

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF FLORIDA
3 WEST PALM BEACH DIVISION

4 CASE NO. 20-md-02924-ROSENBERG

5 **IN RE: ZANTAC (RANITIDINE)** .
6 **PRODUCTS LIABILITY** . West Palm Beach, FL
7 **LITIGATION.** . October 4, 2021
8 .
9 .

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

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Official Court Reporter: Pauline A. Stipes
HON. ROBIN L. ROSENBERG
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1 *THE COURT:* All right. Good morning, everyone. We
2 are here in the Zantac Products Liability MDL litigation, Case
3 Number 20-md-02924, and we are here on two Motions to Dismiss.

4 At Docket Entry 4403, the Court entered an order
5 regarding the October 4 hearing on the Motions to Dismiss and
6 set forth that the motions that the Court was going to hear
7 argument on today included the Docket Entry 4106, which is
8 Defendants' Motion to Dismiss amended consolidated medical
9 monitoring class action complaint, and then following arguments
10 on that motion, the Court will hear arguments on Docket Entry
11 4107, the brand OTC Defendants' Rule 12 partial Motion to
12 Dismiss Plaintiffs' second amended economic loss class
13 complaint as preempted by Federal law.

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

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

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

1 cocounsel can also put his or her screen on.

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

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

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

15 *THE COURT:* All right. Good morning.

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

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

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

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

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

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

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

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

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

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

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

19 *MS. COHAN:* Perfect.

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

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

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

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

3 Do you have any questions before we get started?

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

5 *MS. MEEDER:* No.

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

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

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

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

25 In the AMMC, Plaintiffs have not even attempted to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 entire monitoring regime.

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

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

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

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

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

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

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

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

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

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

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

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

4 Thank you.

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

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

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

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

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

15 *THE COURT:* You may proceed.

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

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

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

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

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

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

25 The MMC said that Ms. Ball took Ranitidine for 21

1 years, some combination of prescription Zantac and 150 and
2 300 milligram prescription generic medication, but it didn't
3 describe how often she took the medication, which product she
4 took when or why.

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

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

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

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

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

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

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

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

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

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

1 product.

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

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

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

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

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

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

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

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

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

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

1 Defendants.

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

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

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

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

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

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

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

25 Yet these allegations were enough to overcome a Motion

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

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

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

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

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

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

1 support of a significantly increased risk.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Those are just worlds away from the allegations that

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 *THE COURT:* Okay. Another question for Plaintiffs.

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

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

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

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

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

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

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

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

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

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

25 *THE COURT:* Okay, thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 *THE COURT:* Okay. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

20 THE COURT: Okay.

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

22 THE COURT: Sure.

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

1 they don't support Defendants'.

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

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

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

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

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

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

4 Thank you.

5 *THE COURT:* Okay, thank you.

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

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

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

16 *MS. COHAN:* Can you hear me?

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

19 *MS. COHAN:* No problem. I apologize.

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

25 Perhaps if taken, Plaintiffs' allegations, as true,

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

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

13 *THE COURT:* Okay, thank you.

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

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

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

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

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

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

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

22 From the --

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

25 *THE COURT:* How about from Plaintiffs?

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

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

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

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

20 Again, thank you so much for your time.

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

25 *MS. COHAN:* Thank you.

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

7 From the Defense who do we have?

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

11 *THE COURT:* Okay. Good afternoon. From the
12 Plaintiffs?

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

18 *THE COURT:* Okay.

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

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

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

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

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

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

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

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

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

15 *MS. EISENSTEIN:* Thank you, your Honor.

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

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

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

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

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

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

19 *MS. EISENSTEIN:* Absolutely, your Honor.

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

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

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

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

17 Meanwhile, the express preemption provision, Section
18 379r(a), bar state law claims against OTC manufacturers that
19 seek economic loss damages from challenging FDA's judgment.
20 Otherwise, it would be a claim that would seek a label that was
21 different from, in addition to, and not identical with that
22 required by Federal law.

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

1 that that the FDA approved.

2 If this weren't apparent from Section 379r(a), the OTC
3 preemption provision makes crystal clear under Section
4 379r(c)(2), that is the provision that defines the scope of
5 express preemption, and it provides that express preemption
6 scope includes any requirement relating to public information
7 or any other form of public communication relating to a warning
8 of any kind for a drug.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 *THE COURT:* Okay, thank you. That was ten minutes and
4 19 seconds when I stopped the clock for a short bit when you
5 had to repeat, so you have the remaining time for your
6 rebuttal.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 the label for Zantac was false or misleading.

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

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

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

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

25 Buckman sharply distinguished traditional state law

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

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

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

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

25 And it is worth emphasizing that word "solely" because

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 The motion should be denied.

21 *THE COURT:* Okay, thank you very much.

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

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

25 *MS. EISENSTEIN:* Your Honor, Plaintiffs' argument is

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

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

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

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

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

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

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

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

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

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

25 Federal law is clear on this point, and the reliance

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

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

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

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

20 So, for the Defendants, Ms. Eisenstein, the first
21 question is, the Court understands that your argument, at least
22 in part, is that this Court has already ruled at Docket Entry
23 3715 that the only OTC product refund claims to survive express
24 preemption are those based on deceit of the FDA, and for that
25 proposition you argue that the claims for deceit of the FDA are

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

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

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

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

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

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

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

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

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

21 *THE COURT:* Okay, thank you.

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

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

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

8 *MS. EISENSTEIN:* Your Honor, they have not
9 differentiated their claims against OTC prescription
10 manufacturers from their claims against the prescription
11 manufacturers for their failure to warn claims. In fact, their
12 claims in the economic loss complaint against OTC branded
13 manufacturers are nearly identical to their failure to warn
14 claims in the personal injury complaint, and they are
15 absolutely identical to the claims they have made against
16 prescription manufacturers.

17 That is exactly the point. They have made essentially
18 what they claim is a misbranding claim in failure to warn
19 clothing, or the opposite, failure to warn claims in
20 misbranding clothing, and that is because they have failed to
21 adhere to the limiting principles that this Court articulated
22 on what can constitute a parallel claim because all that they
23 can -- they can't just challenge the FDA approved label.
24 379r(a) makes that clear. This Court's order makes that clear.

25 There is a narrow path forward that they have not

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

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

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

15 If you can answer that question.

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

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

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

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

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

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

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

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

1 identical with the Federal determination and Federal
2 requirements.

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

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

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

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

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

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

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

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

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

16 That is what Congress intended when it passed Section
17 379r(a). Uniformity in drug labeling was paramount in that
18 provision and that is the result that flows from that provision
19 and it is the correct result.

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

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

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

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

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

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

24 *MR. KELLER:* Very good.

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

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

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

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

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

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

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

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

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

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

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

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

17 309 reads: Defendants ignored these regulations and,
18 disregarding the scientific evidence available to them
19 regarding the presence of NDMA in their products and the risks
20 associated with NDMA, did not report to the FDA significant new
21 information affecting the safety or labeling of Ranitidine
22 containing products.

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

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

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

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

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

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

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

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

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

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

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

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

8 From Ms. Eisenstein first.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 And then again, at Docket Entry 3684, at pages 44 to
10 46, the Plaintiffs explain that, I still do not believe -- I
11 think that is also the transcript. "I still do not believe
12 that we have taken a position on when temporally the label
13 became false or misleading in any particular. That is a fact
14 question that we are still exploring through discovery."

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

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

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

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

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

9 Can you clearly follow me on that question?

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

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

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

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

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

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

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

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

23 *THE COURT:* Yes.

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

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

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

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

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

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

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

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

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

13 What is the concern with that scenario?

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

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

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

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

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

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

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

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

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

1 not how Plaintiffs have pleaded their claim.

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

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

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

16 *THE COURT:* And response from Plaintiffs, if any.

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

25 Those State causes of action are not trying to enforce

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

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

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

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

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

19 *MS. EISENSTEIN:* Nothing further, your Honor.

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

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

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

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

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

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

7 * * *

8
9 I certify that the foregoing is a correct transcript
10 from the record of proceedings in the above matter.

11
12 Date: October 6, 2021

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

14 Signature of Court Reporter
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Pauline A. Stipes, Official Federal Reporter

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106 [1] 29/4	300 [1] 16/7	above [22] 7/20 10/12 10/15 10/20 11/17 12/10 17/24 18/17 20/18 20/21 29/23 31/18 33/12 33/21 35/1 41/4 41/11 48/11 51/21 51/22 64/1 90/10
107 [1] 29/4	300 milligram [1] 16/2	above the [1] 41/4
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