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
October 4, 2021

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

FOR THE PLAINTIFFS:

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

JESSICA MEEDER, ESQ.
Fegan Scott LLC
150 S. Wacker Drive
Chicago, IL 60606
312-741-1019

FOR THE DEFENDANTS:

LINDSEY B. COHAN, ESQ.
Dechert LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036
212-698-3814

ILANA EISENSTEIN, ESQ.
DLA Piper LLP
1650 Market Street
Suite 5000
Philadelphia, PA 19103
215-656-3307

Official Court Reporter: Pauline A. Stipes
HON. ROBIN L. ROSENBERG
West Palm Beach/Ft. Pierce, FL
561-803-3434

THE COURT: All right. Good morning, everyone. We are here in the Zantac Products Liability MDL litigation, Case Number 20-md-02924, and we are here on two Motions to Dismiss.

At Docket Entry 4403, the Court entered an order regarding the October 4 hearing on the Motions to Dismiss and set forth that the motions that the Court was going to hear argument on today included the Docket Entry 4106, which is Defendants' Motion to Dismiss amended consolidated medical monitoring class action complaint, and then following arguments on that motion, the Court will hear arguments on Docket Entry 4107, the brand OTC Defendants' Rule 12 partial Motion to Dismiss Plaintiffs' second amended economic loss class complaint as preempted by Federal law.

Pursuant to that order, the Court allocated 15 minutes to each side to make arguments, and the Court also indicated that there would be some extra time allotted should there be NextGen or LDC members arguing, and it appears as if we do have that for each of the motions and responses.

You can clarify that if I am mistaken and we will go over that as the group comes up for each motion. I know in the past I had given three extra minutes for each NextGen or LDC member.

So, what we will do is, we will have the persons who are arguing the motion, even if it is one person, but there is another cocounsel that is part of that argument, that the

cocounsel can also put his or her screen on.

We will begin with Docket Entry 4106, the Motion to Dismiss the amended medical monitoring class complaint. We will have counsel turn their videos on, and we will do a sound check, and I will just clarify who is arguing, and also whether there is any additional time that you want to save of your 15 minutes, any time for any rebuttal argument, and whether you want me to give you any notice of your time or whether you are going to be monitoring your time yourself.

So, who do we have arguing the Docket Entry 4106, Motion to Dismiss amended medical monitoring complaint?

MS. COHAN: Good morning, your Honor, this is Lindsey Cohan, I will be arguing for Defendants the Motion to Dismiss medical monitoring complaint. I am an LDC member.

THE COURT: All right. Good morning.

MS. MEEDER: Good morning, your Honor, Jessica Meeder. I will be arguing for the Plaintiffs, and I am a NextGen attorney.

THE COURT: Okay. All right. That is good then. So, we will have you both stay on the screen at the same time, and does an extra three minutes work for you? Do you each want 18 minutes or do you think -- you want to do it in 15? It is up to you. I can give you extra time if you want it and feel you need it.

MS. COHAN: Thank you, your Honor. I am never going

to refuse additional time, so I will take the 18 minutes. In all honesty, I hope to do it in 15.

THE COURT: Okay. If you take the 18, then Ms. Meeder will get the 18, too. Ms. Cohan, do you want to split up your time at all?

MS. COHAN: I would like to please reserve three minutes for rebuttal. Thank you.

THE COURT: You would be doing 15 and then three. Do you want me to give you any notice or are you keeping track of your time?

MS. COHAN: If you could flag that, that would be helpful.

THE COURT: Sure. How much advance notice do you want?

MS. COHAN: Just give me a reminder at the three minute mark, that is fine.

THE COURT: At 12 minutes I will let you know you have three more minutes left for the 15.

MS. COHAN: Perfect.

THE COURT: Ms. Meeder, do you want the same, a three minute notice?

MS. MEEDER: Thank you, your Honor, yes. Hopefully I don't get there, but it will be nice to know.

THE COURT: Okay. Is there anything else we need to go over? Do you have any questions?

I am assuming, Pauline, you can hear everybody clearly.

Do you have any questions before we get started?

MS. COHAN: I don't believe so. Thank you.

MS. MEEDER: No.

THE COURT: Okay. Perfect. With that, you may proceed. I look forward to the arguments.

MS. COHAN: Good morning, your Honor, Lindsey Cohan for GSK, however, I am arguing on behalf of all Defendants on the Motion to Dismiss the amended medical monitoring class action complaint. As an LDC member, I first just wanted to express my thanks to the Court for this opportunity and for your Honor's continued support for the members of the LDC.

The question before the Court is whether the AMMC fixes the MMC's failure to plead a significantly increased risk of cancer.

The Court dismissed the MMC because Plaintiffs did not plausibly plead that they were exposed to NDMA as a result of taking Ranitidine in amounts that significantly increased their risk of cancer. That was because two key allegations were missing from the MMC, first, the amount of NDMA that creates a significantly increased risk of cancer; and second, the amount of NDMA that each Plaintiff consumed as a result of their Ranitidine ingestion.

In the AMMC, Plaintiffs have not even attempted to

plead either of these amounts. Instead, they suggest that they have taken a new approach to pleading a significantly increased risk of cancer, and therefore they don't need to plead these amounts at all.

The problem with Plaintiffs' argument is that they didn't actually take a new approach to the pleading. Instead, they just repackaged all of the same allegations from the MMC, most times verbatim, without addressing any of the serious defects that the Court told them they needed to fix if they were going to replead those allegations.

So, what are the new allegations in the AMMC? Because that is what we are really talking about now. We know that the old allegations from the MMC are insufficient, so what did Plaintiffs add to the AMMC, and are those allegations enough?

When you hold the AMMC up to the MMC, they look remarkably similar, and there are really only three new sets of allegations in the AMMC that did not appear in the MMC.

First, additional studies that Plaintiffs claim link NDMA to cancer. Second, additional testing that Plaintiffs claim show that Ranitidine contained NDMA above the FDA's ADI; and third, additional frequency and duration of use allegations for each Plaintiff.

These handful of new allegations do not come close to curing the MMC's pleading deficiencies, and that is because these allegations suffer from the same defects the Court

identified in the MMC, and which Plaintiffs failed to address when they repleaded.

First, as to the additional studies that purport to link NDMA to cancer, almost all of these studies are more of the same types of studies that were in the MMC. And these are studies that looked at dietary consumption of NDMA from non-Ranitidine sources and essentially purport to state that X nanograms of NDMA per day increases the risk of developing a type of cancer by some percentage.

First of all, these studies are duplicative because these types of studies were already included in the MMC. I am happy to point your Honor to where those were.

Recall that in dismissing the MMC your Honor considered these studies that assessed dietary non-Ranitidine consumption of NDMA and associated increased cancer risk, and what the Court found was that these studies do not plausibly support an allegation that the NDMA in Ranitidine causes a significantly increased risk of cancer.

That is because without knowing how much NDMA significantly increases the risk of cancer, how much NDMA is in each dose of Ranitidine, and how much NDMA a typical Plaintiff consumes, outside of Ranitidine, these studies say nothing about whether Plaintiffs could have consumed enough NDMA from Ranitidine to be at a significantly increased risk of cancer.

As the Court found, the amount of NDMA that a typical

Plaintiff consumes from other sources "is a number that matters" in this case, and Plaintiffs needed to plead that amount if they were going to rely on these studies. Yet Plaintiffs ignored the Court's order and did not plead that amount anywhere in the AMMC.

More importantly, though, is that Plaintiffs cite these studies that they claim show that NDMA significantly increases the risk of cancer, but Plaintiffs refuse to say what the amount of NDMA that creates a significantly increases risk is.

Why? If these studies show that X amount of NDMA significantly increases the risk of breast cancer, for example, why won't Plaintiffs just plead that amount as the Court told them to do? They could have, but they didn't, and so these studies don't add anything to the allegations that were previously rejected in the MMC.

The second new allegation in the AMMC is testing data that purports to show that Defendants' products contained amounts of NDMA greater than the ADI, and that testing is from Emery, the FDA, and Defendants GSK and Sanofi.

I should clarify that the testing data is only partially new. In the MMC Plaintiffs relied on some of the same testing. For example, the MMC included allegations about Emery and the FDA's testing results which again appear in the AMMC, and the MMC also references GSK's and Sanofi's testing

results. Plaintiffs have, however, dropped the references to Valisure's testing which we saw in the MMC that the Court and FDA found methodologically unsound.

Let's look at these testing results cited in the AMMC. With respect to the FDA testing, the Court in its prior order actually considered whether the FDA testing results could plausibly plead a significantly increased risk of cancer from Ranitidine, and the Court said they did not for several reasons.

First, the Court noted that the FDA testing did not find that there was any consistency in the amount of NDMA in the products tested, some product tested above the ADI, some tested below the ADI, and some product had no NDMA at all. Therefore, it was not plausible to assume that every dose of Ranitidine contained any level of NDMA above the ADI -- let alone some specific level of NDMA -- when the testing itself showed that simply was not the case.

Second, the Court noted that the FDA itself described the levels of NDMA detected as "low", including those that were above the ADI, and compared those levels to the levels someone would consume when eating grilled meat.

For this reason, the Court instructed Plaintiffs that if they intended to rely on the FDA testing data in their repleading they needed to explain why the Court in assessing the plausibility of Plaintiffs' allegations should not consider

the FDA's statement about the low levels of MDMA detected.

Despite once again relying on the FDA's testing results in the AMMC, and despite the Court's clear instruction, the AMMC says nothing about the FDA's "low" level finding.

Plaintiffs' failure to cure this problem in the AMMC renders these FDA testing results just as insufficient in the AMMC as they were in the MMC. How could ingestion of "low" levels of NDMA from Ranitidine place Plaintiffs at a significant enough increased risk of cancer such that they are entitled to an entire monitoring regime distinct from what the average patient would receive, when the FDA itself has described those levels of NDMA as present in common everyday food that almost all people consume.

As to the GSK and Sanofi testing data cited in the AMMC, that testing suffers from the same issues as the FDA testing. Just like the FDA's testing, both GSK's and Sanofi's testing show ranging results, with some products testing above, and some, in fact most, testing well below the ADI.

So, it is simply not a plausible inference that every Ranitidine pill Plaintiffs took contained six or eight times the ADI when the testing shows that just was not the case. And when the FDA has described four times the amount of ADI as "low", it simply is not plausible to conclude that six or eight times the amount of ADI presents such a significant increase in the risk of cancer that a prescribing physician would order an

entire monitoring regime.

Just taking a step back, as to all of these testing results cited by Plaintiffs, they claim they plausibly allege that every Ranitidine dose contains levels in excess of the ADI because, to be clear, that is what they need to plead here.

But, first of all, we know that is not what those testing results show. Even if they did, Plaintiffs refuse to say what the amount of NDMA in each dose of Ranitidine was. Why? If these results show that every dose of Ranitidine contained at least some amount of NDMA above the ADI, why won't Plaintiffs plead that amount as the Court told them to do? They could have, but they didn't.

So, these testing results don't add anything to the allegations that were previously rejected in the MMC.

Finally, as to the new frequency of use allegations that Plaintiffs added, they also remain deficient, particularly when Plaintiffs provide no context for those allegations.

For many Plaintiffs it remains impossible to tell just how many doses of branded Zantac they ever took, and at what frequency, to determine whether Zantac ingestion put them at increased risk. They say things like "I took branded Zantac when I ran out of my prescription," or "I took branded Zantac two to six times a week."

Frequency and duration of use are crucial allegations when we are talking about the levels of NDMA that Plaintiffs

claim are in Ranitidine and that significantly increase their risk of cancer, four, six, eight times the ADI.

The ADI is calculated based on 70 years of exposure. When the duration of use gets smaller, the amount of NDMA you can be exposed to and still be at or below a .001 percent increased cancer risk goes up. In other words, NDMA exposure can be a lot higher than 96 nanograms per day for a shorter period of time and still be below the FDA threshold.

We know that Plaintiffs did not take Ranitidine for 70 years because it wasn't available for that long. So, knowing how long and how often Plaintiffs ingested Ranitidine are critical allegations that are necessary to determine if they plausibly pleaded exposure to NDMA in substantial excess of the ADI, and that demands much more specificity in the frequency and duration of use allegations than what was pleaded in the AMMC.

More fundamentally, though, without knowing the amount of NDMA in each dose of Ranitidine, and the amount of NDMA that creates a significantly increased risk of cancer, these frequency of use allegations, even if they had been perfectly pleaded, which they were not, tell us nothing.

In conclusion, the Court told Plaintiffs how to fix the problems with their allegations in the MMC and they chose not to follow that guidance in the AMMC. By relying almost entirely on the same or similar defective allegations in the

AMMC as they did in the MMC, what Plaintiffs are really asking the Court to do is reconsider and reverse its prior ruling. The Court should decline to do so and dismiss the AMMC.

Thank you.

THE COURT: Okay, thank you. You had ample time left.

MS. COHAN: I apologize, Judge Rosenberg, I don't know if others are having difficulty hearing you, but --

THE COURT: Sorry, I had turned my mike off so I wouldn't be distracting during your presentation, and then I forgot to turn it on. I just said you came in well under -- you have ample time on your rebuttal should you need it.

Okay. All right. So, Ms. Meeder, your response, and I will give you a three-minute notice as well if you need it.

MS. MEEDER: Yes, thank you, your Honor.

THE COURT: You may proceed.

MS. MEEDER: Good morning. Consistent with the substantive law and the Federal pleading standards, the Court's order recognized that there are many different ways Plaintiffs can plausibly allege a significantly increased risk of the subject cancers and state a medical monitoring claim, but you had some questions and concerns.

So, in response, we carefully revised the complaint to more clearly explain the nature of Plaintiffs' NDMA exposure, the nature of their risk, and the connection between the two, which I think in truth was the Court's concern.

Now, Defendants have just finished telling you all of the reasons that they think the AMMC still isn't enough, but in reality, Courts across the country have held that complaints with much less detail than the AMMC plausibly state a medical monitoring claim, and anything more is a fact summary judgment or Daubert question. They don't even attempt to explain the internal inconsistency that their position would create in this case.

The Court already has found that the AMPIC, a substantially similar complaint -- excuse me, your Honor -- plausibly alleges causation, which is a much higher standard than significantly increased risk.

I would like to start by first explaining the amendments that we made because the Defendants have really underestimated the changes that the AMMC includes, and then I will discuss why, when you look at foundational medical monitoring law and recent 12(b)(6) decisions, it is clear that the AMMC plausibly alleges a significantly increased risk of the subject cancers.

First, in actuality, the AMMC is meaningfully different from the MMC. We started by taking a careful look at each Plaintiff's usage allegations, and we used all available information to expand upon them. So we can take Plaintiff Felicia Ball as an example.

The MMC said that Ms. Ball took Ranitidine for 21

years, some combination of prescription Zantac and 150 and 300 milligram prescription generic medication, but it didn't describe how often she took the medication, which product she took when or why.

As a result of our amendment, the AMMC now explains that Mrs. Ball took prescription Zantac at least once a day for that 21 years, 150 and 300 milligram tablets. She supplemented with prescription generic only when her insurance wouldn't pay for brand, and she took the medication to treat her irritable bowel syndrome.

While it is much more than any pleading requirement, with this information the Court could estimate the number of pills that Mrs. Ball took, more than 7,000 doses.

We made similar substantive amendments for every Plaintiff. Now the AMMC explains how long each Plaintiff took Ranitidine, it identifies how often they took it, which is something the MMC didn't do, and it explains the medical condition underlying the usage.

In total, Plaintiffs took Ranitidine products regularly for an average of 17 years, usually at least once a day, and this type of data is consistent with the registry. Filed personal injury Plaintiffs consumed Ranitidine products for an average of 15 years, usually also taking it once a day.

Next, we wanted to better connect Plaintiffs' exposure to their increased risk, more clearly articulate why that

increased risk is significant, and explain the role that FDA's ADI plays in all of it. Generally, this is not an aspect of our amendment the Defendant discussed. We went back to the drawing board, we rebuilt the scientific allegations.

First, we explained that the purpose of the ADI is safety, and we clarified that we were using it as a touchstone, then we walked through the supporting facts. The Court knows that we are only now receiving product from Defendants for testing, so the AMMC included new manufacturer product testing data alongside the FDA product testing data.

Both show the Defendants' Ranitidine contained NDMA at levels at least three to eight times greater than the ADI, and because GSK manufactured for Pfizer, these allegations apply to Pfizer as well.

We explained that the product testing data, though, is only one part of the picture because it doesn't include any of the additional NDMA that forms during storage, transport, over time or post ingestion, and so the data itself significantly underestimates Plaintiffs' exposure.

Now, conclusions reached by Valisure, Emery Pharma, and the FDA, along with other sources, support the plausibility of that allegation. In fact, once it had all of this information in hand the FDA concluded that NDMA contamination above the ADI made Ranitidine too dangerous for consumers, and it requested a full market withdrawal of all manufacturers'

product.

So, on this basis, we explained that Plaintiffs' NDMA exposure was actually many times greater than the ADI and posed a significantly increased risk of harm.

We also critically reviewed the scientific literature that we cited to support Plaintiffs' significantly increased risk. For every subject cancer, we identify at least one study that shows exposure like Plaintiffs significantly increases the risk of disease, sometimes up to more than 50 percent.

We added additional studies that found high rates of rectal, lung, and gastric cancer when people were exposed to NDMA at the levels we allege, and we included a recent study that found a significant increase in bladder cancer in individuals who consumed Ranitidine. We explained that when all of these studies are read together, they support our allegation that Plaintiffs' NDMA exposure, again at many times above the ADI, significantly increases the risk of each cancer.

We included citations to the studies to add plausibility to our allegations so the Court could be sure that the allegations were accurate and scientifically based.

Now, remember, the issue here is how much risk is created by the exposure to NDMA and Ranitidine, not any other type of NDMA risk or any background risk like dietary consumption that a Plaintiff might have because of other types of exposure.

Finally, we explain that all of these facts when taken as a whole would prompt a reasonable medical practitioner to order additional monitoring.

Now, the law is clear that these allegations are enough to state a significantly increased risk of the subject cancers, and therefore enough to state a claim.

You can take a first look at bedrock medical monitoring law. It explains that a risk is significant if it warrants the change in the medical monitoring a reasonable physician would prescribe. I believe that your Honor noted this in your previous order. So, ultimately, significance is an issue for expert testimony and it is a question of fact.

It follows, then, that Plaintiffs can allege a significantly increased risk even if they don't quantify their exposure, the amount of contaminant that causes a significantly increased risk, or the risk itself, and we cite numerous foundational medical monitoring cases that stand for this principle, cases like Bowers, Hansen, In re: Paoli and others.

Nearly all of these cases were decided at the summary judgment, in limine, or Daubert post trial stages. They are the controlling authority that establishes the proof required for medical monitoring in their jurisdictions, much more than the plausibility required under 12(b)(6), yet these cases reject a quantification requirement like that advanced by

Defendants.

For example, the Utah Supreme Court explained that no particular level of quantification is necessary to show that exposure is sufficient to significantly increase the risk.

Similarly, in Bowers the Supreme Court of West Virginia explained that a Plaintiff must prove exposure, which this Court already found we plausibly alleged, and a significantly increased risk of disease as compared to their risk absent exposure, but it specifically said again that proof of this element does not require any particular level of quantification.

In re: Paoli says the same thing, incorporating Hansen. Recent medical monitoring Rule 12(b)(6) decisions further illustrate these principles and demonstrate the AMMC's sufficiency.

Bell, which is Defense counsel's case, is particularly instructive. There, Plaintiffs allege that their municipal water system was contaminated with PFCs at levels "above the EPA's health advisory." They described their exposure as significant and occurring over years, but they didn't quantify it. They described contaminant levels as elevated or "above the EPA health advisory," but they didn't quantify them. And they described the risk of harm as increased, where the literature demonstrated an association between exposure and cancer, but they didn't further specify.

The Bell Defendants made the same arguments Defendants make here. They said that Plaintiffs had to measure their exposure rates and provide more of a basis for why that exposure was significant. They also claimed that a regulatory standard isn't enough to plausibly allege that exposure and increased risk are significant, but the Court wasn't persuaded. It found that Plaintiffs' medical monitoring claim was plausibly alleged and it noted, "while Plaintiffs have not yet proven what a significant level of exposure is, they need not do so at this stage."

It also held that a Plaintiff can employ a regulatory standard -- there it was the EPA health advisory, here it would be the FDA's ADI -- to plausibly plead significant exposure to a significant level of toxins, the very issue we are talking about here.

The Grayson case holds similarly. Plaintiffs there alleged that they were exposed to multiple carcinogens through the air and soil. They described the contamination as extensive and high, but they didn't quantify it. They alleged harmful inhalation, ingestion, and dermal contact at levels far higher than normal background levels, but they didn't further specify, and they described extremely harmful effects, including various illnesses allegedly caused by the contaminants, but they provided no further specificity.

Yet these allegations were enough to overcome a Motion

to Dismiss and both the briefing and the opinion confirm that the Court addressed and found plausibly alleged all of the elements of the claim, including significantly increased risk.

So too go Baker and Vavak, cases involving exposure through airborne bacteria and beetle parts in baby formula respectively. Neither Plaintiff identified how much bacteria or beetle parts they were exposed to, explained how much exposure caused a significantly increased risk, or quantified the risk itself.

In fact, neither Plaintiff was actually certain they had been exposed, and Plaintiffs provided, at most, only circumstantial support for their allegation that the bacteria and the beetle parts caused them illness or would.

Nonetheless, each Court still found that Plaintiff had plausibly alleged a medical monitoring claim, including a significantly increased risk of harm. All of these holdings are consistent with substantive medical monitoring law.

Ultimately, the claim is plausibly alleged when, as here, a Plaintiff describes a meaningful exposure to a harmful toxin that allegedly increases the risk of, or causes a dangerous disease, and which would prompt a doctor to order more monitoring.

No quantification is necessary, but most importantly, if the Court compares the AMMC to the complaints in Bell, Grayson, Baker, and Vavak it will see how much more we plead in

support of a significantly increased risk.

To the extent that the Defense has tried to distinguish these cases in their briefing, their assertions either don't make any logical sense or are belied by a plain reading of the cases and of the briefing.

Against the weight of this substantial authority Defendants have only ever been able to point to one case, which was Riva v. PepsiCo, but that case just isn't enough. The Riva Plaintiffs' failure to plausibly allege threshold exposure, which was the way that they chose to plead significantly increased risk, but not ours, has little bearing here, and their reliance on a mouse study to support causation in humans, especially when that study disclaimed extrapolation to humans, doesn't compare to the AMMC's robust allegations and scientific support.

For all of the reasons stated in our briefing, Riva doesn't go as far as Defendants think it does. It is distinguishable and should be accorded no weight.

One other issue I would like to address is Defendants' repeated assertion that the FDA found NDMA levels in Ranitidine low. Now, the Court already found that we plausibly alleged NDMA exposure. So, the Defendants' position is really a request for the Court to make a factual determination on a Motion to Dismiss without a complete record. It is also a misrepresentation of the allegation.

What they ignore is that any notion that NDMA levels were low was merely the FDA's initial impression. It then realized that additional NDMA was formed during storage, transport, over time, post ingestion, and on that basis, it realized that exposure to Ranitidine was too dangerous for consumers because of NDMA contamination and it requested a withdrawal.

At bottom, your Honor, we made meaningful edits that ensure the AMMC connects the dots in a way the MMC didn't, addresses the Court's concerns, and thus plausibly alleges a significantly increased risk of the subject cancers. We ask that Defendants' motion be denied.

THE COURT: Okay. Thank you so much. That was under your time. That was 14:14. I appreciate that.

Let me turn it back to Defense for any rebuttal argument that you have.

MS. COHAN: Thank you, your Honor. I just want to address a few different points. One is, there was this point made that because causation was found with respect to the AMPIC, that somehow this element requires less than in the amended medical monitoring complaint. Those issues are simply not comparable.

Significantly increased risk as an element of a medical monitoring claim serves both as the causation and the injury element for a medical monitoring claim. In a medical

monitoring claim you are not saying that I presently have an injury, such as cancer, you have to allege that you are at a significantly increased risk of cancer in order to have even alleged an injury at all.

That is why having to plead the significance of your increased risk is so critical here in a medical monitoring claim. It just simply is not analogous to the issues that are present in the AMPIC with respect to causation and whether that element of their claim was adequately pled at the threshold pleading stage.

I also just want to talk a little bit about the allegations that the Plaintiffs say that they have, you know, included or supplemented in the MMC. They point to the fact that they have amended allegations that NDMA has significantly increased the risk of the subject cancers. But what do they point to? They point to allegations concerning the FDA's decision to withdraw Ranitidine from the market. Those same allegations appeared verbatim in the MMC. The sections are identical in the complaints.

They point to allegations that NDMA is a known carcinogen, but those allegations aren't new. In fact, the Court in its prior order stated that the MMC alleged that NDMA is a carcinogen.

They point to allegations concerning the studies that link NDMA to cancer. We talked about the new additional

studies already in my first discussion. All of the rest of the studies that they are pointing to are exactly the same studies that were from the MMC and that the Court already found were legally insufficient.

So, I think it is really important to keep in mind that when Plaintiffs are saying they tied it all together, that -- all of those same allegations were before the Court already, and so there is just not a whole lot that is new here.

If you look at the fact that they say they claim they amended their allegations to plead that they were exposed to significant levels of NDMA, separate and apart from the new testing data that I discussed in my opening presentation, the allegations that they are pointing to, such as the NDMA forms from heat and humidity and transport, and endogenously post ingestion, those sections of the AMMC are verbatim the same allegations from the MMC.

So, they just don't say anything more about those issues than they said in the MMC where the Court found that those allegations were legally insufficient.

I also want to briefly touch on the case law that Plaintiffs discussed. Is there a world in which Plaintiffs could have pleaded exposure to NDMA that significantly increased their risk of cancer without reference to the amount of NDMA generally that creates a significantly increased risk of cancer and the amount of NDMA in each Ranitidine pill?

Based on the case law, if they had had the facts to support such allegations, they could have. For instance, when you look at the Bell case that they cite to, the Court there said they didn't have to quantify the exact amount of increased risk because there the allegations were that the wells that they were testing in these communities of people that had contaminated water were 20 times the amount of the regulatory threshold.

The Grayson case, I believe the allegations were that there was something like seven to 10,000 times the amount of the regulatory threshold.

So, facially those allegations are substantially different than the ones that we are seeing here where they are saying, you know, four, six, eight times the ADI, but we have no idea if facially that is a significant enough increased risk of cancer because we have statements from the FDA saying that they are not, that they don't significantly increase the risk of cancer, and that these are low levels of NDMA that you would get from everyday foods.

And finally, on the Baker case, there again you have patients that were exposed to aerosolized bacteria at a facility where people died from those bacterial infections and the health authorities had linked the allegedly defective medical equipment to those deaths and infections.

Those are just worlds away from the allegations that

are here in this AMMC. So I think, as much as Plaintiffs keep trying to distinguish Riva, that case is just so on point as to the facts here.

You have a situation where Plaintiffs are claiming that they were exposed to some amount of a carcinogen that is sort of omnipresent in the environment, and haven't stated what level of exposure is sufficient to create a significantly increased risk of cancer, what level of carcinogen did they receive from their ingestion, there it was a soda product, and what level they were getting from other sources where the Court knew that this carcinogen was everywhere.

Those are exactly the facts here, and I think the outcome, as the Court indicated, is likely the same. Without pleading that there is some threshold level of NDMA and that Plaintiffs were exposed to greater than that they have not met their pleading burden.

THE COURT: Okay, great. That is your time there, thanks.

All right. You both are there, and that is good because I have questions, a couple of questions, a few questions directed to both sides.

Let me begin with a question for Ms. Meeder on behalf of the Plaintiffs.

We know that in some states background exposure to a carcinogen is an express element of a medical monitoring claim.

For example, in Florida the first element of a medical monitoring claim is "exposure to greater than normal background levels." That is quoting Petito versus A.H. Robins Company, Inc. 750 So. 2d 173, 106 to 107, a Florida District Court of Appeal 1999 case.

Do you think that you, that is the Plaintiffs, need to plead background exposure to NDMA in the complaint? It appeared that, except for the introduction of the AMMC, I could not find the word "background" in the complaint, so I just wanted to get your thoughts on that.

MS. MEEDER: Thank you, your Honor. I'm not quite clear whether you are asking if we need to plead background at all or whether we need to quantify the background, but in --

THE COURT: Let's start with background at all.

MS. MEEDER: No, your Honor, I don't think so. I think that -- I mean, first of all, I will say that the AMMC does discuss NDMA existing in other things the Plaintiffs are exposed to. We have talked about that in previous hearings. And so, obviously, that type of allegation is in there, but I don't think we need to do more than that.

It is clear that what we are saying is that Plaintiffs' consumption of Ranitidine which contained NDMA is what caused them to be exposed to NDMA above anything they otherwise would have been. Anything more than that, any quantification of those amounts is just not certainly a

pleading requirement, and in many instances, not even a requirement of proof.

So, I think standing the way it does now, the AMMC does plausibly allege that exposure in the way it needs to and it clarifies that the exposure from Ranitidine is more than what a Plaintiff would have otherwise received.

THE COURT: So, for example, your named Plaintiffs, I think you allege, were consuming NDMA through their diet, water, and air, which the scientific studies cited in the AMMC confirm.

So, I just want to be clear, is it your position that the Plaintiffs do not, or do and you have; and if so, tell me how, so do or do not need to plead background exposure in order to plead the Plaintiffs' exposure to NDMA through Ranitidine was "greater than normal background levels?"

MS. MEEDER: I think that Plaintiffs are not required to provide specification of what background levels are or would be. If you look at a lot of the other cases that I was referencing during my presentation, in those cases it is clear that Plaintiffs are exposed to those types of contaminants in other parts of their life, but it's not something that they explicitly allege in any sort of quantified way.

So, I think that the AMMC does allege exposure beyond what Plaintiffs would otherwise be exposed to, which is the background level.

THE COURT: Okay. Another question for Plaintiffs.

Are you asking for the Court to infer that even though some of the Ranitidine tested by the FDA had very low NDMA, within the FDA's acceptable daily limit, the NDMA in the Ranitidine consumed by the Plaintiffs was very high?

In other words, is the Court to infer that each Ranitidine pill the Plaintiff consumed over the course of decades had NDMA in a high amount and did not contain NDMA in any of the low amounts tested by the FDA; and if not, are you asking the Court to make any inferences; and if so, what are those inferences?

That was kind of three different questions, and if you need me to repeat any of them, I am happy to do that.

MS. MEEDER: Your Honor, I think at this juncture all the Court has to conclude is that it is plausible that Plaintiffs consumed Ranitidine that contained high levels of NDMA. The Court does not have to conclude that every single pill contained NDMA levels above the ADI to find that we plausibly allege the claim.

And you can look at other cases again, so I would like to kind of go back to Bell because I think that is a really helpful case, and I heard how Defense counsel was attempting to distinguish it.

In that case, the Plaintiffs were exposed to contaminants through a municipal water system supply. So,

obviously it was the water system through wells, and there are many wells in the water system, that then transferred the water through into their homes, and they consumed it. The system itself was found to have high contamination. One single well of the many municipal wells at one point had 20 times level of the toxins, but none of that translated into Plaintiffs having been exposed to 20 times the toxins, or even a certainty about what Plaintiffs had been exposed to, but it was enough to plausibly state the Plaintiffs have been exposed to that contamination.

And I think that is similar to our case here. The Court doesn't have to make some sort of determination at this juncture about whether the levels were low or high. That is really a fact determination. The question is whether we plausibly allege they were high.

It is not just the product levels -- I hate to sound like a broken record. It is not just the product testing levels, but it is the other facts we allege, which we did in a really meaningfully different way than the MMC did that describes why it is that Plaintiffs were exposed much more than the ADI.

So, all of that taken together, your Honor, I think is my best way to answer your question and kind of frame the issue that we are asking the Court to determine.

THE COURT: Okay, thank you.

Again, for the Plaintiffs, you argue that the Plaintiffs don't need to plead a threshold level of exposure in the complaint.

Do you think that you will eventually need to identify a threshold level such as at Daubert or summary judgment, and does your response differ depending on the jurisdiction?

MS. MEEDER: Your Honor, my response doesn't differ depending on the jurisdiction. I think ultimately that Plaintiffs are going to have to prove down the road whether the amount of NDMA that they were exposed to was enough to merit monitoring. I don't know that that means, again, that we have to identify a hard stop level above which is true.

But ultimately, that is going to be a question for an expert opinion, and so it may be that the experts can reach that type of conclusion to support that aspect of our claim for the Court without having to go into that level of granularity, and I think that would be consistent with what happens in a lot of other cases.

At this point, we are, obviously, referencing ADI as kind of a touchstone, I have called it, and alleging something above that, and for the purpose of pleading, that is enough to meet that requirement.

THE COURT: For the Plaintiffs as well, the Defendants argue that certain Plaintiffs have not ingested branded Zantac frequently enough to allege a significantly increased risk of

cancer. For example, they note that Plaintiff Ronda Lockett alleges taking prescription Zantac from 1990 to 1995, and OTC Zantac from 1966 to 2000.

Can the Court conclude that she is at a significantly increased risk of cancer based on her allegations that she took branded Zantac over a ten-year period more than 20 years ago?

MS. MEEDER: The Court can conclude that we have plausibly alleged Ms. Lockett is at a significantly increased risk of disease because of her Ranitidine usage.

Now, Defendants' argument on this point is one they could have made well prior to this time and they didn't do that. It was available to them then, but they made a strategic decision not to discuss brand versus generic usage for the Plaintiffs in earlier briefing. So, as an initial matter, your Honor, I would argue that they be precluded from doing that now. That is not really an issue before the Court.

Secondarily, the argument still fails on its merits because at this juncture, our allegations are that the Ranitidine itself caused the significantly increased risk of disease.

Now, regardless of how you look at it in terms of black letter tort law, anything more is an issue for far down the road. For example, if Defendants' position -- and I'll note that they have really no legal support for this argument at all, but if their position were that generic usage increases

the risk above what would have otherwise been the risk because of brand usage, then that is an eggshell Plaintiff issue that is not relevant to liability.

If the question is how much of the risk is Defendants' fault and how much is the generic manufacturers' fault, that is an apportionment issue. The Defendants have the burden of proof on that. Again, that is an issue for way down the road.

None of these things are relevant to what the Court has to determine on a Motion to Dismiss.

And I also wanted to again refer back to Bell. If your Honor looks at that complaint and briefing, you will see that the Bell Plaintiffs actually sued a large number of manufacturers of PFCs, firefighting foam companies, and that case proceeded through a Motion to Dismiss notwithstanding the fact that the Plaintiffs didn't somehow try and point to how much of the contamination they were exposed to was because of Defendant A or Defendant B, and I think even returning back to basic tort law in a personal injury case, these are simply not questions that are relevant on a Motion to Dismiss, your Honor.

THE COURT: Do you know how many years had passed or how much time had passed in the Bell case where they drank from the well and then brought their claims, for example?

MS. MEEDER: Your Honor, I don't off the top of my head. I can see if I can find it quickly.

THE COURT: In that vein, is there some point -- if,

say, a Plaintiff took the branded product over 30 years ago, is there some point at which the sheer lapse of time renders it implausible?

MS. MEEDER: Well, Ms. Lockett took Ranitidine, I want to say up until at least 2000, and I think any issue of whether there is some cutoff period for how long ago she consumed it and whether that creates a risk is really an expert issue, a determination at Daubert and that type of evaluation.

Obviously a lot of these cancers have a latency period as well, so just because they didn't contract cancer within a certain amount of time afterwards, or just because we are years down the road does not mean that there is not a significantly increased risk, but the information that the Court would need to consider those issues is simply not before it right now because it is really an expert question.

THE COURT: Okay. Thank you.

For the Defendants, Ms. Cohan, other than the Riva case, have you cited to a case where a Plaintiff's medical monitoring claim was dismissed because the complaint lacked sufficient specificity on the question of whether the Plaintiff had alleged a significant increase in the risk of injury?

MS. COHAN: Your Honor, I believe the Riva cases are our primary authority on that, but I think that actually speaks to why these cases where you do not have sort of uniform exposure, such as in the traditional toxic tort contamination

case, are just inappropriate for medical monitoring because the Plaintiffs cannot sufficiently plead that every single Plaintiff ingested a certain amount of the contaminant that exceeded a threshold amount, whatever that amount is, as opposed to, for example, in the Bell case where you have three local communities that all share the same water supply.

The water supply was tested, it was found to have 20 times the amount of the regulatory threshold amount and, you know, there, there wasn't testing that showed that some of the wells didn't have any contaminant at all, which is what we have here.

We have those varying, you know, results from testing that show that, you know, there is some Ranitidine that had some marginal or more levels of NDMA in excess of the ADI, some that were below, or had none at all.

So, I think the lack of case law on that very particular issue just speaks to the fact that these cases where you do not have uniform exposure to a contaminant are not appropriate for medical monitoring since you cannot show by whole swaths of Plaintiffs that they were at a significantly increased risk of cancer or disease generally.

THE COURT: Is it not a matter for medical monitoring or is it perhaps not a matter for a Motion to Dismiss?

We heard a lot from the Plaintiffs that these issues are better suited for either a summary judgment stage of the

proceeding or Daubert. What would you say in response to that?

MS. COHAN: I would say that Twombly and Iqbal are very clear that you have to plausibly plead the threshold elements of your claim. The threshold element of medical monitoring is that you are at a significantly increased risk of cancer, and again, that is the injury that in these unique medical monitoring cases. Right?

I think it is always important to remember we are only talking about eight jurisdictions in this case that have even recognized medical monitoring because it is such a unique -- whether they style it as a claim or a remedy, it is because there is no actual injury. They are talking about increased risk of disease as the injury, so that is a threshold pleading question that they have to plausibly plead.

I think while there haven't been a lot of medical monitoring Motions to Dismiss on these grounds, there have been a plethora, as your Honor is well aware, of 12(b)(6) motions where the Plaintiff has just failed to plausibly plead the elements of the claim.

THE COURT: Okay.

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

THE COURT: Sure.

MS. MEEDER: There are four 12(b)(6) decisions decided after Iqbal, Twombly that this particular issue was addressed in and I cited them, but they support Plaintiffs' position,

they don't support Defendants'.

There are two others, Riva, then there is also In Re: Jewel, which is actually out of the same district as Riva, where the Court evaluated the elements of the medical monitoring claim and found that they were plausibly alleged. If you look at that complaint, it is substantially similar to our complaint as well.

I thank you, your Honor, for just allowing me a minute. I wanted to respond to this idea of uniform exposure, because I am not sure where this fact came from. That is a contrived sort of distinction in the case law.

There is no allegation in Bell about whether a Plaintiff consumed more or less water than the person next to them, I mean presumably they did, but all of those issues simply were not relevant to whether it was plausibly alleged as a claim.

So, talking about commonality of exposure and trying to use that as a way to distinguish Riva versus other cases is simply not borne out in the case law, your Honor.

I also don't know where this assertion came that in Bell there were no wells that had no contaminant. I don't see a fact either way in that regard in Bell. The point is, obviously, in the water system you have multiple wells, they are going to show different things, and then the water is all transferred to Plaintiffs and they are all going to experience

different things in different amounts, but none of that was relevant because the claim was plausibly alleged the way it was stated, your Honor.

Thank you.

THE COURT: Okay, thank you.

For Ms. Cohan on behalf of the Defendants, would you agree that because the Plaintiffs have alleged that NDMA is formed through exposure to heat and over time, the Plaintiffs have necessarily alleged, once inferences are viewed in their favor, that the NDMA consumed by the Plaintiffs was greater than the NDMA found in products tested by the FDA?

MS. COHAN: I don't believe that is a fair inference and mostly --

THE COURT: What did you say your answer was? You just froze.

MS. COHAN: Can you hear me?

THE COURT: I can hear you now, so let me just have you start your answer again because I didn't quite hear it.

MS. COHAN: No problem. I apologize.

So, you know, I do think it is -- it is not a fair inference to say that some level of NDMA was added to whatever was tested initially by the FDA, or whoever else, and that some additional amounts of NDMA were added because what -- how much more?

Perhaps if taken, Plaintiffs' allegations, as true,

there was some amount of NDMA added due to heat, humidity and storage, what were those amounts? We don't know. We don't know if those amounts are significant. We don't know if they added to get Plaintiffs above the threshold of the NDMA amount that significantly increases the risk of cancer.

So, even assuming that your Honor could reasonably infer that some amount of NDMA was added post, you know, post ingestion or as a result of storage and transport, we still don't know anything from the complaint itself about how much was added, and that is a crucial fact because, you know, we still don't know if it would get them above whatever the threshold amount is, which we also don't know.

THE COURT: Okay, thank you.

Another question for the Defendants, which picks up on one of the points that Ms. Meeder discussed.

If the Plaintiffs have plausibly alleged that brand consumption significantly increased their risk of cancer, why wouldn't the subsequent consumption of generic Ranitidine go to apportionment of damages rather than dismissal?

MS. COHAN: So, I think if you look at the cases cited by Plaintiffs in their briefing on this point, really what their cases are talking about are sort of the eggshell Plaintiff, where somebody was injured by a Defendant and their injury was significantly greater because of some sort of preexisting condition or some other issue that caused them to

have sort of an unexpectedly great injury that couldn't have been anticipated by the Defendant, but the Defendant is nevertheless liable for those damages because their product, or whatever it was, caused the injury.

Here, we are not talking about that. What we are looking at is, at a threshold pleading level, have Plaintiffs plausibly pleaded that a brand product that they took 20 years ago for a year, that has not manifested in cancer yet, would therefore be the cause of a significantly increased risk of cancer.

So, I think the issues are really -- it is not an issue of apportionment, it is an issue of looking at the pleading and saying could a brand product plausibly have resulted in a significantly increased risk of cancer based on the facts alleged in the AMMC. I don't think for some of those Plaintiffs at least, many of which we identified in our briefing, that that is not a plausible inference.

THE COURT: All right. Was there anything else that either one of you wanted to say? I am all out of questions. Did you feel you got to say everything or was there any last remarks that you had?

From the --

MS. COHAN: Nothing further, your Honor. Thank you very much for your attention and time today.

THE COURT: How about from Plaintiffs?

MS. MEEDER: Your Honor, I just have one point I would like to make. In their reply brief Defendants made an effort to distinguish several of the 12(b)(6) cases that I discussed in my presentation, and I just wanted to suggest that if the Court takes a close look at those cases, it will see that those efforts are really just not borne out in the opinions or in the briefing.

For example, in Vavak, the Court didn't look at -- I am sorry. In Vavak, the Court only considered the Plaintiffs' symptoms in the context of whether there was a product defect. It had nothing to do with the medical monitoring evaluation.

If the Court looks at Grayson, it is obvious that the Court in that case specifically addressed each of the medical monitoring elements.

My point is really just that, since we didn't have a chance to kind of dig down into those things, that I wanted to make sure the Court was aware of our position on why those cases and the efforts to distinguish them really just don't make a huge difference here, your Honor.

Again, thank you so much for your time.

THE COURT: Thank you both for your very excellent presentation and preparation and elucidation as to my questions. So you both did an excellent job and I very much appreciate it. Thank you so much.

MS. COHAN: Thank you.

THE COURT: Okay. We are going to turn our attention now to the partial Motion to Dismiss amended economic loss complaint, and that is at Docket Entry 4107. If I could have counsel come on for that motion, and once you are all on, I will have you state your appearance so we can make sure we can hear everybody.

From the Defense who do we have?

MS. EISENSTEIN: Good afternoon, your Honor, Ilana Eisenstein on behalf of Sanofi, and I will be presenting argument on behalf of the branded OTC manufacturers.

THE COURT: Okay. Good afternoon. From the Plaintiffs?

MR. KELLER: Good afternoon, your Honor, Ashley Keller for the Plaintiffs. My role at first is just to introduce my colleague, Noah Heinz, who is going to handle the prepared portion of our presentation and then I will join you again for the Q and A.

THE COURT: Okay.

MR. HEINZ: My name is Noah Heinz, representing the Plaintiffs.

THE COURT: Good afternoon. So, Mr. Heinz, as a NextGen, I guess you are, if you need it, entitled to a few more minutes. Would that be something that would be desirable, so maybe three additional minutes?

MR. HEINZ: I am happy to take it. I think it is

unlikely I will use it, but happy to keep it in reserve.

THE COURT: Okay. Would counsel for Defense like any kind of a warning, actually for both of you, any warnings? Also, how would you like to split up your time, if you would like to split it up at all?

MS. EISENSTEIN: Thanks, your Honor. I will keep track of my own time and I will take about three minutes for rebuttal.

THE COURT: Okay. Mr. Heinz, do you want to keep track of your own time or do you want a time tracker?

MR. HEINZ: I will keep track of my own time, your Honor.

THE COURT: All right. With that, then, let me turn it over for argument on the motion. You may proceed.

MS. EISENSTEIN: Thank you, your Honor.

This Court's prior orders have narrowed Plaintiffs' refund claims against OTC branded manufacturers of Zantac. What is left after this Court's express preemption ruling is a theory that necessarily runs into a different problem, implied preemption.

The only claims that survive express preemption under this Court's ruling depend on the allegation that the FDA approved label for OTC Zantac was misbranded because Defendants failed to provide information about NDMA or cancer risk to the FDA at the time of approval, i.e., if the Defendants had

provided information about these risks to the FDA, it never would have approved OTC Zantac.

Because Plaintiffs' response to our motion seeks to reconsider this Court's prior ruling, and in fact asserts a far broader theory of liability, I want to take a few minutes to explain how we got to this point and why the Court limited these refund claims in this way.

First, in the January 8, 2021 order this Court made clear that Plaintiffs can proceed at most on only labeling claims, and in the process this Court recognized that simply asserting that the FDA approved label is inadequate does not get beyond express preemption. It cited the many Courts that have held that claims founded on the FDA approved label are --

THE COURT: Hold on one sec. We need to have you slow down a little bit. I stopped the clock, so I'll keep it stopped for a minute or two. Go back, if you would, to where you were describing the January order. Try to maybe go a little bit slower, if you could.

MS. EISENSTEIN: Absolutely, your Honor.

In this Court's January 8, 2021 order, this Court recognized that Plaintiffs' claims could proceed at most with respect to labeling claims, but in the process, this Court recognized that simply asserting that the FDA approved label is inadequate does not get beyond express preemption, and this Court cited the many Courts that have held that claims founded

in the FDA approved labeling are preempted under Section 379r, regardless of how those claims are styled.

In the second round, Plaintiffs tried to get around that problem by focusing on their alleged misbranding claim and Section 352a(1). That section prohibits a drug label that is false and misleading.

This Court recognized significant limits on that theory because when the FDA approved the label for OTC Zantac, it was required to and necessarily made the finding that the approved label was not false and misleading. This is plain from 21 U.S.C. Section 355d(7), which provides the FDA must reject a new drug application if, based on a fair evaluation of all material facts, such labeling is false and misleading in any particular, exactly mirroring the misbranding provision, and it is also clear from the FDA regulations of OTC drugs which provides nearly the same thing.

Meanwhile, the express preemption provision, Section 379r(a), bar state law claims against OTC manufacturers that seek economic loss damages from challenging FDA's judgment. Otherwise, it would be a claim that would seek a label that was different from, in addition to, and not identical with that required by Federal law.

In fact, Congress was particularly concerned about the uniformity in OTC's labeling, and wanted to foreclose economic loss claims just like this one that seek a different label from

that that the FDA approved.

If this weren't apparent from Section 379r(a), the OTC preemption provision makes crystal clear under Section 379r(c)(2), that is the provision that defines the scope of express preemption, and it provides that express preemption scope includes any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

In other words, Congress was clear it meant to preempt state law refund claims that seek to recover economic damages based on warnings above and beyond what Federal law provides.

Recognizing how these provisions work together to limit Plaintiffs' misbranding theory, the Court's prior ruling saw a narrow path forward for Plaintiffs based on the theory that Zantac could be rendered misbranded based on the FDA approved label if when FDA approved Ranitidine it did not have full and accurate information.

And the Court further held that the Plaintiffs had alleged that if the FDA had the information in the past that the FDA possesses in the present, the FDA never would have permitted Ranitidine to be sold.

But the failure to warn FDA is a necessary component of this theory and this Court did not reach in that express preemption ruling the problem of implied preemption. A straightforward application of this Court's ruling on that

issue in the last go-round shows that the narrow theory that this Court held survived express preemption runs right into implied preemption under Buckman, Mink, and 21 U.S.C. 37(a).

As this Court found, implied preemption applies to claims like this one that would depend, as a critical link in the theory of liability, some type of fraud on the FDA, the failure to provide information to the FDA. Mink and the cases that have applied it in this circuit have not limited that analysis to only direct efforts to privately enforce the FDCA, but have also found state law and common law claims impliedly preempted when the substance of that complaint is that the manufacturer failed to tell the FDA information required by Federal law.

That is the essence of the sole theory of liability remaining after this Court's express preemption ruling on June 30, 2021, that manufacturers were required to, but failed to disclose the NDMA Ranitidine link to FDA, and that if OTC Defendants had disclosed this information they would not have approved Zantac or would have been required to withdraw it from the market.

I wanted to say a few words about Plaintiffs' broader theory because Plaintiffs' argument is essentially, no, our claims are not so limited based on the Court's prior ruling, but rather, they assert that a far broader degree of claim remains in this litigation. In fact, a redline of the

complaint reveals that Plaintiffs have barely adjusted their actual pleadings to reflect the reasoning in this Court's order.

Plaintiffs broadly claim in their opposition that the drug was defective, that the drug label was defective, and that the key question is the adequacy of the label, the safety of the product, and the deceptiveness of advertising and warning. They continue to assert allegations that cover expiration dates and packaging sizes, while at the same time, and this is really the key thing, nowhere asserting the theory of liability that allowed them to proceed past express preemption.

That theory remains a hypothetical theory that could have gotten them past express preemption, runs into implied preemption, but is absent from their actual pleadings as now stated.

In their briefing, Plaintiffs now assert they don't need to challenge the initial approval, but rather, assert in their opposition to our Motion to Dismiss that at some unspecified point the drug became misbranded. That is not what their complaint says. It claims all along OTC labels were false and misleading when made based on information purportedly possessed by Defendants, but not provided to FDA.

Moreover, Plaintiffs try to invoke the CBE process and Wyeth versus Levine to again get around express preemption and implied preemption. The CBE process allows Defendants to

update their labels, but this is not really about a manufacturer putting a warning on a label pursuant to the CBE process, like their personal injury claims are.

They assert that once FDA knew about the risk of NDMA it was pulled from the market full stop, not that it was allowed to proceed with this additional warning.

But even still, Plaintiffs are simply wrong that they can avoid express and implied preemption by simply asserting that any time that Defendants could have used the CBE process to update the label they were required to do so on pain of criminal misbranding. The Supreme Court rejected that argument in Wyeth and it confuses the rigorous doctrine of impossibility preemption with express preemption, which preempts a far broader swath of claims.

Even Footnote 4 of Bartlett went no further than contemplating misbranding based on information withheld from FDA. This preemption motion is narrow, it does not affect personal injury claims and it does not affect the economic loss claims against the prescription drug manufacturer. It tracks the Congressional judgment that forecloses state law claims seeking an economic remedy above and beyond -- for warnings above and beyond that required by FDA.

The limited window that this Court left open from express preemption under this misbranding theory runs into implied preemption and cannot help Plaintiffs who, in any

event, have not availed themselves of that window by failing to adjust their pleadings accordingly.

THE COURT: Okay, thank you. That was ten minutes and 19 seconds when I stopped the clock for a short bit when you had to repeat, so you have the remaining time for your rebuttal.

And for the response from the Plaintiffs, Mr. Heinz.

MR. HEINZ: Thank you, your Honor. Good afternoon and may it please the Court, my name is Noah Heinz, H-E-I-N-Z, for Ms. Stipes. I represent the Plaintiffs.

The claims here do not allege fraud on the FDA. They do not depend on any allegation that the Defendants misled the FDA. As pleaded and argued, the claims are based on the false or misleading labels on Zantac. They do not allege that Defendants should have stopped selling, which was the subject of the January order Ms. Eisenstein referenced.

Instead, it alleges that the Defendants should have changed the label, which as branded manufacturers they could have, as this Court recognized in its prior order.

Imagine there is no Food, Drug and Cosmetics Act, there is no FDA and no NDAs, no relevant regulations. Would these claims still exist? The answer is obvious: They plainly would. The Defendants are conflating their own preemption defense with the nature of the claim.

Now, it is true that if the FDA knew about NDMA and

nonetheless approved branded Zantac as it was for OTC use, we would lose. It is a shield for the Defendants in that sense, but the Defendants infer that a key part of our claim must be that the FDA did not know about the cancer risks, but that is not quite right. It is a key part of our affirmative response to their defense, but forms no part of the claims themselves. The Plaintiffs are not using the FDCA as a sword in other words.

An example helps to illustrate this key point. Imagine two Plaintiffs, two consumers, suing branded manufacturers over OTC Zantac. One is a cancer victim and is alleging failure to warn, or a similar tort of that sort. The other seeks a refund and is again relying on traditional state law claims such as consumer deception. They both argue that the label is inadequate because it is false or misleading because it doesn't state anything about cancer.

They both have winning claims under state law. They both have evidence that the manufacturers could have changed the label using the CBE process, but they both argue that the manufacturers never submitted that new information to the FDA and never did seek to change the labels.

Under Wyeth versus Levine, that means that the FDA's prior approval of the OTC product does not block the suit. So, this motion addresses the question that comes after that, does Buckman bar the suit? And the answer is, obviously not.

The consumer deception Plaintiff is not arguing in that case that the Defendants are liable for misleading the FDA, and that is not different in any way from the cancer victim. They are both saying that the label is false or misleading, and nothing about the violation of Federal misbranding law runs the consumer into Buckman, any more than it would for the cancer victim because they are going to have to argue that the brand manufacturer failed to submit new information to the FDA and failed to try to change the label.

If it were otherwise, it would run headlong into Wyeth versus Levine and must be rejected for precisely that reason. Though that example is a simplified one, it essentially describes this case.

I want to describe next what the economic loss claims are and what they are not, and after that, I will discuss Mink and Buckman and apply them.

So, what are the economic loss claims in the second amended economic loss class action complaint? The claims are traditional state law claims based on the Zantac label. The very specific counts rely on theories such as deceptive advertising, unjust enrichment, warranties, and similar claims that states have been regulating for centuries, decades at least.

All of the claims after the Court's last order are based on the label. So, take an example, consumer deception

claim under state law. The element of that would be, first, that the Defendants' advertising or label was false or misleading; second, that the practice occurred in the course of the Defendant's business; and third, that it caused damages to a consumer.

So, what are the claims not? You can hear from running through those labels they don't -- running through those elements, they don't include as an element that the manufacturer deceived the FDA, and the Defendants don't show otherwise. They do point to isolated allegations about good manufacturing practices, failure to report containers and expiration dates that are in one or two paragraphs in the complaints, and some of these, for example expiration dates, are on the label, so there is no possible concern there.

Even for the other ones, essentially none of the allegations are incorporated into a relevant count. Any that are incorporated either link to the label or are harmless background information. It simply can't be the case that the claim is preempted merely because it describes what the Federal good manufacturing practices regulation requires.

Ultimately, the Defendants are not pointing to any actual counts that they think are preempted because an element enforces the FDCA. The best they can argue is that there are a few facts in the complaint somewhere, anywhere, whether incorporated or not, and whether about OTC products or about

prescription products, that they think relate to their argument. That simply is not enough.

The Defendants' real argument is not that the complaints do not properly allege that -- do not allege that the manufacturer deceived the FDA, but that they should have argued that. They argue that at page seven of their reply where they say for the first time the complaint "appears to have made no effort to implement this Court's prior orders," and they double down on that in footnote 2, and that is in response to the very uncomfortable fact that the failure to report allegations that they almost solely relied on in their opening motion are not incorporated into any of the counts that they are seeking to dismiss.

But no matter say the Defendants in footnote 2 of their reply, Plaintiffs' "disregard for the order's reasoning and holding cannot save this complaint." But if the Defendants actually thought that the Court's order required that new allegations needed to be added to every count, they should have made that the basis of their motion.

They received a redline and they were told to limit their arguments, but instead they chose to raise an arguably new point about implied preemption.

In any case, the Court's order did not tell the Plaintiffs to add any allegations to the economic loss complaint. Plaintiffs spent painstaking hours making the

complaint as long as it is not for their health or because we enjoyed it, but simply because the Defendants argued that otherwise it would be a shotgun pleading and that it need to carefully incorporate by reference certain things and not other things.

After having done that and made this Court review the complaint and decide that it is not a shotgun pleading, Defendants can't just pretend at this point that they missed what was all along incorporated into which counts. What the Defendants really mean is made clear on page eight of their reply. "The only parallel claim that survived the Court's express preemption ruling is the OTC Defendants' alleged deception of the FDA."

But if that were true, the complaint needed a total rewrite after this Court's orders because the counts at issue simply never alleged deception of the FDA in every count, as anyone can check as the redlined complaint. They are not in the complaint in those counts because they are not the basis of those claims anywhere except the Defendants' imagination.

The Court's order confirms what is obvious from the pleadings. The Defendants try to splice quotations from this Court's prior order to make it seem as though the claims rely on deception of the FDA, but it is not true at all.

What the Court's order actually said is that the complaint adequately alleged misbranding, and that was because

the label for Zantac was false or misleading.

Now, Ms. Eisenstein is simply wrong in asserting that that holding was hypothetical. The Court didn't say hypothetically the complaint could be changed, and at that point would then be misbranded. The Court held that the complaint as written at that point adequately alleged misbranding, and that holding cannot be revisited at this stage and certainly did not require the Plaintiffs to amend all of the counts to add new allegations.

In fact, the Court was clear that the Plaintiffs were to remove counts and Defendants, and not to add more to the existing counts. With what was pleaded clearly in mind, I want to address implied preemption precedent.

Applying Buckman and Mink here is straightforward. Buckman was a case about bone screws that were still on the market at the time of the litigation and even when the Supreme Court heard the case.

The Plaintiffs there sued the FDA -- sorry, sued a consultant for FDA approval, not the manufacturer, arguing that they fraudulently failed to list spinal use as an indication for the bone screws on their application with the FDA, even though, Plaintiffs argued, they planned the whole time to use the bone screws for spinal use, and that was because they planned to use it off label.

Buckman sharply distinguished traditional state law

claims with the new fangled fraud on the FDA claims that the Plaintiffs had brought up in that case. Here, it is clear that we are on the traditional state law side of that argument and the Defendants didn't argue otherwise by pointing out, for example, that the statutes for deceptive trade practices were passed far after Buckman or anything like that.

Buckman also focused at length on the fact that the claims did not turn on the actual defectiveness of the device, the label, or anything else.

The FDA's amicus brief though that this was especially important and the Court accepted the reasoning in distinguishing the case in Buckman from a prior case called Medtronic. Quote, "It is clear that the Medtronic claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements."

Reading those two sentences, it is clear that this case fits into the first sentence, the Medtronic bucket, not the second sentence. You could say it like this: It is clear that the Zantac claims arose from the manufacturer's alleged failure to use reasonable care in drafting the label for the product, not solely from FDCA requirements.

And it is worth emphasizing that word "solely" because

in what possible sense are the claims here solely based on the FDCA? If there were no FDCA, if it were abolished tomorrow retroactively, these claims would still exist.

Not only that, but think about it the other way. If the Defendants had violated the FDCA, but still had accurate labels in some way, these claims also would not exist. The FDCA in this case is purely a shield for the Defendants, not a sword for the Plaintiffs.

Mink was the same as Buckman, it focused for the failure to report claim on the fact that the reporting was only required because of FDA regulations and wouldn't have existed but for those regulations. It was about sending information to the FDA, not about anything to do with the product itself.

By contrast, the manufacturing claims in Mink were related to the product themselves, and so that succeeded. This is the explanation that the Eleventh Circuit gave in Mink saying that "in both cases" -- drawing an analogy to Buckman and Mink -- "a Plaintiff alleged a manufacturer failed to tell the FDA those things required by Federal law."

Again, that is plainly not this case. We would still be suing even if they had sent reports about this, if they did not try to change the label using the CBE process.

The Defendants' Buckman argument is ultimately rooted in refusing to concede that they lost an argument in the last round, that the Court rejected their argument that FDA approval

is determinative of compliance with Federal law. That is the linchpin of their Buckman argument, no less than it was the linchpin of their express preemption argument.

Your Honor heard it again today. Ms. Eisenstein said Section 379r bars liability based on, I believe she said "a label different from what the FDA approved." That is certainly not a quotation of the statute. The requirement is that it is different from what is required by Federal law, and what the FDA approved and what Federal law requires are simply not the same thing.

If the FDA approval were an alternative, it is true that a Plaintiff pleading a parallel claim necessarily must attack the approval process, and that is what the Defendants think we are doing. They are saying we must be attacking the approval process as flawed from its inception, but that is not what we are doing.

We are not saying and didn't allege that the FDA got it wrong because of fraud or a failure to follow their own procedures or incompetence. We are saying that the approval process that the FDA went through simply does not purport to determine compliance with Federal law except on the information the agency actually reviewed.

That is what the FDA itself says. FDA regulations say that the misbranding provisions apply even to an approved drug, as this Court accepted in the last round of briefing. And why

is that? Again, this Court explained, quoting Justice Thomas in Wyeth, "FDA approval does not represent a finding that the drug, as labeled, can never be deemed unsafe by the application -- later Federal action or the application of state law." New information vitiates a defense based on prior approval, and there is undisputed new information here.

Ultimately, the Defendants are trying to say that because we make arguments that defeat their preemption defense our claims are based on the FDCA, but that is wrong and it is nonsensical. If the FDCA did not exist these claims still would. The complaint doesn't plead fraud on the FDA and the Court's orders did not require us to.

That makes this case like every drug case and like Wyeth v. Levine itself and defeating their affirmative defense, as required in every drug case, does not implicate Buckman. Ruling that it did would be tantamount to reviving the approach of the Wyeth dissenters who themselves cited Buckman for the now discredited proposition that FDA approval is determinative for all time irrespective of new information.

The motion should be denied.

THE COURT: Okay, thank you very much.

MS. EISENSTEIN: Thank you, your Honor. May I proceed?

THE COURT: Yes, let me -- okay, you may proceed.

MS. EISENSTEIN: Your Honor, Plaintiffs' argument is

essentially a complete concession that they made no effort to plead a parallel misbranding claim. Express preemption imposes a pleading burden on Plaintiffs. It is not just a affirmative defense that gets asserted later.

Mink and Wolicki-Gables were clear about that. It is the Plaintiffs' burden to carefully plead, in fact is what the Court said, a claim that parallels Federal requirements and doesn't run into the separate problem of implied preemption by raising a claim that exists by virtue of the FDCA, Federal requirements, or duties owed to the FDA.

Plaintiffs also cite the two hypothetical regime under Wyeth where they say that the Plaintiff who alleges a refund claim would have their claim blocked, while the Plaintiff who alleges a product liability and personal injury claim could proceed. Exactly. That is precisely what Congress intended when it enacted Section 379r.

It couldn't have been clearer, 379r carves out product liability claims from its scope while preempting claims like this one that are predicated on refund claims against OTC manufacturers that try to impose some kind of different, additional, or not identical requirement than that imposed by Federal law.

Wyeth versus Levine is inapposite for another reason. In Wyeth versus Levine not only was there no express preemption provision, something that the Court put heavy emphasis on when

it made the statement that it allowed states to go above and beyond Federal requirements in finding adequacy of the warning.

Here, of course, there is an express preemption provision, but there is also another important difference. Wyeth versus Levine was about impossibility preemption, something that the Court in Wyeth, and later in Merck versus Albrecht, make clear was extremely rigorous. It is only when it is impossible for a manufacturer to comply with both Federal and State requirements that preemption applies.

It is the critical difference between whether a defendant may take action, in which case it doesn't get an impossibility preemption defense, or whether it must take action under Federal law, in which case that is the only situation where Plaintiffs can get beyond express preemption.

There is a huge amount of daylight between those two things, and so the two cases that Plaintiffs cite are not similarly situated.

I want to make one more comment about that with respect to the FDA approval. Plaintiffs are incorrect that when FDA approved the label, that that was not a determination about the adequacy, the safety, and indeed the fact that the drug was not misbranded, that the label was not false and misleading at the time.

Federal law is clear on this point, and the reliance

that they place in their briefing on cases like Bates and Wyeth and others are not applicable here in the OTC regime.

So, for all these reasons, your Honor, we are not asking this Court to do anything other than to apply its prior orders. In its prior orders the Court saw a narrow path forward under a parallel misbranding claim, but the path that the Plaintiff must walk to get there goes through information not provided to the FDA, and that runs right into the Court's order on the implied preemption it saw in the FDA holding that correctly found that claims that are premised on a theory, not an element, but a theory that depends on information withheld from FDA are preempted.

Mink held that and the cases that have applied Mink in this circuit have consistently held that it does not depend on there being an element of fraud on the FDA, but rather, that that is an essential part of the claim, and that is the case here.

THE COURT: Okay, thank you so much. If we could have all counsel on the screen who will be fielding the questions.

So, for the Defendants, Ms. Eisenstein, the first question is, the Court understands that your argument, at least in part, is that this Court has already ruled at Docket Entry 3715 that the only OTC product refund claims to survive express preemption are those based on deceit of the FDA, and for that proposition you argue that the claims for deceit of the FDA are

preempted under cases such as Buckman Company versus Plaintiffs' Legal Committee, 531 U.S. 341, a 2001 case.

The Plaintiffs dispute your interpretation of the Court's prior ruling, and the Court is certainly in a position to understand its own ruling, but putting aside for a moment that argument, that is that the Court has ruled that only claims based on FDA deceit survive express preemption, what is your best argument for why OTC refund claims in the ELC are barred by obstacle preemption?

MS. EISENSTEIN: So, your Honor, the reason that we not only read the Court's language of that order, but believe that that was the correct limitation on the Court's order, that nothing more, at least, than claims that depend on information withheld from the FDA can survive, comes from Federal law and statute, which is that FDA expressly had to make a determination under Federal statute and OTC regulations that the approved label was not false and misleading based on the information provided to it.

I think you heard counsel for Plaintiff argue exactly that, that it would have to be information that was not examined by FDA that could render the product misbranded.

So, this really all comes down to a funneling effect of what -- the effect of the express preemption provision on the broad swath of Plaintiffs' claims that they continue to assert. Express preemptions does not permit Plaintiffs to

proceed with that broad swath, only this narrow claim that all depends on information not presented to FDA.

And then we go to the next stage, which is the Court's order on fraud on the FDA claims and claims that depend on that theory of liability. It's not just limited to claims that are titled fraud on the FDA or failure to report to the FDA; it includes, and Mink makes this clear, a negligence case, so were the other cases that applied Mink in the Eleventh Circuit and in the District Court cases, they were common law cases that depended on a theory that the manufacturers were liable because they failed to provide information to the FDA.

That is the necessary link in the chain in order for Plaintiffs to get past express preemption, and that is why the obstacle preemption applies here. It's a form of implied preemption because it intrudes on the FDA's authority and its purview of being the one to determine what information was appropriately before it.

If you read Plaintiffs' complaint, it is essentially that if it weren't for the failure to provide this information to FDA, Zantac would not have been approved.

THE COURT: Okay, thank you.

Again for Ms. Eisenstein on behalf of the Defendants, you argue that the Plaintiffs have limited their OTC refund claims to those based on deceit of the FDA, but what is it about the way that the OTC refund claims in the ELC have been

pled that differentiates them from the other labeling-based claims pending in this litigation, such as the ELC prescription refund claims or the warning claims in the second amended master personal injury complaint?

If the Court were to view the OTC refund claims as claims for fraud on the FDA, would every labeling-based claim in this MDL be a fraud on the FDA claim?

MS. EISENSTEIN: Your Honor, they have not differentiated their claims against OTC prescription manufacturers from their claims against the prescription manufacturers for their failure to warn claims. In fact, their claims in the economic loss complaint against OTC branded manufacturers are nearly identical to their failure to warn claims in the personal injury complaint, and they are absolutely identical to the claims they have made against prescription manufacturers.

That is exactly the point. They have made essentially what they claim is a misbranding claim in failure to warn clothing, or the opposite, failure to warn claims in misbranding clothing, and that is because they have failed to adhere to the limiting principles that this Court articulated on what can constitute a parallel claim because all that they can -- they can't just challenge the FDA approved label. 379r(a) makes that clear. This Court's order makes that clear.

There is a narrow path forward that they have not

taken. Instead, they have continued to assert a broad swath of claims that are expressly preempted, and the narrow set that could have survived that they do not articulate runs into implied preemption.

So, if this Court were to rule in our favor, yes, the claims against prescription manufacturers would proceed, as well as the personal injury claims, because those are not subject to express preemption.

THE COURT: Followup for you, Ms. Eisenstein. What is it about the way that the OTC refund claims in the ELC have been pled that makes them similar to the claims barred by obstacle preemption in Buckman Company versus Plaintiffs' Legal Committee, 531 U.S. 341, 2001, and Mink versus Smith and Nephew, Inc., 860 F.3d 1319, Eleventh Circuit, 2017?

If you can answer that question.

MS. EISENSTEIN: Your Honor, I am going to go back to my prior answer, which is, I agree that Plaintiffs have pled a much broader set of claims. They plead even product container claims that they said and admitted were expressly preempted.

If you run a redline of their prior complaint before this Court's June 30th order and their new complaint, the only things that have been changed are the removal of generic retailer and distributor Defendants, some tweaking of the incorporated claims, and the removal of the RICO claim, which the Court held by separate order was preempted, but they have

not adjusted to the misbranding and parallel claim part at all.

What makes their claims, if they had followed this Court's order, that which would survive express preemption run into Buckman and Mink is this, as this Court found in its prior order, the Plaintiffs have met the standard for getting past express preemption the Court found because:

One, they have alleged Defendants withheld information about Ranitidine's propensity to form NDMA from the FDA; two, they have alleged that the FDA recently learned about Ranitidine's propensity to form NDMA; and three, they allege that the FDA issued a voluntary recall.

Construing inferences in favor of Plaintiffs, as the Court must, the Plaintiffs have alleged that if the FDA had the information in the past that the FDA possesses in the present, the FDA never would have permitted Ranitidine to be sold.

That was the essence, as we read it -- of course your Honor knows your own order and its intent, but we think that that was correct, that if there was anything that survived express preemption, it would be under that narrow theory because we know that FDA, considering the information it had in front of it, had to have made a finding that the label it approved was not misbranded, it was not false and misleading.

So, a contrary determination by the state that says this warning will be required, otherwise it would be misbranded, is really different from, in addition to, and not

identical with the Federal determination and Federal requirements.

So, that narrowing effect of express preemption is what leads the Plaintiff into implied preemption. It does not come from their pleadings which have failed to adhere to those principles.

THE COURT: One difference the Court noted, and this is for Ms. Eisenstein, that paragraphs 305 to 312 alleging failure to report to the FDA, but to the best of the Court's review, it has not located an OTC refund claim that incorporates 305 to 312.

What is the Court to make of the fact that they are not included or have not -- they are included in the complaint, but they are not incorporated into any claim?

Can the Court, in other words, conclude that the Plaintiffs' claims are based on failure to report to the FDA when these allegations are not incorporated into the OTC refund claims?

MS. EISENSTEIN: I agree that the Plaintiffs have not incorporated those allegations. That was one of the changes they made, was to take that out of the incorporation by reference.

The problem is that they took out the very theory that let this Court allow the Plaintiffs to escape express preemption from their claims, so they are between a rock and a

hard place. In other words, they have been squished between the narrow gap that Mink and other Courts have recognized exists between express and implied preemption.

To get out from implied preemption they have run back into express preemption because now they assert that broad swath of claims entirely untethered to the misbranding allegations which they say are the way in which they parallel Federal law.

They can't just slap a failure to warn claim with a misbranding and false and misleading label and get beyond express preemption. The way that they got beyond express preemption was through those allegations and those allegations -- without them, they are expressly preempted, and with them, they are impliedly preempted, so Plaintiffs' claims fail either way.

That is what Congress intended when it passed Section 379r(a). Uniformity in drug labeling was paramount in that provision and that is the result that flows from that provision and it is the correct result.

THE COURT: For Ms. Eisenstein also, what is it about the way the OTC refund claims in the ELC have been pled that differentiates them from the claims not barred by obstacle preemption in Wyeth versus Levine, 555 U.S. 555, 2009? I do recognize that Wyeth involved a prescription, not OTC, but taking that into account.

MS. EISENSTEIN: I think that they are very similar to the claims that were not barred by impossibility preemption in Wyeth versus Levine, but Wyeth versus Levine involved a prescription drug, not an OTC drug, it involved a no express preemption provision, and this does involve an express preemption provision.

I think that is exactly the point, is that this is just a run-of-the-mill failure to warn claim relying on the CBE process and trying to transform that into a claim that parallels criminal misbranding.

That cannot happen just based on the FDA approved label because FDCA regulations and the FDA -- FDCA itself provides that the FDA cannot approve a label if it were false and misleading. So that is the -- those are crucial differences in the statutory regime that differentiate the operation of preemption here versus -- in Wyeth versus Levine that concerns only the very rigorous and hard to prove impossibility preemption.

MR. KELLER: Your Honor, I don't want to interrupt your flow, can I just briefly respond?

THE COURT: Actually, this is the last question I have for Ms. Eisenstein, so if I can just finish that, then I can let you respond before I go into a question for you.

MR. KELLER: Very good.

THE COURT: Is it your position, Ms. Eisenstein, that

all claims related to OTC drugs are barred by obstacle preemption?

MS. EISENSTEIN: It is my position that those labeling claims that survive express preemption are barred by implied preemption. I think that the operation of the two together preempt the claims as pleaded by Plaintiffs.

That is not to say that claims that -- you know, other claims that they have not pleaded could, you know, could have threaded that narrow gap. We talked about that the last time.

Yes, as they have pleaded them in the economic loss complaint, those that -- the very narrow bits that get past express preemption, which is dependent on information not provided to FDA, is impliedly preempted.

THE COURT: Okay. Mr. Keller, first let me let you respond to any points you would like to before I have any questions directed to you independently.

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

The only point that I wanted to quickly make, as you heard my colleague say a couple of times that Wyeth versus Levine was only an impossibility preemption case, but Justice Alito's dissent expressly brought up Buckman to say that Buckman, which is not an impossibility preemption case, it's an impled objects and purposes preemption case, should have preempted the claims, and the majority opinion of Justice

Stevens expressly repudiated that position. So, I think that Wyeth versus Levine expressly grapples with the Buckman question that is presented by the Defendants' motion.

THE COURT: Okay. Were there any other points made by Ms. Eisenstein that you wanted to respond to at this point?

MR. KELLER: No, your Honor. I am happy to take your questions.

THE COURT: Okay. The Plaintiffs allege in the ELC paragraphs 306 and 309, that the Defendants concealed the danger of Ranitidine by failing to report to the FDA. For example, paragraph 306 reads: Defendants concealed the Ranitidine NDMA link from ordinary consumers in part by not reporting it to the FDA, which relies on drug manufacturers or others, such as those who submit citizen petitions, to bring new information about an approved drug like Ranitidine to the agency's attention.

309 reads: Defendants ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in their products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of Ranitidine containing products.

So, those are the allegations in those two paragraphs. You argue that such paragraphs are not incorporated into any OTC refund claim. In fact, the Court just posited that point

in the followup question to Ms. Eisenstein. And you argue that the Court -- and the Court has not located any ELC claim for either OTC or prescription products in which they are incorporated. That is based on the Court's own review.

What is the Court to make of the fact that these allegations appear in the ELC, even if not expressly incorporated into any claim? Can you speak to why they are there, if they are to be ignored in evaluating your claims, and anything else that you would like to comment on with respect to those paragraphs?

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

So, we took your Honor's shotgun pleading order very seriously and went through in painstaking detail to make choices about which allegations to incorporate by reference and which not to. The reason we didn't incorporate the allegations that you just pointed to, as well as some others like paragraphs 308, 310, and 311, the ones cited in the motion, is because they are not elements of the prima facie case for these traditional state tort law claims.

That doesn't mean you should ignore the allegations, they are still relevant. Any time we are talking about preemption where the Defense raises that affirmative defense, we, as the Plaintiffs, are going to have to point to Federal law and regulations to explain why we overcome the defense, and

here the defense was initially express preemption, so of course we have to talk about Federal law and explain why the State causes of action are parallel.

So, that is what these paragraphs do, but they are not us through the State Court regime, through these deceptive State practices act statutes, or fraud based claims, or warranty claims saying that fraud on the FDA is an element of the case, which is decidedly different from the situation in Buckman.

The claim in Buckman was fraud on the FDA. It was a State Court law that essentially had as an element lying to the Food and Drug Administration. None of these causes of action reference the FDA, care about Federal law. These aren't even pharmaceutical-based common law causes of action, they are mostly statutory and they speak to all sorts of different Defendants, whether they make prescription drugs, over-the-counter drugs, or widgets, some of which might be regulated by Federal law, some of which are not regulated by Federal law.

So, that is the reason we didn't incorporate these allegations by reference. They have nothing to do with our prima facie case.

THE COURT: Okay. This is a question for both of you, so you can both listen carefully, and then I will have Ms. Eisenstein answer first and then Mr. Keller.

In both Buckman and Wyeth, the Supreme Court had the benefit of knowing the FDA's position through amicus briefs when making its rulings on obstacle preemption. Do you have a position on whether the Court would benefit from knowing the FDA's position as to whether it views Plaintiffs' claims as being for fraud on the FDA before the Court makes its obstacle preemption ruling?

From Ms. Eisenstein first.

MS. EISENSTEIN: Let me say as an initial matter, your Honor, I don't think so because I think that Plaintiffs, as you just heard, have sworn off this very claim that got them past express preemption.

I think actually, as it stands, and Plaintiffs' unwillingness to narrow their claims at all beyond a traditional failure to warn, product liability, unfair competition type of claim to the more limited set of allegations that would be constituting a parallel claim that could survive express preemption, that the Court need not go further than express preemption and finding that claims as pleaded now to be expressly preempted and therefore dismissed.

If you reach the issue of whether what was left based on the Court's prior order of the Plaintiffs' claim, you know, I think that Mink and Eleventh Circuit precedent is clear, and so I don't think that we need to seek the views of the FDA to know that claims that are premised on the failure to provide

information to the FDA that the Plaintiffs say would have led the FDA to take further action and would have even rendered it criminally misbranded, that that type of allegation is preempted. I think that is clear from Circuit precedent.

THE COURT: Okay, thank you. Mr. Keller.

MR. KELLER: Thank you, your Honor.

I am not sure I totally understood my colleague's remark when she said we have effectively abandoned the claims that allowed us to survive express preemption. They are the exact same claims that you had when you had the previous version of the complaint. Consult the redline, the different allegations are incorporated by reference. The title of the causes of action for all of the various jurisdictions are the same.

So, I am having a little difficulty discerning what my colleague meant about that.

To directly answer your question, we think that Federal regulations and the statutory text of the Food, Drug and Cosmetic Act are clear, and so you don't need to solicit the opinion of the Food and Drug Administration to resolve this issue, but we would have no objection if your Honor sought to ask the agency to weigh in.

We think their previous amicus submissions support us, not the other side. I'd note as a practical matter that the United States often doesn't -- declines invitations to submit

amicus briefs in the District Courts, but this might be a different situation and we completely defer to your Honor if you would like to solicit the views of the Food and Drug Administration.

THE COURT: Okay. Mr. Keller, going back a moment before this round of questioning, I just want to make sure I understood.

Are you saying that the Court can rely upon allegations that are not incorporated into account to conclude that your claims, that is the Plaintiff's claims, survive express preemption? I just wanted to make sure I heard you clearly.

MR. KELLER: Well, first and foremost, I don't think, despite my colleague bringing it up a bunch of times, that we're here talking about express preemption. You have already ruled on that, and the predicate of their motion is implied objects and purposes preemption.

To reinterpret your question -- and if I am doing it wrong, you can, of course, correct me -- are you allowed to look to those unincorporated allegations to address the preemption issue? Yes, you are, because those allegations can be relevant to their affirmative defense.

They are not relevant to our claims. They don't make the prima facie case for our claims. The elements of these deceptive trade practices and fraud and warranty based claims

do not reference the FDA at all, but when they bring up the affirmative defense of preemption, we are allowed to point to allegations and facts and really law in the complaint to muster our response.

So, I think we properly didn't incorporate them by reference, but you can properly look to them to see that we anticipated what they were going to say about preemption, and if I could just put an accent on that point.

There is case law, we admit, that says that the Plaintiffs basically have to anticipate the affirmative defense of preemption and put facts in their complaint that talk about it. I respectfully think those cases are wrong. Preemption is an affirmative defense, just like res judicata or Statute of Limitations.

We as Plaintiffs don't have the burden to anticipate affirmative defenses, but recognizing that there is contrary case law, we though it was prudent to anticipate what they would say, and we have had a couple of rounds of briefing on this already, so it wasn't that hard to anticipate, and that is why you see allegations unincorporated that talk about the Federal regulatory regime.

THE COURT: Okay. I want to go back a moment to something you said at the prior hearing, Mr. Keller. I asked you, is it the Plaintiffs' position that the drug should not have been approved, and would not have been approved had the

FDA been aware of all the information that the Defendants allegedly knew, but didn't conceal, or didn't reveal that they did conceal.

And you answered: We have not taken a position on whether FDA would have approved the product. We are only bringing theories against the Defendants based on what they could have done, and FDA yanking it or not, approving it at inception is not one of those theories.

And then again, at Docket Entry 3684, at pages 44 to 46, the Plaintiffs explain that, I still do not believe -- I think that is also the transcript. "I still do not believe that we have taken a position on when temporally the label became false or misleading in any particular. That is a fact question that we are still exploring through discovery."

So, my question is, once you fully explore that question, the temporal nature of the allegations of the falsity of the label, will that have some bearing on -- go past the pleading stage, beyond the Motion to Dismiss stage.

Say hypothetically the Plaintiffs' claims survive, but down the road through discovery, the discovery reveals in whole, or even in part perhaps, that the falsity or misleading nature of the label occurred at the time, or prior to the time and at the time the Defendants sought approval from the FDA.

Is that a scenario where this issue, upon revisiting at, say, a different procedural juncture, the summary judgment

stage, may then not survive summary judgment on these preemption arguments?

In other words, I am trying to understand the temporal nature of this. Is it the Plaintiffs' position that the evidence shows the false nature of the claims occurred at one point, arguably. Those may be preempted, but if they show the false nature of the label occurred at another point, claims based on that point would not be preempted?

Can you clearly follow me on that question?

MR. KELLER: Yes, that makes good sense to me, your Honor, and I will note as well that your order also observed that we have not yet taken a position on this issue, which we took to mean that we don't have to for pleading purposes. We weren't ordered to replead on that point, but I totally understand the thrust of your question.

I view it as a relationship between damages and preemption. So, in order for the brand manufacturers to be able to change their label they have to have new information as defined by FDA regulations. The FDA regulations define new information as actually new information, which is to say new and emerging science that came out at a subsequent point in time, or as information that the FDA didn't have originally, so perhaps information that the manufacturers withheld from the agency.

If there is no new information, you can't use the CBE

process, and so up until that point in time claims would be preempted. So, we haven't locked ourselves in yet to a position as to when that new information came out.

I am quite sure that at summary judgment we are going to have to take a position on that, and that could impact the damages. So completely hypothetically, I am not locking us into this in any way, I am just doing it for illustrative purposes, if the new information came out in 1990, we say, in a way that would have allowed a label change, that is very different than if it came out in 1995.

The difference of those five years would potentially be the difference in damages that both economic loss Plaintiffs and personal injury Plaintiffs could recoup, and prior to the new information being available, you couldn't use the CBE process, and so you couldn't change the label.

So, whether you call it preemption or damages, I do think the answer to your question will be relevant at a subsequent phase of this litigation, but we have not yet taken a view as to when that new information sufficient to satisfy the CBE regulation existed and, respectfully, we don't think we have to on a 12(b)(6).

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

THE COURT: Yes.

MS. EISENSTEIN: So, I am just reading from Mink, because Plaintiffs keep asserting that this isn't something to

be decided at this stage, but when it comes to express preemption, it is.

Mink said: To avoid having the claims preempted a Plaintiff must carefully plead a claim that implicates the safety or effectiveness of a Federally regulated device, and must do so by first avoiding express preemption that bars State law claims that impose a requirement different from, or additional to Federal requirements, and that implied preemption prohibits State law claims that seek to privately enforce duties owed to the FDA, and that this is a pleading burden, that they may proceed on their claims only if they articulate that.

You just heard Mr. Keller say that his claims depend on some type of new information that allows the manufacturer to change a label under the CBE process, but that is not a parallel claim.

A parallel claim could only be one where the manufacturers would have violated the Federal misbranding requirements, according to them, by failing to update the label, and in this case, by failing to let FDA know information at the outset, they say, that would have prevented the Zantac product from getting on the market at all.

What Mr. Keller said is not what their pleading says. They say it was misbranded from the outset. The label was always the same, and so they do need to and fail to articulate

the point at which the product was not just capable of being changed with a different label, but was actually rendered criminally misbranded for failing to do so. Their pleadings say nothing of the kind.

THE COURT: So, if the Plaintiffs, through discovery, discover that new information became available to the Defendants about the product that would have obligated the Defendants to go through the CBE process and they didn't in that hypothetical, what is the Defendant's response?

Is it they haven't pled that, so that is the problem, or that is not -- that doesn't survive preemption or that is not parallel?

What is the concern with that scenario?

MS. EISENSTEIN: I think the concern is, your Honor, that the FDA made a determination that reflects on the misbranding allegation here, which is that when it approved the label, which hasn't changed, it found that the label is not false or misleading.

So, Plaintiffs need to do more than just say that manufacturers could have changed the label. They have to somehow impugn that determination of the FDA, and that comes back to the information not given to the FDA.

Another problem is with Plaintiffs' allegation that once this information came to light, the response was for FDA to withdraw the product entirely. This isn't really a failure

to warn claim that if this information had come to light the warning could have been placed on the product.

Really, the only plausible scenarios are either no Zantac on the market or Zantac proceeds with the existing label. That is the way their pleadings read right now, not like a product liability claim where we should have been warned or I would have avoided my injury.

It is really about -- and the second amended economic loss complaint continues to say this -- about the withdrawal of Zantac from the market and the fact that consumers should not have been purchasing this product at all.

Those points together point to the fact that if you look at the reality of their pleading, it is far, far broader than the narrow concept of misbranding. It doesn't have this temporal notion in there at all, and it is Plaintiffs' burden to plead a parallel claim, and they have failed to do it. This isn't something for summary judgment.

THE COURT: But you are not saying that just because the FDA once upon a time approved the product, along with the label, that that precludes any claim afterwards as to mislabeling, are you?

MS. EISENSTEIN: I agree that, and this Court has ruled, misbranding can't -- the FDA approved label, you have held, can be misbranded based on information potentially that later came to light that was not before the agency, but that is

not how Plaintiffs have pleaded their claim.

They say that it was misbranded all along. They don't purport to try to find a time or allege a time that this product became misbranded.

Again, I think that this differentiates this type of claim from one that is just subject to impossibility preemption like that considered in Wyeth versus Levine because here you have an express preemption provision where Congress has made a very considered judgment that differentiates refund claims against OTC manufacturers, and even called out warnings in particular, is just the kind of claim that should not be able to proceed on a state law by state law basis.

So, you have to read the Plaintiffs' pleading burden in light of that express preemption provision and that is what Mink provided in the very similar medical device context.

THE COURT: And response from Plaintiffs, if any.

MR. KELLER: Very briefly, your Honor. I think that despite saying in their papers that they accept your Honor's express preemption decision, and are going to argue implied preemption, you are hearing a lot about express preemption today, and I think that they are uncomfortable with your prior order, but we have met our burden to plead a parallel claim by pleading the State law causes of action that are based solely on a false or misleading label.

Those State causes of action are not trying to enforce

the Food, Drug and Cosmetic Act, as we noted in the prior round of briefing. Almost none of them use the word misbranding, but as your Honor already found, a false or misleading label under the plain text of the Food, Drug and Cosmetic Act is a misbranded drug.

So, the reason the claims are parallel is because the duties imposed by State and Federal law are the same. So, we have met our burden on that score and your Honor has already held that we met our burden on that score.

What we should be talking about is Buckman and implied objects and purposes preemption, but my colleague wants to keep coming back to 379r and express preemption, and that has already been decided.

THE COURT: Okay, thank you. Have both of you been heard in full or is there any last point that you feel you need to make or would like to make?

MR. KELLER: Nothing further for the Plaintiffs, your Honor.

MS. EISENSTEIN: Nothing further, your Honor.

THE COURT: Thank you both so much, I appreciate it.

That concludes our hearing on the two pending Motions to Dismiss. Counsel in the last round, just as in the first round, did an excellent job.

I appreciate the time, the preparation, the thoroughness, the earnest efforts to answer the Court's

questions and make sure that the Court is fully informed on the issues that have been presented in these motions, so I thank you for that.

I wish everyone well, and until our next gathering, we will conclude. Thank you so much.

(Thereupon, the hearing was concluded.)

* * *

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

Date: October 6, 2021

/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter