims are basically one of three theories. Given the inherent propensity of this molecule to degrade the generic

Defendants should somehow warned of it, that is number one.

Number two, they should have changed the design of the drug and should have changed the manufacturing process to prevent the inherent flaw from occurring.

And three, it is so dangerous that generics should have stopped selling Ranitidine or never have sold it in the first place.

All of the causes of action, your Honor, basically fall within that framework.

So, as we go through this, just remember this -- the fundamental feature of this case is the uniformity in the design being the issue, there is no exemption, there is no safe harbor, no period, no formulation that they claim is reasonably safe.

With that, let me move on to another subject, and that is, so, given the clear holdings and the uniform application in Federal Courts of Mensing and Bartlett to dismiss product liability claims against the generics, how can the Plaintiffs proceed here?

If you go through the complaint, all 15 causes of action, and you go to the case law, every one of them have been found to be preempted and dismissed as a matter of law. What they do is, they say, well, there are alternate theories of liability that are distinct from the holdings in Mensing and Bartlett, and that these theories actually are so different

that they are immune from the implied preemption case law.

The Plaintiffs' briefs are well presented, but to read their briefs one gets the impression that these theories have somehow escaped the gaze of Federal Courts and the Plaintiffs Bar in this country over the past nine years, and actually all of these theories have been considered and uniformly rejected.

So, while the arguments are presented with a level of certitude, that doesn't exist in the case law at all.

Starting with Mensing and continuing to the present, Courts time and time again have declined these theories, they are always found to be preempted. In reality, Courts recognize that these are usually a product of pleadings that are created to find a loophole, to find some end run around the Mensing and Bartlett decisions.

Simple fact, your Honor, Plaintiffs have failed to produce a single case in which a Court, faced with a Motion to Dismiss a generic drug case, has accepted any of the Plaintiffs' alternate theories sufficient to overcome implied preemption under Mensing, Bartlett, and the substantial Federal Court jurisprudence on implied preemption.

Your Honor, I think it is fair to say that the Plaintiffs are asking this Court to become the first one anywhere in the country to accept this approach and find a loophole, find an alternate theory to let their state law claims survive.

I would like to spend my time walking through these alternate theories, and there are, to our reading, four basic approaches that the Plaintiffs are urging the Court to accept.

The first one is a duty to warn the FDA. There is a duty to warn third parties, in this case the Food and Drug Administration.

Reframing their failure to warn case in this manner basically is their way of saying that, well, we have -- we have our way through, but Mensing actually dealt with this issue and explicitly rejected an alternate theory of failure to warn the FDA as a premise of a state law cause of action, and Mensing does this at 564 U.S. at 620 and 621.

This principle was also rejected in the Allbright case from the Southern District of Florida, rejected the same failure to warn the FDA theory, and that's Allbright versus Teva, Southern District of Florida, 2017.

The authorities that Plaintiffs provide the Court in support of this are from the express preemption jurisprudence in the medical device context and the context of parallel claims, and that is far afield from the supremacy clause jurisprudence and implied preemption.

Your Honor, express preemption is express because it is expressed in a Federal Statute, it is a creature of statute, and Courts construe the intention of Congress in the words of a statute.

The words at issue here, the medical device amendments, is that -- the express preemption clause is 21 U.S.C. Section 360(k). It provides that only state laws that are different from or in addition to Federal law are preempted.

So, Courts in the medical device field looking at this specific statutory language have held that state laws that are merely parallel, which is construed as being identical to Federal law as to medical devices are not expressly preempted. The word "parallel" in this context means parallel between the state law and the Federal law. So, it arises from statutes and it arises from the express intention of Congress.

This concept of express preemption and parallel claims and parallel lawsuits have no application in implied preemption. It is foreign to the supremacy clause where that language does not appear anywhere. The supremacy clause deals with the superiority of Federal law as it relates to conflicting state law, and in that situation state law gives way.

So, all of these cases in their brief that they insert into the implied preemption arguments simply have no --

THE COURT: Wait, Mr. Barnes, just hold on one moment.

If there is somebody here, a participant who has not muted your audio, please do so. We hear noise in the background. Thank you.

MR. BARNES: Thank you, your Honor.

There are several Courts that have held that the concept of express preemption, parallel claims has no place in the generic drug preemption jurisprudence. We have cited those cases in our briefing, and the contrary view is all based upon express preemption in medical device cases.

I want to point the Court to what the Court in Mensing said towards the end of the opinion, and the Court recognizes that different statutes and different repertory schemes may result in very different outcomes with respect to Federal preemption. The Mensing opinion points out as to implied preemption, Federal Courts should not distort the supremacy clause to create similar preemptive outcomes across dissimilar repertory schemes.

Nothing could be more different than the medical device amendments, which there are no such thing as a generic medical device, so it is a very distinct repertory program.

The bottom line, your Honor, is that express preemption cases upon which the Plaintiffs base their efforts to avoid preemption should not be viewed as overriding the very clear holdings of Mensing, Bartlett, and the dozens and dozens and dozens of Federal Court cases that have found implied preemption in favor of the generic manufacturers.

So that is the first effort, and then in a related concept, there is an argument about parallel misbranded. It fails for the same reason as a parallel claim, it is derived

from medical devices -- express preemption case law, maybe even a case or two thrown in that is herbicides, not a generic drug, it is a different reparatory scheme, so the parallel misbranding claim fares no better.

Ms. Eisenstein will be handling this argument as it relates and was primarily briefed in the OTC express preemption motion which the brands files that the generics join, so I remind your Honor that we are joining in her argument on express preemption there, and she will spend a little more time on this parallel misbranding issue.

So, in the interest of time, I am going to focus on a few brief points as it relates to the generics.

Again, it is a creature of express preemption. Second, Plaintiffs' parallel misbranding theory has never been adopted by any Court with respect to a generic manufacturer. There have been three Courts that have declined to adopt the parallel misbranding approach.

First, the Supreme Court in Bartlett, it did not accept the premise of a parallel misbranding cause of action against a generic manufacturer, the Sixth Circuit in Darvocet, and then the Southern District of Illinois in Yasmin & Yaz, and that was an MDL.

The fundamental reason that all Courts that have considered this issue have rejected it is that it creates such a broad loophole into the bright line generic drug preemption

jurisprudence.

I want to point out in Darvocet that the Court basically looked at it this way, and it arises from the Bartlett decision, but they said if this cause of action would be viable against a generic drug manufacturer, it would only apply in a pure design defect context. A pure design defect context does not implicate the warnings.

The Plaintiffs have stated very clearly that their design defect theory is based solely upon inadequate label. That runs squarely into Mensing and should be rejected on that score, and I think under Bartlett and Darvocet, it would not survive preemptive challenge.

Our position is, if you accept that point of view, Mensing is a nullity and the supremacy clause becomes really meaningless with respect preemption to generics. It is just too simple a formulaic allegation that obliterates the entire line of cases.

Plaintiffs' testing claims are preempted. I just want to remind the Court that this has been addressed in two cases, one is Drager versus PLIVA, Fourth Circuit, and in Morris versus PLIVA in the Fifth Circuit, and in this Court also in Allbright in the Southern District of Florida.

The fundamental premise here is that because the ultimate duty to the consumer is that the -- it is not to conduct a specific test, but it is not to have a negligent sale

or sell an unsafe product, and the way that manufacturers do that is either warn of the latent defects discovered by the test, redesign the product, redesign the drug, or simply stop selling it.

All of these, again, in this functional analysis, the Courts look at it and say this law requires actions that are preempted, and they reject this sort of approach. It also applies to failure to inspect and other such theories.

They say, well, we could have had a shorter expiration date. I remind the Court that this case is about every drop, every pill, every capsule is prone, according to the Plaintiffs, to degrade and do so promptly. That is why we are here. They don't allege that from a two-year expiration date to a one-year expiration date creates a safe product. It is a product line defect, it starts on manufacture and continues.

So, I would say that even if you assume that a shorter expiration date, they make this point, would result in less NDMA, they don't say that makes the product safer, and that people aren't prone to cancer.

To the contrary, every pill counts according to their cause of action and their arguments yesterday. Time and time again they made the point that it is a dangerous product and no exceptions. Well, if that is the case, that expiration date would not alleviate State Court liability for the generics. There is no reason not to reject this claim.

Manufacturing and storage, briefly, storage is preempted under the duty of sameness. I'll just point out, your Honor, that a syrup generic and a syrup brand have the same storage conditions by the duty of sameness and comparable formulations would have to follow the brand.

Secondly, on the manufacturing defect, it is really a design defect. You can make the product perfectly and they are claiming it will degrade into NDMA.

I'd also point out that the relevant change here, if they were going to change the manufacturing, would affect the purity profile, the quality of the drug, and under 21 CFR 314.70(a)(2), that would be a major change that requires FDA pre-approval and thus, would be preempted under Mensing and Bartlett.

Your Honor, I think that is the summary of our argument and we will be happy to take questions later. Mr. Gugerty will now proceed on Magnuson-Moss. Thank you, your Honor.

THE COURT: Thank you. It is about 20 minutes and 26 seconds.

MR. GUGERTY: Thank you, your Honor. All right.

Your Honor, for the Magnuson-Moss claim there are two points for the dismissal of that claim. Number one, it is undisputed that the Magnuson-Moss Act, which is a Federal Statute, requires a predicate state law claim for breach of

warranty in order to move forward.

As Mr. Barnes explained, all of Plaintiffs' state law warranty claims are preempted and must be dismissed as to the generic manufacturers, and as I'll go through in just a moment, the same is true for the state law warranty claims as to the repackagers. They, too, are preempted and must be dismissed under Mensing.

The Plaintiffs lack that state law anchor claim for breach of warranty that they would need for the Magnuson-Moss Act and therefore the Magnuson-Moss Act claim fails and must be dismissed.

The second point for Magnuson-Moss is that Section 2311(d) of that statute provides that it is inapplicable to any written warranty the making or content of which is otherwise governed by Federal law. That is true, of course, for generic drugs, their labeling is governed under the Federal duty of sameness.

The majority of Courts who have considered the issue have held that Section 2311(d) requires the dismissal of Magnuson-Moss Act claims and claims for generics or other FDA approved drugs. Those decisions have primarily been at the Rule 12 stage. The Plaintiffs only counter to that, your Honor, they argue that their Magnuson-Moss implied warranty claim should somehow escape preemption, and that claim fails.

The only case they cite is a homeopathic drug case,

which is distinguishable. The FDA doesn't review labeling for homeopathic drugs, so it doesn't have any bearing on generics where the FDA does.

The Plaintiffs are very clear in their complaints that both their implied and express warranty claims are based entirely on the labeling. That is paragraph 425 of the personal injury complaint, 342 of the TTP complaint, and similar allegations in the class.

Lastly, your Honor, as to the repackager complaints -- excuse me, the state law claims against repackagers, they, too, are preempted and must be dismissed under a straightforward extension of Mensing and Bartlett.

The repackagers did not hold the FDA approved drug applications for the products they sold. That is undisputed. Because of that, under Federal law, only the applicants, the holders of the NDAs or the ANDAs, can make changes. The repackagers could not under Federal law. So, Federal law conflicts with the state law claims brought against the repackagers. Under the principles of Mensing and Bartlett, those claims fail and must be dismissed.

Numerous Courts have so held, including most recently in the country this Court in the Smith v Teva decision from February of this year, and that's 47 F.Supp.3d 1159. And the Plaintiffs' only response to that is to cross reference their opposition to the retailer and distributor groups motions, and

I know their counsel will address that, so I won't say anything on that subject, your Honor. Thank you very much.

THE COURT: Okay, thank you very much.

Okay. If we could have Plaintiff come on the screen, counsel for the Plaintiffs, for a 20-minute presentation, and state your appearance for the record.

MR. KELLER: Good morning, your Honor, Ashley Keller for the Plaintiffs. Can you see me and hear me okay?

THE COURT: Yes, I can see you and hear you. You may proceed.

MR. KELLER: Good morning, your Honor, may it please the Court, Ashley Keller again for the Plaintiffs.

I would like to start with principles of preemption law and then apply those principles to our misbranding theory, failure to warn the FDA, and expiration dates, but because misbranding is a theory that applies to all Defendants, I would like to take a moment and set the stage for that discussion.

It is worth zooming out to see the big picture as described in the master complaints. Zantac was first approved by the FDA almost 40 years ago in 1983. Post approval, it quickly became one of the best selling drugs of all time. In fact, the industry defines a blockbuster franchise as a drug that achieves a billion dollars in annual sales. Zantac was the first drug ever to reach that milestone.

When generics entered the market two expected things

happened, the price went down and total consumption went up. All told, millions upon millions of Americans have taken Ranitidine on a daily basis for years or even decades. To say the drug was ubiquitous in the United States is an understatement. Yet, as we all know, Ranitidine is not lawfully sold anywhere in the United States today.

Why is that? As alleged in the complaints, it is not because Ranitidine is just as safe as bacon or smoked meat, and I promise, your Honor, it is not because the Defendants no longer care about making a profit. No. The drug is off the market everywhere because of new and scientifically significant information that was not in front of the FDA.

The FDA didn't know in 1983 what we know today, that Ranitidine breaks down in significant quantities over time into NDMA, which is a deadly compound that causes cancer. That is why it is off the shelves.

This situation is the textbook case the FDA had in mind when it embraced our theory of liability seven years ago. Though the agency couldn't have known about this MDL in 2013, when it submitted its amicus brief in Bartlett, this MDL captures the precise fact pattern where states' stop selling duties and Federal law aligned.

Unlike in Bartlett, we are not asking the Court to let us argue to a jury that the FDA made a mistake when it reviewed the same scientific evidence in 1983. We are arguing that a

jury should agree with the agency, the devastating new information the FDA never saw confirms that Ranitidine meets the definition of a misbranded drug. If our misbranding theory can't succeed, the FDA is wrong and no theory can.

If our misbranding theory can't succeed, then state law will be barred from imposing civil liability, even where it is clear as day that such liability promotes and furthers the precise policies embodied in the national regulatory scheme set up by Congress. That is not the law, as I hope I am about to demonstrate to your Honor.

Let me return to the background principles of preemption jurisprudence. Preemption is about conflict of law and it flows from the Constitution. Federal law is the supreme law of the land. Anything in the constitution or laws of any state to the contrary notwithstanding, that's Article VI, Clause 2.

There are several different categories of preemption, as we just heard. There is express versus implied, and then within the implied category there is objects and purposes preemption, field preemption, and as primarily relevant here today, implied impossibility preemption. As the Supreme Court said just two terms ago in Allbright, implied impossibility is a demanding defense. To win the Defendants must show that it is impossible to simultaneously comply with state and Federal law.

On the flip side, it follows that where state and Federal law are parallel, where they are the same, it can't be impossible to comply with both.

Courts begin the preemption analysis by comparing state and Federal duties to see if they conflict. The Supreme Court has said this multiple times in cases like Moore, Bartlett, and Mensing.

There are three corollaries to this starting rule, your Honor. First, state and Federal duties don't have to use the same words to be in harmony, they just have to be substantively consistent. "To survive preemption the state law requirement need not be phrased in the identical language as its corresponding Federal law requirement. Indeed, it would be surprising if a common law requirement used the same phraseology as Federal law." That is the Supreme Court in Bates at 454.

The Defendants accuse us repeatedly of not styling our cause of action misbranding, or not using the word misbranding enough in the complaints, but that ignores the teaching of Bates. It is not about matching words for preemption purposes, it is about the substance of the state and Federal duties.

Second, your Honor, as the Eleventh Circuit observed in Mink, state law claims can create multiple duties, and only some of them might conflict with Federal law. Where that is the case, preemption applies only to the extent of the

difference between state and Federal responsibilities. That is once again Bates at 453.

So, to offer your Honor a highly stylized example, suppose a state cause of action creates duties A, B, and C, and Federal law makes it impossible to comply with duty C. A Plaintiff can still plead and prove her case based on either duty A, a breach of duty A, or a breach of duty B. There is only preemption to the extent of the difference.

Finally, your Honor, to go back to where we began, preemption is about comparing duties, not the other elements of state torts. Though those additional elements such as causation or injury must be pleaded or proved, "such additional elements would make the state requirements narrower and provide a strange reason for finding preemption of a state rule insofar as it duplicates the Federal rule." That is the Supreme Court at Moore, at 495.

Let's apply these principles to our misbranding theory, your Honor, to demonstrate that they are not preemptive. Once again we begin by comparing state and Federal duties. Nobody disputes that state design defect law imposes multiple duties, one of which is to not sell a defectively designed product.

The Supreme Court accepted that formulation of design defect duty in Bartlett under New Hampshire law and the law of design defect is virtually the same everywhere. You must not

sell a defectively designed product. That is the state side of the ledger.

Let's compare that to the Federal responsibilities created under the FDCA. In order to do that we first have to turn to the statute's definition of a misbranded drug. A drug is misbranded if its label is false or misleading in any particular. That's 21 U.S.C., Section 352(a)(1), or if it is dangerous to health when used in the dose, manner, or frequency stated on the labeling thereon. That's Section 352(j).

With that definition in mind, what are the duties created by the Federal misbranding provision? This is contained at Section 21 U.S.C., 331(a), (c) and (g). Quite simply, you cannot manufacture, introduce, deliver, or receive a misbranded drug in interstate commerce. In other words, the Federal duty exactly matches the state responsibility, do not sell a misbranded drug.

The Defendants offer several rebuttals, but none of them are persuasive.

First, the Defendants say that they cannot as a matter of law sell a misbranded drug so long as they affix the FDA approved label. In other words, FDA approval in the past, back in 1983, guarantees that a drug is not misbranded any time after that.

That is false, your Honor. The Supreme Court rejected that in Bartlett in Footnote 4 saying, "the misbranding statute

requires a manufacturer to pull even an FDA approved drug when it is dangerous to health." The Code of the Federal Register says the exact same thing, 21 CFR 314.170, all drugs, including those the FDA approves, are subject to the adulteration and misbranding provisions of the FDCA.

There is, quite simply, no shield to liability just because a drug was approved 40 years ago.

Let's address the elephant in the room, your Honor, which is the Supreme Court's decision in Bartlett. Every category of Defendant accuses us of trying to make an end run around the decision. You just heard the exact same thing from my friend. I think it is important for us to not overstate or understate what the Supreme Court said in Bartlett.

Footnote 4 is crystal clear that it is not deciding the question that we pose today. The generic manufacturers say that Footnote 4 is obscure and mere dicta, so the Court should pay no attention to it.

With all due respect, your Honor, when the Supreme Court of the United States announces the scope of its holding, that is part of the holding, not dicta. When the Supreme Court of the United States leaves a question open, it is inviting lower Courts not to apply principles of vertical stare decisis. It is saying that you get to decide this issue de novo based on first principles of preemption jurisprudence.

It is not an end run around the Supreme Court's

decision to take up the invitation that they left open to us, and our case is nothing like Bartlett. There the Plaintiffs were asking the jury to second-guess the FDA science determinations by presenting the same evidence that the FDA considered and rejected as to the safety profile of Sulindac.

Here, we are arguing that new and meaningful science came to light since in 1983 that caused the FDA to agree with us. They told every Defendant, stop selling Ranitidine, it is dangerous. What possible policy is served by not allowing liability here?

Our duties under state law are exactly parallel to the duties under the misbranding statute. There cannot be preemption when there are parallel claims like this, which raises an important objection, your Honor, that the Defendants made, and you heard it from my friend a few moments ago.

They say we have committed a category error because we are using the language of parallel claims and that is an express preemption concept and we borrowed that from a bunch of Medical Device Act cases that we say are on point that we cited to the Court, but pay no attention to that, they say, because ours is an implied impossibility preemption theory, so those express preemption cases are inapposite.

Your Honor, we agree that the parallel claims concept is something we borrowed from the Medical Device Act, but the Defendants are profoundly mistaken about the ramifications of

that for their theory and makes our theory ironclad and disposes of their theory.

To see that, let's recall the language of the express preemption clause from the Medical Device Act, which is actually quite broad and it mirrors the language of the OTC regulation at issue here, 379(r). State duties are preempted if they are in addition to, different from, or not identical with Federal law. The only duties that can survive preemption are the ones that are exactly the same as the Federal duties.

So, I have a simple question for my friends. How can Federal law make it impossible to do what state law requires when both state and Federal law require the exact same thing? If state law says do X, and Federal law says do X, how can it be impossible to do X?

I pose my question as a challenge. I challenge any Defendant to stand before the Court today and offer a single concrete example from a real case, or one that they come up with hypothetically, where state and Federal duties are identical, there's no daylight between them, and yet it is impossible to do both.

They cannot meet this challenge, your Honor. It is a logical and legal impossibility to show impossibility when you survive an express preemption clause as broad as the one under the Medical Device Act, which is a good segue, your Honor, to the failure to warn the FDA claims because they make the same

objection with respect to that theory.

Once again we begin by comparing state and Federal duties.

Under the state law of states such as California, which recognize the theory in Coleman versus Medtronic, as well as other states like New York, or Pennsylvania, or Mississippi, the common law duty to warn includes a duty to update third party agencies such as the FDA when the agency is the most efficient means of getting the warning to the ultimate consumer. No one disputes that state law embraces that form of duty under the law of some states.

What is the Federal set of duties? The FDA says they are the exact same ones. The FDA's position, backed up again by the Code of the Federal Register, states that generic manufacturers, just like their branded counterparts, have an obligation, a duty under Federal law to keep the agency abreast of new and emerging science that would call into question the safety and efficacy profile of their drugs.

So, once again, because the state and Federal duties are parallel, it can't be impossible to comply with both, and an unbroken line of cases, starting with the Ninth Circuit's unanimous decision en banc in Stengel, followed by Basch and Striker and Mink, reaffirm this point.

The first objection the Defendants make is the one that we already went over, that we are talking about parallel

claims, but that can't bear on their impossibility analysis. As I have already demonstrated, that is a logical fallacy. It proves that our claims aren't impossible to simultaneously comply with.

The next objection that the generic manufacturers made is, they said we played a game of hide the ball with respect to Stengel, your Honor, because the Arizona Supreme Court subsequently said Arizona does not recognize the California common law duty to update third party agencies like the FDA.

With all due respect, we didn't cite the Ninth Circuit's decision for the Erie guess that it made. We agree it made an erroneous Erie guess and Arizona is entitled to not embrace the same form of duty as California law.

We didn't cite Arizona as an example of a state that embraces the California style duty to warn. We cited Stengel for the proposition that there is no preemption under the supremacy clause under these circumstances and it remains perfectly good law on that Federal question.

The next objection that the Defendants lodge is Buckman preemption, but Buckman doesn't apply. The penultimate paragraph oh Chief Justice Rehnquist's opinion, and for the Court is the relevant one, it says you can't try to enforce state duties that rely solely on Federal law, but our theory under California and other state's law doesn't rest solely, primarily, or at all on Federal law.

If the FDCA were repealed tomorrow, if the FDA tomorrow repealed the regulation requiring generic manufacturers to keep the agency abreast of emerging science, state law under the common law of California would still impose the exact same duties. So, our duties don't rest on trying to enforce the Federal statutory scheme.

Finally, your Honor, they say once again that Mensing squarely foreclosed our theory, but it doesn't. In Mensing the Court said, quote, "the only action the manufacturers could take asking for the FDA's help is not a matter of state law concern." That's at 604. And at 619, the Plaintiffs expressly denied "that their state tort claims are based on the manufacturer's alleged failure to ask the FDA for assistance in changing the label."

Our claims do make those issues matters of state law concern because that is what the law of California says. Like it or not, the generic manufacturers have to accept the duties as announced by the state courts under the state's common law.

Let's transition in conclusion, your Honor, to the expiration date theory because I think once again Mr. Barnes has changed his position from the opposition that he initially expressed through the reply brief. So, we begin once more by comparing state and Federal duties.

The state failure to warn clearly encompasses a duty to have an accurate expiration date. Federal law says the

exact same thing for both branded and generic manufacturers. In their opening brief the Defendants attempted to say that we conceded that the duty of sameness said they couldn't have a different expiration date, or they tried to say that maybe the initial expiration day when they submitted their ANDA could be different from the reference listed drug, but they couldn't make any changes after the fact.

All of that is incorrect under the regulatory regime, as we demonstrated in our opposition. Let's start with the duty of sameness, the so-called duty of sameness. That is 21 CFR 314.94(a)(8) little 4.

It does say that the branded label has to match the reference listed drug in most respects, but there is an express exception for differences in expiration dates. There is no ambiguity about that. The expiration dating provision expressly says that the original date might need to be changed post approval through a supplement. That is 211.166(b).

ANDA holders are subject to the same provisions as NDA holders to make changes through supplements. That is 314.97(a).

The rules for supplementing an application for an ANDA holder are the exact same ones that apply for the original ANDA. That is 21 CFR 314.71.

So, there is no duty of sameness with an exception for expiration dates that applies only initially as opposed to for

the supplemental process.

As Mr. Barnes already covered, 314.70 is the provision that governs ANDA holders for making changes, and the FDA has already said through interpretive guidance that making a change to shorten an expiration date is a moderate change under subsection C. That is the exact same CBE provision that was at issue in Wyeth versus Levine.

So, the generic manufacturers have shortened their expiration date without the FDA's special permission or assistance, there is, therefore, no preemption.

They run from this argument in their reply brief, and you heard Mr. Barnes did the same thing in his presentation saying, maybe as a matter of law we could have shortened our expiration dates, so pay no attention to our opening submission. But then they just ignore the 12(b)(6) standard and say, even if we could have legally done that, the Plaintiffs' theory doesn't allow it because we allege that Ranitidine is always dangerous.

Your Honor, we also allege that the expiration dates are inaccurate and could have been shortened, and this again forgets the teaching of Bates. Just because they can't do everything required by state law, such as changing the formulation of the molecule, doesn't mean that they are absolved from doing some things that state law allows.

They could have changed their expiration date

consistent with both sovereigns' set of duties. They were required to do so. And the fact that they couldn't also change the molecule, because that would have been a major change that would have fueled the finding of preemption, doesn't shield them from liability.

Thank you, your Honor. I am happy to come back on to field any questions at the appropriate time.

THE COURT: Thank you. You can actually stay on and I will invite the Defense to come on as well. Turn your audio and video on so we make sure we have everybody. And again, when you speak, if you'd state your name for the record. And I will leave it up to you, at least as among the Defendants, who wants to answer the question, because I see there are several counsel for the Defense.

So, for the Defense, the preemption motion states that it is a Rule 12 motion. Is it correct that the motion is a Rule 12(b)(6) motion based on an affirmative defense?

MR. YOO: Correct, your Honor, it is a 12(b)(6) motion based on Plaintiffs' failure to state a claim.

THE COURT: For the record, that is Mr. Yoo.

MR. YOO: Thank you, your Honor.

THE COURT: Again, for the Defense, but Plaintiffs can listen, it will be the same question.

Does Plaintiff agree that impossibility preemption means that a state law imposes a duty or obligation to do

something, but Federal law prevents you from doing it? For the Defense.

MR. YOO: I'm sorry, your Honor. I apologize, could you repeat that question, please?

THE COURT: Sure. Do you agree that impossibility preemption means that a state law imposes a duty or obligation to do something, but Federal law prevents you from doing it?

MR. YOO: This is Thomas Yoo for the Defense. Yes, your Honor, that is part of the implied preemption impossibility analysis.

THE COURT: And from the Plaintiff.

MR. KELLER: We agree, your Honor. We don't think it is part of the implied impossibility analysis, that is the analysis.

THE COURT: That was Mr. Keller. So, just again remember to state your name before you speak. Would you say that again, please.

MR. KELLER: Of course. I'm sorry, Ashley Keller for the Plaintiffs. Yes, we agree that that is the entirety of the analysis, is it impossible to comply with state and Federal duties at the same time.

THE COURT: This question is both for Plaintiffs and defense as well. You both have cited to an April 2004 FDA manual titled "Guidance for Industry: Changes to an Approved NDA or ANDA" in the briefing for the Motion to Dismiss on

preemption grounds.

Are the parties, then, in agreement that the Court can take judicial notice of this FDA manual and consider it at the Motion to Dismiss stage? From the Defendants.

MR. YOO: Thomas Yoo for the Defendants. Yes, your Honor.

THE COURT: For the Plaintiffs.

MR. KELLER: Ashley Keller for the Plaintiffs. Yes, your Honor.

THE COURT: This is a question for Plaintiffs.

Can you identify for the Court any generic drug that has ever had a different expiration date period than the brand name version?

MR. KELLER: Yes, your Honor, Ranitidine.

THE COURT: Can you identify any generic drug that has ever been found by the FDA, a court, or a jury to require a different expiration date period than the brand name version?

MR. KELLER: Your Honor, the FDA's regulations impose this duty on the manufacturers to choose the expiration date. So, I would argue that, under FDA regulations, it is the FDA insisting that the ANDA holder for Ranitidine have a shorter expiration date, but I can't cite to you an express finding by the agency itself that Ranitidine, or any other drug, should have had a shorter expiration date. I don't have that at my fingertips.

Ashley Keller again for the Plaintiffs. I am sorry, Ms. Stipes.

THE COURT: Again this is for the Plaintiffs.

Could a state, for example, impose a law that all drugs sold within the state must have a three-month expiration date period, for example? Or that all generic drugs must have a three-month expiration date period? Would that be preempted, and why or why not? That is for the Plaintiff.

MR. KELLER: Your Honor, that would potentially be preempted to the extent that three months is not an accurate expiration date under the FDA regulations.

So, the FDA insists that an expiration date be set to ensure the qualities of identity, strength, quality, and purity of the drug. So, if a three-month period would not be accurate under that standard, there would be preemption because it would be impossible for a manufacturer to comply with that while also complying with the Federal regime insisting on accuracy in the date.

THE COURT: And the same would go if a state imposed an even shorter expiration date such as one week? Would it be the same answer?

MR. KELLER: I believe that it would be the same answer to the extent that one week was inconsistent with the date that should be set based on the Federal stability testing that the manufacturer is supposed to undertake.

So, the state duty would be consistent with Federal law if it said, put an accurate expiration date on your product. If it is requiring it to be shorter, even if that is not accurate, I think there could be impossibility preemption there. That would be a tougher case, but I think there could be impossibility preemption in that instance.

THE COURT: For the Plaintiffs again, if a drug manufacturer learned that its drug, if it sits on store shelves for too long, causes cancer, would the law of any state be satisfied with simply shortening the expiration date on the packaging?

A followup question would be: Why wouldn't a state also require better warnings, a redesigned drug, and/or removal of the drug from the market? Those are the totality of questions on that topic.

MR. KELLER: Ashley Keller for the Plaintiffs. That is a great question and it illustrates the point I was making at the end of my prepared remarks.

No, the law of no state would be fully satisfied by just shortening the expiration dates, however, the law would be partially satisfied by complying with those state duties. As the teaching of Bates reminds us, preemption only applies to the extent of a difference between state and Federal law.

So, if state duties are A, B, and C, and A is the most maximalist one, it requires the manufacturer to do the most

things, but that is impossible under Federal law, they are not absolved from responsibility for performing duties B and C.

So, to put this back into the context of Ranitidine, we agree that no manufacturer post approval of their drug could, without the FDA's special permission or assistance, to use the language of Mensing and Bartlett, redesign the molecule or change the formulation. Those are major changes that would require FDA approval, but they could have changed the expiration date. The brand manufacturers could have added a cancer warning.

Those lesser responsibilities under state law still have full force and effect and are not in conflict with Federal law.

MR. YOO: Your Honor, may I be heard on this issue?

THE COURT: Yes.

MR. YOO: With regard to the Plaintiffs' arguments concerning expiration dates, we have to start by recognizing that the Plaintiffs have made it clear by their allegations that there is no safe effective expiration date.

Despite their efforts to use expiration date as a hook in their opposition to our Motion to Dismiss, if you look at their complaints, they have made it very clear that NDMA is inherent in Ranitidine. NDMA is, according to the Plaintiffs, immediate.

I would remind the Court at page two of the

Plaintiffs' opposition they make the challenge to the generic Defendants very clear. At the top of page two the Plaintiffs state, under both state and Federal law they, meaning the generics, were duty bound to act independently to prevent Plaintiffs' injuries.

So, I think it is important to keep in mind the Plaintiffs aren't really talking to your Honor about expiration dates in a vacuum. What they are really saying is that the Defendants are liable because we failed to set a correct expiration date to avoid consumer exposure to NDMA or the risk of cancer. And the regulations make it very clear and the case law makes it very clear that that is a major change that a generic manufacturer cannot make independently or unilaterally.

That, too, is an important part of the implied preemption analysis, as your Honor knows from Mensing. The question is, could a generic manufacturer take that step that the Plaintiff is alleging the Defendant should have taken to avoid liability under state law, and do so independently or unilaterally? If it is something they could not do independently or unilaterally, there is impossibility preemption.

Under 21 CFR 314.70(b), any change, whether it is a quality related change or a manufacturing, any type of process related change that affects the safety or purity profile of the drug is a major change and it requires FDA approval.

In the Gustafson case out of the First Circuit the Court held preempted a claim that implicated the manufacturer's change to a container for prescription eye drops because the Court found that the change affected the purity profile of the prescription eye drops.

This idea that a generic manufacturer -- each generic manufacturer on its own could have and should have determined what is a correct expiration date, or a storage condition for that matter, to ensure that consumers aren't exposed to NDMA or the risk of cancer and then slap that date on each package, and everyone can do so on their own independently, unilaterally, and inconsistently, that is just false, and it is inconsistent with the law.

THE COURT: Response from the Plaintiff.

MR. KELLER: Thank you, your Honor. It is not false, it is completely consistent with the law. That is why we went through the regulatory regime to demonstrate that each ANDA holder has the right and obligation to set an accurate expiration date for its product.

I also want to return to the pleading argument that my friend is making, because it really is not a preemption argument anymore, it is a pleading argument.

They are saying that our sole theory is that Ranitidine, the moment it comes off the manufacturing line, is so dangerous it must be pulled from the market. That is what

state law requires. They couldn't do that under any theory but misbranding, so they are off the hook on expiration dates.

But the complaints are replete with allegations that their expiration dates were inaccurate. To cite just a couple of examples, paragraphs 302, 373, 385, 423, 481, 486, 552 of the master personal injury complaint demonstrate that they had inaccurate expiration dates.

Once again, though we say that Ranitidine is dangerous, at the pleading stage we don't say how much time has to lapse before enough NDMA forms in the product to necessarily cause a particular Plaintiff's cancer. We don't say how much is formed through the manufacturing process. We don't say how much is formed as a result of the conditions of the human stomach. We say that some is formed, but we don't have the answers to those scientific questions at this procedural posture.

They don't get to flip the rule around on a normal 12(b)(6) and say all reasonable inferences should be drawn in their favor and only the theory of liability that lets them off the hook for implied impossibility preemption purposes is the one that the Plaintiffs plead.

Yes, we plead that Ranitidine is dangerous, but we also plead that their expiration dates were inaccurate, and we are entitled to all reasonable inferences in our favor on that score, not the other way around.

THE COURT: Okay. Let me move on to the topic of storage and transportation conditions. This question is directed to the Plaintiffs.

Your opposition contains arguments on page 32 relating to storage and transportation conditions. When you allege, for example, in 496(e) and 536(e) of the master personal injury complaint that Defendants failed "to implement appropriate handling instructions and storage conditions," what precisely do you mean by that and where is that explained in the master complaints?

Do you mean that any Defendant kept Ranitidine products under the wrong conditions within their own facilities, or do you mean something else?

MR. KELLER: We mean the former, your Honor. We agree that changing the storage and transport conditions to the extent that it could impact the identity, quality, and purity profile of the drug and pose risk to the ultimate consumer would constitute a major change, but our plausible allegation in the complaints is that this wasn't adhered to.

That's why, for example, lots of Courts have held, turning to manufacturing defects, that at this procedural posture we are allowed to proceed. It's not because they could have made major changes to their manufacturing process without preemption. We agree once again that that would constitute a major change. But if they didn't adhere to the manufacturing

process that they set forth to the FDA, then there is no preemption and state duties can track Federal law one for one.

THE COURT: For the Plaintiffs, if a drug product said on the packaging, for example, that the product should be stored between 50 to 80 degrees Fahrenheit, and a drug manufacturer discovered that the product starts to break down into a cancer-causing material at 75 degrees, would the law of any state be satisfied with simply reducing the storage temperatures on the repackaging to a range of 50 to 70 degrees?

MR. KELLER: That is a great question, your Honor. Yes, that could potentially satisfy the laws of the states, but a different way to satisfy the law would be to simply store it at the low end of the range, which would not be inconsistent with Federal law.

If Federal law says store this product between 50 and 80, to use I think your Honor's hypothetical, but it doesn't really matter, and state law says store this at 51 degrees, there is no impossibility under those circumstances. State law and Federal law are not identical, but it's not impossible to comply with the state requirement because Federal law gives a choice within a range, and as long as the state requirement is inside of that range, there is no impossibility.

THE COURT: Wouldn't the state also require better warnings, a redesigned drug, and/or removal of the drug from the market?

MR. KELLER: Yes, your Honor, it would also require those different duties. Once again, just because a Defendant can't comply with all state duties doesn't absolve them from responsibility from complying with the ones that are consistent with federal law.

So, you are correct, the state would impose additional duties that would potentially be preempted under the Federal regulatory scheme, but that doesn't shield the manufacturer from liability from flouting the duties they could have consistently complied with under both state and Federal law.

THE COURT: Again, the primary case that you rely upon, because you have put forth this principle now on several occasions, is -- did you say Bates?

MR. KELLER: The Supreme Court's decision in Bates, your Honor, the Eleventh Circuit's decision in Mink from 2017. There are countless other cases that stand for this proposition. It is not some novel point that I am making, this is well established in the case law, but those are two good illustrations.

THE COURT: Thanks. All right. Defendants --

MR. YOO: Your Honor, may I respond to those points?

THE COURT: Briefly, yes.

MR. YOO: To the extent the Plaintiffs want to allege that the Defendants failed to adhere to establish storage parameters set by the brand manufacturer and the FDA, that

would be an alleged FDCA violation, and that is preempted under 337(a), and numerous Courts have so held, including the Sixth Circuit in In Re: Darvocet.

As to this idea that if state law were to require Defendants to store their products at the low end of the range, that that would not be inconsistent with Federal law, I think that is false because Federal law, as it states here, provides for a temperature range. And here, Ranitidine is a controlled room temperature product, which means by established guidelines the product is being kept between 20 and two five degrees Celsius, with permitted excursions between 15 and 30 degrees Celsius.

If Federal law establishes a range, but state law comes in and says you can't have the benefit of that full range, you get a much smaller range and you have to stay on the shallow end of that, well, that is an inconsistency.

Finally, I would like to make an overarching point about Plaintiffs continuing reliance on non-drug cases, non-implied preemption cases. Their whole opposition is reliant on, I believe by my count, 19 medical device express preemption cases, one tobacco case, and one case involving a brand drug. They cited exactly one case involving a generic drug for an entirely irrelevant opposition.

Numerous Courts have instructed that express preemption principles and case law should not be used to infect

the implied preemption analysis.

The Lashley Court out of the Fifth Circuit, Strahorn in the Sixth Circuit, as well as in the Middle District of Florida at the trial Court level, the Guarino decision, the Court stated aptly, "Plaintiffs' focus on the questions involving express preemption is misplaced. Mensing involved conflict preemption which does not depend on limitations of the language in a preemption provision." In other words, no parallel state law claim or alternative theories of liability survive the Supreme Court's ruling in Mensing. That is at page 1292.

Thank you, your Honor.

THE COURT: Thank you.

Followup question for Plaintiff. You said that you made a plausible allegation that the Defendant is liable for storage conditions at their facility. What specifically is it that you allege that they did? Was it temperature, something else? What actions did the Defendants take?

MR. KELLER: That is a fair question. Ashley Keller for the Plaintiffs.

To be candid, we don't know the answer to that. The facilities that the Defendants maintain are obviously things that we can only get access to through discovery, but here is why I think our inference is plausible at this procedural posture.

As your Honor is aware, the FDA has done limited batch testing of different Ranitidine containing products to see how much NDMA forms over time, and there is a lot of dispersion in the FDA's results. There is always some NDMA that forms, but for reasons that we don't yet know, some Ranitidine containing products have a lot more, and some have comparatively less.

I think a plausible inference, again, given that we don't have access to all of these materials yet, is that the storage conditions at the facilities and during transportation and while the product is on the shelves, which would apply to distributors and retailers, are widely disparate, and that is part of the explanation for why different Ranitidine containing products the FDA has found have different amounts of NDMA.

We don't need anything more than that at this juncture, your Honor, because, again, we don't have access to these facilities. That, I would think, is what discovery is for.

THE COURT: Okay, thank you.

For the Defendants: Plaintiffs argue on pages 21 to 24 of their opposition that some states recognize a claim for failure to warn the FDA, with the duty being owed to consumers. The Court understand the following three things:

Number one, Defendants maintain that the cases on which Plaintiffs rely arose in the medical device context and are distinguishable for that reason. And that has been

discussed at some length here today.

Number two, in Mensing, the consumers did not base their claims on the generic drug manufacturers' failure to ask the FDA for assistance, and the Supreme Court stated without providing any citation that, quote, "asking for the FDA's help," end of quote, new quote, "is not a matter of state law concern." PLIVA, Inc. v Mensing, 564 U.S. 604, at 619 and 624, 2011.

The law of the states at issue in Mensing, however, "demanded a safer label" and "did not instruct the manufacturers to communicate with the FDA about the possibility of a safer label." That is at 619.

Third, if Plaintiffs were alleging a claim of failure to warn the FDA, with the duty being owed to the FDA, that claim would be preempted under Buckman versus Plaintiffs' Legal Committee, 531 U.S. 341, 2001, as the Eleventh Circuit explained in Tsavaris versus Pfizer, 717 F.App'x 874, Eleventh Circuit, 2017.

Keeping in mind that the Court understands these three things, explain precisely how, if a state recognized a claim of failure to warn the FDA, with the duty being owed to consumers, the claim would be preempted.

In other words, what is the conflict between state law, if state law were with to require warning the FDA under certain circumstances, and Federal law?

MR. YOO: Your Honor, I think the Court's question already touched on the answer, and that is, the Mensing Court stated that state law demanded a safer label in that case, it didn't instruct the manufacturers to communicate with the FDA about the possibility of a safer label.

So, as the Moreno Court stated in the Eleventh Circuit decision that it doesn't matter what guard you try to put on it, you look at the core allegation and what logically is it that the Plaintiffs are alleging the Defendant should have done, and you use that for the implied preemption analysis.

Here, even assuming hypothetically there is a state out there that has fashioned a cause of action based on the Defendant's failure to seek help from the FDA, that still would not absolve a drug manufacturer from alleged liability because the consumer still needs a safer drug or a different warning based on the Plaintiff's allegations.

Those are the things where the rubber meets the road, those are the things that either would absolve a Defendant from allegedly liability or implicate a Defendant in alleged liability. Those two things are not things that a generic Defendant can do under the duty of sameness.

That is where the conflict exists, your Honor, and that is not going to change no matter how Plaintiffs want to reimagine Mensing or Bartlett or any of the dozens of other cases that have explained the Courts' holdings in those cases.

MR. GUGERTY: Your Honor, this is Sean Gugerty for the Defendants. Could I expand very briefly on this one point?

THE COURT: Yes.

MR. GUGERTY: So, when Mr. Yoo said --

THE COURT: Wait, just a minute. Can you turn your volume up?

MR. GUGERTY: I will step up a little closer to the mic.

THE COURT: Yes, just start over. Thanks.

MR. GUGERTY: Yes, your Honor. Just to expand on what Mr. Yoo said, the cases that say that, in your Honor's hypothetical, the ultimate duty owed -- it would be a duty to warn the FDA, but the ultimate duty to the consumer, and there are multiple Courts that have held -- have looked at the analysis as what the manufacturer would need to do to prevent harm to the consumer. If all of the actions are things that are preempted under the principles of Mensing and Bartlett, then that claim fails.

It is a sort of causation focused inquiry. I know Mr. Keller has taken the position that causation is irrelevant to this inquiry, but that is not what the Courts in generic drug cases have done. They have looked at what a manufacturer would need to do to prevent the harm to the consumer. That is the Drager case from the Fourth Circuit and also the Morris v PLIVER case from the Fifth Circuit.

Turning this back to the failure to warn the FDA claim from your Honor's hypothetical, the Court in Mensing was very clear that it is inherently speculative about what action the FDA would take if a manufacturer did go to it and did provide a warning, and the Supreme Court, in fact, expanded on this concept at length, referring to the notion of providing a warning to the FDA as starting a speculative mouse tracking about what the FDA might have done.

Because, based on that analysis, it is completely unclear and speculative as to whether going to the FDA would prevent the ultimate harm to the consumer, your Honor's hypothetical claim would still be preemptive under the principles of Mensing and Bartlett.

Thank you, Your Honor.

THE COURT: Thank you.

MR. KELLER: Your Honor, can I respond?

THE COURT: Yes.

MR. KELLER: Thank you, your Honor. Ashley Keller for the Plaintiffs.

Let me start with a response to Mr. Yoo. This is not some hypothetical state that might impose these duties. As we note in our papers, there are multiple states that do, and California is one of them, so I would commend to the Court the Coleman versus Medtronic case that discusses these principles. We did not make this up.

We have to follow state law in an Erie case and we recognize not every state does it, but there are states that have embraced this duty to update the agency even though the duty is ultimately owed to consumers.

And to the points that are just made, once again, it is not Mr. Keller arguing that causation is not part of the preemption analysis, that is the Supreme Court's decision in Moore.

I would also commend to the Court Judge Watford's concurrence in the Stengel case which I think does a very trenchant job of describing the distinction between the duties on the one hand and the causation inquiry on the other. Judge Watford says, sort of to the last point that was just made, Plaintiffs will often face a difficult causation hurdle because as was just described, it is not easy to know what the FDA will do this with this information even if the manufacturer satisfies its duty.

Inherent in Judge Watford's analysis I think is some skepticism that Plaintiffs will succeed on this, and I suspect in many cases, even though there is no preemption of the duties, just on state law causation principles Defendants might be entitled to judgment as a matter of law because Plaintiffs can't establish their causation burden.

That is not going to be a problem here, your Honor. We don't have to speculate about what the FDA would have done

if the manufacturers had stayed true to their state duties under the laws of states like California. The mouse trap game has already been played, the FDA has instructed them, get Ranitidine off the market.

While I think Judge Watford is right, and in a lot of cases causation could be a hurdle, it is not going to be a problem for Plaintiffs in this case, and it is certainly not a problem on a 12(b)(6) motion.

MR. YOO: Your Honor, may I respond?

THE COURT: Briefly.

MR. YOO: Let's look at actual drug cases involving implied preemption instead of medical device cases and other express preemption cases.

Plaintiffs have tried negligence and negligence per se causes of action, purportedly under state law, but premised on a variety of theories, many of which the Plaintiffs are trying to invoke here, and in every instance that effort has been rejected.

So, in Guarino, Drager, Guarino in the Eleventh Circuit, Drager, a Fourth Circuit decision, Tsavaris, as your Honor mentioned, out of this Court, Allbright also out of this Court, and your Honor's ruling at the State Court level in the Dietrich case, all of those cases, and many more, involve Plaintiff negligence or negligence per se claims based on alleged failure to test, failure to communicate with health

care providers, failure to discover latent defects and report those to the FDA, or simply for selling an allegedly misbranded product.

In all of those instances the Courts have found, as your Honor did in Dietrich, that these are "alternative theories" in an effort to circumvent Mensing, and they have all been rebuffed at every turn.

THE COURT: Thank you. Let me ask a followup question for Plaintiffs.

You have argued that the Court need not look at all of the duties that state law would impose and that the Court can look at a specific duty that the Defendant could unilaterally do under state law, but you have not brought a cause of action, that is the Plaintiffs have not brought a cause of action that is specific to, for example, expiration dates, nor have Plaintiffs brought a cause of action for failure to warn the FDA under a state law.

What you have brought is, for example, strict product liability claims.

Why would the Court not look at all the duties imposed under strict liability?

MR. KELLER: This is Ashley Keller for the Plaintiffs, your Honor.

That is another good question, and we believe that the duties we are arguing for here are subsumed within those state

causes of action. Again going back to the teachings of Mink, the same cause of action can impose multiple different duties. That was my A, B, and C highly stylized hypothetical. So, we bring claims for strict liability failure to warn, strict liability design defect, negligent failure to warn, negligent design defect, and those are the causes of action that impose these those specific duties. So, the state failure to warn claim encompasses within it, for the brand manufacturers, a duty to change the label on the warnings and precautions section to add a cancer warning.

We acknowledge that that duty is not something that the generic manufacturers could can comply with, but the exact same titled cause of action, failure to warn, also includes a duty not to put inaccurate expiration dates on your label.

So, we don't have to have, I think, a separate cause of action that says negligent failure to warn, expiration date, negligent failure to warn, warning and precaution section. Our view is, those are all duties subsumed within the overall title of that cause of action under state law.

However, if your Honor disagrees with that and doesn't buy my reading of Mink, we, at a minimum, ask for leave to replead because we are more than happy to break these out as separate causes of action if your Honor thinks that is necessary. I don't think it is under state law, but we would be happy to do it in a repleading.

THE COURT: Okay. Let's see. You may have just answered it in the way you just answered that question. It may be that it is subsumed in the other claims, but I will ask the question as I thought of it coming into the hearing.

You argue, this is for the Plaintiffs, on pages 21 to 24 of your opposition that claims for failure to warn the FDA of potential hazards, with the duty being owed to consumers, are not preempted, and so I wanted you to point to examples of allegations in your master complaints where you have raised such claims.

Is that what you just answered, Mr. Keller, that I am not necessarily going to see failure to warn? Are there certain of the counts, all of the counts that subsume this duty that you are speaking of?

I will give you an example to -- an opportunity to respond.

MR. KELLER: Thank you, your Honor, Ashley Keller for the Plaintiffs.

No, I don't think it is all of the counts. The failure to update the FDA pursuant to laws like the one in California, Coleman versus Medtronic, those are failure to warn claims, so it wouldn't be that, for example. It would be failure to warn strict liability and negligent failure to warn are the ones that come to mind. It certainly could be in other counts, I don't want to lock myself into that, but there are

other counts where that would not be the duty.

THE COURT: You have two failure to warns, Count 1, strict product liability failure to warn, and Count 4, negligence failure to warn.

MR. KELLER: Correct, your Honor, those are the counts that I think capture the heartland of these claims, and if you will just reserve for me the opportunity perhaps later to say I forgot about one, but I think those are the two that are the most relevant for this particular theory.

THE COURT: Okay. Also for the Plaintiffs, if a generic drug manufacturer learned that its drug caused cancer, would the law of any state be satisfied with the manufacturer simply telling the FDA?

Following up on that after you answer that question, why wouldn't the state also require better warnings, a redesigned drug and/or removal of the drug from the market?

MR. KELLER: Thank you, your Honor, Ashley Keller for the Plaintiffs.

I sort of view that as a variance of a question I tried to answer before, which is, I don't think the law of any state would be fully satisfied by just updating the FDA. To the extent a state did impose that duty as one of several that manufacturers should take, they can't get out from responsibility for breaching that duty just because there were other duties they also breached because Federal law didn't

allow compliance.

In that particular hypothetical, your Honor, where they know that a drug causes cancer, and they don't provide that information to the experts at the FDA to make a determination, that, I think, runs squarely into our misbranding theory, where I do think state stop selling duties and Federal law are perfectly consistent with each other, and once again, our position is that Bartlett left this question open for the Court to decide in the first instance.

THE COURT: Okay. Turning to the Magnuson-Moss Warranty Act for the Plaintiffs, Defendant argues at pages 32 and 33 of the Motion to Dismiss that Plaintiffs' Magnuson-Moss Warranty Act claims must be dismissed because, under 15 U.S.C. Section 2311(d), the act is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal Law." Counsel for Defense has made that point also here today.

You argue on page 33 of your opposition, that is the Plaintiffs, that this argument is "inappropriate for a Rule 12 motion."

Why is the argument and a ruling on the argument inappropriate at this stage of the litigation?

MR. KELLER: A couple of points, your Honor. Ashley Keller again for the Plaintiffs.

We cite a California case for that proposition, and we

do allege in the complaints that there may have been other statements that were made with respect to these products that weren't necessarily just the label and weren't fully regulated by Federal law, and that is where I think summary judgment could be the more appropriate procedural posture to dispose of these claims.

But then coming back to the core argument, first and foremost, the provision of Federal law that your Honor read isn't a preemption provision, it is just a carve out from Mag-Moss. An express warranty that's completely regulated by Federal law can't serve as the anchor claim to establish a Mag-Moss violation, but by its terms, that provision only applies to written warranty claims.

We also, of course, have implied warranty claims, and it is worth noting here, the brand manufacturers don't even bother to move, I believe, to dismiss the Mag-Moss claims. They don't incorporate by reference any of the other arguments from the other Defendants on this.

I suspect, and you can ask them when it's their turn, that they made a tactical decision to just be intellectually honest with the Court, because they are not moving to dismiss our failure to warn labeling based claims because they recognize at this procedural posture that the labels can serve as a basis for a warranty that was breached, there is an implied warranty of merchantability that comes along with those

express warranties and that can serve as the Mag-Moss anchor.

If your Honor agrees with us at least on expiration dates, the same logic would apply to the generic manufacturers. They could have had a label that warranted the safety of the product was actually accurate. They didn't do it. Though the express warranty itself couldn't get us a Mag-Moss claim, the implied warranty of merchantability that comes along with stating that on the label can serve as a basis for the Mag-Moss claim.

THE COURT: A followup question for Plaintiffs on the Mag-Moss.

15 U.S.C. Section 2311(d) makes the Magnuson-Moss Warranty Act "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law." You argue at page 34 of your opposition that even if this language forecloses Magnuson-Moss Warranty Act claims relating to express warranties -- this may go to what you just said, but I want to give you an opportunity to answer the question that I had crafted in advance of the hearing.

Even if this language forecloses the Magnuson-Moss Warranty Act claims related to express warranties for products with FDA regulated labeling, the language does not foreclose claims relating to implied warranties.

Aren't implied warranty claims tied to the labeling, in this case labeling that the FDA had approved? For example,

California's implied warranty statute defines implied warranty of merchantability as meaning, among other things, that the product conforms to the promises or affirmations made on the label. That is California Civil Code Section 1791.1(a).

Under any state's law can an implied warranty claim be separated and independent from the label?

MR. KELLER: Thank you, your Honor. Ashley Keller again for the Plaintiffs.

I do think that my previous answer largely addresses that, but I can amplify just a little bit. I definitely think that the implied warranties can be keyed off of the label, so you would have to agree with us, if we were focused only on the label, that there is something that the generic in this argument, or the brand manufacturers with respect to their argument, could have done to make the label more accurate.

It is also true that the label itself would be an express warranty which is completely regulated by Federal law and so that couldn't serve as the anchor, but the implied warranty claim, as your Honor just read it, under California law, which is keyed off of the label, is outside of the carve out, it is implied, not written.

So, even though there is a relationship between the implied warranty claim turning on the label, and the express warranty claim, which is the label, I think the implied warranty claims can serve as that anchor to allow the Mag-Moss

claim to proceed, but you still have to do the preemption analysis to make sure that there is something that the manufacturer could have changed on the label.

THE COURT: Okay. All right. Thank you. That concludes the first motion, 1582. I want to thank all counsel for your presentations and for answering the Court's questions. I am most appreciative of that. You can turn your videos and audios off, although some of you may be coming back on.

We will do this one before the lunch hour and then we'll break for our lunch break. 1583 is the next motion that the Court will hear, and this is the distributor Defendants' Rule 12 Motion to Dismiss on the ground of preemption and incorporated memorandum of law.

If we could have counsel for Defense and counsel for Plaintiff.

MR. KAPLAN: Good morning, your Honor, Andrew --

THE COURT: I'm sorry about that, just Defense. Go ahead and introduce yourself.

MR. KAPLAN: Andrew Kaplan, I represent Cardinal Health, Inc. and Medicine Shop International, Inc. in this litigation and I am here today to argue on behalf of all of the distributors for their Motion to Dismiss on the grounds of preemption, Docket Entry 1583.

THE COURT: You have 15 minutes. Do you want to reserve any or use it all on the front end, and do you want any

warnings?

MR. KAPLAN: Yes, your honor. I actually have two requests. I don't think I will use near my entire time, so I would like to reserve five minutes, but because of the overlap between the retailer and pharmacy and the distributor briefs, the issue of the Drug Supply Chain Security Act, which is in both of the briefs and is essentially the same, Ms. Kapke, who represents the retailers and pharmacies, is going to address that issue.

I would ask that if I have time remaining from my 15 minutes that that be reserved for Ms. Kapke, because she will be arguing that issue on behalf of both sets of Defendants.

THE COURT: Okay. It might help you to know this, that I am going to defer any questions specifically for distributors until after I hear the presentation from the retailer and pharmacy on their motion at 1584, in which case I will hear presentation then I will ask all counsel from this motion and that motion to come on for any questions.

If that helps you in terms of how you want to include other counsel for purposes of your argument here, just keep that in mind.

MR. KAPLAN: Thank you.

THE COURT: Okay. So I will let you begin, then.

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

Distributors have a unique role in the supply chain. Distributors do not design, manufacture, or label pharmaceuticals, nor are they permitted to do so because they do not hold an NDA like the brand named Defendants, and they do not hold an ANDA like the generic Defendants. Plaintiffs don't allege otherwise. Distributors do not diagnose medical conditions, nor do they write or fill prescriptions. Plaintiffs do not allege otherwise.

Distributors do not in the normal course have any contact with the consumers of the products that they distribute. Again, Plaintiffs do not allege otherwise.

Distributors simply serve as a passthrough, distributing product between pharmaceutical manufacturers and retailers. Distributors' uniquely insulated role in the supply chain means that Plaintiffs' arguments and theories simply do not apply to them and necessitate the dismissal of Plaintiffs' claims against them with prejudice.

You have heard a lot over the past day plus, all of these arguments apply derivatively to the distributors, so to the extent a manufacturer cannot be liable, neither can the distributor.

Even if the Court were to deny any part of the motions against the companies that designed and manufactured the product at issue, the claims against the distributors should still be dismissed.

Your Honor, the distributors who are named only in the master personal injury complaint and the consumer class action complaint have four high-level arguments for preemption.

First, under the Supreme Court's precedent in Mensing and Bartlett, impossibility preemption bars all claims against the distributors. This eliminates all counts in both complaints against the distributors.

Second, the express preemption provision in Section 379(r) of the Federal Food, Drug and Cosmetic Act expressly preempts all economic loss state law claims against distributors related to OTC Ranitidine products. And I should mention that that issue is going to be covered in the brand argument by Ms. Eisenstein and Ms. Horton later.

Third, the Drug Supply Chain Security Act expressly preempts all state law claims based on nonidentical requirements for prescription Ranitidine.

And finally, the Magnuson-Moss Warranty Act claims, Count 3 of the consumer class complaint, fail because the necessary underlying warranty claims are preempted, and as just discussed, the act prohibits claims related to written warranties that are governed by Federal law, as they are here with the Federal Food, Drug and Cosmetic Act.

Turning to Mensing and Bartlett, generics counsel covered this issue well so I won't repeat most of what was discussed, but the premise is that where the Defendant cannot

comply with state law and Federal law, there is impossibility preemption. Under Mensing and Bartlett, it was established that where a Defendant cannot act unilaterally to meet the alleged duty without violating the FDCA, then the claim is preempted and there is no loophole for arguments that the Defendant could just stop selling the product or the Defendant could just pay fines and compensation.

In those two Supreme Court cases, the Court made clear that the failure to warn based claims and the design defect based claims were preempted against generic drug manufacturers because they did not hold the NDA, only an ANDA. They were required to have the same formulation of the drug and the same labeling for the drug as the NDA holder. They had no ability to unilaterally change the design or labeling with their ANDA.

The distributors are even one more step removed from the ability to impact any changes to the drug because, not only do they not hold an NDA, but they do not hold an ANDA either. The distributors may not do anything to the drug. They are not allowed to change the warnings and labelings. They are not allowed to change the formulation or design, and they are not allowed to change the storage temperatures for the drug.

For this reason, Courts have held that claims against distributors for allegedly defective pharmaceuticals are preempted under the principles of Mensing and Bartlett. We have cited at least six cases where Courts have held that

downstream Defendants like distributors or retailers and pharmacies are subject to the same preemption principles articulated in Mensing and Bartlett.

Plaintiffs' only response to this appears to be the placement of strict and absolute liability, but the Supreme Court rejected this end run around preemption in the Bartlett decision. There the Court stated "but respondent's argument conflates what we will call a strict liability regime in which liability does not depend on negligence, but still signals the breach of a duty, with what we call an absolute liability regime in which liability does not reflect the breach of any duties at all, but merely serves to spread risk." That is 570 U.S. at 481.

The Bartlett Court then held that the strict liability claim at issue was preempted.

While the Supreme Court declined to address the hypothetical absolute liability scheme, as the Court noted, it is unlikely that one exists. Plaintiffs have neither pled an absolute liability cause of action, nor have they even identified such a state law claim that would allow them to do so.

For those reasons, all of the claims against the distributors must be dismissed under Mensing and Bartlett.

I will turn briefly to the Magnuson-Moss Warranty Act claims. Again, I think those issues were almost fully

addressed with respect to the generics' arguments, but the basic principle applies as well to the distributors. To state a claim under the Magnuson-Moss Warranty Act, a Plaintiff must state a valid state law breach of warranty claim. The Plaintiffs do not dispute this in their briefs.

So, if the warranty claims fail against distributors, so too must the Magnuson-Moss claims.

As previously discussed, because the distributors do not hold the NDA or ANDA for the drugs they distribute, they lack the legal capacity to change their formulations or warning labels, and thus are immune from the claims for alleged design defects or failures to warn under Mensing and Bartlett.

Federal Courts have applied this principle to exclude warranty claims similarly premised on allegedly unsafe drugs. We cite the Strahorn decision and the Moore decision in the briefing.

As discussed, the Magnuson-Moss Warranty Act does not apply to written warranties controlled by Federal law. Therefore, any express warranties that could be subject to FDA regulation are not a proper basis for the Magnuson-Moss claim and implied warranties, to the extent that they are derived from what is written, are also not a proper basis for the Magnuson-Moss claim.

I will note that, I think it is in the consumer class complaint, there are all -- 52 times, I believe, where the --

excuse me -- where the Plaintiffs repeated the same phrase, the Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, do not con form to the promises and affirmations of fact made on the products' containers or labels. They are directly tying their implied warranty claims to the labeling.

For these independent reasons, the Magnuson-Moss claims fail as well against the distributors.

I will just note that I believe I heard Mr. Keller say earlier that there were statements -- there could be statements that wouldn't be impacted by the Federal statutory regime that we argue under 2311(d) which would preclude such Magnuson-Moss claims, but I am not aware, having looked through the lengthy complaints, of any allegation that the distributors made any other statements about the products other than what is on the product that they pass through from the manufacturer to the retailer.

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

THE COURT: Thank you. And from the Plaintiffs. Mr. Kaplan can come off, and Mr. Keller can come on to argue for the Plaintiffs.

MR. KELLER: Thank you, your Honor, Ashley Keller on behalf of the Plaintiffs. Your Honor, I will be brief, I don't

need to use my entire 15 minutes.

I think it is prudent that we lump together the distributors and the retailers for purposes of Q and A because I think a lot of the arguments overlap. So, I am about to touch on a point that perhaps Mr. Kaplan's colleague is going to address in the retailer motion, but I did want to revisit misbranding, not to repeat the arguments that we already extensively went over in the generic presentation, but to talk about a twist that the retailers and distributors introduced that they say is specific to that category of Defendants.

Very quickly once again, the misbranding theory that we pursue says that they have to stop selling a dangerous drug, and we argue that, under the FDCA, the definition of misbranding and the Supreme Court's footnote in Bartlett, that remains available and not preempted.

So, state and Federal duties are the same, and those duties apply up and down the chain of distribution. So, it's not just the duties under Federal law that applies to the manufacturers, it also applies to distributors and retailers. That is under 21 U.S.C., Section 331(a), (c) and (g) again.

The twist that the distributors and retailers introduce in their papers is they say that there is a good faith exception under the FDCA that alleviates any responsibility for them and shields them from the duties imposed by Federal law, and that is the point that I want to

hit with respect to this category of Defendant because it is not correct under the FDCA.

Once again, the duties are created by Section 331. There is no good faith exception in that provision of Federal law, there is no dispensation, there is no discrimination between categories of Defendants. It is an absolute statement of the duties created by Federal law, you must not sell a misbranded drug, period. That applies to the distributors and retailers.

As the Supreme Court noted in the Datareich (phon) case that we cited from Justice Frankfurter, this is a strict liability criminal offense, it doesn't even require mens rea for a criminal conviction. The good faith exception is not contained in Section 331, it is contained in Section 333, 21 U.S.C., Section 333.

Section 333(a)(1) creates the criminal penalties that violators are subjected to under the statute. You can go to jail for a year or pay a thousand dollar criminal fine, or both.

The good faith exception that my friends from the retailers and distributors cite comes from Section 333(c), which says the penalties under subsection (a)(1), it references that single paragraph, "shall not apply to someone who took a misbranded drug in good faith in interstate commerce."

They then say, as a result of that, any state that

does not have a good faith exception read in to its civil liabilities are somehow violating the supremacy clause and those causes of action would be preempted. That once again confuses the lesson of in Moore and cases like Regal, your Honor, which says that preemption is about comparing duties, not the punishments or remedies.

Specifically here where the carve out, where the good faith exception is so limited in its scope, it by its plain terms doesn't apply to our causes of action.

I know this is obvious to the Court, but to make the point squarely, we are here as Plaintiffs in a civil proceeding. We are not pretending to act as private Attorneys General on behalf of the states enforcing their penal codes. We are not seeking to impose on these Defendants a year in jail or a thousand dollar criminal fine. We are seeking civil damages as redress for the cancer and other injuries that Plaintiffs have suffered.

So, there is no good faith dispensation in the statute for civil liability and to confirm that that is true, your Honor, you can look at the very next section of the statute, 21 U.S.C. Section 334.

This allows the Government to seek civil remedies against retailers and distributors through an injunction to seize their misbranded drugs. It doesn't matter what their knowledge was. It doesn't matter that they took in good faith,

it doesn't matter that they paid good money for the drugs and had good title. The Government is to ensure the safety and efficacy of the drugs in interstate commerce and civil liability can be imposed without any good faith dispensation. So, the good faith exception is not a work around to our misbranding theory.

The final point that I want to hit, your Honor, goes back to our negligence claims to demonstrate they survive. I don't think I heard my friend argue otherwise, although of course they do in their papers.

I would point your Honor to paragraph 407 in the master personal injury complaint that says that FDA testing has confirmed that the inadequate storage and transportation conditions are responsible for some of the high levels of NDMA contained in these products.

Once again remembering the pleading standard that we are subjected to, we don't yet have access to all of the factual materials that we would need to confirm this well pleaded allegation. We don't know whether the distributors left Ranitidine on a hot truck in the Arizona desert during the summer for extensive periods of time creating temperature ranges that vastly exceeded those on the label. We don't know if retailers did the same thing in your hometown of South Florida during the hot summer months before they put the Ranitidine on the air conditioned shelves.

So, based on the information we have today and once again the dispersion that we noted from FDA batch testing that shows that NDMA does not form at a uniform rate through all of the batches that thy have tested, it is plausible at this procedural posture that distributors and their retailer counterparts didn't engage in proper storage and transportation conditions and that would support a negligence claim because the duties, of course, as every first year law student knows, for negligence is to behalf as a reasonably prudent person would.

It is obviously reasonably prudent when you are dealing with a pharmaceutical product that's been approved by the FDA and has specific ranges of temperature and other conditions like exposure to light put on the labels, that those conditions have to be satisfied and met by distributors and retailers in order to ensure that consumers don't get a dangerous product.

So, there wouldn't be any preemption that would prevent these negligence claims from proceeding if the retailers and distributors were flouting the instructions that the FDA and the manufacturers put on the labeling and packaging of these products.

I will pause there, your Honor, and go off screen and await the retailer presentation.

THE COURT: Thank you. Any rebuttal from the

Defendant?

MR. KAPLAN: Your Honor, very briefly. I will reserve the issue of the conveyed exception for the retailer and pharmacy counsel to address that in their briefing.

But briefly on the issue of misbranding, that was covered at length in the generics argument, so I won't rehash all of the arguments there. The distributors, as I said earlier, are one step -- another step removed from this process. They can't change the labeling, they can't change the design, they can't change the storage requirements, they can't change the expiration dates.

It is the very definition of a conflict with Federal law for the distributors to make a unilateral stability determination apart from the FDA and apart from the NDA holder, and handle the drug in accordance -- in a way that is different than what the FDA has required and in a way that could cause adulteration of the product.

So, we agree with the generics that this exception that the Plaintiffs are arguing to try to get around the Bartlett and Mensing decisions is not viable, but to the extent it were theoretically viable, it wouldn't apply here to distributors.

Thank you.

THE COURT: Thank you very much. That concludes the morning session.

We will resume at 1:15. It is about twelve o'clock now, 12:02. We will resume at 1:15. We will have the final two motions of the day heard, 1584 and 1580. As I said, after presentations on 1584, I will invite all counsel who have argued 1583, as well as 1584, to be on the screen to address any questions that the Court may have.

So, with that, have a nice lunch, and stay on the Zoom as we discussed yesterday. Don't leave the meeting if it is possible, just turn your video and audio off. This makes it easier on those who are admitting people. And we will see you back at 1:15. Thank you.

(Thereupon, a luncheon recess was taken.)

THE COURT: Okay, welcome back, everybody. If we could have the attorneys for 1584, which is the retailer and pharmacy Defendants' Rule 12 Motion to Dismiss on the grounds of preemption and incorporated memorandum of law.

We will have counsel introduce themselves, and I understand you have allotted 15 minutes for yourselves in conjunction with the Court and discussions between counsel, so let me know how you want to break that up, and whether you want any warnings.

MS. JOHNSTON: Good afternoon, Sarah Johnston on behalf of the retailer and pharmacy Defendants. Also with me is my colleague, Kara Kapke, also for the retailer and pharmacy Defendants.

I will be speaking to the substantive issues set out in the Motion to Dismiss and Ms. Kapke will be speaking to the Preemption and Securities Act. She will be doing it on behalf of the retailer, pharmacy Defendants, and distributor Defendants.

And in terms of timing, I wanted to follow up on a question that Mr. Kaplan asked when he was speaking for the distributors, which is whether his remaining time could be allocated to Ms. Kapke for the DSCSA arguments. They will be on behalf of both groups of Defendants. I believe the Court was amenable to that, I want to make sure before we allocate time.

THE COURT: Right. Yes, that is a fair question.

The Defendants did have from the last motion five minutes and 11 seconds left of their allotted time and the Plaintiffs had eight minutes and four seconds left. So I will give both sides the remaining time to be fair.

So you have 15 minutes, plus five minutes and 11 seconds. You have 20 minutes and 11 seconds, and so you can divide it up among yourselves however you want. Just tell me whether you want any rebuttal period so I can let you know, and whether you want any warnings.

MS. JOHNSTON: Sure. I think on my part, I probably need eight or nine minutes maximum, and Ms. Kapke I think will need roughly the same, and we will reserve whatever is left for

rebuttal if necessary.

THE COURT: Okay. So I will let you run through, if you use all of your time you won't have any rebuttal. If you don't use your time, you will have rebuttal. Okay. That sounds straightforward.

Okay, you may proceed.

MS. JOHNSTON: Good afternoon again, your Honor, Sarah Johnston on behalf of the retailer and pharmacy Defendants. For ease of efficiency, I will be referring to both groups as the retailers. We will distinguish among them as necessary throughout the argument.

As the Court and counsel know, we have spent a fair amount of time over the last two days, and particularly today, addressing the issues of Mensing and Bartlett preemption, because the -- as set forth in the generic and distributors briefs, it is my goal not to retread over a lot of that ground, but there are a few areas that warrant revisiting, especially since they pertain to the retailer Defendants.

And since they are preempted as to this group of Defendants, I think it is important that we explore that with an eye towards the retailers for two reasons.

The first is, as we heard yesterday during the pleading arguments, the complaints fail to distinguish among the different levels of supply chains as to the allegations of liability.

And second, and I think this is more important, what the Plaintiffs here are asking for as to the downstream Defendants is to do something that has never been done before in the context of pharmaceutical product liability MDLs, and that is to extend liability beyond manufacturers and into the entire supply chain and thereby holding dozens of retailers, pharmacies, and distributors liable, or potentially liable for an alleged latent defect in a drug.

So, jumping into that, the master complaints, as Mr. Petrosinelli explained yesterday, at most, put the 90 or so Defendants here on notice that Plaintiffs are pursuing claims related to an alleged latent defect in Zantac and basically that, with minimal exceptions, everybody is on the hook for it.

Despite the fact that common sense would inform the difference between a manufacturer and a pharmacy, Plaintiffs make the same general allegations fairly indiscriminately against all Defendants, including the retailer Defendants, with the only distinction as to the retailers being that the retailers are not part of the so-called knowledge Defendants.

In other words, the retailers are -- I think this is identified in paragraph 360 of the master PI complaint, but the retailers are the sole group of Defendants here who are not even alleged to have knowledge of the risk of NDMA formation in Zantac from its inception.

Setting that aside and working through the noise of

the complaints, as we heard from both the generics and the distributors today, the claims basically break down into one of two arguments, the first being that Zantac is inherently defective because of its molecular instability and that that leads to the formation of NDMA, and/or that the warnings are inadequate because they fail to inform of that risk.

For the same reasons that we have heard from the other Defendants today, those claims are also preempted as to the retailer Defendants, and that's because the analysis here turns on whether the retailers could have done anything independently with respect to the design or the warnings of Zantac or Ranitidine which, as we now know, retailers cannot do.

The retailers, like the distributors, never applied to FDA for approval of any formulation of Zantac or Ranitidine. That means the retailers, as non NDA holders or even ANDA holders here, have no ability to effect change in the design or the warnings of Zantac or Ranitidine.

This is the principle of Mensing and Bartlett and this is the precise reason why these claims are preempted. In a perfect world that stops the discussion, it ends the analysis.

This is the motion that we put before the Court, but unfortunately, because it seems the Plaintiffs have recognized the fundamental challenges of trying to expand potential liability so deep into the rest of the supply chain, they now appear to have changed course.

So, while the master complaints, and particularly the master PI complaint asserts 11 causes of action against the retailers related to the design and warnings associated with Ranitidine, they appear to have abandoned those claims as to the downstream entities for purposes of their opposition.

I will quote from their opposition at page two where they state, "the basis of state law liability is not the failure of a distributor, retailer, or pharmacy to redesign Ranitidine or modify its label. No Court or legislature expects a retailer to detect and fix defects in drugs any more than in Coca-Cola or a lawnmower." They go on at page 13 to say Plaintiffs, quote, "do not dispute that manufacturers, not retailers, design, manufacture, and label regulated drugs."

So, in other words, Plaintiffs concede that they have no viable nonderivative claim of product defect against this group of Defendants, and said slightly differently, that means that any massive litigation formed by the JPML for the purpose of determining the alleged defect in Zantac, Plaintiffs concede that they don't have product liability claims against the downstream Defendants.

This is borne out in their opposition. They do not respond to any of the authority that is cited in our briefs. That includes the Smith case that we cite from the Southern District of Florida. And they also don't cite any preemption authority to the contrary.

This is important given that the expansion they are suggesting is so broad that the preemption analysis apparently is just thrown away, and that, also, should end this discussion, but unfortunately, instead of accepting Bartlett and Mensing for what they stand for and proceeding against manufacturers of the drug at issue and admitting the claims against the retailers and distributors are nonstarters, Plaintiffs have decided instead to get creative, and I think incorrectly creative, but creative, and that is in their opposition.

While the Plaintiffs concede that they don't have product liability claims against the retailer Defendants, they have now advanced for the first time this novel argument that preemption is completely inapplicable here because these Defendants, the retailers, were, in Plaintiffs' words, absolutely liable.

This is a novel, untested theory, it is not recognized by any Court and it shouldn't be entertained here, particularly given the issues at stake in this litigation.

In short, Plaintiffs shouldn't be rewarded for attempting to create law out of thin air even if it is creative, and particularly when to do so would upend preemption law that we have been discussing all day, that preemption law that applies in drug litigations and MDLs like this one, and the effect of which would render Bartlett and Mensing and its

preemption principles basically toothless.

With that, I am going to turn to Ms. Kapke and allow her to address the Drug Supply Chain Security Act and then we may have some discussion on rebuttal, and happy to answer any questions. Thank you.

MS. KAPKE: Kara Kapke presenting the argument on behalf of pharmacies and distributors under the Drug Supply Chain Security Act. Thank you. May it please the Court.

Although Courts have not previously considered the import of the preemptive scope of the Drug Security Act, that is only because, as my colleague, Ms. Johnston, explained, Plaintiffs rarely sue pharmacies for alleged defects in prescription drugs.

The preemption analysis under the Drug Security Act is straightforward and it compels the conclusion that claims against pharmacies and distributors here relating to prescription Ranitidine are preempted under Federal law.

Any express preemption analysis has two parts. First, what are the requirements Federal law imposes? And second, how do the state law requirements relate to the Federal requirement?

Plaintiffs' opposition focuses entirely on that first part of the analysis. In their response Plaintiffs claim that the act only preempts, quote, "tracing products through the distribution system," which, in their view, means only knowing

where Ranitidine was and where it came from.

That is contradicted by the consumer class complaints' allegations that distributors and pharmacies were obligated under the act to quarantine and investigate potentially illegitimate drugs. That is at paragraphs 675 and 669 of docket number 889.

Regardless of that allegation, what we must do is look at the text of the statute, and the Drug Security Act expressly defines what tracing products through the distribution system means, and that necessarily includes the entirety of the act's requirements. If you look specifically at the test of the statute, both the preemption clause and the savings clause, it explains that tracing products includes any requirements with respect to transaction information, verification, or investigation.

So, any requirement relating to verification or investigation necessarily falls within the scope of the preemption clause, contrary to Plaintiffs' argument.

Pharmacies and distributors are required to capture information necessary to investigate a suspect product and implement systems for quarantining suspect product.

But tracing products also by definition includes requirements with respect to transaction statements. Both pharmacies and distributors are forbidden from accepting a shipment of prescription Ranitidine unless manufacturers

provide a transaction statement along with that shipment. That transaction statement requires the manufacturer to state that it is authorized to ship the drug, that it did not knowingly ship a suspect or illegitimate product, and that it had systems and processes in place to comply with verification requirements.

Let me repeat that. Pharmacies and distributors cannot accept drug shipments unless the manufacturer states that it did not knowingly ship a misbranded product. That is really key here because Plaintiffs' claims against the pharmacies and distributors seek to require more from this transaction statement.

Plaintiffs' claims seek to insist that the transaction statement include a statement from the manufacturer that the product was not, in fact, misbranded. Plaintiffs' claims insist that the pharmacies or distributors investigate whether the drug was misbranded or suspected to be misbranded before accepting shipment, but that very same information is already discussed on the transaction statement.

In defining what must be included on a transaction statement, Congress provided exactly what level of investigation it sought to require from pharmacies and distributors, and in turn, what it expected pharmacies and distributors to require from manufacturers before accepting shipments from them.

The only thing that Congress required is a statement that the manufacturing party and subsequent trading partners did not knowingly ship a misbranded product. Plaintiffs' claims seek to require more, and they are therefore preempted.

A final quick point on the second prong of any preemption analysis, which is how the Federal requirement relates to the state law requirement.

Here again you must look to the explicit text of the statute, and the Drug Security Act preempts any state law requirements which are inconsistent with, more stringent than, or in addition to any requirements applicable under the statute. The more stringent than language is key. That is broader than the express preemption provisions in the medical device amendments or the Federal Insecticide and Fungicide and Rodenticide Act and the Federal Metal Inspection Act, to give a few examples. All of which only reference requirements that are "inconsistent with or in addition to Federal law."

Here, anything more stringent than that transaction statement requirement is preempted. State common law duties that require pharmacies and distributors to investigate manufacturers more than reviewing the transaction statement and confirming that the manufacturer did not knowingly distribute suspect or misbranded drugs are certainly more stringent than what the Drug Security Act preempts and are thus preempted.

I will reserve the remainder of my time for rebuttal to address Plaintiffs' responses and Mr. Keller's arguments both forthcoming and the remaining responses.

THE COURT: Thank you. You used about 13 minutes and 23 seconds, so you do have remaining time for your rebuttal.

So, now if we could have Mr. Keller, who is on the screen, to respond from the Plaintiffs.

MR. KELLER: Thank you, your Honor. Good afternoon, Ashley Keller on behalf of the Plaintiffs.

I think it is always useful, where possible, your Honor, to start with places of common ground.

So, I want to concede that we agree with our friends that they are not NDA holders, they are not ANDA holders, and as a consequence, they can't redesign the Ranitidine molecule. Even manufacturers can't do that without the FDA's special permission or assistance. They also can't change the label. So, we agree that they can't comply with either of those sets of state's duties.

That actually resurrects a topic that your Honor was asking me about during the Q and A that I want to revisit, which is, if you can't comply with all of the state responsibilities that are imposed on you, does preemption nevertheless prevent you from complying with the ones that you can meet under both state and Federal law?

And you may recall that we were talking about

expiration dates in that context where we said the generics could change the expiration date, but they couldn't necessarily redesign the Ranitidine molecule, can that theory proceed?

This applies with equal force to the distributors and the retailers where we concede they can't comply with any state duties that would be imposed on them in order to change the molecule or change the label, but they can still comply with other duties. I pointed your Honor to cases like Bates and Mink that stand for that proposition.

I wanted to frame it in slightly a different way to maybe get to the same conclusion because I think this is maybe a useful frame of reference to guide this discussion. Let's take ourselves completely out of the preemption context. Let's imagine that Federal law didn't exist with respect to prescription drugs or over-the-counter drugs, or the FDA hadn't implemented the regulations that we are going to be talking about and have been talking about during today's discussion.

Just starting from basic first principles, a Plaintiff is clearly master of her own complaint. If Ranitidine were being sold on the exact same facts that we allege, she would have a lot of different choices that she could pursue under state law.

She could plead an expiration date theory against the generic manufacturers. She could plead a negligence theory against the distributors and retailers. She could plead a

design defect theory against all of the different Defendants and say that they should have redesigned the molecule, and if there are no Federal requirements that make it impossible to comply with the state duties, all of those theories could proceed.

But similarly, imagine a Plaintiff who just decided to pursue an expiration date theory, or just decided to pursue a negligence theory against the distributors and retailers. We might scratch our heads and say, that is not customary, usually the Plaintiffs don't choose to rein in their claims, they try and bring everything that they can. But you would never throw that out on a 12(b)(6) and say, well, you only brought the expiration date theory, so the fact that you didn't bring the redesign theory means you're of court. No, of course not.

The normal state substantive principles and the fact that a Plaintiff is master of her own complaint would control there. Her choice to pursue a narrower theory is not a shield for the Defendants from liability. Preemption doesn't operate that differently from that sort of stylized hypothetical. The only difference is, under Federal law, the Plaintiff doesn't have full flexibility.

If it is impossible to simultaneously comply with state and Federal responsibilities some theories are foreclosed to the Plaintiff, but others are not, and those theories remain available to her to state a well-pleaded claim.

That is the situation that we have here with respect to the distributors and retailers, as well as the other categories of Defendants. We freely concede that they can't redesign the molecule. We freely concede they have no ability to change the label. That doesn't do anything to undermine the other theories that we plead against them.

And it is true, in our original complaint we pled all theories available under state law because we don't have an obligation to anticipate an affirmative defense. They are the ones who have to raise all of the Federal regulations and statutory provisions that make it impossible to do certain things under state law, and we agree that they have done that successfully with respect to some of the things that we plead in the complaint.

So, that is fine, those theories aren't available to us any more based on the concession I just made as to certain Defendants, but the remaining theories remain good, and we can't be faulted for pleading all of the things available to us under state law without knowing in advance which specific affirmative defenses and arguments that they were going to make.

They have that burden and they have satisfied it. We are willing to agree with them that they satisfied it with respect to certain theories, but the remainder of our theories remain untouched.

Let me turn, your Honor, to the absolute versus strict liability distinction which was left available in Bartlett. I think we are a little bit of ships passing in the night on this score, and I would just remind the Court of the teaching of Bates, state duties, state requirements are not required to use the same language or phraseology as Federal law.

We think that all of these causes of action against the retailers and the distributors sound in strict liability. So, my friend is not quite correct when she says that we gave those up and we are only pursuing "absolute liability" claims.

There is no such thing under state law so far as we know as a cause of action titled absolute liability, but under strict liability principles, the Supreme Court in Bartlett was leaving available an absolute liability regime and that is what state law imposes on retailers and distributors under strict liability theories as opposed to manufacturers.

The key insight to see here, your Honor, is that under strict liability law that has existed for 50, 60, 70 years in most states, the regime against manufacturers and the duties imposed on manufacturers are different. Everybody recognizes that manufacturers are the ones responsible for the labels and the design of their products. Nobody puts those responsibilities or duties on retailers and distributors.

And to once again remove us from the preemption context to just a more commonplace example to put this into

focus, let me offer the following hypothetical.

Imagine that your Honor wanted to buy a light bulb, so you went to Home Depot, you found a General Electric light bulb that you like, you took it home. It came in the exact same packaging that General Electric gave it to Home Depot in, there was no alteration by Home Depot. You read the instructions, you looked at the label, you screwed it into your lamp, you flipped the switch, electricity flowed, and it exploded and caused you injury, unfortunately. This is, of course, only a hypothetical.

Under the law of almost every state, strict liability, there is no doubt that you can sue Home Depot for your injury. Why is that? It's not because state law imposes a duty on Home Depot to redesign light bulbs delivered by General Electric. Nobody thinks that.

It's not because Home Depot needs to have a team of scientists on staff to review the label and make sure that General Electric did a good job alerting you to all of the risks associated with their product. Nobody thinks that either.

The reason that Home Depot is liable, quite simply, holding on the logic of luminaries such as Justice Traynor, is that society has made a policy choice. We want downstream providers like retailers and distributors, even though they weren't at fault, even though they did nothing wrong, to pay to

protect hapless consumers from the vagaries of chance.

That is why strict liability as to retailers and distributors is more like the absolute liability regime that the Supreme Court was referencing in Bartlett. It is liability without fault because we recognize that the retailers didn't necessarily do anything wrong, but they nonetheless have to pay to serve important public policy reasons.

Your Honor, I think the retailers and the distributors in other contexts are already familiar with this. They make the same arguments themselves. As Ms. Goldenberg said yesterday, states like Minnesota, and others like Texas, have passed, at the retailers' behest, so-called innocent seller statutes. We talk about that in our second round of Motion to Dismiss debriefing.

There are important exceptions that are relevant, but for purposes of the preemption discussion, it is relevant to note that they characterize themselves as innocent sellers, as those who didn't breach any duties. They have persuaded state legislatures in some states to agree with them.

I admit we all have a strong intuition that if you haven't done anything wrong, maybe you shouldn't be made to pay. The states, as sovereigns in an Erie analysis, have every right to listen to their arguments and to embrace those public policy principles, but the states who have chosen not to enact those innocent seller statutes, they have the same right to

adhere to the more ancient principles that say even though they have done nothing wrong, they should have to pay. That sure sounds like absolute liability to me, your Honor.

Innocence means you are not at fault and you haven't breached any duty, but conscripting the retailers and distributors into the role of an insurance provider is something we have been doing since, like I said, 50, 60, 70 years ago. It is a perfectly legitimate practice, and preemption has nothing to say about it.

There is no duty under Federal law that they can point to that says the public policy choices of the states that adhere to the traditional rules of strict liability need to be cast aside.

The final point that I want to address is the one my friend concluded with, which is the Drug Supply Chain Security Act, and once again, your Honor, let's start with what we agree on.

We both seem to agree that no Court has ever construed this provision, and so as a consequence, this Court has to return to first principles and the canons of statutory interpretation. As the Supreme Court and the Eleventh Circuit have said multiple times, the first canon is the statutory text.

Where the statutory text is plain, the sole function of the Courts, at least where the disposition required by that

text is not absurd, is to enforce the statute according to its terms.

We think that this entire regime comes down to the word "tracing". Contrary to what my friend said, tracing is not a defined term in the statute. The T in tracing in the express preemption clause is not capitalized and so the word gets its ordinary meaning.

Before turning to that, I just want to make sure that I read the provision to the Court in full, because I think that my friend omitted some key language that is important.

The statute's express preemption clause is 21 U.S.C. Section 360eee-4. It says, "Beginning on November 7, 2013, no state or political subdivision of a state may establish or continue in effect any requirements for tracing products through the distribution system."

There is then a parenthetical, including any requirements with respect to statements and distribution history, transaction history, it goes on and on, and then it says, "or recordkeeping relating to such systems."

The "relating to such systems" language is crucial. It means that the entire parenthetical is modifying the tracing products through the distribution system language. So, once again tracing is the crucial word that we need to define not based on a statutory definition, but the plain and ordinary meaning, your Honor.

How is trace defined? Well, Miriam Webster defines trace as a verb, to follow the footprints, track or trail of. The American Heritage Dictionary defines it as to locate or ascertain the origin of. Roget's Thesaurus gives synonyms for trace: Birddog, chase, follow, track, and hound.

None of our claims against the distributors or retailers hinge on how they tracked Ranitidine through the distribution system. We are willing to stipulate that they followed the footprints of the Ranitidine containing products perfectly. They knew which manufacturer it came from, when it arrived at the distributor, where the distributor took it, when it was dropped off, and when the pharmacist dispensed it to a particular patient.

We will stipulate that they did all of that without a breach of any state responsibilities.

None of our arguments hinge on a breach of those sorts of duties. This is a very narrow express preemption clause, and as my friend pointed out, there is a saving clause, and the saving clause makes it even clearer that the statute is only talking about tracing. Once again, tracing doesn't have a capitalized T in the saving clause. It is based on the ordinary meaning of that word that the Court should approach the statutory interpretation question.

Thank you, your Honor.

THE COURT: Okay, thank you.

Did the Defendants want to come back on for any kind of a rebuttal?

MS. KAPKE: Yes, your Honor, I would like to first briefly address Mr. Keller's argument regarding our reply brief on misbranding.

The retailers and pharmacy Defendants primarily defer to the arguments ably made by the generics counsel and forthcoming by the brand counsel.

But we did offer in reply an example of why Plaintiffs' misbranding of parallel claim argument makes little sense when applied to the retailers and pharmacies.

It is true that Section 333's good faith exception only relates to criminal liability, but what that provision does is demonstrate that Congress recognizes the difference between manufacturers who have some control over the design and labeling of a product and downstream Defendants who do not.

When a pharmacy dispensed Ranitidine as manufactured by an FDA approved manufacturer, it was engaged in an act that FDA specifically allowed. So, the misbranding argument doesn't make sense to us as applied to the downstream Defendants. That was in response to Mr. Keller's argument to the distributors.

In response to our Mensing, Bartlett claim, Mr. Keller explained that the retailers and pharmacies could comply with other duties, but he never explained what duty that the

retailers and pharmacies violated other than to stop selling or dispensing Ranitidine, and Bartlett squarely forecloses the stop selling theory.

On the absolute liability versus strict liability idea, it is interesting to me because he said in earlier arguments that strict liability is based on a duty not to sell a defective product. That is a duty in and of itself, and it is different than absolute liability because there is an aspect of defectiveness to the claim. Plaintiffs cannot prevail on their claim unless they prove that Ranitidine is defective.

Now, they have alleged that Ranitidine is defective, and we will accept that for purposes of a 12(b)(6) motion, but absolute liability is very different. Absolute liability is worker's compensation or a vaccine act claim where all you have to do is prove causation, you don't have to prove some sort of defect.

The duty here is a duty not to sell a defective product. Plaintiffs want to focus on a duty to compensate versus a duty not to sell. There is no duty to compensate injured parties under a strict liability theory. A strict liability theory is what Plaintiffs are relying on in this discussion, supposedly, according to my friend, Mr. Keller, but, really what they are doing is a duty not to sell, and that is where Bartlett squarely forecloses their theory.

Finally, I will turn back to the Drug Security Act and

in claiming that this is a narrow preemption clause, Plaintiffs for the first time make an argument that the last part of the parenthetical modifies the entire part, but I'm reading it right now, and I just don't understand this argument.

It says, "any requirements for tracing products through the distribution system, including any requirements with respect to transaction statements." The transaction statement is the centerpiece of this preemption argument, and Plaintiffs have no response to it.

What my friend did not address, but he did in opposition, was retroactivity, so I want to spend a few minutes on retroactivity because there are two fundamental reasons why Plaintiffs' claims about retroactivity are wrong and why it makes sense for us to address now in rebuttal.

First, Plaintiffs don't sit Landgraf in its proper context. The Landgraf Court confirmed the principle in Bradley versus School Board at 416 U.S. 696. The Court should apply the law in effect at the time the Court renders its decision. There is no issue of retroactivity when a Court simply applies the law as it applies now to claims that vested after the announcement of the Drug Supply Chain Security Act.

Indeed, to quote Landgraf directly, "A statute does not operate retrospectively merely because it is applied in a case arising from conduct antedating the statute's enactment." That is at PIN cite site 269416 U.S., at 269.

Landgraf dealt with whether a new law can pose new penalties for prior conduct without an expressed statement that Congress intended to do so.

There is a significant difference between ensuring that punitive measures are imposed only when Congress spoke clearly and prospectively limiting future claims that have not yet arisen, which is what Congress did in this particular preemption provision.

Second, Landgraf makes clear that you only apply the presumption against retroactivity when the statute is not clear. Here, the statute is clear. Congress said that states may not continue in effect any state law requirements, continue in effect. In Re: Fontem, cited in the distributors' reply brief and at 2017 WestLaw 10402988, makes clear that the words continue in effect "evinces an intention" to bar any conflicting state requirements that may have existed before the preemption clause came into effect.

Plaintiffs' response to the words "continue in effect" is to attempt to relitigate the idea of whether state-law common law duties are, in fact, requirements, citing language from Bates that jury verdicts are not requirements when they merely motivate an optional decision.

But Plaintiffs' omit several important points. First, the Bates Court agreed that common law duties are state law requirements in a different part of its opinion.

Second, Bartlett discussed this portion of Bates in depth explaining that Bates found the design defect claim not preempted because the claim in question in Bates did not fall within the scope of the express preemption provision of the Federal Insecticide, Fungicide and Rodenticide Act.

Common law duties are requirements under consistent and repeated Supreme Court precedent. The only specific law cited in the briefs on the effect of the words "continue in effect" respond to In Re: Fontem and Colgate versus Juul Labs, both of which found that the words "continue in effect" show clear Congressional intent to apply preemption to all claims.

To quote Fontem, "If this Court concluded that the final rule does not preempt Plaintiffs' claims arising prior to the date of the enactment of the final rule in Fontem then it would continue to apply conflicting state restrictive requirements, however, the statutory language expressly prohibits this," end quote.

Thank you, your Honor. We are happy to answer any questions.

THE COURT: Okay, thank you. So we can have all of the attorneys for both motions 1583 and 1584 to come on the screen since I said I was going to defer any questions from 1583 until after I heard 1584. You can decide who among yourselves will want to answer the questions as I pose them.

Okay. Let me just begin with the same question I

asked earlier this morning. For the preemption motions that were filed by the Defendants, as to the two motions we are discussing, 1583 and 1584, the motions state that they are a Rule 12 motion.

I just want to confirm that each motion is a 12(b)(6) motion based on affirmative defenses.

MS. JOHNSTON: Your Honor, Sarah Johnston for the retailer and pharmacy Defendants. That is correct.

MR. KAPLAN: Your Honor, Andrew Kaplan for the distributor Defendants. That is correct.

THE COURT: Okay. With respect to -- let's see. Also a similar question, and I know that Mr. Keller for the Plaintiffs already answered it when I posed it earlier this morning.

Do Defendants agree that impossibility preemption means that state law imposes a duty or obligation to do something, but Federal law prevents you from doing it?

MS. JOHNSTON: Your Honor, Sarah Johnston for the retailers. Is that a question for the Defendants?

THE COURT: Yes.

MS. JOHNSTON: We agree.

MR. KAPLAN: Your Honor, Andrew Kaplan for the distributors. I would agree except for the issue of stopping selling, which I think falls outside that rubric because that is an action that you could take, but it is still preempted.

THE COURT: Okay.

I want to follow up first with a couple of things that Mr. Keller said before I get into more particular questions that I have.

Going back to your presentation, Mr. Keller, a moment ago, I just want to confirm, did I hear you correctly when you said that you are aware of no state that has an absolute liability cause of action against the retailers and the distributors?

MR. KELLER: Ashley Keller for the Plaintiffs, your Honor. Yes. I want to make sure that I am clear, though, we are aware of no state that calls it an absolute liability cause of action. They call it strict liability.

THE COURT: And you have referenced several times that retailers and distributors don't necessarily do something wrong, but isn't the proper way to frame it under strict liability that what they did wrong was to sell a defective product? Which I think Ms. Kapke was touching on.

MR. KELLER: Ashley Keller again for the Plaintiffs, your Honor. No, I don't think that that's the right way to frame it. I think that is the right way to frame it for a manufacturer.

With respect to a retailer, they are not in any position to know if the product is defective, that is particularly so for prescription drugs. Unlike a manufacturer

who, acting even above a negligent standard of care 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. So, there is no duty that they breached that they could have complied with.

THE COURT: Okay. As to the Plaintiffs, as of today, could a retailer or a distributor sell Zantac? In other words, does the voluntary recall issued by the FDA mean that a retailer or a distributor is compelled by Federal law not to sell Zantac?

MR. KELLER: Is that for the Plaintiffs, your Honor?

THE COURT: Yes.

MR. KELLER: Ashley Keller for the Plaintiffs. Your Honor, the FDA's direction that the retailers, distributors, and manufacturers should pull Zantac from the market was a voluntary recall, so that action by itself wouldn't make it unlawful for them to start selling again.

It would nonetheless be unlawful for them to start selling again because Zantac or Ranitidine is misbranded. It meets the definition of a misbranded drug.

The FDA in its amicus brief in Bartlett noted that even though the misbranding statute is satisfied, the FDA will often go through the route of a voluntary recall instead of a required recall because there are due process considerations with telling an NDA or an ANDA holder that they have to stop

selling, and so the FDA typically prefers to say you better pull this from the market or we'll do something more formal, and uniformly the manufacturers, retailers, and distributors agree with that.

Technically, the recall as it stands right now is voluntary, so that by itself doesn't require them to stop selling. It's the fact that they meet the statutory definition of misbranding that requires them to stop selling.

THE COURT: Okay. To the Plaintiffs as well, Mr. Keller, following up on the topic of absolute liability. There is much discussion in your briefing and here today over whether the retailers and the distributors are absolutely liable for the sale of drugs.

Assume for the moment that the quintessential absolute liability cause of action, and again this was also referenced today, is something akin to worker's compensation. We know that in worker's compensation one does not need to prove that the employer actually did something wrong, the injured employee is entitled to payment even if the employer was not negligent. That is Holliday versus Personal Products Company, 939 F.Supp. 402, at 404, Eastern District of Pennsylvania, 1996.

I have two questions. First, if you were to try a strict products liability case against a retailer, would you agree you would have to prove that the product was defective regardless of whatever state you were in?

And second, are you aware of any state that would permit you to try a strict products liability case over Zantac, but where you would not be required to show any evidence that something was wrong with Zantac or Zantac's label?

MR. KELLER: The answer to question one is yes. The answer to question two is no. Ashley Keller again for the Plaintiffs. I am sorry, Ms. Stipes.

THE COURT: Okay, thank you. Another question for Mr. Keller for the Plaintiffs, and this relates to the Drug Supply Chain Security Act. And there has been much discussion of that as well today in your presentations, so you may have answered it in part, but let me pose the question nevertheless.

The Drug Supply Chain Security Act lists the criteria that must be present to accept a shipment of drugs. For example, and this has been referenced, you must refuse to accept a shipment of drugs if the shipment is missing certain information about the drugs. That's 21 U.S.C. Section 360eee, subsection 26 to 27.

The list of criteria, however, does not include any requirement to refuse to accept a shipment of drugs if you have not independently verified that the drugs are pure or otherwise do not have a defect.

The Drug Supply Chain Security Act expressly preempts any state law that would seek to impose additional requirements in a supply chain that pertain to investigation. That is at 21

U.S.C. Section 360eee-4(a).

Is it Plaintiffs' position that a distributor should have refused to accept a shipment of Zantac from the manufacturers?

Similarly, is it the Plaintiffs' position that the retailers should have refused to accept a shipment of Zantac from the distributors? If so, why should they have refused? In other words, what would be the basis for the refusal?

MR. KELLER: Ashley Keller for the Plaintiffs. Yes, it is our position that they should have refused to accept shipments of Ranitidine containing products regardless of what information they had on these tracing statements because of the misbranding provisions of Federal law.

The provision that you referred to, 360eee-4, as well as the other provision, does nothing to alter the misbranding statute and the duties created under it. The misbranding statute is a strict liability offense that imposes an absolute duty without any knowledge requirement, without any good faith dispensation to stop selling a misbranded drug or to not receive it in interstate commerce.

And once again, the proof for that, outside of the criminal context where there is a good faith exception, is the United States can seek an injunction and seize all of the Zantac that a distributor has received, and they can't point to any statement they have in their possession saying we didn't

know it was misbranded to avoid that injunction and that civil remedy. It's absolute, they must stop selling or receiving that product in interstate commerce.

THE COURT: Another question for the Plaintiffs, Mr. Keller.

Let's say that state law would require a retailer to store Zantac at 50 degrees Fahrenheit. Let's also say, however, that FDA approved storage conditions contain a range of temperatures for storage, but the range is above 50 degrees. For example, suppose the range of FDA approved storage conditions is 55 degrees to 80 degrees.

Would you agree that impossibility preemption would apply to the state law, that is, you can't simultaneously store a drug at two different temperatures?

MR. KELLER: Ashley Keller for the Plaintiffs. Under your hypothetical, if the state law were so specific as to say you must store it at 50 and the Federal law said you must store it between 55 and whatever else, higher temperatures, yes, that 50-degree example would be preempted because it is impossible to square with the range created by Federal law.

We, of course, not to fight your hypothetical, don't think that that's our case. Our negligence allegations against the retailers and the distributors are that they didn't comply with the Federally mandated temperature ranges, and as a consequence, allowed NDMA to form in Ranitidine containing

products.

But under the example you gave, yes, there would be preemption.

THE COURT: Can you point the Court to a case cited in your briefing where a Plaintiff was found to have stated a claim of any sort where the allegation was that the Defendant had stored drugs in accordance with FDA approved storage conditions, and should be found liable for such storage?

And relatedly, can you direct my attention to where, if it exists in your briefing or complaint, the Plaintiffs contend that an entity did not store Zantac pursuant to FDA approved storage conditions?

MR. KELLER: Ashley Keller for the Plaintiffs. I don't believe that we point to a case, your Honor, that addresses your first situation, but it's worth noting that the situation here is fairly unique.

The cancer causing compound, NDMA, forms precisely because of the storage conditions of the drug, at least in part, and so there probably aren't a lot of examples of a molecule that inherently contains within it a cancer causing compound that gets released when it is stored at particular temperature ranges.

So, the lack of a case, I don't think is fatal to our theory. Just basic preemption principles support our analysis, and I don't believe there is any case on the other side of the

ledger either that the other side has cited, recognizing again that it is their burden to establish an affirmative defense. I don't think they point to any temperature changes where state law says, to change your hypothetical a little bit, store this at 55 degrees, Federal law says store it between 55 and 80, and that is found preemptive. So, based on first principles, we are in good shape.

I would point the Court to the master personal injury complaint for your second question, to paragraph 407 that talks about the fact that there was improper storage and transport conditions. I think those factual allegations have to be accepted as true.

And as I noted to your Honor earlier, I think that these allegations are more than plausible when you look at the FDA batch testing that shows, again, the different amounts of NDMA forming in Ranitidine containing products.

A plausible inference that should be drawn in our favor here, since we don't have full discovery yet, is that a significant part of that dispersion was caused by the storage and transport (inaudible) that were undertaken by these Defendants.

MR. KAPLAN: Your Honor, this is Andrew Kaplan. May I respond to that point about the allegations in the complaint?

THE COURT: Yes. I wanted to confirm with Mr. Keller, it is paragraph 407 is what you are relying upon of the

MPIC?

MR. KELLER: Among others. Paragraph 409, paragraph 457 would also be relevant. But 407 is where we talk about testing by the FDA and we say that it resulted in extremely high levels of NDMA because of improper storage conditions, and that is backed up by some other paragraphs like the ones I just mentioned.

THE COURT: So, are you saying implicit, for example, in 407 is an allegation that the entity did not store -- or entities did not store Zantac pursuant to FDA approved storage conditions?

MR. KELLER: Correct, your Honor, I think that is a plausible inference, again, just given the different levels of NDMA we have seen in the different batches. We don't know for sure what temperatures they stored this at because we don't have access to that full discovery yet.

So, we have to plead based on the facts we can glean from the public record. We have the FDA's public record of how much NDMA was formed in Ranitidine. We think it is plausible at this stage that a good portion of that, especially because there were differences between different batches, is the storage and transport conditions.

THE COURT: Mr. Kaplan, did you want to say something?

MR. KAPLAN: Yes, Andrew Kaplan on behalf of the distributor Defendants.

I would like to respond to the suggestion that the complaint pleads that the distributors have violated the shipping and storage requirements on the labeling.

First of all, we don't see that clearly in this lengthy complaint, and Mr. Keller has pointed to paragraph 407 earlier today and again now. Instead, they allege a contrary claim that the product should have been stored or shipped at cool temperatures that are outside the room temperature storage ranges on the labels. And the claim that Plaintiffs have actually pleaded is preempted, especially for distributors who can't change the label or required storage conditions.

Mr. Keller, in pointing to paragraph 407 of the master personal injury complaint which states "testing conducted by the FDA confirms that the improper storage of Ranitidine has resulted in extremely high levels of NDMA."

And earlier Mr. Keller referenced in the footnote 120 to that paragraph where they cite to an FDA letter to Emory Pharmaceuticals that they contend supports the suggestion that this is a -- plays a plausible allegation of deviation from the required temperature storage and shipping.

First, we don't read this as a direct allegation that any specific Defendant, or even a group of Defendants, actually did violate label required storage and shipping requirements, and even if one were to stretch in an interpretation of this one sentence that is in the factual background section, the

letter it cites as support does not actually provide that support.

The Emory letter only says that "elevated temperatures can lead to the presence of NDMA in the drug product." In fact, the letter went on to say that a root cause analysis was still ongoing.

Bottom line is, they have no specific allegation against any specific distributor that they did anything wrong, it is all speculation. Plaintiff must have a plausible basis for a claim before they file their complaint, not wait until discovery to hope they turn up a good faith basis for the claim.

They can't plausibly allege that the distributors violated shipping and storage requirements. Mr. Keller contends that the variation of NDMA in samples tested make it plausible that the distributors didn't handle the product correctly, but Plaintiffs acknowledge that under label required storage and shipping temperatures there is a range of allowable temperatures.

Any variation in tested batches, to the extent that it is even related to temperature, which is conjecture, could differ based on the permissible temperature ranges, and beyond that, the storage and shipping requirements specifically allow excursions from the standard temperature range and, indeed, Plaintiffs argue for cool storage that would presumably deviate

from the standard temperature range, and any variations in tested batches could just as easily result from the normal handling with different permissible excursions.

Under Twombly and Iqbal, that a theory is merely possible according to factual allegations is not sufficient to make it plausible. So, to the extent that the Court credits Plaintiffs' current argument that this claim is in the complaint, it should be dismissed because as not plausible.

To the extent the Court agrees that it is not in the complaint, as we see, Plaintiff has not offered a Rule 11 good faith basis to replead to add such an allegation.

THE COURT: I have a followup question for Mr. Keller just in this topic.

What are the improper storage conditions that are being alleged here? If you don't know what the temperatures are, which I am understanding that you don't because you haven't conducted discovery, how do you know that they don't comply with FDA storage conditions?

MR. KELLER: Ashley Keller for the Plaintiffs.

I think that this whole discussion shows that we have veered, appropriately, from preemption to the 12(b)(6) standard, and we think we do satisfy Iqbal and Twombly which, of course, says you don't credit mere conclusory statements or threadbare recitals of the elements of the cause of action, but you do credit well-pleaded factual allegations even if they are

short statements of fact.

We have all throughout the complaint -- I pointed to paragraph 407 as an example, but it is just one example -- statements saying that Ranitidine breaks down at higher temperatures into NDMA. This is not just mere conjecture. It might be proven true at summary judgment, to Mr. Kaplan's point, but it is more than plausible based on the studies that have already been conducted when exposing Ranitidine to much higher temperatures that a much greater amount of NDMA is formed.

So, when you take that, coupled with the fact that there is dispersion in the batches and FDA has noticed different Ranitidine containing products with significantly different levels of NDMA, we think it is quite plausible that the reason for that is the storage and transport conditions.

I agree I can't say, under Rule 11, that this particular distributor took that particular batch and stored it, even with the excursions, outside of the temperature range contained on the label, in violation of both state and Federal law. I don't have that level of specificity right now, but I would respectfully posit that Rule 12(b)(6) doesn't require that of a Plaintiff to get past this phase of the proceedings.

We have pled enough to get discovery. If it turns out on summary judgment, after taking depositions and getting documents, they did everything right, everything was within the

temperature ranges contained on the label, they can get summary judgment on this question.

We agree that staying within the ranges of the label is required by Federal law, so we are willing to stipulate to that proposition. We do not agree and we don't think the complaint is faulty for saying that they didn't comply with that.

MS. JOHNSTON: Your Honor, if I may I briefly respond to that?

THE COURT: Yes.

MS. JOHNSTON: Sarah Johnston for the retailer Defendants. I would just add that in this discussion of what the complaint actually says and the Plaintiffs' opposition actually says, one paragraph we are skipping over is paragraph 408, which is the only paragraph in the complaint that identifies what the obligation is. The obligation, according to Plaintiff, is that we were obligated to ensure cool storage and transport.

That is very different than room temperature and it is very different than Mr. Keller's recollection of the complaint as he said. Paragraph 408 is repeated verbatim in Plaintiffs' opposition to our Motions to Dismiss, and this is an allegation that, as we have looked through this complaint, doesn't appear anywhere, nothing that says that we went outside of the labeled conditions.

And we have brought a Motion to Dismiss based on the complaint before us, and this is not the complaint before us.

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

THE COURT: You may.

MR. KELLER: Thank you, your Honor. Ashley Keller for the Plaintiffs. This once again returns to a concept that I understand why we have kept coming back to, which is that state law can often require a broader set of responsibilities than Federal law does, but there is only preemption to the extent of the difference.

Yes, we think that state law could have required them to store, if you were only looking to state law, at even colder temperatures than the ones on the label, but those colder temperatures, if you went below the bottom of the range, would be preempted.

That doesn't absolve them from responsibility for sticking with the temperature ranges contained on the label. To the extent that they violated that responsibility, there is no preemption.

Once again, we pleaded these complaints before seeing their affirmative defense. We don't have to anticipate the affirmative defenses that they are going to make to have a well-pleaded complaint under Rule 8. Once they file their oppositions and try to dismiss on the basis of preemption, of course we react to that and we are willing to stipulate, as

officers of the Court with the duty of candor, that they have made some preemption arguments that have teeth, and that's fine, but we are still allowed to proceed on the narrower theories that are still actionable under state law.

THE COURT: Okay. Thank you. For the Plaintiffs, Mr. Keller, you argue that the Drug Supply Chain Security Act is only about tracing a product through the drug supply chain, and since you argue that the Plaintiffs' claims have nothing to do with product tracing, the act does not apply.

If your allegations supporting general negligence are that, at some point, the drugs were overheated and therefore produced NDMA, doesn't that involve tracing the product through the supply chain?

In other words, if a retailer sold NDMA-laced Zantac as a result of exposure to high temperatures, where did those exposures to high temperatures occur, at the store? With one of the distributors? At the factory waiting for pickup?

Wouldn't answering that question necessarily involve tracing a product through the supply chain?

MR. KELLER: Thank you, your Honor, Ashley Keller for the Plaintiffs. First a quick clarification and then directly answering your question.

I don't think we said that the Drug Supply Chain Security Act was exclusively about tracing. What I meant to say, if I didn't say this correctly, is that the express

preemption clause is exclusively about tracing. Section 360eee-4, which is the express preemption clause, is about tracing. There are indeed other provisions of the act, but Congress only saw fit to expressly preempt things involving tracing.

To go to your Honor's question, no is the answer. I don't think that them leaving Ranitidine on a hot truck outside of the variances that are allowed for a significant period of time are about tracing. It is not about them breaching their duty to know where the product is; it is about them breaching their duty to store it at the ranges contained on the label.

They may have perfectly documented, in fact, I hope they have perfectly documented exactly where that product is so that we, as Plaintiffs, can trace it and get access to the discovery. I hope they have all the paperwork that the act requires of them so it will be easier for us to make the case to you, as we plead plausibly now, that they actually stored this outside of the temperature ranges.

But storing it outside of the temperature ranges isn't tracing. Maybe identifying that they stored it outside of the temperature ranges is tracing, but the two are not (inaudible).

THE COURT: For the Plaintiffs, Mr. Keller, are you aware of any MDL wherein retailers or distributors were named as defendants in a master complaint and a claim against those defendants survived a Motion to Dismiss post Bartlett and post

Mensing MDLs?

MR. KELLER: I am not aware of one, your Honor, and I am also not aware of one where evidence of misbranding is as strong as it is here.

THE COURT: This is a question for the Defendants. If all of the claims against the retailers and distributors are preempted, the second round motions, the distributors' Rule 12 Motion to Dismiss on various group-specific grounds, and the retailer and pharmacy Defendants' Rule 12 Motion to Dismiss on state law grounds, do those motions become moot?

MR. KAPLAN: Your Honor, this is Andrew Kaplan for distributor Defendants. If the Court accepts our arguments on preemption, this would apply to all of the claims in the master personal injury complaint and the consumer class complaint, and therefore the remaining motion would be moot, yes.

MS. JOHNSTON: Sarah Johnston for the retailers. We agree, your Honor.

THE COURT: Okay. All right. Thank you all so much, I appreciate it. That concludes the discussion on 1583 and 1584, the questioning.

I would now ask that counsel come up for the last motion to be heard today, which is 1580. Actually this would just be Defendants coming up. This is Defendants' Rule 12 partial Motion to Dismiss Plaintiffs' three complaints as preempted by Federal law and incorporated memorandum of law.

And as I understand it, there will be 18 minutes allotted to the Defendants.

And so, if counsel could state their appearance for the record, and let me know if you would like to divide your time up; and if so, how.

MS. EISENSTEIN: Good afternoon, your Honor, this is Ilana Eisenstein. I represent the Sanofi Defendants, and in this motion we will be speaking on behalf of the branded Defendant manufacturers. With me is my associate, Rachel Horton, who will be introducing this motion.

If we could, we would like to divide it up, I believe Ms. Horton will take approximately three minutes of time to introduce the matter, and then I would like to leave three minutes or so for rebuttal.

THE COURT: Dividing it up, 15 and three, and any kind of a warning?

MS. EISENSTEIN: When there is three minutes left of time, if you don't mind, and we can decide whether to proceed or dig into the rebuttal time, that will be great. Thank you.

THE COURT: All right. You may proceed.

MS. HORTON: Good afternoon, your Honor. Can you see and hear me?

THE COURT: I can see and hear you. Good afternoon. Sorry, I can see and hear you, thank you. You may proceed.

MS. HORTON: Wonderful. I am Rachel Horton and I am

joined by my colleague Ilana Eisenstein. Ms. Eisenstein and I will be arguing on behalf of the branded Defendants about why Plaintiffs claims are preempted by Federal law. My introduction will provide an overview of Ms. Eisenstein's arguments.

Plaintiffs are correct that the preemption analysis compares Federal and state requirements, however, Plaintiffs misstate both. Plaintiffs claim that any unsafe aspect of a medication violates the Federal misbranding statute. That is incorrect. The source of Federal requirements is the NDA.

The Federal misbranding statute is only violated with a departure from the FDA approved labeling or formulation.

In defending against these Motions to Dismiss Plaintiffs ignore the gravamen of the complaints which allege that Zantac is inherently unsafe, Zantac should have been labeled differently, that Defendants should have made statements other than what was in the label.

Plaintiffs fall back on narrow, isolated allegations in their complaint. In doing so, Plaintiffs seek an order that Defendants stop selling, which has been rejected by every Court that has considered such a demand.

Having excised the preempted theories of liability, the next step is for the Court to evaluate whether any viable claims remain. Plaintiffs here cannot use their narrow theories of liability to save the remainder of their claims

from preemption.

Next I will address express preemption and then implied preemption. Plaintiffs in the MDL have brought 320 state law claims, either individually or on behalf of the putative class, that seek economic damages or refunds for over-the-counter Zantac, however, the Federal Food, Drug and Cosmetic Act expressly preempts claims that seek a refund for over-the-counter Zantac.

Section 379(r), subsection a, bars consumers from filing state law claims for economic harms relating to over-the-counter products that are different from, in addition to, or otherwise not identical with the FDCA's requirements. All three complaints allege that the FDA approved formulation and label were not worth the purchase price. Such claims are expressly preempted.

State and Federal Courts throughout the country have so held because Plaintiffs merely base their claims on a manufacturer's failure to change medication labeling, packaging, or other branding which would sidestep Federal law.

Plaintiffs are incorrect that their claims are saved by Section 379(r), subsection e's narrow personal injury savings clause. Plaintiffs have not alleged any physical injury or property damage. That means Plaintiffs have no personal injury claims under Federal law, which is the standard this Court should apply, or even under the law of the vast

majority of states.

Plaintiffs seek to bypass express preemption by claiming that they are asserting a parallel claim based on a purported violation of the Federal misbranding statute. That argument fails because it is based on an internal contradiction. No Court has found that the medication that complies with its FDA approved labeling and formulation is "misbranded". Such medications are by definition correctly branded because the FDA has approved their label and formulation.

As to implied preemption, Plaintiffs assert design defect claims for both over-the-counter and prescription Zantac in the personal injury and consumer class action complaints.

The heart of those 49 claims is that the branded Defendants should have designed Zantac or Ranitidine differently. Under the Supreme Court's precedent in Mensing, such claims are impliedly granted. It was impossible for the branded Defendants to comply with an alleged state duty to redesign medication where FDA regulations prohibit a manufacturer from unilaterally doing so.

Plaintiffs assert no viable response to the branded Defendants' implied preemption argument. Instead, they say their design defect claim merely states redundant failure to warn and labeling claims. Thus, this Court should dismiss with prejudice Plaintiffs' challenges to the design, formulation,

and chemical composition of Zantac.

Thank you.

MS. EISENSTEIN: Thank you, Ms. Horton. This is Ilana Eisenstein.

Your Honor, we have heard the term "misbranding" countless times today on the part of the Plaintiffs, and I am sure your Honor is left wondering, how does this really play into the preemption arguments that we are asserting here as a basis to dismiss.

I want to clarify a few things to build on what Ms. Horton argued about how express preemption works and how implied preemption works and why this misbranding theory simply is no defense to the motion that seeks preemption of broad swaths of the Plaintiffs' consumer class action claims and the design defect claim.

Let me start with the express preemption provision. I think there is one thing that Plaintiffs and Defendants can agree on. Mr. Keller states that the Federal preemption inquiry with respect to the express preemption in particular requires a comparison of the state requirements on the one hand to the Federal requirements on the other to see if they are the same, and state requirements are preempted to the extent they differ from, or add to, or are not identical with the Federal requirements, but here is where we depart.

The Plaintiffs try to use the staggering breadth of

their own allegations and a mistaken mischaracterization of Federal misbranding law to obscure the preemption of really the heart of their complaint, and in particular, their class action complaint with respect to the consumer claims that seek a refund for the price of Zantac.

This boils down in their brief to the claim that both state and Federal law impose the same duty, do not sell a dangerous drug. This simplistic view is a mischaracterization of their own claims and it's a mischaracterization of misbranding law.

Let me start with the Federal side. It is simply incorrect that Section 352 makes it a crime to sell a product that complies with the Federally approved label and composition. It is departures from the approved label and departures from the approved formulation and design, or departures from Federal manufacturing standards that can give rise to a misbranding violation.

Plaintiffs have not pointed to a single Court regulatory action or other place where they can say that here has been a misbranding allegation under these circumstances.

Instead, if you look at what is the source of Federal requirements, the source of Federal requirements isn't the misbranding statute, so the other problem with the Plaintiffs' allegations is, they try to hinge the source of Federal requirements on these generalized notions in the misbranding

statute, not the NDA itself.

You look at Court after Court when they have tried to evaluate what are the Federal requirements to which we're comparing the state requirements, they look to the NDA, and that is true in the cases that involved OTC preemption, which are fewer and farther between, but they include the Carter case, the Mills case, the Canter case, all of which are cited in our briefs.

It is also true in the much more robust arena of the medical device amendments where, when Courts try to evaluate in the medical device amendments what are the Federal requirements at issue, they look to the premarket approval, which is the equivalent for devices of an NDA. It is the premarket approval, along with certain manufacturing requirement, and perhaps storage and transportation requirements, that form the Federal requirements to which state requirements are compared.

So, the premise of Plaintiffs' claim that misbranding is this catchall that sucks in any unsafe product is simply untrue, and when stripped away from that premise and focused instead on the true Federal requirements, I think it is clear why the consumer class action claims are preempted.

Before I get to that, I do want to refute one thing that I heard earlier today from Mr. Keller.

He stated on at least a couple of occasions that the

FDA regulatory action in this case, the voluntary recall by manufacturers and then the FDA recall of Zantac, established in some conclusive way either that Zantac is dangerous, or he even stated early on in his argument that it is misbranded.

That is simply not the case. There is no finding by the FDA of danger with respect to Zantac. There has been no findings by the FDA at all other than a precautionary measure to remove Zantac from the market in light of the allegations that were made.

There are legions of cases that have held that a recall doesn't create evidence of a violation of Federal law. It is certainly not evidence of misbranding, much less even a presumption that that is the case, and that is because a recall is a different kind of regulatory action. It is not a finding of misbranding, a violation of Federal law.

What this really comes down to is, what are the state law requirements that Plaintiffs are trying to impose?

If you look at the consumer class action, it is rife with allegations that amount to a head-on challenge to the safety and efficacy of Zantac, Zantac as a molecule, the Ranitidine molecule, as well as the Federally approved label and formulation.

Plaintiffs acknowledge as much. What they do is they fall back on a sliver of allegations that they say do lead -- do assert some kind of departure from Federal requirements.

They say that there might have been storage problems when outside the storage limitations of the label, that perhaps there was a manufacturing issue, perhaps there was a failure to adhere to reporting requirements to FDA.

But those grabs at claims that are left are not sufficient to state their claim, and that is something that I think Plaintiffs in both the implied and the express preemption realm obscure, which is the process that this Court should go through is first strip away the vast majority of these allegations that are preempted, and then the little slivers that are left, then we will see if these amount to a claim that can continue to state a cause of action.

Some of those little slivers might lead to a claim that survives this preemption motion, but this Court should narrow the theories of liability. I think that is one of the key planks of Mr. Keller's presentation, is some kind of assertion that what should happen at the end of the day is that all of these preemptive theories should still survive so long as some sliver of their claim could support a cause of action, or any cause of action in these broad complaints.

That is not the way this should work, especially in an MDL this size and scope. It is the normal course, but also the appropriate course to strip away the preemptive theories of allegation and to strip away the preemptive claims and then see what is left.

And then, as your Honor knows, there is a third round of Motions to Dismiss and we will see if any of these claims end up surviving that third round when we have now narrowed the field.

THE COURT: I just want to let you know you are at 13 minutes.

MS. EISENSTEIN: Ms. Horton covered, I believe, on the design defect component the fact that the Plaintiffs have really backed away from the design defect claim and have resorted to redundant failure to warn claims. We have heard nothing today that departs from that.

And just as in the express preemption realm, this Court should strip away the preemptive theories in the implied preemption context, strip away the design defect theories that Plaintiffs have admitted multiple times even today that they cannot proceed with because it is impossible for manufacturers to modify the FDA approved design.

I will leave it at that, your Honor, and save a couple of minutes for rebuttal.

THE COURT: Okay, thank you. We will have Mr. Keller for the Plaintiffs for his 15 minutes.

MR. KELLER: Thank you, your Honor. Good afternoon, Ashley Keller for the Plaintiffs.

I'll be talking about misbranding and some of the points that were just raised. I will then turn to the

over-the-counter preemption argument under 379(r).

To begin, we have been sort of accused, I think, by my friends on the other side of mischaracterizing the misbranding statute. Your Honor, in my earlier remarks I quoted the definition of misbranding directly from the Food, Drug and Cosmetic Act and then I quoted the duties created by the misbranding statute.

They, on the branded side, want to come up with this alternative theory that they didn't ground in statutory text, that they didn't ground in the Code of the Federal Register that says as long as we complied with the FDA label back in 1983, and we affix that to the product, we cannot ipso facto as a matter of law be accused of misbranding, and that is just simply incorrect.

It appears nowhere in the text of the statute the Supreme Court rejected that proposition in Footnote 4 in Bartlett, which nobody has grappled with. I quoted the CFR that says that that is not true. Even an FDA approved drug can be misbranded if new and scientifically significant information comes to light.

So, the brands are simply saying that because we complied with the label you have to give us a get out of liability free card, and that appears nowhere in the law.

I think it is also important to note, your Honor, that the categories of Defendants don't seem to agree with each

other on what the misbranding statute is. I quoted the text, they are making these other arguments and they are at cross purposes with each other. For example, the generic manufacturers incorporate by reference the brand briefing on misbranding. This is in the generic reply at 10. But then they contradict the brands.

The generic manufacturers say, this is in their reply at 11, that misbranding claims can only apply to those that bear no connection to the label. But the brands say just the opposite at page 14 of their reply brief, and you just heard it now. They say that by simply complying with the NDA and the label that was affixed to the product by the FDA back in 1983, we are automatically shielded from liability on misbranding.

So, neither of those propositions are consistent with each other, neither of them are entirely correct. The Court should just look to the statutory scheme to discover the definition of misbranding. Congress put it in plain English. Similarly, the duties associated with misbranding are stated in plain English. There is no ambiguity surrounding that.

I have to clarify as well something that my friend just said because I think she may have misheard me, and your Honor can pull the transcript. I am not confident of that many things, but I am a hundred percent positive on the following point.

I never said, in response to your Honor's question,

that the FDA's requiring the Defendants through a voluntary recall establishes misbranding as a matter of law. I said, no, that by itself doesn't establish misbranding as a matter of law, it is that coupled with the new scientific information that we say in the well-pleaded complaints meets the definition of misbranding.

Yes, a voluntary recall by itself is not proof of misbranding, it is probative. The FDA didn't tell all of these Defendants to pull Ranitidine from the shelves because it was no big deal that NDMA was forming, but they didn't technically go through the mandatory recall provision, and they didn't make a misbranding finding, and we never stated anything to the contrary.

There is a little bit of a technical point that is going on here, your Honor, but technical points can still be important so I want to respond to it. We say in our briefing, and I am sure your Honor picked up on this, that Courts dismiss claims, not theories. So, the Motion to Dismiss, if it is going to be granted, has to be because we state no theory that is possible to pursue consistent with Federal law.

My friend just said that my position previously was that even though there are a bunch of theories that we now recognize based on their arguments in their Motions to Dismiss can't proceed under the supremacy clause, that we should just ignore that and the theories should be allowed to move forward.

Absolutely not, that is not what I am saying. The theories that are preempted cannot be pursued, but Courts don't dismiss theories, they dismiss claims.

If there is a different theory that could support the claim, even if it is narrower, that theory needs to be allowed to proceed.

So, there is a little bit of us talking past each other, but I think that that is an important point, that it ties back in to all of the discussions we have been having before about Bates and Mink and preemption only applying to the extent of a difference between state and Federal law.

Our design defect claim can be stated with a theory that the label was defective. Yes, that is a narrower theory than saying the brands had to redesign the molecule, but it is a viable theory under the law of New Hampshire, under the law of basically every state. Bartlett embraced this. So, they can't get dismissal of a design defect claim when there is an available theory for us to pursue.

Let me turn to the over-the-counter provision, your Honor, and there is, of course, an express preemption clause here with a saving clause, and I will address them both separately.

It is worth noting at the outset that the brand manufacturers don't even move to dismiss our failure to warn claim. So, at least for the purposes of a 12(b)(6) -- they

have, of course, reserved all of their rights for summary judgment, but for purposes of a 12(b)(6), they acknowledge that they could have changed the warnings and precautions section of the label.

Maybe they also acknowledge that they could have changed the expiration dates, but they certainly could have changed the warnings and precautions section, because they know that Wyeth versus Levine squarely holds that the CBE regulation is available to them and they don't need the FDA's prior permission or approval in order to make that sort of change.

How does that square with their argument on the express preemption clause? Under the express preemption clause, a state duty like failure to warn, to change the label so that you add warnings and precautions about cancer is not preempted to the extent that it is the same as Federal law, and Federal law also requires them to have an accurate label.

When new and emerging science comes to light that demonstrates that your label is inaccurate, it is not incumbent on the FDA to tap you on the shoulder and say you need to make this change. Wyeth versus Levine is crystal clear, the FDCA places primary responsibility on the manufacturers to keep abreast of this emerging science and new information.

So, they had a duty under state law and under Federal law to change their labels. Those duties are completely parallel with each other, and as a consequence, there can't be

preemption with respect to those claims.

Similarly with our misbranding theory, your Honor, they had an obligation to stop selling a defectively designed product. We have already marched through the statutory definitions, and state law created the exact same duty as a matter of design defect law. So, once again there is no preemption on the terms of the express preemption clause because state and Federal responsibilities are identical to each other.

Let's turn to the saving clause, your Honor, because even if you don't find that there are parallel claims, to the extent that we are pursuing product liability law of any state, that is expressly carved out of the express preemption clause.

The key point to note here, your Honor, is every single case that the Defendants cite, Carter, Cantor, Mills, and others, which they say we found a few cases, we didn't find these cases, these are the brands' cases. They all look to the law of the states to determine what a product liability claim is, and that makes sense given the text of the saving clause. It says the product liability law of any state.

The only response that they have to this, your Honor, in their reply is to say, well, those cases that the Plaintiffs found, even though the Defendants are the ones that cited them and found them, those were a different context, those were single cases. This is a big complex MDL sitting in diversity,

so it is more important here to have a Federal definition of a product liability claim instead of relying on the uniform line of authority that says you look to state law.

With all due respect, your honor, the definition of a Federal statute doesn't turn on whether the case is complex or not, or an individual case. Whether product liability law of any state refers to state law or Federal law can't turn on the complex manual for litigation in MDLs, which the brands also cite. Every case that they cite points to state law, it is uniform in that regard. And not all states have the same definition of a product liability claim.

So, the only way that they can prevail under the savings clause is to go state by state and point out the ones that would define a product liability claim to defeat the claims brought in the class complaints. They haven't met that burden.

There are some states, we acknowledge, that would define a product liability claim as one that would preclude liability here, but the states are not uniform on this front, and this is a theme that has recurred throughout these oral arguments. Treating the states as the sovereign entities that they are, with the nuances that they are allowed to have within their own state system is the appropriate course of conduct.

It doesn't matter whether the MDL is complex, that is the only approach that makes sense.

The final thing that I would like to conclude with, your Honor, is that the challenge I set forth at the beginning of these oral arguments has not been met. I asked any category of Defendant to offer a single concrete example of parallel claims where the state and Federal duties were the same, but it was nonetheless impossible to comply with both. No one has met this challenge, your Honor, because they cannot as a matter of logic.

Instead, you have heard some citations, snippets of cases that say just because you survive express preemption, that doesn't mean that you survive implied preemption. We heard about the Guarino case and others.

We agree that the Supreme Court has said in a case called Guyer (phon) that just because you survive express preemption, it doesn't mean you survive implied preemption. How is that consistent with the challenge that I set forth earlier? It is his consistent for two different reasons.

First, not every express preemption clause is as broad as the one here under 379(r), or under the Medical Device Act. Those are extremely broad express preemption clauses that require identity between the state and Federal duties in order for the state duties to survive preemption.

You could imagine narrower express preemption clauses where there still might be some space for implied impossibility preemption to exist, but not with these express preemption

clauses.

The other reason that Guyer is consistent with our view, your Honor, is because implied impossibility is not the only type of implied preemption. There is also objects and purposes preemption or field preemption. Importantly, they haven't briefed those branches of the preemption doctrine. If they did, we would respond and they would lose, and I can demonstrate why field and objects and purposes preemption have no space here to preempt our claims, but that is beside the point.

The Supreme Court was merely saying just because you make it through express preemption, doesn't mean you don't have to walk through the mine field of the other categories of implied preemption. They were not talking specifically about implied impossibility preemption, your Honor, and it is impossible for there to be impossibility on the facts that we allege here.

Thank you.

THE COURT: Thank you. Did the Defendants want to come back on for any rebuttal?

MS. EISENSTEIN: Yes, your Honor. This is Ms. Eisenstein.

Your Honor, let me start with Bartlett. Footnote 4 posed a hypothetical and left open the question of whether misbranding could exist based on the lack of safety of a

product, but either before that time or since that time there has been no case where that has occurred.

While misbranding -- compliance with the label is not an antidote to misbranding if there was some other provision of Federal law that was violated, there has to be a separate provision of Federal law that is violated. Some Courts have described misbranding as a derivative violation. It is derivative of violations of other requirements of Federal law. In and of itself it doesn't impose a free-standing criminal violation for selling an unsafe product.

I want to point to something else that Mr. Keller just said. He said that he recognized that this Court could dismiss his claims to the extent they are preempted, and we agree.

I think the Mink case that Mr. Keller is very fond of is illustrative because in Mink the Plaintiff wisely pled his claim, state law claims, only to the extent they directly paralleled the Federal claim. That was specified in the decision, and that is in serious contrast to this wide-ranging complaint that states allegation after allegation that directly challenges the FDA approved label and design of Ranitidine.

So, what we ask is that those claims are dismissed to the extent they are preempted.

And lastly, on product liability, the product liability savings clause under 379(r), Mr. Keller says that we need to go state by state.

Well, it is his burden, first of all, because it is a savings clause. But even apart from that, even if we were to look to state law, Plaintiffs have pointed to no state law that imposes product liability, or characterizes product liability as a refund claim. Refund claims are not product liability claims. Product liability claims are claims that reach harms that are derived from the use of the product, not a claim for the refund itself.

In their briefing and here today they have pointed to no case that puts refund claims in the category of product liability under any state law.

I will conclude there and leave it to your Honor's questions. Thank you.

THE COURT: Thank you. If we can have all counsel come on. One last round of the same questions just so I am crystal clear.

The Defendants' motion, preemption motion, stated that it was a Rule 12 motion. Is it correct that the motion is a 12(b)(6) motion based on an affirmative defense?

MS. EISENSTEIN: Yes, your Honor.

THE COURT: Okay. Do you agree that impossibility preemption means state law imposes a duty or obligation to do something, but Federal law prevents you from doing it?

MS. EISENSTEIN: Yes.

THE COURT: For Plaintiffs, misbranding. The master

complaints do list several -- and we have talked about it at length today, counsel have on both sides in their presentation. The master complaints list several subsections of the Federal statute defining misbranding. That is at 21 U.S.C Section 352, which Mr. Keller cited into the record today. And that is also at your master personal injury complaint, paragraph 419, and the consolidated consumer class action complaint at 599, and the consolidated third party payor class complaint at paragraph 185.

In pages 15 and 16 of your opposition where you explain Zantac was misbranded, you cite only 21 U.S.C. Section 352(a)(1) and -- actually (a), I think it is (l) and (j).

Let me just look at your response. I want to make sure I have -- no, it is 352(j), and then you have and Section (a)(1).

So that the Court is clear, are subsections (a)(1) and (j) of Section 352 the only subsections that you maintain are at issue? And if not, could you specifically identify the other subsections that you maintain apply in this case?

MR. KELLER: Ashley Keller for the Plaintiffs, your Honor. For purposes of the definition of misbranding that we offered, I believe these are the only sections that we were referring to.

THE COURT: Are any other subsections at issue in the misbranding statute?

MR. KELLER: Ashley Keller again for the Plaintiffs, your Honor. For purposes of the definition or just at large for the other --

THE COURT: Including the other propositions. It was unclear from your briefing, matching it up with your allegations in your complaint, so I just want to make sure I understand.

MR. KELLER: Understood, your Honor. The next page, so Section 331, is also definitely at issue. That is what announces the duties associated with the misbranding definition. That is a crucially important provision of the statute that we also think is relevant.

For purposes of rebutting some of the points that you have heard and that we didn't see until the reply briefs came in, there may be other sections relevant like the good faith carve out which is, I believe, contained in Section 333, and the criminal penalties contained in Section 333(a)(1).

But for purposes of our main argument, it is 352 and 331.

THE COURT: Do you know of any states that recognize causes of action sounding in "misbranding" that you maintain are parallel to the Federal misbranding statutes?

MR. KELLER: Ashley Keller again, your Honor. Yes, the duties created by state law I think almost uniformly would apply, but the title of the cause of action is not misbranding,

it is design defects. That is why in my opening remarks I reminded the Court of the teaching of Bates, which is that state law doesn't have to use the same phraseology as Federal law. They don't have to title their cause of action misbranding. As the Court said in Bates, it would be unusual and surprising for the states to do that. That is not how they announce their common law. It is just that the duties have to match.

No. To answer your question with a yes or no, no, I am not aware of states that call the cause of action misbranding, but the duties created by the state causes of action parallel the misbranding duties.

THE COURT: And those causes of action would include design defect causes of action, and what other types causes of action?

How would one survey all state laws to ascertain a duty that one can glean from a state statute among many state statutes that, based on the argument you were making earlier, that even if there are many duties, and some of those duties are in conflict, as long as there is one duty that may be parallel to a Federal duty such that it is not impossible to fulfill or to meet that duty? What does that look like?

MR. KELLER: A good question, your Honor. I am happy to narrow it for the Court so that it's an easier inquiry.

We will rest it on design defect for purposes of the

duty to not sell a defectively designed product in this regard. The Supreme Court accepted that in Bartlett under New Hampshire law, as we noted. But this would be true of common law design defect throughout the 50 states. There would be an obligation to stop selling a defectively designed product. So, if you focus on design defect, I think that will get you there.

The consequences of recognizing the stop selling duty, to the extent the facts establish misbranding, could have impacts on other claims, but because Bartlett has already accepted the formulation under design defect law, I think it is easiest to focus on that for purposes of this analysis.

THE COURT: Have the Plaintiffs undertaken that analysis of all design defect laws in all states to ascertain which claims may survive an impossibility preemption?

MR. KELLER: Ashley Keller for the Plaintiffs. We haven't conducted a 50 state survey of design defect causes of action. We know that we have binding Supreme Court precedent on one state, the state of New Hampshire, but I surmise that the law is going to be the same everywhere having looked at enough different states on design defect and the duties associated with it.

For purposes of a master personal injury complaint, I think it is sufficient if even a single state lets this theory go forward and, obviously, once we are not dealing with cross-cutting issues anymore, but we're focused on specific

Plaintiffs at the bellwether phase or some subsequent round of motion practice, it may be more appropriate to zero in once a choice of law analysis has been done on particular state law.

MS. EISENSTEIN: May I respond to that, your Honor?

THE COURT: You may.

MS. EISENSTEIN: Your Honor, I just feel I need to respond to what Mr. Keller said about Bartlett. Bartlett did not accept that misbranding is an exception to implied preemption. In fact, it said exactly the opposite. It directly rejected the idea that stop selling is an exception to implied preemption when a manufacturer cannot comply with Federal law. It says so explicitly. It says --

THE COURT: Wait. When you put your head down it made it difficult for us to hear.

MS. EISENSTEIN: I'm sorry. So, Bartlett rejected exactly the point that Mr. Keller is suggesting, that somehow there is an exception to implied preemption where a manufacturer can otherwise -- it is impossible for the manufacturer to comply with both the state law and the Federal duty that stop selling is the result.

In fact, it said that explicitly. It says preemption law does not presume that an actor seeking to satisfy both his Federal and state obligations that it is not required to stop acting in an attempt to avoid liability.

What Mr. Keller said is wrong both as a matter of

Footnote 4, which related to a hypothetical and was not something that the Supreme Court decided, but it also is wrong with respect to the conclusion for implied preemption. If it is the case that as designed and labeled under Federal law, that states would have deemed it a design defect, the result is not stop selling. The result is that state law theory of design defect is preempted.

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

THE COURT: You may.

MR. KELLER: Ashley Keller for the Plaintiffs. I think once again my friend and I are talking past each other. When I quoted Footnote 4 in Bartlett what I was rejecting was the brands' argument that just because they have the FDA approved label on their product that shields them from misbranding.

Footnote 4 says the opposite. "The misbranding statute requires a manufacturer to pull even an FDA approved drug from the market when it is dangerous to health, even if used in the dosage or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

I never said that Bartlett embraced our theory. I was candid with the Court in my opening, I'll be candid with the Court again, Bartlett left the question open. We are not saying that Bartlett squarely embraced the theory that we are

pursuing. It left it open.

And the cases that have addressed this situation since have also left the question open. The Sixth Circuit case that you heard about in Darvocet, it didn't reject the misbranding theory, it said we don't need to decide it because the Supreme Court left the question open in a narrow set of circumstances. It is not opening the barn doors for any type of misbranding theory to proceed. There has to be new and scientifically significant information that the FDA never previously considered.

That is our case, not the Darvocet case. That is our case, not Bartlett. I have never over stated Bartlett to this Court. I agree that the question is an open one and your Honor is free to answer it.

MS. EISENSTEIN: Your Honor, I just wish that Mr. Keller would read the entirety of Footnote 4 instead of exerting the key portion where the Supreme Court says we do not reach. So I think that is very telling that he read the portion that goes to (inaudible).

THE COURT: Wait, wait, Ms. Eisenstein. Why don't you start over. Maybe you are too close to the microphone.

MS. EISENSTEIN: Your Honor, thank you very much. This is Ms. Eisenstein.

What I was hoping was that Mr. Keller would read the entirety of Footnote 4, instead of only the portion where he

talks about the requirement. What he misses, we do not reach the issue that was raised as a hypothetical by the Government. He doesn't hit at all the actual holding of Bartlett which said that stop selling is not an antidote to implied preemption.

He makes this logical leap based on this concept of -- hypothetical concept of misbranding that Bartlett did not recognize, and then tries to import something that directly contravenes the actual holding of the Supreme Court's case.

THE COURT: Be assured, both sides, that I have Bartlett, I have Footnote 4 in front of me, and I appreciate the positions articulated and I think we can move on from that particular question.

Question for Plaintiffs. Mr. Keller, the Defendants contend that your claims for economic loss, refunds in other words, for over-the-counter Zantac are preempted pursuant to 21 U.S.C. Section 379r. Pursuant to that statute, consumers may not bring claims for economic harm under state laws that are different than, in addition to, or otherwise not identical to Federal requirements under the FDCA.

You contend, that is the Plaintiffs, Plaintiffs' claims are not preempted because Section 379r(e) contains a preemption carve out, which you have referenced today, and the statute doesn't apply to state product liability law, and that some states permit economic damages under product liability law.

You and I got into this a little bit already, so it might be a bit repetitive. This is discussed on page 30 of your response where you say that "several" states permit economic loss for a product liability claim. This is a little bit different question.

Do you concede that if a specific state does not permit a recovery for a specific type of injury, economic loss here, a refund that is for a purchase price, under a product liability claim that your claim for the same would be preempted?

MR. KELLER: Ashley Keller for the Plaintiffs, your Honor. I would concede that we would fall outside of the saving clause. I don't think I would technically call that preemption, I would say the state doesn't recognize the claim, but we would lose either way. It would be a 12(b)(6) dismissal.

The only caveat, though, is before you get to the savings clause, you first have to see that there are nonparallel claims. So, to the extent that we can allege a breach of identical duties, and they have to be identical, that is what it means for the claims to be parallel, we don't even need to get to the savings clause and have a fight over the definition of products liability law.

And with respect to the brands, there are some parallel claims, as we note in the brief. Once again

misbranding, I won't go back to Footnote 4, taking your Honor's admonition that you have it in front of you. And with respect to the brands in particular, there are claims with respect to the labeling, and they don't move the dismiss our failure to warn claims label. So, they recognize that they could have complied with state duties in that regard.

If our claims hinge on those theories, on those duties, we don't get to the savings clause, but yes, if we are in the territory of the savings clause, and a particular state says, no, we don't recognize your right to seek money damages, that doesn't fall within our definition, for example, California of a products liability claim. I wouldn't call it preemption, but we would lose.

MS. EISENSTEIN: May I respond, your Honor, to the last point about the warning?

THE COURT: Yes.

MS. EISENSTEIN: Mr. Keller said this a couple of times, that we somehow conceded that claims based on warnings express preemption because we didn't move to dismiss as a matter of implied preemption. We didn't move to dismiss (inaudible).

I want to note, first of all, that we do not make that concession that we (inaudible) claims that challenge the label of Zantac or Ranitidine were expressly preempted. Court after Court has held that.

I don't think Mr. Keller is really suggesting that it is something other than that, but I also want to make clear that we are not conceding that there is a (inaudible) failure to warn claim.

THE COURT: Wait, wait, wait.

MS. EISENSTEIN: Is that better?

THE COURT: I think it is. For purposes of the transcript, I was able to hear you, but I am not recording in the same difficult manner that Ms. Stipes is. If you could pick up with, I want to make clear, so if you want to state your argument again so we make sure we get it on the record.

MS. EISENSTEIN: Sure. I apologize for the sound. I hope it is better now.

I wanted to be clear, in response to Mr. Keller's argument, that by not raising an implied preemption failure to warn claim that we are in no way conceding that issue, but we certainly are not conceding that as a matter of express preemption that challenges to the FDA approved label are not expressly preempted. They are expressly preempted.

Every Court to have addressed the question of whether a direct challenge to the FDA approved label has found that that falls squarely within the express preemption provision.

There is good reason for that. There is a window here between what is possible to do as a matter of label changes and what constitutes an additional, or different, or nonidentical

requirement, and it is clear that imposing a label that is something other than what the FDA approved is a different, additional, or nonidentical requirement that falls within the express preemption provision.

MR. KELLER: Your Honor, may I touch on that point?

THE COURT: Yes.

MR. KELLER: Thank you, your Honor. I think my friend keeps putting words into my mouth and saying that I was not trying to suggest that there could be parallel claims. Yes, I absolutely am trying to suggest that.

The FDA's position is that when a brand manufacturer has the ability to make a labeling change because new information has come to light requiring the manufacturer to change the warnings and precautions section under state law, it is also required by Federal law. It is a floor and a ceiling according to the FDA.

So, it is not just implied impossibility preemption that would not apply, it would also be express preemption that would not apply if the FDA is correct on this score. Brand manufacturers have to change their labels on the basis of new information, it is not an option.

So, that is the difference between implied versus express preemption here where they are both requirements, as opposed to the Federal law saying you can if you want and state law saying you have to. That would be a situation where there

wouldn't be implied preemption, but there would be express preemption.

Here there is a requirement for both, so we think the labeling argument applies to the express preemption clause. My friend can disagree with that, but that is actually what I was implying.

MS. EISENSTEIN: May I disagree, your Honor?

THE COURT: Let me go back. I want to ask Mr. Keller a question that was a followup from the previous question regarding the injury and if a state did not permit a recovery for a specific type of injury, economic loss.

So, if the Court permitted Plaintiffs to replead, should there be a scenario where there would be some repleading, and provided you specified which states permit recovery for an injury in the form of a purchase price, a refund under a product liability theory, do you know approximately how many states would be pled?

MR. KELLER: Ashley Keller for the Plaintiffs, your Honor. I don't. I came armed with one example of a state where we think we could survive, Arkansas. I don't have a 50-state survey yet, but because I have at least one, I think that we would get through and at least some Plaintiffs would be able to rely on that state's law, assuming you agreed with us, and the uniform line of authority that you should be looking to state law, not Federal law.

I have one illustration and, of course, we would search all of the other 49 states and the two territories and give the Court our best guess based on defining what the state law says and making Erie predictions and things of that nature.

THE COURT: For Defendants, you contend that instead of looking to state law to determine which states allow for recovery of the purchase price under a product liability theory, that the Court should look to Federal common law.

Do you have any citation to a case where a Court relied upon Federal common law to interpret or apply Section 379(r)?

MS. EISENSTEIN: Not to 379(r) specifically, your Honor, and the cases -- the very few cases that have addressed this, which are cases that we cited in our own brief, cases like Cantor and Mills -- I am sorry, Carter and Mills, the Courts have looked to the state law, we acknowledge that, but in other contexts -- in those particular cases it was really one state law at issue, it wasn't a multi-state MDL, and it really didn't make a difference ultimately to the outcome in the case.

Here we still don't think it actually makes a difference to the outcome of the case because we have undertaken the exercise of looking at the state laws, and the vast majority of states don't define product liability at all. So, it would be very odd for Congress to have defined the

savings clause where most states don't have a definition of product liability per se.

You could look to the law of torts or the type of torts that generally are considered product liability, and there we have looked at the law of all of the states and we found none that characterize this kind of refund claim as something that could fairly be characterized as a product liability claim. We have put in that work and we don't see it.

I would also note that the economic loss doctrine, which I think was referred to about purely economic harms that flow from the use of the product might be recoverable, is a different issue. So, there is the refund of the price itself, and then there are some states that recognize that economic harms that flow down, purely economic harms, a minority of states, that flow down from the use of the product standing alone can still constitute a claim.

That is not even at issue here, it is this first refund claim piece, that there is simply no state that recognizes such a claim as anything remotely defined as a product liability action.

THE COURT: Okay, all right. That concludes the questioning for that motion, so, thank you both.

And that does conclude our day as all motions have now been heard that the Court had set to be presented over these past two days.

So, with that, I want to thank everyone. I know they have been two long days and we have had many people either presenting and/or participating by listening and watching, and I want to thank you for your patience over the two days. I want to thank all of the attorneys for careful preparation both in your briefing and in your oral presentation to the Court. It has been most helpful.

At this point, the Court will endeavor to prepare the orders that address the motions in a timely and expeditious manner so as to be able to keep the case moving along in a manner that is consistent with the deadlines that have been set forth in the case management schedule. That is the Court's task.

I will look forward to seeing some, if not many or all of you, later in the week when the Court has set a status conference on Friday where we will take up other matters, but for purposes of our oral arguments on the first round Motions to Dismiss this does conclude our proceeding.

Thank you very much. Everyone be well, have a nice rest of the day and evening.

(Thereupon, the hearing was concluded.)

* * *

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

Date: December 21, 2020

/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter